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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

HAMID RAVANSARI, DERIVATIVELY ON  
BEHALF OF INSYS THERAPEUTICS, INC.,

PLAINTIFF,

VS.

JOHN N. KAPOOR; MICHAEL BABICH;  
DARRYL S. BAKER; PATRICK  
FOURTEAU; PIERRE LAPALME; STEVEN  
MEYER; BRIAN TAMBI; THE ESTATE OF  
DR. THEODORE STANLEY; AND  
SANTOSH J. VETTICADEN,

DEFENDANTS,

AND

INSYS THERAPEUTICS, INC.,

NOMINAL DEFENDANT.

Case No.:

**VERIFIED SHAREHOLDER  
DERIVATIVE COMPLAINT**

**(DEMAND FOR JURY TRIAL)**

## **INTRODUCTION**

Plaintiff Hamid Ravansari (“Plaintiff”), by his undersigned attorneys, derivatively and on behalf of Nominal Defendant Insys Therapeutics, Inc. (“Insys” or the “Company”), files this Verified Shareholder Derivative Complaint against Individual Defendants John N. Kapoor, Michael Babich, Darryl S. Baker, Patrick Fourteau, Pierre Lapalme, Steven Meyer, Brian Tambi, the Estate of Dr. Theodore Stanley, and Santosh J. Vetticaden (collectively, the “Individual Defendants,” and together with Insys, the “Defendants”) for breaches of their fiduciary duties as directors and/or officers of Insys, unjust enrichment, waste of corporate assets, abuse of control, gross mismanagement, and violations of Sections 14(a), 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”). As for his complaint against the Individual Defendants, Plaintiff alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Insys, news reports, securities analysts’ reports and advisories about the Company, the documentary entitled *Death By Fentanyl*, court documents containing factual allegations filed in the following matters: *United States v. Alfonso*, No. 3:15-cr-00111-MPS (D. Ct.); *United States v. Roper*, 1:16-mj-03628 (S.D.N.Y.); *United States v. Serrano*, 1:16- mj-03629 (S.D.N.Y.); *United States v. Couch*, 1:15-cr-00088 (S.D. Ala.); *Insys Therapeutics, Inc. v. Ferraro*, 7:15-cv-03613 (S.D.N.Y.); *State of Illinois v. Insys Therapeutics, Inc.*, 2016-CH-11216 (Cir. Ct. Ill.); *United States v. Pearlman*, 3:16-mj-00437 (D. Conn.); *United States v. Perhacs*, 1:16-cr-00024-CG (S.D. Ala.); *United States v. Rosenberg*, 17-cr-00009 (D. R.I.); *United States v. Gurrieri*, 1:16-

mj-07218 (D. Mass.); *United States v. Babich et al.*, 16-cr-10343 (D. Mass); *United States v. Clough*, 17-cr-00037 (D. N.H.); *Attorney General of N.J. v. Insys Therapeutics, Inc.*, No. A 8:54 (filed Oct. 5, 2017); *Blue Cross of California Inc., et al. v. Insys Therapeutics Inc.*, No. 2:17-cv-02286 (D. Ariz.), the Notice of Unlawful Trade Practices and Proposed Resolution issued to Insys on July 10, 2015 by the Oregon Department of Justice in the matter captioned *In re Insys Therapeutics, Inc.*, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

### **NATURE OF THE ACTION**

1. This is a shareholder derivative action that seeks to remedy wrongdoing committed by Insys's directors and officers.

2. From August 12, 2014 through the present day (the "Relevant Period"), the investing public was under a false impression of the Company's business, operations, and prospects.

3. Insys is a pharmaceutical company. Insys's lead product is Subsys, a transmucosal immediate-release fentanyl ("TIRF") medication responsible for substantially all of the Company's revenues during the Relevant Period. Subsys is administered as a sublingual pain relief spray.

4. Fentanyl is a potent synthetic opioid, purportedly fifty times stronger than heroin. As such, it is highly addictive and responsible for a growing number of overdose deaths in the United States. An autopsy report revealed that popular musician Prince was found to have had an "exceedingly high" concentration of fentanyl in his body at the time of his death.<sup>1</sup>

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<sup>1</sup> Dennis Thompson, *'It's Getting Exponentially Worse': Fentanyl Behind Latest Spike in Opioid Overdose Deaths*, CHICAGO TRIBUTE (March 29, 2018 3:22 PM),

5. Fentanyl is categorized by the U.S. Drug Enforcement Administration as a Schedule II substance under the Controlled Substances Act. Consequently, its manufacture, shipment, storage, sale, and use are highly regulated.

6. Subsys is subject to the TIRF Risk Evaluation and Mitigation Strategy (“REMS”) Access program (“TIRF-REMS”) under which all prescriptions of Subsys are tracked and reported in real-time, allowing Insys and the Individual Defendants to monitor sales of Subsys.

7. Subsys was approved by the U.S. Food and Drug Administration (the “FDA”) in January 2012, for the narrow indication of breakthrough cancer pain (“BTCP”). Thus, Subsys was approved for use in cancer patients whose around-the-clock opioid therapy was not sufficient to manage their pain, allowing the pain to “break through” the opioid treatment.

8. While doctors have the discretion to prescribe drugs outside of the FDA’s approved uses (known as “off-label use”), it is illegal for a manufacturer to market or promote a drug for off-label use. 21 U.S.C. §§ 331(d), 355(a).

9. Despite the limited use for which Subsys was approved, the Individual Defendants caused the Company to aggressively and illegally market Subsys to physicians who did not treat cancer patients and promoted Subsys for off-label uses.

10. Following the FDA’s approval of Subsys, Insys sought out and hired several members of a competitor’s sales team to market Subsys. That competitor, Cephalon, Inc. (“Cephalon”), had pleaded guilty and paid a \$425 million fine in 2008 to settle claims related to off-label marketing of Actiq, a Subsys competitor.

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<http://www.chicagotribune.com/lifestyles/health/ct-fentanyl-opioid-overdose-deaths-20180329-story.html>

11. The Individual Defendants caused Insys to target those physicians who wrote the largest volume of pain-management prescriptions, whether or not such physicians treated cancer patients. The Individual Defendants also caused the Company to implement a highly incentive-based compensation scheme for its largely-neophyte sales force—a combination which encouraged off-label marketing.

12. This was combined with intense pressure from management to market Subsys aggressively. In a May 1, 2013 email to the sales force, one of the managers hired from Cephalon wrote: “pick an office that your gut tells you is worth going after – pack your bags – move in – don’t leave until you have seen the Subsys prescription you need on a daily basis ‘with your own two eyes!’”

13. The Individual Defendants caused the Company to create a speaker program. The official purpose of this program was to educate medical professionals on TIRF. However, the program was used to funnel cash and other remuneration to doctors who prescribed Subsys, and to encourage doctors in the speaker program to increase the number of prescriptions that they wrote for Subsys in a *quid pro quo*.

14. As a result of the Company’s aggressive and illegal marketing strategy, Subsys’ market share grew rapidly, from 0% at the beginning of 2012 to nearly 10% by the end of the year. Subsys commanded 31.4% of the market by September 2013, and 41.6% of the weekly market by February 2014, making it the most prescribed rapid onset opioid in the Country.

15. The sale of Subsys is Insys’s core business. As the Company repeatedly acknowledged in SEC filings during the Relevant Period, “[Insys is] largely dependent on the commercial success of our product, SUBSYS®...[w]e anticipate that in the near term our ability to maintain profitability will depend upon the continued commercial success of our main approved product, SUBSYS®.”

16. In order to achieve this rate of growth, the Individual Defendants, in breach of their fiduciary duties, caused Insys to engage in unethical and illegal conduct to induce physicians to prescribe Subsys to non-cancer patients and manipulate third party payors into approving Subsys prescriptions regardless of whether patients suffered from BTCP—or, in fact, had ever had cancer.

17. During the Relevant Period, in violation of the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), the Individual Defendants caused the Company to: (1) use its speaker program to make payments to physicians to incentivize those physicians to prescribe Subsys; (2) artificially inflate the costs of such events in order to increase the amount of funds that went to individual physician speakers; (3) falsify sign-in sheets at speaker events to create the impression that they were better-attended and more legitimate than they actually were; (4) provide prescribing physicians with food, alcohol, and other forms of entertainment to incentivize such physicians to prescribe Subsys; (5) hire sales representatives with connections to prescribing physicians, such as relatives and romantic interests, to induce doctors to prescribe Subsys; and (6) provide doctors with support with administrative tasks, including by hiring individuals on the Insys payroll to work directly in doctors' offices (collectively, the "Kickback Misconduct").

18. Further, during the Relevant Period, in violation of the False Claims Act (the "FCA"), the Individual Defendants caused the Company to build an entire department—the Insys Reimbursement Center ("IRC")—the purpose of which was to: (1) provide IRC employees with scripts designed to make misleading statements to insurers to create the impression that Subsys patients who did not have cancer were suffering from BTCP; (2) falsely represent patient diagnoses; (3) misrepresent patients' tried and failed medications; (4) change insurance codes to mislead third party payors as to a patient's diagnosis; and (5) pretend to be employees of the prescribing doctor, all in order to obtain payment from third party payors,

including Medicare and Medicaid (collectively, the “FCA Misconduct”).

19. Moreover, during the Relevant Period, in violation of, *inter alia*, 21 U.S.C. § 355(a) and (b), and FDA Regulations, the Individual Defendants caused the Company to engage in an off-label marketing campaign for Subsys, including offering patients free product to switch to Subsys from a competitor regardless of their medical condition and pushing practitioners to ignore FDA-approved dosing instructions (the “Off-label Misconduct”).

20. The Off-label Misconduct, FCA Misconduct, and Kickback Misconduct are referred to collectively herein as the “Sales Misconduct.” The Individual Defendants breached their fiduciary duties by engaging in the Sales Misconduct.

21. Also during the Relevant Period, the Individual Defendants caused the Company to issue statements to the investing public which falsely and misleadingly created the impression that the success of Subsys was the result of a clinically superior product, on-label sales practices, and lawful interactions with third party payors, when, in reality, it was due to the Sales Misconduct.

22. Insys received a subpoena from the Department of Health and Human Services (“HHS”) Office of Inspector General on December 12, 2013, which was disclosed to the Company’s Board of Directors (the “Board”). This was the first of several regulatory inquiries to be received by the Company.

23. Insys’s legal troubles mounted from there, with additional subpoenas issued, with, *inter alia*, medical professionals from its speaker program and Insys sales employees being arrested and indicted, federal and state investigations of the Company being conducted, and senior executives of the Company, including Defendants Michael Babich and John N. Kapoor, being indicted.

24. The Department of Justice of the State of Oregon (“ODOJ”) filed a Notice of

Improper Trade Practices against Insys in connection with the Company's Subsys marketing activities. This ultimately resulted in a \$1.1 million settlement.

25. The U.S. Department of Justice ("DOJ") has prosecuted several Insys employees, and obtained a number of guilty pleas, for violating federal law in connection with the marketing and sale of Subsys.

26. On June 23, 2015, Heather Alfonso ("Alfonso"), a Connecticut nurse, pleaded guilty in the District Court of Connecticut to accepting kickbacks from Insys for prescribing Subsys. The *New York Times* published an article the following day titled, "Nurse Pleads Guilty to Taking Kickbacks from Drug Maker," which suggested that guilty plea might suggest prosecutors were seeking to make deals in exchange for information about Insys's sales practices. Following these revelations, the Company's closing stock price dropped \$5.17 per share, or 12.64%, over the next two trading days, to a closing price of \$35.74 on June 25, 2015, on heavy trading volume.

27. On December 3, 2015, the *Southern Investigative Reporting Foundation* ("SIRF") reported on the FCA Misconduct, including the Company's unusual incentive structure for those handling third party payors. Following this publication, the price of Insys's common stock dropped \$5.93 per share, or 18.54%, from the previous day's closing price to a closing price of \$26.06 per share on December 3, 2015, on heavy trading volume.

28. In February 2016, the Company disclosed that it was under investigation by the States of Arizona, Massachusetts, Illinois, and New Jersey, and that physicians with ties to the Company were being investigated by the U.S. Attorneys Offices of Michigan, Rhode Island, Florida, Connecticut, New Hampshire, and Alabama. The Board was advised of these investigations.

29. Increased regulatory scrutiny and increasing public knowledge of Insys's

wrongdoing eventually stymied the Company's continued growth in Subsys sales. On April 11, 2016, Insys issued a press release announcing expected net revenues for Subsys in the quarter ended March 31, 2016 would be \$61 million to \$62 million – significantly lower than consensus expectations of \$86 million for the same period. In response to this news, the closing price of Insys's common stock dropped \$3.42 per share, or 19.37%, from the previous trading day's closing price to close at \$14.24 per share on April 11, 2016.

30. Six Insys executives, including Defendant Michael Babich, were indicted on December 6, 2016 in connection with, *inter alia*, the Sales Misconduct (the "Federal Indictment"). By December 8, 2016, the Company's stock price had declined to close at a price of \$9.43 per share, down 16%, or \$1.85, from its closing price of \$11.28 per share on December 5, 2016. The Federal Indictment was replaced by a superseding indictment on or about October 26, 2017, which added charges against Defendant John N. Kapoor (the "Superseding Federal Indictment").

31. In addition to the Sales Misconduct, the Individual Defendants caused the Company to fail to properly record revenue, report rebate obligations, report earnings, and issue financial statements in compliance with generally accepted accounting principles ("GAAP").

32. Insys participates in various rebate programs, through which Insys provides discounted prescriptions to qualified insured patients. Under these rebate programs, Insys pays a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled.

33. In a Form 10-K filed with the SEC on April 3, 2017, the Company reported that it accrues rebates at the time revenue is recognized "based on current contract prices, historical and estimated future percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel." The allowance for rebates reduced reported net revenue.

34. In SEC filings throughout the relevant period, Insys represented that it recognized revenue from the sale of Subsys when “(i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.” In violation of Insys’s stated policies, the Company recognized revenue on sales of Subsys when it was sold to the distributor, rather than when the drug was sold to the actual end-user or the right of return had expired.

35. Distributors were allowed to return Subsys for a full refund “within six months before and up to 12 months following its product expiration date.” As the shelf life of Subsys is 36 months from the date of manufacture, distributors had up to four years to return Subsys after the date of its manufacture, and could return Subsys even after the product had expired.

36. Although Insys represented during the Relevant Period that they “have monitored actual return history since product launch, which provides us with a basis to reasonably estimate future product returns, taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products,” the 36-month Subsys shelf life meant the first supply sold would no longer be able to be returned in 2016. Thus, management could not properly estimate returns based on historical returns in a reasonable manner until 2016, at the earliest.

37. As a result, the Company was forced to announce on March 31, 2017 that it would be restating its audited financial statements for the quarters ended March 31, June 30, and September 30, 2015 and 2016.

38. The Individual Defendants further breached their fiduciary duties by causing the Company to fail to maintain internal controls.

39. Moreover, the Individual Defendants breached their fiduciary duties by making and/or causing the Company to make a series of materially false and misleading statements regarding the Company's business, operations, prospects, and legal compliance. Specifically, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements and/or omissions of material fact that failed to disclose that, *inter alia*: (1) the Company failed to maintain a proper "tone at the top" resulting in premature recording of revenue, overstatement of earnings, the failure to properly account for sales allowances, and GAAP violations; (2) the Company engaged in the Sales Misconduct; (3) the Company's revenues were artificially inflated as a result of the Sales Misconduct; (4) the Company failed to maintain internal controls; and (5) a result of the foregoing, statements about the Company's business, operations, and prospects were materially false and misleading and lacked a reasonable basis at all relevant times.

40. The Individual Defendants failed to correct and/or caused the Company to fail to correct these false and misleading statements and/or omissions of material fact, rendering them personally liable to the Company for breaching their fiduciary duties.

41. Furthermore, during the period when the Company's stock price was artificially inflated due to the false and misleading statements discussed herein, the Individual Defendants caused the Company to repurchase its own stock at prices that were artificially inflated due to the foregoing misrepresentations, while five of them engaged in lucrative insider sales, netting proceeds of about \$15.3 million. Some 1,403,275 shares of the Company's common stock were repurchased between September 2015 and June 2016 for approximately \$32.6 million. As the Company stock was actually only worth \$9.97 per share during that time, the closing price for Insys stock on March 17, 2017, the Company overpaid approximately \$18.6 million in total.

42. The Individual Defendants' breaches of fiduciary duty and other misconduct have subjected Insys, three of its former its Chief Executive Officers ("CEO"), and its former Chief Financial Officer ("CFO"), to a consolidated federal securities fraud class action lawsuit pending in the United States District Court for the Southern District of New York, and Insys, two of its former CEOs, and its former CFO, to a federal securities fraud class action lawsuit pending in the United States District Court for the District of Arizona (the "Securities Class Actions"); Investigations by the HHS and the U.S. Attorney's Office for the District of Massachusetts (the "DOJ Investigation"); open investigations by the Attorney General of Arizona, Colorado, Florida, Kansas, Kentucky, Maryland, Minnesota, Missouri, New Jersey, New York, North Carolina, Pennsylvania, Rhode Island, Virginia and Washington; complaints filed in and by the states of Arizona, New Jersey, and North Carolina under those states' consumer fraud and protection acts; a complaint in and by the state of New York asserting claims related to alleged deceptive acts and practices; the need to undertake internal investigations; losses due to the Company's overpayment of approximately \$18.6 million for the repurchases of its own stock and the unjust enrichment of the Individual Defendants who were improperly over-compensated by the Company, and will cost the Company going forward many millions of dollars.

43. The Company has been substantially damaged as a result of the Individual Defendants' knowing or highly reckless breaches of fiduciary duty and other misconduct.

44. In light of the breaches of fiduciary duty engaged in by the Individual Defendants, three of whom are current Company directors, of the substantial likelihood of the three directors' liability in this derivative action, and of their not being disinterested and/or independent directors, a majority of the Board cannot consider a demand to commence litigation against themselves on behalf of the Company with the requisite level of disinterestedness and

independence.

### **JURISDICTION AND VENUE**

45. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims raise a federal question under Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), Rule 14a-9 of the Exchange Act, 17 C.F.R. § 240.14a-9, Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b), 78t(a) and 78t-1), and SEC Rule 10b-5 (17 C.F.R. § 240.10b-5) promulgated thereunder and raise a federal question pertaining to the claims made in the federal securities class action based on violations of the Exchange Act.

46. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367(a).

47. This derivative action is not a collusive action to confer jurisdiction on a court of the United States that it would not otherwise have.

48. Venue is proper in this District because one or more of the Defendants either resides or maintains executive offices in this District, Defendants have conducted business in this District, and Defendants' actions have had an effect in this District.

### **PARTIES**

#### **Plaintiff**

49. Plaintiff is a current shareholder of Insys common stock. Plaintiff has continuously held Insys common stock at all relevant times.

#### **Nominal Defendant Insys**

50. Nominal Defendant Insys is a Delaware corporation with its principal executive offices at 1333 S Spectrum Blvd, Suite 100, Chandler, AZ 85286. Insys stock trades on the NASDAQ under the ticker symbol "INSY."

**Defendant Kapoor**

51. Defendant John N. Kapoor (“Kapoor”) served on the Board from the Company’s formation in 1990 until October 29, 2017 and was Chairman of the Board from 1990 until January 2017. He also served as the Company’s President and CEO from November 2015 to January 2017, and, as the Company admits, was a non-independent director. According to the Company’s Schedule 14A filed with the SEC on April 18, 2017 (the “2017 Proxy Statement”), on March 15, 2017, Defendant Kapoor beneficially owned 48,294,303 shares of the Company’s common stock, which represented 67.1% of the Company’s outstanding stock on that date.<sup>2</sup> Given that the price per share of the Company’s common stock at the close of trading on March 15, 2017 was \$10.55, Defendant Kapoor owned over \$509.5 million worth of Insys stock.

52. For the fiscal year ended December 31, 2016, Defendant Kapoor received \$550,745 in compensation from the Company. This included \$420,000 in salary, \$126,000 in bonus, and \$4,745 in all other compensation.

53. The Company’s 2017 Proxy Statement stated the following about Defendant Kapoor:

*John N. Kapoor, Ph.D.*<sup>3</sup> has served on our Board since our formation in 1990. Since our formation, Dr. Kapoor also served as Chairman of the Board

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<sup>2</sup> Includes 31,982 shares held by Defendant Kapoor in his individual capacity; 69,387 shares that Kapoor has the right to acquire from the Company within 60 days of March 15, 2017 pursuant to the exercise of stock options; 42,430,310 shares held by The John N. Kapoor Trust, dated September 20, 1989, of which Kapoor is the sole trustee and sole beneficiary; 4,557,950 shares held by The Kapoor Children’s Trust, the trustee of which is an employee of EJ Financial Enterprises Inc., a company for which Kapoor serves as President, and the beneficiaries of which are Kapoor’s children; 56,288 shares held by EJ Financial/NEO Management, L.P., of which Kapoor is Managing General Partner; 18,662 shares held by The John and Editha Kapoor Charitable Foundation, or the Charitable Foundation, of which Kapoor is a joint trustee; and 1,129,724 shares of common stock owned by several trusts, the trustee of which is an employee of EJ Financial Enterprises Inc., a company for which Kapoor serves as President, and the beneficiaries of which are Kapoor’s family.

<sup>3</sup> Emphasis in original unless otherwise noted throughout.

until he stepped down in January 2017. Dr. Kapoor also served as our President and Chief Executive Officer from November 2015 to January 2017. Dr. Kapoor also served as a director of Insys Pharma from its inception in 2002. Dr. Kapoor has served as the President and chairman of the board of directors of EJ Financial Enterprises since forming the company in 1990. Dr. Kapoor is also the Managing Partner of Kapoor-Pharma Investments, an investment company that he founded in 2000. Dr. Kapoor serves as the chairman of the board of directors of Akorn, Inc., a publicly traded specialty pharmaceutical company, where he previously served as the interim Chief Executive Officer from March 2001 to May 2002 and as chief executive officer from May 2002 to December 2002. Dr. Kapoor also served as the chairman of the board of directors of Sciele Pharma and OptionCare, a specialty pharmaceutical services company, where he served as Chief Executive Officer from August 1993 to April 1996. Dr. Kapoor received his Ph.D. in Medicinal Chemistry from the State University of New York at Buffalo and a B.S. in Pharmacy from Bombay University in India. We believe that Dr. Kapoor's leadership experience in the biopharmaceutical industry and his success as a venture capitalist add valuable expertise and insight to our Board.

### **Defendant Baker**

54. Defendant Darryl S. Baker ("Baker") served as the Company's CFO from October 2012 to July 18, 2017. According to the 2017 Proxy Statement, on March 15, 2017, Defendant Baker beneficially owned 447,523 shares of the Company's common stock.<sup>4</sup> Given that the price per share of the Company's common stock at the close of trading on March 15, 2017 was \$10.55, Baker owned over \$4.7 million worth of Insys stock.

55. For the fiscal year ended December 31, 2016, Defendant Baker received \$680,876 in compensation from the Company. This included \$273,000 in salary, \$40,950 in bonus, \$358,026 in option awards, and \$8,900 in all other compensation.

56. The Company's 2017 Proxy Statement stated the following about Defendant Baker:

*Darryl S. Baker* has served as our Chief Financial Officer since October 2012. From 2001 to 2012, Mr. Baker served as Chief Financial Officer and Corporate

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<sup>4</sup> Represents 18,312 shares held by Mr. Baker and 429,211 shares that Defendant Baker has the right to acquire from the Company within 60 days of March 15, 2017 pursuant to the exercise of stock options.

Controller for iGo, a developer of power management solutions and accessories for mobile electronic devices. From 2000 to 2001, Mr. Baker served as the Corporate Controller for Integrated Information Systems, Inc., a provider of secure integrated information technology solutions. From 1997 to 1999, Mr. Baker served as the Corporate Controller for SkyMall, Inc., a specialty retailer. Prior to 1997, Mr. Baker was an audit manager for Ernst & Young. Mr. Baker earned his B.S. in Accountancy from the Marriott School of Management at Brigham Young University and is a Certified Public Accountant in the states of California and Arizona and is also a Chartered Global Management Accountant. We believe that Mr. Baker has extensive experience in public equity markets, accounting, and SEC compliance, which qualifies him to serve as our Chief Financial Officer.

57. Defendant Baker is a citizen of Arizona.

**Defendant Vetticaden**

58. Defendant Santosh J. Vetticaden (“Vetticaden”) served as the Company’s CEO and Chief Medical Officer following Defendant Kapoor’s abrupt resignation, from January 9, 2017 to his resignation on April 11, 2017, just seven business days after the Company announced that it would be issuing restated financials. In the Company’s January 9, 2017 press release announcing Defendant Vetticaden’s appointment as Interim CEO, Insys emphasized Defendant Vetticaden’s experience and “passion for drug development and commercialization for over 20 years in diverse areas.” Defendant Vetticaden received his Ph.D. from the Virginia Commonwealth University, his M.D. from the University of Maryland, and his M.B.A. from the Sloan School of Management at the Massachusetts Institute of Technology.

**Defendant Babich**

59. Defendant Michael L. Babich (“Babich”) served as a member of the Board starting in 2008, became the Company’s President in November 2010, and became its CEO in March 2011. He resigned from all these positions on November 4, 2015.

60. During the period of time when the Company materially misstated information to keep the stock price inflated, and before the scheme was exposed, Defendant Babich made the

following sales of company stock, and made no purchases of Company stock:

<b>Date</b>	<b>Number of Shares</b>	<b>Price</b>	<b>Proceeds</b>
May 17, 2015	27,400	\$58.09	\$1,591,748
May 16, 2015	47,600	\$59.33	\$2,824,012
November 4, 2014	7,500	\$37.27	\$279,502
November 3, 2014	72,500	\$39.06	\$2,831,560
October 21, 2014	20,000	\$40.17	\$803,400

Thus, in total, before the fraud was exposed, he sold 175,000 Company shares on inside information, for which he received over \$8.3 million. His insider sales made with knowledge of material non-public information before the material misstatements and omissions were exposed demonstrate his motive in facilitating and participating in the scheme.

### **Defendant Fourteau**

61. Defendant Patrick P. Fourteau (“Fourteau”) served as a Company director from March 2011 to October 29, 2017 and was a member of the Audit Committee. According to the 2017 Proxy Statement, on March 15, 2017, Defendant Fourteau beneficially owned 221,174 shares of the Company’s common stock.<sup>5</sup> Given that the price per share of the Company’s common stock at the close of trading on March 15, 2017 was \$10.55, Fourteau owned over \$2.3 million worth of Insys stock.

62. For the fiscal year ended December 31, 2016, Defendant Fourteau received \$321,428 in compensation from the Company, comprised of \$112,000 in fees paid or earned in cash, and \$209,428 in option awards.

63. The Company’s 2017 Proxy Statement stated the following about Defendant Fourteau:

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<sup>5</sup> Represents 49,682 shares held by Defendant Fourteau and 171,492 shares that Fourteau has the right to acquire from the Company within 60 days of March 15, 2017 pursuant to the exercise of stock options.

*Patrick P. Fourteau* has served on our Board since March 2011. Since May 2016, Mr. Fourteau has served as the Chairman of the Board of Directors of Repros Therapeutics, Inc. a publicly traded pharmaceutical company. Mr. Fourteau served as the Chief Executive Officer and a member of the Board of Directors of New Haven Pharmaceutical from 2008 to 2017. Mr. Fourteau served as President and Chief Executive Officer of Shionogi from 2008 until 2010. Prior to the acquisition of Sciele Pharma by Shionogi, Mr. Fourteau served as President and CEO of Sciele Pharma from 2003 until 2008 and served on the board of directors of Sciele from 2004 until 2008. Mr. Fourteau served as President of Worldwide Sales of inVentiv Health, Inc. from 2000 to 2002. Mr. Fourteau served as President of various divisions of St. Jude Medical, Inc. from 1995 to 2000 and as an Executive of Eli Lilly and Company prior to 1995. Mr. Fourteau earned his MBA from Harvard University and a B.A. and M.A. in Mathematics from the University of California, Berkeley. We believe that Mr. Fourteau's leadership experience in the pharmaceutical industry adds valuable financial, operational and other expertise and insight to our Board.

64. During the period of time when the Company materially misstated information to keep the stock price inflated, and before the scheme was exposed, Defendant Fourteau made the following sales of Company stock (and made no purchases of Company stock):

<b>Date</b>	<b>Number of Shares</b>	<b>Price</b>	<b>Proceeds</b>
August 11, 2016	15,000	\$18.46	\$276,900
November 12, 2015	30,000	\$26.48	\$794,400
May 27, 2015	1,311	\$60.14	\$234,546
May 26, 2015	4,784	\$60.00	\$287,040
May 20, 2015	6,095	\$60.00	\$365,700
May 19, 2015	2,969	\$60.00	\$178,140
March 11, 2015	10,000	\$59.94	\$599,360
November 19, 2014	25,000	\$39.11	\$977,675

Thus, in total, before the fraud was exposed, he sold 95,159 Company shares on inside information, for which he received over \$3.7 million. His insider sales made with knowledge of material non-public information before the material misstatements and omissions were exposed demonstrate his motive in facilitating and participating in the scheme.

### **Defendant Lapalme**

65. Defendant Pierre Lapalme ("Lapalme") has served as a Company director since March 2011. According to the 2017 Proxy Statement, on March 15, 2017, Defendant Lapalme

beneficially owned 171,492 shares of the Company's common stock.<sup>6</sup> Given that the price per share of the Company's common stock at the close of trading on March 15, 2017 was \$10.55, Lapalme owned about \$1.8 million worth of Insys stock.

66. For the fiscal year ended June 30, 2017, Defendant Lapalme received \$299,428 in compensation from the Company, comprised of \$90,000 in fees paid or earned in cash, and \$209,428 in option awards.

67. The Company's 2017 Proxy Statement stated the following about Defendant Lapalme:

*Pierre Lapalme* has served on our Board since March 2011. Mr. Lapalme is Chairman of the Board of Pediapharm Inc., a publicly traded pharmaceutical company traded on the Toronto Stock Exchange, and has served on their Board of Directors since January 2014. From January 2004 to June 2016, Mr. Lapalme served on the Board of Directors of BioMarin Pharmaceutical Inc., a publicly traded pharmaceutical company. From August 2004 until January 2015, Mr. Lapalme served as Chairman of the Board of Directors of BioMarin Pharmaceutical Inc. From 2009 to 2016, Mr. Lapalme served on the Board of Directors of Aeterna Zentaris, Inc., a biopharmaceutical company publicly traded on the Toronto Stock Exchange. From 1995 until his retirement in 2003, he served as the President and Chief Executive Officer of North America Ethypharm, Inc., a drug delivery company. Throughout his career, Mr. Lapalme held numerous senior management positions in the pharmaceutical industry, including Chief Executive Officer and Chairman of the Board of Rhône-Poulenc Pharmaceuticals, Inc., in Canada, from 1979 to 1994, and Senior Vice President and General Manager of North America Ethicals, a division of Rhône-Poulenc Rorer, Inc. (now known as Sanofi) where he oversaw the development of the ethical pharmaceutical business in the United States, Canada, Mexico, and Central America. Mr. Lapalme served on the board of the National Pharmaceutical Council and was a board member of the Pharmaceutical Manufacturers Association of Canada, where he played a leading role in reinstating certain patent protection for pharmaceuticals. Mr. Lapalme also previously served on the board of directors of two other public companies: Sciele Pharmaceuticals Inc. from 2000 to 2008 and Bioxel Pharma from 2004 to 2009. He also served on the board of two private biotech companies. Mr. Lapalme studied at the University of Western Ontario and INSEAD France. We believe that Mr. Lapalme's experience

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<sup>6</sup> Represents 171,492 shares that Mr. Lapalme has the right to acquire from the Company within 60 days of March 15, 2017 pursuant to the exercise of stock options.

in the pharmaceutical industry gives him a valuable understanding of our industry which qualifies him to serve as a member of our Board.

**Defendant Meyer**

68. Defendant Steven Meyer (“Meyer”) has served as a Company director since November 2010, as Chairman of the Board since January 9, 2017, and is a member of the Audit Committee. According to the 2017 Proxy Statement, on March 15, 2017, Defendant Meyer beneficially owned 194,226 shares of the Company’s common stock.<sup>7</sup> Given that the price per share of the Company’s common stock at the close of trading on March 15, 2017 was \$10.55, Meyer owned over \$2 million worth of Insys stock.

69. For the fiscal year ended June 30, 2017, Defendant Meyer received \$306,428 in compensation from the Company, comprised of \$97,000 in fees paid or earned in cash, and \$209,428 in option awards.

70. The Company’s 2017 Proxy Statement stated the following about Defendant Meyer:

*Steven Meyer* has served on our Board since November 2010 and has served as our Chairman of the Board since January 9, 2017. From August 2007 until November 2010, Mr. Meyer served as a director of Insys Pharma. Mr. Meyer has served as a director of Akorn, Inc., a publicly traded specialty pharmaceutical company, since June 2009. Since November 2005, Mr. Meyer has served as the Chief Financial Officer of JVM Realty Corporation, a private investment firm specializing in the acquisition, re-positioning and management of real estate for investors. Prior to that, Mr. Meyer was employed by Baxter International Incorporated, a global healthcare company, where he served as Corporate Treasurer and International Controller and VP of Global Operations during a 23-year career at this company. Mr. Meyer earned his MBA in finance and accounting from the Kellogg Graduate School of Management at Northwestern University and his B.A. in Economics from the University of Illinois in Champaign-Urbana. He is an Illinois Certified Public Accountant. We believe that

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<sup>7</sup> Represents 44,083 shares beneficially held by Mr. Meyer and 150,143 shares that Mr. Meyer has the right to acquire from the Company within 60 days of March 15, 2017 pursuant to the exercise of stock options.

Mr. Meyer's management experience and his knowledge of the finance and healthcare industries give him a valuable understanding of our industry which qualifies him to serve as a member of our Board and as our Chairman of the Board.

71. During the period of time when the Company materially misstated information to keep the stock price inflated, and before the scheme was exposed, Defendant Meyer made the following sales of Company stock (and made no purchases of Company stock). On June 5, 2015, Defendant Meyer sold 5,000 shares of Company stock for \$63.00 per share. On May 11, 2015, Defendant Meyer sold 18,000 shares of Company stock for \$56.72 per share. Thus, in total, before the fraud was exposed, he sold 23,000 Company shares on inside information, for which he received over \$1.3 million. His insider sales made with knowledge of material non-public information before the material misstatements and omissions were exposed demonstrate his motive in facilitating and participating in the scheme.

**Defendant Stanley**

72. The Estate of Dr. Theodore H. Stanley shall be referred to as "Defendant Stanley" herein. Dr. Stanley, the inventor of Actiq, served as a Company director from March 2013 until his death on July 13, 2017. According to the 2017 Proxy Statement, on March 15, 2017, Defendant Stanley beneficially owned 221,174 shares of the Company's common stock.<sup>8</sup> Given that the price per share of the Company's common stock at the close of trading on March 15, 2017 was \$10.55, Stanley owned over \$2.3 million worth of Insys stock.

73. For the fiscal year ended June 30, 2017, Defendant Stanley received \$321,428 in compensation from the Company, comprised of \$112,000 in fees paid or earned in cash, and \$209,428 in option awards.

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<sup>8</sup> Represents 49,682 shares held by Mr. Fourteau and 171,492 shares that Mr. Fourteau has the right to acquire from the Company within 60 days of March 15, 2017 pursuant to the exercise of stock options.

74. The Company's 2017 Proxy Statement stated the following about Defendant Stanley:

*Theodore H. Stanley, M.D.* has served on our Board since March 2013. Since July 2009, Dr. Stanley has served as a managing director of UpStart Ventures, a venture capital fund focusing on investments in life sciences companies, and since 1978, Dr. Stanley has been a full time professor in the Department of Anesthesiology at the University of Utah, School of Medicine. In 1985, Dr. Stanley co-founded Anesta Corp., a publicly held pharmaceutical company focusing on the development of transmucosal drug products, including its lead product, Actiq, which was co-invented by Dr. Stanley in 1983. From 1985 to December 1997, Dr. Stanley served as chairman of the board of Anesta and served as Anesta's Medical Director until April 1994, following which he served as founding chairman from January 1998 until the sale of Anesta to Cephalon in October 2000. In 1996, Dr. Stanley co-founded ZARS Pharma, Inc., a privately held specialty pharmaceutical company that focused on the development and commercialization of topically administered drugs primarily in the area of pain management. Dr. Stanley served as chairman of the board of directors of ZARS Pharma until its acquisition in May 2011 by Nuvo Research Inc., a publicly held Canadian pharmaceutical company, of which Dr. Stanley currently serves as a director. Dr. Stanley also serves on the board of directors of seven privately held life sciences companies, four of which he serves as chairman of the board. Dr. Stanley earned his M.D. degree from Columbia University, College of Physicians and Surgeons (Medical Science), as well as an A.B. from Columbia College. We believe that Dr. Stanley's extensive operational and leadership experience in the pharmaceutical industry, including his experience in the development and commercialization of transmucosal drug products, brings valuable expertise and insight to our Board.

75. During the period of time when the Company materially misstated information to keep the stock price inflated, and before the scheme was exposed, Defendant Stanley made the following sales of Company stock (and made no purchases of Company stock):

<b>Date</b>	<b>Number of Shares</b>	<b>Price</b>	<b>Proceeds</b>
August 11, 2016	15,000	\$18.46	\$276,900
November 12, 2015	30,000	\$26.48	\$794,400
May 27, 2015	1,311	\$60.14	\$234,546
May 26, 2015	4,784	\$60.00	\$287,040
May 20, 2015	6,095	\$60.00	\$365,700
May 19, 2015	2,969	\$60.00	\$178,140
March 11, 2015	10,000	\$59.94	\$599,360

November 19, 2014	25,000	\$39.11	\$977,675
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Thus, in total, before the fraud was exposed, he sold 45,000 Company shares on inside information, for which he received nearly \$1.3 million. Many of these sales were not made pursuant to a 10b5-1 trading plan. His insider sales made with knowledge of material non-public information before the material misstatements and omissions were exposed demonstrate his motive in facilitating and participating in the scheme.

### **Defendant Tambi**

76. Defendant Brian Tambi (“Tambi”) served as a Company director from November 2010 until May 10, 2018, when he resigned. He was a member of the Audit Committee. According to the 2017 Proxy Statement, on March 15, 2017, Defendant Tambi beneficially owned 200,226 shares of the Company’s common stock.<sup>9</sup> Given that the price per share of the Company’s common stock at the close of trading on March 15, 2017 was \$10.55, Tambi owned over \$2.1 million worth of Insys stock.

77. For the fiscal year ended June 30, 2017, Defendant Tambi received \$266,428 in compensation from the Company, comprised of \$57,000 in fees paid or earned in cash, and \$209,428 in option awards.

78. The Company’s 2017 Proxy Statement stated the following about Defendant Tambi:

*Brian Tambi has served on our Board since November 2010. From August 2007 until the November 2010, Mr. Tambi served as a director of Insys Pharma. Mr. Tambi has served as a member of the Board of Directors of Akorn, Inc., a publicly traded specialty pharmaceutical company, since June 2009. Since forming the company in January 2006, Mr. Tambi has served as the Chairman of the Board, President and Chief Executive Officer of Antrim Pharma (formerly*

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<sup>9</sup> Represents 200,226 shares that Mr. Tambi has the right to acquire from the Company within 60 days of March 15, 2017 pursuant to the exercise of stock option.

BrianT Laboratories LLC), a pharmaceutical company currently focused on developing, manufacturing and marketing combinations of leading single agent drugs and delivery systems. From 1995 to January 2007, Mr. Tambi served as the Chairman, President and Chief Executive Officer of Morton Grove Pharmaceuticals, Inc. Prior to Morton Grove, Mr. Tambi served as President of Ivax North American Pharmaceuticals and as a member of the board of directors of Ivax Corporation (acquired by Teva), a publicly traded pharmaceutical company. Mr. Tambi also served as Chief Operating Officer of Fujisawa USA, Inc., a subsidiary of Fujisawa Pharmaceutical Company, Ltd. Mr. Tambi also held executive positions at Lyphomed, Inc. and Bristol-Myers Squibb. Mr. Tambi earned his MBA in International Finance & Economics and his B.S. in Corporate Finance from Syracuse University. We believe that Mr. Tambi's drug development and commercialization expertise in the pharmaceutical industry, as well as his experience in the finance sector, brings important strategic insight to our Board.

79. During the period of time when the Company materially misstated information to keep the stock price inflated, and before the scheme was exposed, Defendant Tambi made the following sales of Company stock (and made no purchases of Company stock):

<b>Date</b>	<b>Number of Shares</b>	<b>Price</b>	<b>Proceeds</b>
May 27, 2015	3,100	\$60.09	\$186,279
May 26, 2015	1,800	\$60.00	\$108,000
May 20, 2015	3,900	\$60.00	\$234,546
May 19, 2015	1,200	\$60.00	\$72,012

Thus, in total, before the fraud was exposed, he sold 10,000 Company shares on inside information, for which he received over \$600,837. His insider sales made with knowledge of material non-public information before the material misstatements and omissions were exposed demonstrate his motive in facilitating and participating in the scheme.

#### **FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS**

80. By reason of their positions as officers, directors and/or fiduciaries of Insys and because of their ability to control the business and corporate affairs of Insys, the Individual Defendants owed Insys and its shareholders fiduciary obligations of trust, loyalty, good faith,

and due care, and were and are required to use their utmost ability to control and manage Insys in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Insys and its shareholders so as to benefit all shareholders equally.

81. Each director and officer of the Company owes to Insys and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company and in the use and preservation of its property and assets and the highest obligations of fair dealing.

82. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Insys, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

83. To discharge their duties, the officers and directors of Insys were required to exercise reasonable and prudent supervision over the management, policies, controls, and operations of the Company.

84. Each Individual Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the highest fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Insys, the absence of good faith on their part, or a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company. The conduct of the Individual Defendants who were also officers and directors of the Company has been ratified by the remaining Individual Defendants who collectively comprised Insys's Board at all relevant times.

85. As senior executive officers and directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, the Individual Defendants had a duty to prevent and not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, operations, financial statements, business, products, management, earnings, internal controls, and present and future business prospects, so that the market price of the Company's common stock would be based upon truthful and accurate information. They also had a duty not to engage in the Sales Misconduct.

86. To discharge their duties, the officers and directors of Insys were required to exercise reasonable and prudent supervision over the management, policies, practices, and internal controls of the Company. By virtue of such duties, the officers and directors of Insys were required to, among other things:

- (a) ensure that the Company was operated in a diligent, honest, and prudent manner in accordance with the laws and regulations of Arizona, Delaware, the United States, and pursuant to Insys's own internal guidelines, including its Code of Business Conduct and Ethics ("Code of Conduct");
- (b) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;
- (c) remain informed as to how Insys conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;

- (d) establish and maintain systematic and accurate records and reports of the business and internal affairs of Insys and procedures for the reporting of the business and internal affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records;
- (e) maintain and implement an adequate and functioning system of internal legal, financial, and management controls, such that Insys's operations would comply with all laws and Insys's financial statements and regulatory filings filed with the SEC and disseminated to the public and the Company's shareholders would be accurate;
- (f) exercise reasonable control and supervision over the public statements made by the Company's officers and employees and any other reports or information that the Company was required by law to disseminate;
- (g) refrain from unduly benefiting themselves and other Company insiders at the expense of the Company;
- (h) examine and evaluate any reports of examinations, audits, or other financial information concerning the financial affairs of the Company and to make full and accurate disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set forth above; and
- (i) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock.

87. Each of the Individual Defendants further owed to Insys and the shareholders the duty of loyalty requiring that each favor Insys's interest and that of its shareholders over their own while conducting the affairs of the Company and refrain from using their position, influence or knowledge of the affairs of the Company to gain personal advantage.

88. At all times relevant hereto, the Individual Defendants were the agents of each other and of Insys and were at all times acting within the course and scope of such agency.

89. Because of their advisory, executive, managerial, and directorial positions with Insys, each of the Individual Defendants had access to adverse, non-public information about the Company.

90. The Individual Defendants, because of their positions of control and authority, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by Insys.

**CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION**

91. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their wrongdoing. The Individual Defendants caused the Company to conceal the true facts as alleged herein. The Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

92. The purpose and effect of the conspiracy, common enterprise, and/or common course of conduct was, among other things, to: (i) facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, waste of corporate assets, gross mismanagement, abuse of control, and violations of Sections 14(a), 10(b) and 20(a) of the Exchange Act; (ii) to engage in the Sales Misconduct; (iii) to conceal adverse information concerning the Company's operations, financial condition, future business prospects, and internal controls; and (iv) to artificially inflate the Company's stock price.

93. The Individual Defendants accomplished their conspiracy, common enterprise, and/or common course of conduct by causing the Company purposefully, recklessly, or negligently to conceal material facts, fail to correct such misrepresentations, and violate

applicable laws. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants who are directors of Insys was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.

94. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each of the Individual Defendants acted with actual or constructive knowledge of the primary wrongdoing, substantially assisted in the accomplishment of that wrongdoing, and was or should have been aware of his or her overall contribution to and furtherance of the wrongdoing.

95. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and of Insys and was at all times acting within the course and scope of such agency.

#### **INSYS'S CODE OF CONDUCT**

96. The Company's Code of Conduct states that "[r]egardless of your position, location or tenure, we must all comply with this Code. This means that whether you are an officer, director, employee or a consultant, you are responsible for [complying with the Code]."

97. The Code of Conduct states, with regard to "Compliance with Laws and Regulations," that:

We take our commitment to complying with all laws and regulations seriously. Accordingly, ***all INSYS employees must comply with the letter and spirit of all applicable laws and regulations including those that relate to the development, distribution and commercialization of our pharmaceutical products.*** It is therefore imperative that you comply with all FDA and state requirements that you are aware of, and all Controlling Guidance that applies to your function. You should also know when to seek advice from your manager, a member of the Executive Committee or the Compliance Committee, and feel free to do so. Insys' Compliance Committee is comprised of its legal counsel, the Chief Compliance

Officer, the CEO and the heads of the Company's Medical, Sales, Marketing, Finance, Quality, Regulatory and Human Resources departments.

(Emphasis added.)

98. With respect to "Fraud and Abuse," the Code of Conduct provides:

We operate under the scrutiny of many laws and regulations aimed at preventing, uncovering and punishing fraud and abuse. For example, *some of the laws and regulations are designed to prevent false or fraudulent claims in federal healthcare programs (Federal Civil False Claims Act), while others are meant to ensure that healthcare providers' decisions are not influenced by personal gain (Federal Anti-Kickback statute). We as a Company are committed to adhering to all laws and regulations governing our business activities.*

(Emphasis added.)

99. The Code of Conduct provides, as to "Marketing Truthfully," that:

All employees are responsible for truthfully conveying product and Company information. Accordingly, we must ensure that our marketing and promotional materials are accurate and contain a balanced discussion of the benefits and risks of our products. Furthermore, *employees cannot misstate facts, create false or deceptive impressions, omit material facts or promote a product in a manner that is inconsistent with its approved labeling.* All promotional materials must comply with applicable laws and regulations. We have a committee at the corporate headquarters that reviews and approves all such materials before they are utilized externally. This committee certifies that our materials and claims are based on sound scientific and technical facts and include all required information. Accordingly, once marketing and promotional materials are approved, you may not modify them in any way. Moreover, *the marketing or promotion of INSYS products for purposes other than the FDA approved indication is strictly prohibited.*

(Emphasis added.)

100. The Code of Conduct provides, in a section titled "Interactions with Healthcare Providers," that:

*Building trusting and ethical relationships with our customers is critical to our current and future success.* INSYS has incorporated in its business policies and procedures the guidance provided by the Pharmaceutical Research and Manufacturers of America on Interactions with Healthcare Professionals (the PhRMA Code). The goal of the PhRMA Code is to ensure that HCPs' decisions

are based on their expertise and each patient's medical needs. The *exchange of gifts, meals, entertainment or anything of value is strictly regulated in our industry* and it is therefore important that you know the rules of engagement and also comply with all the Company's Controlling Guidance. Because of this scrutiny, *we must accurately document all payments or other items of value provided to HCPs.*

**1. Payments** to HCPs are scrutinized closely in our industry. *We must therefore monitor all fees, payments and compensation paid to HCPs for advisory boards, consulting or other services to avoid even the appearance of inappropriate influence. Payments for such services must therefore be pursuant to a written contract and at fair market value.* Moreover, all payments in connection with Continuing Medical Education shall be made directly to the organizer without restriction on their use.

**2. Gifts** to HCPs may occasionally be provided if they are of nominal value (less than \$100) and designed for patient or HCP education (e.g., medical books, etc.). According to the PhRMA Code, items that do not serve such educational purposes (e.g., pens, notepads) are prohibited. Permitted nominal gifts must not have value to the HCP outside of their medical practice and must be approved by the Compliance department.

**3. Meals** *may occasionally be provided to HCPs as long as they are modest and shared at a reasonable location that is conducive to discussing educational information.*

**4. Recreation**, entertainment events' (e.g. sports) tickets, trips or other forms of entertainment may not be offered or provided to HCPs.

*We must always document all payments or items of value provided to HCPs on Insys' behalf.* Such documentation will enable us to comply with certain reporting requirements and laws.

(Bold subheadings in original. Bold & italic emphasis added.)

101. The Code of Conduct provides, in a section titled "Bribery and Payments to Government Officials," in relevant part:

We also comply with the Federal Anti-Kickback statute which *prohibits the offer of anything to a person that is intended to influence that person to recommend or purchase a product or service that may be reimbursed by the federal government.* This means that we do not offer, pay or promise any bribe, kickback or anything of value to anyone for obtaining business or any unfair advantage.

(Emphasis added.)

102. In the section titled “Insider Trading,” the Code of Conduct provides, in relevant part:

Employees who have access to confidential (or “inside”) information are not permitted to use or share that information for stock trading purposes or for any other purpose except to conduct our business. All non-public information about the Company or about companies with which we do business is considered confidential information. ***To use material nonpublic information in connection with buying or selling securities, including “tipping” others who might make an investment decision on the basis of that information, is not only unethical, but also illegal.*** Employees must exercise the utmost care when handling material inside information.

(Emphasis added.)

103. Although the Code of Conduct avers that Insys has “adopted a separate Insider Trading Policy,” no such policy is available on the Company’s website.

104. The Code of Conduct provides, in the section titled “Books, Payments and Records,” that:

Accurate books and records are essential to the management of the Company. All Company books and records – including expense reports, time sheets, invoices, payroll, performance evaluations, etc. must accurately reflect Company transactions.

***All monetary payments by INSYS to third parties must be for legitimate business purpose, and shall be made via an approved company financial payment system*** (e.g. by bank transfer, bank check, company credit card, etc.). ***Payments must not take the form of cash or cash equivalent*** (e.g., debit cards, gift cards, gift certificates, etc.), ***and shall be accurately and appropriately recorded in the company’s books and records.*** Where payments are made through a specifically authorized third party, on behalf of INSYS, when genuine business needs require such an arrangement, the third party shall be contractually obligated to accurately document, track and report to INSYS the amounts paid on its behalf and the method of payment.

(Emphasis added.)

105. The Individual Defendants violated the Code of Conduct by making and/or causing the Company to make the false and misleading statements and/or omissions discussed

herein, violating applicable laws and regulations, and engaging in the Sales Misconduct. Moreover, five (5) of the Individual Defendants violated the Code of Conduct by engaging in insider trading.

### **LEGAL AND REGULATORY BACKGROUND**

106. Under the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), it is unlawful to knowingly offer or pay any remuneration in exchange for the referral of any product for which payment is sought from any federally-funded healthcare program, such as Medicare or Medicaid. This law prohibits drug manufacturers from compensating, in cash or in kind, any health care provider where a purpose of the payment is to influence the provider's prescribing habits or to gain favor of its product. Every federally funded health care program requires every provider or supplier to ensure compliance with the Anti-Kickback Act.

107. Prior to Subsys' approval by the FDA, regulators had brought actions and obtained guilty pleas against pharmaceutical manufacturers of opioid painkillers, including painkillers based on fentanyl.

108. Three executives of Purdue Pharma L.P. ("Purdue") pleaded guilty to civil and criminal charges in 2007, agreeing to pay more than \$600 million in fines in connection with the company's marketing and sales of OxyContin. Purdue had targeted the country's highest opioid prescribers, paying them speaking engagement fees and providing them with perks such as gifts and electronics. Purdue sales representatives were also paid lucrative bonuses to increase OxyContin sales in their respective territories.

109. Cephalon Inc. ("Cephalon") pleaded guilty in 2008 and agreed to pay \$425 million to settle claims for its off-label marketing of Actiq, a lollipop or lozenge based fentanyl delivery system that is a competitor of Subsys. Cephalon's marketing activities included: (i) intensively marketing Actiq to physical medicine, rehabilitation, and pain management

specialists; (ii) targeting physicians writing a large number of narcotic and controlled substance prescriptions regardless of specialty, despite the fact that Actiq was approved only for BTCP; (iii) paying kickbacks to physicians in the form of speaking fees; (iv) assisting physicians in securing Medicaid reimbursement for Actiq when off-label use was ineligible for Medicaid payment; and (v) by uncapping the potential bonuses for employees to further encourage off-label sales.

110. Insys submitted a New Drug Application (“NDA”) to the FDA on March 14, 2011 for Subsys. As permitted, the application referenced Actiq. As Actiq was referenced in the application, Defendant Kapoor and other Company leaders would have been aware of Actiq’s history.

111. The FDA approved Subsys on January 2, 2012 “[f]or the management of breakthrough pain in cancer patients 18 years of age or older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.” The risks posed by Subsys, which include addiction and death, resulted in the drug being contraindicated for numerous other kinds of pain, such as migraines, dental pain, and postoperative pain. The FDA recommends that Subsys only be prescribed “by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.”

112. While doctors have the discretion to prescribe drugs outside of the FDA’s approved uses, it is illegal for a manufacture to market or promote a drug for off-label use. 21 U.S.C. §§ 331(d), 355(a). In order to market a product for additional uses, manufacturers must resubmit the drug for clinical trials similar to the original approval process.

**INDIVIDUAL DEFENDANTS' MISCONDUCT**

**Background**

113. Insys is a pharmaceutical company whose lead product, Subsys, is a sublingual fentanyl-based pain relief spray, or TIRF, approved for the treatment of BTCP.

114. As a fentanyl-based product, Subsys is a highly regulated Schedule II drug. Fentanyl has recently become a popular product to use to “cut” illicit drugs, such as heroin and cocaine, due to its relative cheapness and high potency. As a result, fentanyl related overdoses have become a serious issue, killing thousands per year in the past few years in the United States alone.

115. The FDA approved Subsys for BTCP, requiring the following black box warning:

**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 mcg per mcg 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](http://www.TIRFREMSaccess.com) or by calling 1-866-822-1483.

***The Off-label Misconduct***

116. Federal law prohibits distributing drugs in interstate commerce for any intended use not approved as safe and effective by the FDA. 21 U.S.C. § 355(a) and (b).

117. Following FDA approval of Subsyz for BTCP, the Board approved an aggressive

off-label marketing strategy, despite the clear dangers and contraindications noted above in the black box warning. As stated in the July 2015 ODOJ Notice of Improper Trade Practices (the “ODOJ Notice”), “[f]rom the start, Insys made the strategic decision to target doctors who were already prescribing Actiq and other TIRFs and had already been exposed to Cephalon’s unlawful off-label promotional campaign which was the subject of the federal criminal action. Only a minority of these physicians are oncologists likely to prescribe SUBSYS for the on-label indication of breakthrough cancer pain.”

118. The Individual Defendants caused the Company to adopt certain key features of Cephalon’s marketing program in order to gain market share by promoting off-label use of Subsys. In fact, the Individual Defendants caused the Company to recruit individuals from Cephalon’s marketing team. Ultimately, Insys hired Cephalon’s Vice President of Sales, Alec Burlakoff (“Burlakoff”), its VP of Marketing, Matthew Napoletano (“Napoletano”), and several Cephalon sales representatives in order to reproduce Cephalon’s illegal Actiq marketing strategy.

119. An article by the *SIRF* reported that Burlakoff “pushed the boundaries of what defined pharmaceutical sales.” *The Florida Times-Union* reported that Burlakoff had been terminated by the pharmaceutical company Eli Lilly for sending unsolicited mailings of antidepressant Prozac to South Florida residents in an attempt to drive sales.

120. In an article in *Pharmaceutical Executive* from July 2013, a reporter interviewed Defendant Babich. It states that “[s]ome of Insys’ most successful recruits are those who originally worked for small companies that were bought out by big companies.” In the article, Defendant Babich states, “[t]he most difficult part of [his] job is hiring.... Finding the right person who understands we are going to do things very differently from Big Pharma.”

121. The Individual Defendants caused the Company to adopt a highly aggressive

marketing strategy. In at least one district, Insys sales representatives received emails detailing Subsys prescriptions that had not been picked up or gone unrenewed. As a result, sales representatives would go so far as to call the patient and encourage him or her to request a new, stronger prescription from their doctor.

122. The Company also directed sales representatives to seek permission to review patient files in doctor's offices. This information would then be used to identify patients who might qualify for a stronger dose.

123. The Company sought out young and inexperienced sales representatives, and then paid them a low base salary in a heavily incentive based compensation structure. With a salary of just \$40,000, half the industry standard, sales representatives had to rely on incentive compensation in order to earn a decent wage. Such a compensation structure was also employed at Sciele Pharma, another company founded by Defendant Kapoor and managed by Defendants Lapalme and Fourteau.

124. The *SIRF* reported that Burlakoff hired Amanda Corey Emphof, a former reality show star who had previously posed for *Playboy*. Another sales employee, Sunrise Lee ("Lee"), had formerly been an exotic dancer. Jeff Pearlman sold aquariums prior to joining the Insys sales team.

***The Off-label Misconduct***

125. Subsys' label states that physicians are supposed to titrate patients when dosing Subsys. Titration is the process by which patients are started at a low dose of Subsys, working up to higher doses in order to determine the appropriate dose to treat a particular patient's BTCP.

126. Titration affects Subsys' revenues, as higher doses translate to higher revenues. A month's supply of 30 doses of Subsys 100 mcg costs \$1,000 per month, while the highest

available supply of 240 doses of Subsys 1,200 mcg costs over \$21,000 per month.

127. Subsys' FDA-approved dosing instructions clearly state that the "initial dose of SUBSYS to treat episodes of breakthrough cancer is always 100 mcg." When increasing dosage, physicians must prescribe the next highest doses only after finding that the current dosage is insufficient to adequately treat BTCP for several consecutive episodes.

128. For patients already using Actiq, dosage guidelines are as follows. For patients prescribed: (i) 200 mcg and 400 mcg Actiq, the FDA-approved initial Subsys dose is 100 mcg; (ii) 600 mcg and 800 mcg Actiq, the FDA-approved initial dose is 200 mcg, and (iii) 1200 mcg and 1600 mcg Actiq, the FDA approved initial Subsys dose is 400 mcg.

129. According to former Insys sales representatives, sales staff were paid more for selling higher doses, both as a percentage of the sale and as a dollar value, a practice described as "highly unusual" by Pratap Khedkar, who oversees the pharmaceutical practice at sales and marketing firm ZS Associates.

130. Bonuses paid to sales representatives were highly material, with some sales representatives earning five and six figure bonuses per quarter.

131. In order to drive prescriptions at increased strengths, Defendant Babich encouraged sales representatives to lie to doctors. For example, at the Company's September 19, 2012 national sales meeting, Defendant Babich informed all sales representatives that "they should be telling their doctors that while they [i.e., the sales representatives] had to tell the doctor to start patients at 100 mcg, they had heard from other doctors that the doctor could start a patient taking 800 mcg of Actiq on 400 mcg of SUBSYS." This recommendation is contrary to the FDA mandated transitional dosage strength.

132. The Company developed what it termed the "effective dose" defined as 600 mcg to 1600 mcg of Subsys, far above the initial dose mandated by the FDA.

133. The ODOJ Notice alleged that the Company manipulated the definition of BTCP in order to expand the number of qualifying patients. The ODOJ Notice alleges that Insys initially defined BTCP as: a “transitory increase in pain to greater than moderate intensity which occurred on a baseline pain of moderate intensity or less (that is, to an intensity of ‘severe’ or ‘excruciating’).” By June 2012, the Company had relaxed its definition of BTCP to “a flare of mild-to-severe pain in patients with otherwise stable persistent pain.”

134. Insys management further pressured sales representatives to promote off-label uses to doctors. In an August 2012 visit to a pain management doctor, Burlakoff accompanied Ray Furchak. When the doctor asked about Subsys’ indication, the following exchange took place:

Burlakoff: Well, doctor, why do you care about indication? You can write SUBSYS for off-label use. I can’t talk to you about indications with you [sic], but you can write off-label.

Doctor: Insurance companies care about indication.

Burlakoff: Insurance companies do not care about indication . . . eighty percent of SUBSYS prescriptions are off-label.

135. At the Company’s national sales meeting on September 19, 2012, attended by Defendant Babich and other members of Insys management, sales representative Brook Smets asked management how to approach doctors given that 80 percent of Subsys prescriptions are off-label. The representatives were told to explain to their doctors that the evidence showed that “breakthrough pain is the same as breakthrough cancer pain.” This practice was similar to marketing strategies that had been implemented by Napoletano at Cephalon. By September 19, 2012, Napoletano was Insys’s VP of Marketing.

136. Company management even steered its sales force from targeting cancer patients, the most likely group to use the product for on-label use. Former sales representative Shannon

Walsh has stated that management discouraged sales representatives from contacting palliative care centers. As patients at these centers are terminally ill, management viewed them as a waste of time due to their short life expectancy, which limited the opportunity for repeat sales or use of larger doses. Essentially, on-label marketing was discouraged as not providing a good enough return on investment.

137. Instead, the Company encouraged its sales representatives to market to general practitioners, physical therapists, family medicine doctors, sports medicine doctors, and others who had no experience with oncology or pain management. Thus, these practitioners were unlikely to prescribe Subsys for BTCP.

138. Sales representatives were told to target individuals with no experience in prescribing Schedule II opioids, and who were not even enrolled in TIRF-REMS.

139. Burlakoff and Defendant Babich provided employees with lists of practitioners who had previously written off-label prescriptions for TIRF products, ranked in “deciles.” Each sales representative would be assigned a group of practitioners from across the range of the deciles. On one occasion, Defendant Babich received a list of medical practitioners who had written prescriptions for Subsys competitors. In response, he emailed Burlakoff directly stating, “I thought we owned the high decile folks? Lots of big names on there.”

140. Tim Neely (“Neely”), a former Insys sales representative who spoke to the *SIRF*, described Insys as having a form of “corporate schizophrenia.” “Sales training and company-wide phone calls would be by the book, exactly like Merck or someone might do. Then your [district and regional] managers would pull you aside and tell you, ‘Don’t worry about that. Just sell. Do what you need to do.’” According to Neely, Burlakoff told a training class in October 2013: “If you keep [patients] on [Subsys] for four months, they’re hooked . . . Then they’ll be on it for a year, maybe longer.” When Neely privately questioned if by “hooked,” Burlakoff

meant addicted, Burlakoff replied, “It’s not addicted if [the patient] is in pain.”

141. Jaimi Hooker—Insys sales representative to “Dr. Roy,” who is further discussed below—confirmed that she was “implicitly encouraged by [her] superiors to try to get doc[tors] to write” Subsys prescriptions “for back pain” in sworn testimony before the ODOJ. She confirmed that “marketing for off-label uses by implication” was a fair description of what she was asked to do by her superiors. She explained the concept of asking doctors to “write to their capability”—by which sales representatives would ask a doctor to transfer all of its TIRF business to Subsys, and then write more Subsys prescriptions, regardless of whether these patients had cancer or BTCP. She stated that such conversations were usually “difficult,” in part because “it would probably imply writing more off-label.”

142. At the Company’s 2014 national sales meeting, Burlakoff reinforced this strategy, describing cancer patients as “small potatoes”:

*These [doctors] will tell you all the time, well, I’ve only got like eight patients with cancer. Or, I only have, like, twelve patients that are on a rapid-onset opioids [sic]. Doc, I’m not talking about any of those patients. I don’t want any of those 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 [unintelligible] for the breakthrough pain, do you have a thousand people in your practice, a thousand patients, twelve of them are currently on a rapid-onset opioids [sic]. That leaves me with at least five hundred patents that can go on this drug.*

(Emphasis added.)

143. In another instance, a member of Company management texted a sales representative the following:

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

(Capitalized words in original, emphasis added).

144. The Company also maintained what was termed the “Switch Program,” the purpose of which was to switch patients from competing TIRF products to Subsys without regard to patient diagnosis. Under the Switch Program, Insys instructed its sales representatives to target prescribers of competing TIRFs and offer their patients free product if the patients switched to Subsys. In one instance, an Illinois sales representative was told to report back to the representative’s supervisor “the exact day and time [a potential switch patient] is scheduled back for his or her next visit” and then to “be in the office/when the patient is coming in (with coffee/bagels, etc.)” to make certain that the patient was switched to Subsys.

145. Where employees questioned the legality of the Off-label Misconduct, management was forced to lie. In one instance, Defendant Babich responded to a question from a sales representative at a June 2014 Southeast region sales team meeting regarding the legality of off-label sales in context of the Cephalon settlement. Defendant Babich attempted to hide behind TIRF-REMS, responding: “I understand why you’re asking that question. But Cephalon didn’t have TIRF-REMS; we do. You are protected because both the MD and the patient have signed it.” Defendant Babich elaborated that because of the TIRF-REMS briefing requirement for patients, there could not be a plausible claim that the patient (or doctor) did not know what he or she was doing. As the media reported, one sales representative stated: “There wasn’t much else to say about the issue when your CEO sees an information protocol as an insurance policy.” TIRF-REMs do not provide the protection from liability claimed by Defendant Babich in these statements.

146. As Neely told the *SIRF*, “management pushed the sales force to market Subsys ‘to anyone with a prescription pad,’” and, “Anyone who disagreed with that approach, he said, ‘was treated like garbage,’ and eventually fired.”

147. *The New York Times* has reported that within two years of Subsys' launch that just 1% of Subsys prescriptions were written by oncologists.

148. The HHS Office of the Inspector General ("OIG") has issued compliance guidance to aid pharmaceutical companies in developing and implementing internal controls and procedures that drive compliance with relevant federal statutes and regulations. According to the OIG Compliance Program Guidance,<sup>10</sup> a comprehensive compliance program should include, at a minimum:

- 1) Written standards of conduct, as well as written policies, procedures and protocols that address specific areas of abuse, such as illegal sales and marketing practices, kickbacks, and healthcare insurance fraud;
- 2) A compliance officer and oversight committee responsible for monitoring of compliance initiatives and reporting findings to the Board;
- 3) Audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems;
- 4) Regular, effective education and training programs for employees;
- 5) Effective lines of communication between management and employees to ensure receipt of complaints and protection of whistleblowers from retaliation;
- 6) Procedures for disciplinary action against employees or contractors who have violated company policies and procedures and/or applicable federal health care program requirements; and
- 7) Policies and procedures for the investigation of noncompliance or misconduct.

149. Insys had no such program in place for years. Insys had no compliance officer, board-level compliance committee, off-label audit procedures, or regular reporting procedures. The reason for this failure was that the Board was aware that the true purpose of the marketing plan was to pay doctors as an inducement to prescribe Subsys.

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<sup>10</sup> OIG Compliance Program Guidance, 7-9 (April 2003).

150. Insys was aware that patients were being prescribed Subsys for contraindicated uses because the Company filled out prior authorization forms on behalf of doctors and submitted reimbursement forms for patients with diagnoses not related to cancer such as “chronic pain syndrome,” “back pain,” and “neck pain.”

151. Many of the Company’s top prescribers have been disciplined, arrested, or charged for off-label misuse of Subsys. For example, in December 2013, The Texas Board of Medical Examiners temporarily suspended Dr. Judson Somerville’s (“Dr. Somerville”) prescription writing privileges, following the death of three patients within a six-month span. A pain specialist, Dr. Somerville was the 2<sup>nd</sup> highest prescriber of Subsys in 2013 per Medicare part D data, and 8<sup>th</sup> highest as per Tricare records in 2014. Dr. Somerville received \$67,375 in speaker fees from Insys between August and December 2013.

152. Dr. Xiulu Ruan (“Dr. Ruan”) and Dr. John Couch (“Dr. Couch”) were indicted and convicted in Alabama on charges of receiving kickbacks as an inducement to prescribe more Subsys. Dr. Ruan was sentenced to 252 months in prison on May 26, 2017. Dr. Couch was sentenced to 240 months in prison on the same date. Drs. Ruan and Couch were ordered to pay tens of millions of dollars in restitution to Medicare and private insurers.

153. Dr. Gavin Awerbuch (“Dr. Awerbuch”) was arraigned on Medicare fraud charges on May 6, 2014 for, *inter alia*, claims submitted related to Subsys. Dr. Awerbuch was the highest prescriber of Subsys in 2013 per Medicare part D data, writing \$6.4 million in Subsys prescriptions for Medicaid patients in that year. Dr. Awerbuch received \$89,974 in speaker fees from Insys between August and December 2013. On February 26, 2018, Dr. Awerbuch was sentenced to 32 months in prison.

154. Defendant Kapoor was aware of Dr. Awerbuch’s misconduct prior to the latter’s arrest. According to a confidential witness, as cited in a securities class action filed against the

Company,<sup>11</sup> Defendant Kapoor, Burlakoff, and Napoletano had daily morning meetings, which could be overheard by the confidential witness. The confidential witness indicated that he or she had overheard senior management members of Insys discussing Dr. Awerbuch during such meetings.

155. During the Relevant Period, the Individual Defendants caused the Company to issue false and misleading statements to the investing public which created the impression that the success of Subsys was due to legal, on-label marketing. Specifically, the Individual Defendants said publicly, *inter alia*, that: (1) “[w]e are only selling a breakthrough cancer pain drug”; (2) “no one at Insys wants to see anyone taking [Subsys] for anything other than cancer pain”; and (3) Insys was “committed to complying with laws governing [Subsys]’ sales, marketing and promotional practices.”

***The Kickback Misconduct***

156. The Company’s marketing success was also driven by its speaker program. The official purpose of the speaker program was to persuade other doctors to prescribe Subsys through education. However, speaker fees, meals, drinks and entertainment lavished upon speakers were, in fact, designed to encourage the speakers themselves to write more prescriptions for Subsys.

157. Insys spent large amounts of resources on the speaker program, including general payments to doctors for speaking fees, meals, travel reimbursement, and other expenses in the total amount of \$2,775,946 during the last five months of 2012 alone. In 2014 Insys paid nearly \$7.4 million to doctors in “general payments,” including “[c]ompensation for services . . . including serving . . . as a speaker at a venue other than a continuing education program,” “food

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<sup>11</sup> Amended Class Action Complaint for Violations of the Federal Securities Laws, No. 2:14-CV-14-01043-GMS (D. Ariz.), filed October 27, 2014.

and beverage,” and “travel and lodging,” according to the Centers for Medicare & Medicaid Services open payments data. The Company made general payments to doctors for speaking fees, meals, travel reimbursement, and other expenses in the total amount \$6,297,977 in 2015.

158. The speaker program extended to providing doctors with support to market their practices and bolster their social lives. Doctors were often paid to speak at Insys-sponsored social events for the doctors’ family and friends. As an example, Dr. Stuart Rosenblum was paid \$1,600 to speak at the following event, as stated in the invitation: “you are invited to a *social event* this Friday . . . We are having food and drinks supplied by [a sales representative] of Insys. Wives and girlfriends are invited. Scott’s band will be playing. They start about 9pm.” (Emphasis added.)

159. Dr. Rosenblum later informed his clinical staff:

I have rescheduled our dinner event. . . . Our pain clinic staff and our wives are invited. Please feel free to invite any referring physicians and we can use this for marketing as well. Dinner is sponsored by Insys and I will give a brief informal presentation. Otherwise the evening will be for socializing and networking.

160. Speaker program events were typically hosted at upscale restaurants with an “open bar” policy in effect. Defendant Kapoor would host events at his own restaurant, Roka Akor. The media has reported that “[b]ased on interviews with multiple attendees, the expenses often run into the thousands of dollars and, given the sheer number of events, have helped his restaurants capture a handsome revenue stream.”

161. Entertainment for speaker program doctors did not end at dinner. Sales representatives would invite doctors to accompany them to bars and strip clubs, where physicians would be treated using a secret credit card. The *SIRF* has reported that the sales department would use the secret card to expense tickets for concerts and sporting events, and at least one sales representative was instructed that payments using the card had to be done

“quietly.” *SIRF* reported that one employee believed he had expensed hundreds of thousands of dollars in entertainment charges and the employee believed that Defendant Babich was aware of the practice. Former sales representatives interviewed by the *SIRF* relayed having expensed similar amounts.

162. In a criminal action filed against Insys sales employee Joseph Rowan (“Rowan”), the government supplied evidence that the Company used “fake restaurant receipts to cover bribes for prescribers[.]” Rowan explained to sales representatives how to use fake food purchases to hide bribes for doctors in conversations recorded by the government. Rowan told the group, “Find your caterer. Find your guy on the side . . . get away from the freaking Olive Gardens of the world . . . they don’t do it for you.” Defendant Kapoor’s Roka Akor likely provided Insys employees with just the sort of business willing to facilitate such payments.

163. The same criminal filing quoted a text from Burlakoff to a physician: “I can commit to 100k to you via speaker programs or meals toward your restaurant. We don’t need the food, just charge our card and give [us] an itemized receipt. Just need your support with [Subsys].”

164. The ODOJ Notice asserts that Insys was aware that speaking fees “were not for bona fide educational events but rather were an attempt to buy good will and an obligation to prescribe SUBSYS . . . Some of the talks paid for by Insys were shams that were essentially an excuse to make a payment . . . to encourage increased prescribing of SUBSYS.” Federal prosecutors similarly state that: “[w]hile the purported purpose of the programs was for SUBSYS prescribers to convince other doctors to prescribe SUBSYS, the speaker programs, in reality, were a façade used by [Insys] to funnel illegal kickback payments to high volume SUBSYS prescribers.”

165. Within Insys, the true purpose of the speaker program was no secret.

Management repeatedly reiterated to sales representatives that only doctors who prescribe Subsys, and preferably those who prescribe a lot of Subsys, were entitled to speaker program fees. In one instance, Burlakoff, in a text message to sales representative Ray Furchak, stated: “Please be sure [the doctor] is writing more and more SUBSYS to justify these programs.” Burlakoff added that the doctor “needs to find 1 pt [patient] a day. . . . Please do not book any additional programs until we see return on investment.”

166. Burlakoff regularly demanded that “doctors be held accountable,” and that “doctors who are not increasing their clinical experience [prescription writing], please cancel, suspend, and cease doing speaker programs.” Burlakoff expressly stated in a text message to a Subsys sales representative, participants in the speaker program “do not need to be good speakers,” but they do “need to write a lot of [Subsys prescriptions].”

167. On his first day as the VP of Sales, Burlakoff sent an email to a new sales representative, copying Defendant Babich, among others, explaining that “it all starts with choosing the right LOCAL speaker” who “should be your ‘business partner’” and noting that “if your speaker does not see it this way . . . . . (then it is time to identify another speaker).”

168. This nexus between speaker fees and Subsys prescriptions was demanded from the very top of Insys. At one point, Burlakoff wrote: “*Per ‘Dr. Kapur,’* [sic] [S]ubsys speakers should support and show belief in this product. If not – the speaker needs to be removed.” (Emphasis added.)

169. Defendant Babich was directly informed that one of the prescribers the Company was targeting, Dr. Paul Madison (“Dr. Madison”) “was running a pill mill.” On August 19, 2012, the assigned sales representative sent Defendant Babich an e-mail stating:

I call on . . . [him] sometimes twice a week. . . . *Dr. Madison runs a very shady pill mill* and only accepts cash. He sees very few insured patients but does write some Fentora. He is extremely moody, lazy and inattentive. *He basically just shows up to sign his name on the prescription pad*, if he shows up at all. I have

been working more with his MA [medical assistant] who is the one that knows what is going on in his office. He has agreed to try and help me out but I know that he is afraid of Dr. Madison's outbursts and is reluctant to input. I think that being in the office at the right time, when the right patient walks in, on a day Dr. Madison is in a good mood is the only way I will get him to write. This is the reason *I call on him frequently*.

(Emphasis added.)

170. The representative's supervisor wrote: "I am very confident that Dr. Madison will be your 'go to physician.' Stick with him." Dr. Madison ultimately gave at least 46 "speaker programs," despite having minimal, if any experience in treating BTCP. The majority of these programs were held at upscale restaurants, and almost all of them were attended only by Dr. Madison and the sales representative.

171. After receiving the tip about Dr. Madison's "pill mill," Defendant Babich allowed the following email applauding the recruitment of Dr. Madison to be sent companywide: "Great example of how we need to pro-actively manage our speaker data base by both adding and soft deleting speakers on an ongoing basis . . . ."

172. Dr. Madison continued to receive payments to promote Subsys despite being federally indicted in December 2012 and being reprimanded by the Illinois Department of Financial and Professional Regulation in April 2014. Dr. Madison wrote over 1,600 Subsys prescriptions between February 2013 and July 2015.

173. Doctors who did not live up to the Company's expectations were dropped from the speaker program. One speaker program participant, Dr. James Gallant, stated in a sworn interrogatory response that "As a result of my prescribing numbers being considered too low for the company, I was told that I would not be used as a speaker again."

174. The Federal Indictment alleges that on August 1, 2012, Defendant Babich sent an e-mail to the sales representative assigned to a doctor dubbed "Practitioner #9," stating, "I have listed your top targets below [including Practitioner #9] and need a brief weekly emails

summarizing how, if and when the doctor will write, if he is already and can be a bigger doctor to you.” The sales representative reported to Defendant Babich on August 20, 2012 that:

[Practitioner #9 had] dropped off as . . . some of his patients are preferring [a competitor]. . . . But he continues to tell me he will continue to prescribe [SUBSYS] whenever he can. I think using him as a speaker will cause things to pick back up again. I have two programs planned so far.

Defendant Babich ultimately hired Practitioner #9’s girlfriend to work for Insys from inside Practitioner #9’s office. As a result, the practitioner increased his prescriptions of Subsys from 1.9 per week in the second quarter of 2012 to 7.5 per week by September of 2013.

175. In early 2013, the Company’s speaker program had grown to the point that it was multiples larger and costlier than programs operated by similarly-sized pharmaceutical companies. At a February 5, 2013 Board meeting attended by Defendants Kapoor, Fourteau, Lapalme, Meyer, Tambi, and Babich, management informed the Board of the amount of money to be spent on marketing in 2013, including the speaker program.

176. When speaker and nurse practitioner Heather Alfonso (“Alfonso”) asked about the propriety of the speaker program, a Company sales representative responded: “Don’t worry about the dinners. Let [Alfonso’s sales representative] worry about the dinners. You just worry about writing scripts for [Subsys].”

177. Sales representatives were pushed to turn these investments into returns by pressuring speakers to prescribe more Subsys. In an email from sales representative Fernando Serrano’s (“Serrano”) manager on February 20, 2014, the manager stated:

One week until [the national sales meeting], and I need everyone on this team to work their relationships. Ask each of your top prescribers to do whatever they can to make you look like an absolute superstar for the next week, especially while we are [at the national sales meeting]. This is what reps work all year for, do not be hesitant in asking your docs to give you business *in which you are owed*, deserve, and will help in making you shine at [the national sales meeting]. Show everyone at [the Company] that your time has been well spent and *the formula has been followed. All the breakfasts, lunches, ISPs* [speaker programs], and top customer

service to go along with helping provide your docs pts [patients] with the best ROO [rapid onset opioid] product in its class for treating BTCP. ***This has to be reciprocated for all of your hard work!***

(Emphasis added.)

178. In another email from March 28, 2014, Serrano's manager stated:

For the first time as a company, we are facing the challenge of meeting our quarterly goal. That being said, its [sic] time for all you're your [sic] top prescribers (esp. SPEAKERS) to give back for all of the hard work, long days and late nights you have spoiled them with. Keep pushing as hard as you possibly can and remember why today is especially most important being that it will set you up for a few hopeful RXs sat/sun and a HUGE Monday!!!

179. District managers would contact speakers directly where sales representatives were unable to achieve desired results. After one site visit, a Regional Director of Sales reported to Defendant Babich and Burlakoff, that: "I managed to meet [the sales representative's] speakers and challenged each of them (we are paying these guys and not seeing a return on our investment)."

180. After Dr. Ruan increased his Subsys prescription writing in response to receiving speaking engagements, Burlakoff emailed Dr. Ruan's sales representative, Rowan, stating that Rowan was "now officially #1 in the company (with only one doctor). I am pretty sure your formula worked, you may want to pass it along to your team."

181. Company sales representatives even falsified sign in sheets to make speaker events appear more legitimate. In one example, Serrano organized a speaker event where the sign in sheet was found to have a forged signature of a doctor, complete with an incorrect medical license number. The doctor whose name appeared sheet told criminal investigators that he had never heard of Insys or Subsys, nor had he attended any such event.

182. Insys would try and fill the room in order to legitimize speaker events, with individuals who had no interest in their purported educational purpose. Insys employees often

attended speaker events, as would personnel from the respective speaker's office. In one of several examples, an event held on October 16, 2014 and organized by Serrano had six attendees. Of those attendees, each had attended at least three other speaker programs. As a group, the six had attended a combined *fifty-nine speaker programs*. As the presentation was limited to an approved slideshow, there was no ostensible educational benefit to attending multiple speaker programs.

183. On at least one occasion, a speaking event was cancelled in order to hide the lack of legitimate participants. According to a contributor on *Cafepharma.com*, on one occasion, the Company cancelled a speaker program due to the presence of "an inspector . . . because there were no real attendees."

184. However, such efforts were not always made. In one instance a doctor failed to show up to a scheduled event. Regardless, sales representative Jonathan Roper ("Roper") submitted the event as a sanctioned program, and, according to Roper's indictment, the doctor received payment for his no-show.

185. A review of federal Medicare prescribing data and drug company payments undertaken by the *Hartford Courant* demonstrates strong correlation between prescribing habits and speaker fees. Eight of the top 10 Subsys prescribers in the Medicare program in 2013 were paid speaker fees by Insys in 2014 and 2013. The remaining two are physician assistants, who are not included in the Open Payments database. The eight speakers received anywhere from \$67,000 to \$154,000 in total payments from Insys in 2013 and 2014.

186. This strong correlation was no coincidence. Burlakoff, Defendant Babich, and their direct reports tracked and circulated within the Company the total number of planned speaker program events for each participant in the program, including the number of speaker program events completed, as well as at least the following metrics: (1) the number of Subsys

prescriptions written by the participant; (2) the percentage of prescriptions written by the participant for Subsys compared to prescriptions for competitors; (3) the net revenue earned from each speaker, and the total amount of fees paid to each participant; and (4) the Company's "return on investment" for each participant. Defendants utilized these reports to better identify those practitioners to target for inclusion in the speaker program.

187. *The Wall St. Journal* reported in "Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids" that "Insys Executive Chairman John N. Kapoor, the company's billionaire co-founder, personally traveled to Mobile, Ala., to attend a business dinner with [Drs. Ruan and Couch] . . . The doctors were also frequent speakers and consultants for Insys, receiving \$270,700 in combined fees over 21 months." Following this meeting, "the company began selling Subsys directly to the doctors' pharmacy, an uncommon practice for the company." At the trial of Drs. Ruan and Couch, each of whom were convicted of accepting kickbacks from Insys, a witness provided sworn testimony under oath which confirmed facts reported in *The Wall Street Journal* article.

188. Insys paid Drs. Ruan and Couch to speak, at least weekly, at programs during which neither Drs. Ruan nor Couch presented on or even discussed Subsys.

189. Sales representatives were extolled to ensure that there was a *quid pro quo* associated with the speaker program. As demonstrated in the following email sent by Roper on May 6, 2014, speakers were expected to prescribe a lot of Subsys in return for participation:

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

The most common question asked at the conclusion of a speaker program is always[s], "doc, how many pts [patients] 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 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, emphasis added.)

190. The Company's in-house prior authorization unit—the IRC—gave doctors another form of consideration in return for prescribing Subsys by assisting in obtaining the necessary insurance approvals for Subsys prescriptions. By February 2013, at the latest, the Board was aware of the development and build-out of the IRC.

191. Insys hired the children of top prescribers to serve as sales representatives, hired attractive sales representatives, including a former exotic dancer, as an "inducement" for top prescribers to continue to write more Subsys prescriptions, and hired the children and romantic interests of doctors whose business the Company sought. These acts constitute compensation to influence a doctors' prescribing habits, in violation of the Anti-Kickback Act.

192. Natalie Reed Perhacs ("Perhacs") was hired on the recommendation of Dr. Ruan. The federal government has alleged that she "was hired to induce, and in exchange for, Dr. Ruan continuing to prescribe Subsys" as Dr. Ruan had "developed a certain affection" for Perhacs.

193. In one instance, the Company attempted to influence "Dr. Roy," a physical medicine and rehabilitation physician who did not treat any cancer patients, by hiring his son as a sales representative. His son had no background in pharmaceutical sales or healthcare. When Insys was unsuccessful in pressuring the son to induce Dr. Roy to write Subsys prescriptions, Defendant Kapoor, who was aware that Dr. Roy did not treat cancer patients, personally reached

out to Dr. Roy, and supported offering Dr. Roy a speaking engagement. A sales representative stated to Dr. Roy, by email that: “This company really want [sic] to make you a speaker. Apparently Kapoor had good things to say about you.”

194. Despite the fact that Dr. Roy’s practice did not involve treating cancer patients, Company managers put intense pressure on his son to get Dr. Roy to start writing Subsys prescriptions. This pressure led Dr. Roy’s son to send him the following message:

These people from my company are relentless and it’s kind of pissing me off. I have told them multiple times (starting with the interview) that you probably won’t be writing my product due to the type of practice you have, but my manager just called me an[sic] told me that they were ‘concerned’ that I haven’t gotten you tirk rems enrolled. I’m getting ready to tell them to \* \* \* \* off [expletive deleted]. 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.

195. Other sales representatives flirted with Dr. Roy, inviting him on “tequila dates” in an attempt to encourage him to write Subsys prescriptions. Dr. Roy’s son left the sales force after three months, and Dr. Roy resisted the Company’s aggressive sales tactics.

196. Defendant Babich and Burlakoff hired Lee on August 17, 2012 as a regional sales manager and she was promoted a year later. Prior to joining Insys, she was an exotic dancer. In a statement to *SIRF*, Burlakoff said: “Doctors really enjoyed spending time with her and found Sunrise to be a great listener.” He explained that “[o]ften the initial contact [with a doctor] was made by another sales person” and “She’s more of a ‘closer.’” Burlakoff further stated that Lee was effective with pain management physicians who appreciated her “empathy.” According to Burlakoff, “[w]hen you are dealing with [doctors] who are around pain and cancer all day, an empathetic and caring sales person is helpful.”

197. Sales representatives would also ply doctors with drinks, food and entertainment outside of the speaker program in order to induce them to prescribe more Subsys.

198. Other in-kind payments included paying for office parties for physicians and

their offices, and Area Business Liaisons, Insys employees who worked directly in the offices of high prescribing practitioners as support staff.

199. In response to the Kickback Misconduct, many speakers increased their prescriptions of Subsys, including Dr. Madison, Dr. Ruan, and Dr. Couch, all of whom were members of the speaker program.

***The FCA Misconduct***

200. In order to generate revenue from Subsys, it was important that Insys develop relationships with third party payors. As stated in several SEC filings during the Relevant Period:

Our 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. All third-party payers 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 has been, and will likely continue to be, subject to these restrictions and impediments from third-party payers, particularly PBMs and private health insurers.

201. As per criminal charges filed against Elizabeth Gurrieri (“Gurrieri”), who was intimately involved in building the IRC, the Company had difficulty securing pharmacy benefit manager (“PBM”)<sup>12</sup> and insurer approval for patients’ use of Subsys. By the end of 2012, the Company had only secured approval for 30% to 33% of Subsys prescriptions. Gurrieri and others within Insys devised a plan to fraudulently misrepresent patient medical history and diagnosis codes in order to drive greater prior authorization approval rates. As a result, the Company attained significantly increased revenues.

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<sup>12</sup> PBMs are employed by insurance companies among others, and they administer prescription drug benefits for employers and health plans and run large mail-order pharmacies.

202. The Company disclosed the existence of the IRC to shareholders during the Relevant Period in the Company's SEC filings, stating "[w]e provide administrative patient support assistance . . . which provides administrative support assistance to help patients work with their insurance companies." However, the Individual Defendants caused the Company not to disclose its true purpose, which was to facilitate the FCA Misconduct.

203. The IRC not only provided an additional means to provide prescribing physicians with a kickback, but also allowed the Company to defraud third party payors.

204. The IRC obtained completed "opt-in" forms from prescribers, containing information pertaining to the prescriber's practice and its patients. These forms contained confidential information including, *inter alia*: (1) patient's name and date of birth; (2) insurer information; (3) prescriber information; (4) pharmacy information; (5) medical diagnoses; and (6) corresponding insurance code information. The completed opt-in forms were transmitted by prescriber personnel or Insys sales representatives to the IRC in Arizona. The IRC then used this information to seek prior authorization directly from PBMs.

205. As only doctors' staff could request pre-authorizations, the IRC unit trained employees to give the impression that they worked in doctors' offices in interacting with PBMs and other third party payors. The employees were also trained to state or imply that they were physically in the doctors' offices while they spoke to the insurance carriers, and to create the impression that the patient was experiencing BTCP. When all else failed, IRC employees were trained to resort to empathy and fabricate a story about the patient's suffering.

206. As reported by the *SIRF*, the IRC unit was isolated from Insys, housed in an unmarked building across the street, and maintained a different phone exchange and email server than Insys. To further conceal its existence, a system was established to block the number on outgoing calls so that recipients would not know who was calling. The generic 800 number

given out for callbacks was answered by someone named Shannon, who did not identify any organization she was associated with. All of this was done to give third party payors the impression that they were dealing directly with doctors' offices.

207. When prior insurance authorizations became particularly difficult to obtain, Insys's prior-authorization unit employees were instructed to change insurance codes in patients' charts to secure approvals.

208. Like with their sales representatives, Insys relied on a bonus structure to incentivize IRC employees into engaging in misconduct. Such a structure is unusual for a prior-authorization unit.

209. Specialists were awarded bonuses based on the number of approvals secured by the IRC group and by each individual employee. For bonus eligibility, IRC employees had to secure at least 25 approvals in a week. According to press reports, each week Michael J. Gurry ("Gurry"), former VP of Managed Markets, would hold a meeting to tell the prior authorization team the "group gate," or minimum number of total approvals expected for the week. A typical "group gate" was 200. If the group gate was met the Company agreed to contribute \$7 to a bonus pool for every additional approval. IRC personnel also received bonuses for meeting individual goals. For instance, employees who secured 35 approvals in one week received a \$50 bonus, plus \$10 for each incremental approval.

210. Although most patients prescribed Subsys did not have cancer, the Company's IRC program was able to achieve prior authorization approval rates far above those of its competitors. According to media reports, a leading Subsys prescriber estimated that "[i]nsurers cover over 90 percent of [Subsys prescriptions] for at least one [90-day] cycle," compared to rival drugs that maintained an approval rate of approximately 33%. These statements were corroborated in the press by three former Insys staff members and a senior executive at an Insys

rival.

211. Management gave the Board a detailed presentation on “the IRC program and shared initial data regarding the opt-ins, success rate, timelines for reports, and overall trends that will be tracked by the Company” at a February 2013 Board meeting.

212. The Board also received regular updates on the approval rates attained by the IRC unit. Given that the IRC’s approval rate was far higher than the 33% industry average, the Board was aware that the extraordinary approval rates were the result of fraudulent practices. The Board even condoned an over 90% approval rate goal for new patients entering the IRC unit.

213. Patty Nixon, a former Insys employee, gave an interview contained in the documentary, *Death by Fentanyl, Part 3, Insys Noble Drug Mission and Questionable Record*. She explains how Insys employees were taught to mislead medical payment providers about a patient’s condition to obtain approvals for off-label uses. She was told say “uh-huh” when an insurer verbally asked if the patient had “breakthrough cancer pain,” so as not to “lie.” The *SIRF* reported that another employee stated that she was told mislead the insurance companies by answering: “Yes, they have breakthrough pain.”

214. An Insys employee provided the *SIRF* with a recording of an executive in the prior authorization unit, Jeff Kobos (“Kobos”), addressing the entire IRC department. The recording reveals Kobos referencing that the IRC had given insurance companies cancer-related diagnostic codes for patients with non-cancer pain. It also recorded Kobos advising IRC employees to misdirect insurance representatives with non-sequiturs to deter distract the representative from following up on key questions about the patient or the patient’s prescription.

215. When awareness of the IRC spread, including through a subpoena from the U.S. Attorney’s Office for the District of Massachusetts, the IRC adapted to keep approvals high.

Gurrieri developed “the spiel,” under which employees were to reply to queries regarding whether a patient had BTCP by stating either: “[t]he physician has stated that Subsys is approved for treating breakthrough cancer pain so [he] is treating breakthrough pain;” or “[t]he physician is aware that the medication is intended for the management of breakthrough pain in cancer patients. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable).” In addition, employees were instructed to say they were calling on behalf of a doctor office, instead of saying they were “from” the office, as they had before.

216. When the IRC discovered that patients with a diagnosis of difficulty swallowing (dysphagia) were more likely to be approved, employees were instructed to change codes on the most difficult charts to include a diagnosis of dysphagia, even where there was no evidence to support it. The diagnosis was even incorporated into the Company’s model letter of medical necessity.

217. IRC employees were also instructed to change charts to falsely reflect that patients had unsuccessfully tried other medications to increase the chances of approval.

218. Third party payors began to adapt, asking IRC representatives non-negotiable questions like, “On what date did the patient receive their original cancer diagnosis?” and following up with doctor’s office to confirm diagnoses.

219. A group of health insurers have sought reimbursement from the Company for making false statements to obtain authorizations. In a suit filed in federal court in Arizona, the insurers allege that since 2013, “Insys’ schemes . . . [have driven] significant off-label use and secur[ed] payments in excess of \$19 million from Anthem for Subsys® prescriptions that were not covered, in addition to the millions of dollars in cost-sharing obligations imposed on Anthem members.”

***The Board Was Informed of, and Condoned, the Misconduct***

220. Criminal charges filed against Gurrieri state that the Company knew that Subsyst prior authorization approval rates ranged from 30% to 33%, as of the end of 2012.

221. On February 5, 2013, the Board held a meeting to discuss the Company's sales and marketing plan for 2013. Defendants Kapoor, Fourteau, Lapalme, Meyer, Tambi and Babich, as well as Burlakoff and Napoletano, were present. Burlakoff and Napoletano made presentations on Insys's sales and marketing practices.

222. At the meeting, management gave a detailed presentation on "the IRC program and shared initial data regarding the opt-ins, success rate, timelines for reports, and overall trends that will be tracked by the Company," and the Board reviewed a breakeven analysis to recover the costs associated with the IRC.

223. At the meeting, the Board members present were informed that the Company would begin tracking four "Key Growth Parameters": (1) growth of prescriber productivity (i.e., number of prescriptions per prescriber); (2) growth of script size (i.e., number of Subsyst units per prescription); (3) dose escalation (i.e., increase prescription of higher strengths); and (4) growth in subscriber base (i.e., number of prescribers). These parameters each specifically tie to the Company's illegal sales and marketing practices.

224. Management also informed the Board that Insys would stockpile higher dose strengths while avoiding holding 100 mcg, in an effort to circumvent FDA mandated titration procedures.

225. The ODOJ has asserted that, when a doctor would follow the label's instructions and start a patient at a low dose, the doctor's sales representative would receive an email from Insys, copying top management, instructing the representative to "report back to your manager within 24 hours on WHY the low dose was used and HOW the doctor plans to titrate the patient

to effective dose.” In other instances, sales representatives received an email from Burlakoff, copying Defendants Kapoor and Babich, telling them that “every time [they] receive a message from Xu [Sean Yu] indicating that [they] had a prescription written for less than 400 mcg . . . [the sales representative] must following up with the physician within 24 hours and provide specific details to the conversation.” Sales representatives who failed to follow through with these instructions were threatened with immediate negative consequences.

226. Defendant Stanley joined the Board in March 2013. As the inventor of Actiq, he brought significant expertise in TIRF and the sale of TIRF products.

227. Despite the Company’s large number of off-label prescriptions and concerted effort to market off label, the Individual Defendants caused the Company to file a Form S-1 in connection with its initial public offering which misleadingly stated: “As of March 31, 2013 our field sales force included approximately 67 sales professionals who are promoting SUBSYS *primarily* to oncologists, pain management specialists and centers that cater to supportive care in the United States.” (Emphasis added.)

228. By May 2013, Subsys’s market share had grown to over 20%, a figure which expanded to 31.4% by September 2013.

229. The Company held a Board meeting in July 2013 to discuss the Company’s sales and marketing plan. Defendants Kapoor, Fourteau, Lapalme, Meyer, Tambi, Stanley and Babich all attended, as well as Burlakoff and Napoletano. The Board was updated, *inter alia*, on the Company’s efforts to align the sales force with the off-label marketing strategy for Subsys and the IRC program.

230. The Company held a board meeting in November 7, 2013 to discuss the Company’s sales and marketing plan. Defendants Kapoor, Fourteau, Lapalme, Meyer, Tambi, Stanley and Babich all attended, as well as Burlakoff and Napoletano. The Board was updated,

*inter alia*, on the IRC program and informed that Subsys had achieved a 31.4% market share.

231. On December 9, 2013, Insys received a subpoena from HHS the (“HHS Subpoena”), which requested documents relating to the Company’s business, the commercialization of Subsys, and document regarding Insys’s sales and marketing practices for Subsys.

232. In response, the Board convened a meeting on December 13, 2013, which Defendants Kapoor, Fourteau, Lapalme, Meyer, Tambi, Stanley and Babich all attended. The Board as a whole was informed of the HHS Subpoena. The Board passed a resolution forming a special committee, consisting of Defendants Lapalme, Fourteau, and Meyer (the “Special Committee”). The Special Committee was tasked with oversight responsibility of matters relating to legal and regulatory requirements. As part of this responsibility, the Special Committee was to review and oversee Insys’s compliance program, get periodic updates from management, and establish a working relationship with the Company’s employees. It was resolved that the Special Committee “shall meet at least monthly.”

233. The Special Committee did not hire independent counsel during 2013, 2014 or 2015, and did not convene a meeting until August 2015.

234. The Individual Defendants caused the Company to issue a Form 8-K on December 13, 2013, which disclosed the receipt of the HHS Subpoena. It did not, however, disclose the formation of the Special Committee. The Individual Defendants thus were aware of a material fact, the significance of the HHS Subpoena, while the investing public was led to believe it was of minor significance. Several of the Individual Defendants engaged in insider trades with knowledge of this material inside information.

235. In the fourth quarter of 2013, Subsys generated \$39.2 million in revenue, 97.5% of the Company’s consolidated quarterly revenue and a 719% increase in revenue compared to

the fourth quarter of 2012.

236. The Board convened a meeting on February 26, 2014, which Defendants Kapoor, Fourteau, Lapalme, Meyer, Tambi, Stanley and Babich all attended (the “February 2014 Meeting”). Burlakoff and Napoletano were also present.

237. At the February 2014 Meeting, the Board received updates from management of the following:

- The continued and substantial increase in several key growth metrics, such as average dosage strength, unique prescribers, and number of prescriptions;
- Significantly increased activity from top prescribers;
- The approval rates obtained by the IRC;
- The HHS Subpoena

238. Despite the creation of the Special Committee, it had not met and did not report to the Board at the February 2014 Meeting.

239. The Board convened a meeting on May 6, 2014, which Defendants Kapoor, Fourteau, Lapalme, Meyer, Tambi, Stanley and Babich all attended (the “May 2014 Meeting”). Burlakoff and Napoletano were also present.

240. At the May 2014 Meeting, the Board received updates from management of the following:

- The success of the Company’s sales efforts had driven the Company to achieve a 41.6% market share by February 2014;
- The approval rates obtained by the IRC; and
- The HHS Subpoena, and the Company’s lack of compliance therewith.

241. At the May 2014 Meeting, the Board approved plans to maintain an over 90% approval rate for new Subsys prescriptions for the remainder of the calendar year.

242. The Special Committee did not report to the Board. In fact, the Special Committee had not met.

243. The Board knowingly made a sham compliance department for the first time at some point after 2014. The Board hired Danielle Davis (“Davis”) as Director of Compliance, who had no prior experience in compliance at a pharmaceutical company. Davis had worked as Executive Director of the Snoqualmie Gaming Commission from 2008 until her termination on November 28, 2013. According to *Northwest Asian Weekly*, while working for the Snoqualmie Gaming Commission, Davis “managed the Snoqualmie Casino’s successful opening.” Despite the Board resolution requiring the hiring of a Board-level Compliance Officer, Davis reported to Defendant Babich, who appointed himself “Chief Compliance Officer.”

244. The Board was told of Davis’s lack of credentials at the February 2014 Meeting, and in relying on her lack of experience, it ensured that the compliance department would be toothless from day one.

245. Such a scheme appears to have borne fruit. In a civil answer filed by a former Insys sales representative Michael Ferraro (“Ferraro”) in the Southern District of New York on May 28, 2015 (“Ferraro Answer”), the representative alleges that he had expressed “valid concerns and strong beliefs of the conflicts between [Insys’s] Sales Model and processes, and the laws and guidelines governing [the Company] and the pharmaceutical industry.” The Ferraro Answer disclosed a phone conversation between Ferraro and Davis, during which Ferraro discussed detailed examples demonstrating his belief in the Company’s noncompliance with the laws and guidelines governing the pharmaceutical industry. Six days later, Ferraro received a phone call from Franc Del Fosse, General Counsel of Insys, informing him that Insys was terminating his employment due to his connection to another pharmaceutical company.

246. During Board meetings held throughout 2014 and the first half of 2015, Davis

told the Board that she was still in the process of developing basic policies and procedures, establishing that the Board was aware that no such policies existed.

247. The Board convened a meeting on August 7, 2014, to discuss the *New York Times* article reporting that only 1% of Subsys prescriptions were written by oncologists and the Securities Class Actions (the “August Meeting”). Defendants Kapoor, Fourteau, Lapalme, Meyer, Tambi, Stanley, and Babich all attended. Burlakoff and Napoletano were also present.

248. The *New York Times* article was referenced only in connection with the “concern” expressed by Express Scripts, a private specialty pharmacy which dispenses Subsys, and how that concern might affect profitability, despite the numerous red flags raised therein.

249. The Board was informed that approval rates for new patients had fallen because “Compliance Standards [were] Elevated” and “More Opt In Forms Do Not Meet Insurance Co. ‘Gate’ Hurdles.” As a result, the Board discussed ways to “Improve Performance” within the IRC program.

250. The Special Committee did not report to the Board at the August Meeting. In fact, the Special Committee had not met.

251. On September 8, 2014, Insys received a subpoena from the U.S. Attorney’s Office for the District of Massachusetts pursuant Health Insurance Portability and Accountability Act of 1996, requesting documents regarding Insys sales and marketing practices relating to Subsys and the Company’s patient services hub.

252. On the same day, Dr. Jerrold Rosenberg (“Dr. Rosenberg”), a physiatrist from Rhode Island, entered a consent order with the Rhode Island Department of Health. According to Medicare part D data, Dr. Rosenberg was the 11th-highest SUBSYS prescriber in 2013. The Consent order found that Dr. Rosenberg “prescribed SUBSYS to patients who have chronic pain, and did not clearly document the use of SUBSYS ‘off-label’ or for reasons other than

those approved by the FDA, such as for ‘break through’ cancer pain.” In 2013 and 2014, Dr. Rosenberg was paid over \$110,000 as an Insys speaker.

253. An amended complaint was filed in the securities class action that had been discussed at the August Meeting on October 27, 2014.<sup>13</sup> The amended complaint made detailed allegations regarding the FCA Misconduct, including that:

- 1) Gurrieri trained IRC employees to make false representations that the IRC employee worked at and was calling from the doctor’s office, as opposed to Insys. Defendant Babich was explicitly told about this practice.
- 2) Gurrieri provided IRC employees with a “cheat sheet” for each insurer, which contained a list of drugs that had previously worked to gain authorization. When prescribers listed diagnosis codes that third party payors had previously denied, IRC employees were instructed to call the prescriber back and direct the prescriber change the code to another code that IRC knew would be approved.
- 3) Gurrieri trained and directed IRC employees to fraudulently obtain approval from PBMs and insurers, including lying about the dose and the other drugs that the patient had taken.
- 4) Gurrieri also trained and directed IRC employees to lie about the dose and number of units of Subsys the patient had been prescribed, instructing them to tell third party payors that the patient had been prescribed for a three-month supply when prescriptions specified a one-month supply.
- 5) Gurrieri and Gurry held IRC team meetings on Wednesdays to discuss the fraudulent methods that had worked in obtaining prior authorizations. Defendant Babich would frequently visit on Thursdays to get updates about the techniques being used. At times, IRC employees would explain in great detail to the techniques used to get a difficult authorization. In response, Defendant Babich would express his approval upon receiving news that certain patients were approved.
- 6) Defendant Babich assisted IRC employees in carrying out the FCA Misconduct, including by arranging for a new phone system to be installed in order to mask the IRC employees’ phone number in response to third party payors’ suspicions being aroused by receiving a call from an Arizona number when IRC employees were claiming to be with a doctor’s office in another state.

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<sup>13</sup> *Larson v. Insys Therapeutics, Inc.*, 2:14-cv-01043 (Dkt. 41, at ¶¶ 184-96) (D. Ariz.).

254. The Board convened a meeting on November 4, 2014, which Defendants Kapoor, Fourteau, Lapalme, Meyer, Tambi, Stanley and Babich all attended (the “November 2014 Meeting”). Burlakoff was also present.

255. At the meeting, the Board received updates and was informed by management that Subsys had accounted for over 40% of the TIRF market in September 2014—attributed to “Return Patients” (those who had refilled their prescription 13-26+ times). Management presented this as a way to highlight Insys’s best customers, while ignoring the potential implications of these figures for patient addiction to Subsys.

256. The Board was further informed that growth as measured by four key metrics had increased since the prior quarter. The Board further approved a 2015 budget which increased the Company’s marketing budget.

257. Subsys accounted for a 44.7% market share by the end of 2014. In the fourth quarter of 2014, Subsys generated \$66.1 million in revenue, which was 99.4% of the Company’s consolidated quarterly revenue and a 69% increase in revenue compared to the fourth quarter of 2013.

258. On May 5, 2015, the Audit Committee convened a meeting at which Defendants Kapoor, Fourteau, Lapalme, Meyer, Tambi, Stanley, and Babich all attended. The Board members were informed of a Civil Investigative Demand the Company had received from the Attorney General’s Office of Illinois that same day.

259. On August 5, 2015, the Audit Committee convened a meeting at which Defendants Kapoor, Fourteau, Lapalme, Meyer, Tambi, Stanley and Babich all attended. The Board members were informed of a subpoena the Company had received from the Office of the Attorney General of New Hampshire on May 8, 2015.

260. The Company entered into a settlement with the ODOJ in August 2015 for \$1.1 million to settle charges made on July 5, 2015 regarding marketing of Subsys for off-label uses, including to non-cancer patients. The settlement encompassed allegations that Insys: (1) provided doctors improper financial incentives to increase Subsys prescriptions; (2) misrepresented the benefits of Subsys to doctors; (3) targeted doctors who either mis-prescribed Schedule II opioids or prescribed Subsys for off-label uses; (4) implemented an incentive structure which motivated its sales representatives to promote Subsys off-label; and (5) misrepresented to patients that Subsys was safe and effective for off-label uses, including by providing patients prescribed Subsys for off-label uses with free product, co-pay assistance, and prior authorization assistance.

261. The Special Committee met for the first time on August 20, 2015 and it was given an update on the status of regulatory investigations into Insys's business practices. The minutes of the meeting indicate that they took no affirmative action in response.

262. On November 3, 2015, the Board convened a meeting at which Defendants Kapoor, Fourteau, Lapalme, Meyer, Tambi, and Stanley all attended. The Board was given a presentation by Company counsel and management regarding pending regulatory investigations. Following these presentations, which likely outlined much of the misconduct alleged herein, the Board unanimously voted to appoint Defendant Kapoor as President and CEO of Insys.

263. Also on November 3, 2015, the Compensation Committee convened a meeting at which it discussed a severance package for Defendant Babich. In addition to the members of the Compensation Committee, Defendant Kapoor was in attendance. The Compensation Committee unanimously voted to delegate their responsibility to the "executive officers to the company . . . to negotiate and enter into a separation and release agreement with Michael L. Babich in connection with his departure from the Company, with severance . . ." Such a delegation was

not only in contravention of the purpose of the Compensation Committee, but gave Defendant Kapoor, now the CEO, who was implicated in the misconduct with Defendant Babich, the authority to determine the latter's severance.

264. Defendant Babich ultimately received \$4 million in compensation and \$10 million in severance, according to the Company's Schedule 14A filed with the SEC on April 20, 2015. Defendant Babich was also permitted to retain \$29.6 million he had received from sales of Company stock at artificially inflated priced while he was personally directing the Sales Misconduct, \$8.3 million of which was made during the Relevant Period. The Company not only provided Babich with a release except for "criminal activities or intentional misconduct," it stated that "it [was] not aware of . . . any criminal activities or intentional misconduct." This assertion was made, even though the Company expressly admitted that it had not conducted "any independent investigation or inquiry."

265. On February 22, 2016, the Board convened a meeting to discuss reorganizing the sales department at Defendant Kapoor's behest, which Defendants Kapoor, Fourteau, Lapalme, Meyer, Tambi, and Stanley all attended.

266. During the meeting it was revealed that several employees who had recently been directly and publicly implicated in misconduct were being *promoted to leadership positions*. For instance:

- Karen Hill, who had been cited in the ODOJ Notice, was listed as a regional sales director.
- Rowan had been promoted to Regional Director. Rowan had been hired after Dr. Ruan had told Defendant Babich during a speaker program that if the Company hired Rowan as a sales representative, Dr. Ruan would become the number one prescriber of Subsys in the country—a promise which Dr. Ruan kept.

- Brett Szymanski (“Szymanski”) was employed as a District Sales manager overseeing eight territories in Michigan. Szymanski had previously been solely assigned to Dr. Awerbuch, who had been indicted in May 2014. As a result of his work with Dr. Awerbuch, Szymanski became “the #1 rep in the company and was paid over one million dollars per year in bonuses at one point.”
- Another sales manager, Roper, was an Area Sales Director. He was subsequently arrested by the DOJ on June 8, 2016 for violating the Anti-Kickback Statute.

267. On May 3, 2016, the Board convened a meeting to discuss the declining sales of Subsys, which Defendants Kapoor, Fourteau, Lapalme, Meyer, Tambi, and Stanley all attended. The Board was presented with information on the declining approval rates for off-label use of Subsys. The Board redoubled its efforts to sell Subsys through misconduct by, *inter alia*, targeting the highest prescribing doctors who mis-prescribe Schedule II opioids, and continuing the speaker program.

### **Materially False and Misleading Statements**

#### ***August 12, 2014 Press Release, Earnings Call and 2Q 2014 10-Q***

268. On August 12, 2014, the Insys issued a press release announcing its financial results for the quarter ended June 30, 2014. The press release noted the following “highlights” of the quarter, *inter alia*:

- Total net revenue increased to \$55.7 million versus \$18.8 million for the second quarter of 2013;
- Revenues from Subsys<sup>®</sup> (fentanyl sublingual spray) were \$54.6 million, up 195% compared with second quarter 2013 sales of \$18.5 million;
- Net income increased to \$9.5 million, or \$0.28 per basic and \$0.26 per diluted share, compared to net income of \$4.5 million, or \$0.18 per basic and \$0.17 per diluted share, for the second quarter of 2013; . . .

269. The press release quoted Defendant Babich as stating:

The continued growth of our business has enabled us to deliver increased revenue, largely driven by the successful execution of our Subsys strategy, strengthening our cash position and increasing our financial flexibility. In spite of an overall decline in the TIRF market in the second quarter, we had double-digit growth in Subsys scripts and anticipate that Subsys revenue will continue to grow.

270. In an earnings call held the same day, Defendant Babich stated, in relevant part:

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

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

(Emphasis added.)

271. Later during the earnings call, Defendant Babich responded to a question about the Company's communications with PBMs regarding Subsys, stating: "[w]e continue to ***properly communicate with all the major plans and the PBMs to ensure proper access for Subsys.***" (Emphasis added.)

272. Insys filed its quarterly report with the SEC on August 12, 2014 announcing financial results for the quarter ended June 30, 2014, on Form 10-Q (the "2Q 2014 10-Q"), signed by Defendants Baker and Babich.

273. Regarding the growth in Subsys revenues, the 2Q 2014 10-Q stated: "[t]he increase in Subsys revenue is primarily as a result of increased prescriptions and change in mix of prescribed dosages as Subsys was a relatively new product during the three months ended June 30, 2013 and also price increases in January 2014 and April 2014."

274. Attached to the 2Q 2014 10-Q were certifications pursuant to Rule 13a-14(a) and 15d-14(a) under the Exchange Act and the Sarbanes-Oxley Act of 2002 ("SOX") signed by Defendants Babich and Baker attesting to the accuracy of the 2Q 2014 10-Q.

275. In response to the August 12, 2014 filings, several analysts issued positive

reports regarding Insys's business prospects based on those filings, including Oppenheimer, JMP Securities, and Wells Fargo.

276. These statements made in August 12, 2014 press release, the 2Q 2014 10-Q, and during the earnings call held the same day were materially false and misleading because they failed to disclose: (1) the Sales Misconduct; (2) that the Company failed to maintain internal controls; and (3) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***November 11, 2014 Press Release and Earnings Call***

277. On November 11, 2014, the Insys issued a press release announcing its financial results for the quarter ended October 20, 2014. The press release noted the following "highlights" of the quarter, *inter alia*:

- Total net revenue increased to \$58.3 million versus \$29.2 million for the third quarter of 2013;
- Revenues from Subsys<sup>®</sup> (fentanyl sublingual spray) were \$58.2 million, up 105% compared with third quarter 2013 sales of \$28.4 million;
- Net income increased to \$11.5 million, or \$0.33 per basic and \$0.31 per diluted share, compared to net income of \$11.6 million, or \$0.36 per basic and \$0.34 per diluted share, for the third quarter of 2013; . . .

278. The press release quoted Defendant Babich as stating that "[w]e are pleased to report another strong quarter, in which our revenue and gross profit doubled largely driven by the continued, successful execution of our Subsys strategy."

279. In an earnings call held the same day, Defendant Babich stated, regarding the "success" of Subsys, that:

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

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

(Emphasis added.)

280. These statements made in November 11, 2014 press release, and during the earnings call held the same day were materially false and misleading because they failed to disclose: (1) the Sales Misconduct; (2) that the Company failed to maintain internal controls; and (3) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***3Q 2014 10-Q***

281. Insys filed its quarterly report with the SEC on November 12, 2014 announcing financial results for the quarter ended September 30, 2014, on Form 10-Q (the "3Q 2014 10-Q"), signed by Defendants Baker and Babich.

282. Regarding the growth in Subsys revenues, the 3Q 2014 10-Q stated: "[t]he increase in Subsys revenue is primarily as a result of increased prescriptions and change in mix of prescribed dosages as Subsys was a relatively new product during the three months ended September 30, 2013 and also price increases in January 2014 and April 2014."

283. Attached to the 3Q 2014 10-Q were SOX certifications signed by Defendants Babich and Baker, attesting to the accuracy of the 3Q 2014 10-Q.

284. In response to the November 11 and 12, 2014 filings, several analysts issued positive reports regarding Insys's business prospects based on those filings, including Oppenheimer and JMP Securities.

285. These statements made in the 3Q 2014 10-Q were materially false and misleading because they failed to disclose: (1) the Sales Misconduct; (2) that the Company

failed to maintain internal controls; and (3) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***March 3, 2015 Press Release, Earnings Call and 2014 10-K***

286. On March 3, 2015, Insys issued a press release announcing its financial results for the quarter and year ended December 31, 2014. The press release noted the following "highlights" of the quarter, *inter alia*:

- Net revenue increased to \$66.5 million versus \$40.2 million in the fourth quarter of 2013;
- Revenues from Subsys<sup>®</sup> (fentanyl sublingual spray) were \$66.1 million, up 69% over fourth quarter of 2013 sales of \$39.2 million;

\* \* \*

- Net income of \$9.3 million, or \$0.25 per diluted share, compared to net income of \$24.1 million, or \$0.67 per diluted share per diluted share, for the fourth quarter of 2013. The 2013 period includes the impact of a \$9.7 million income tax benefit due to the reversal of deferred tax asset valuation allowance versus tax expense of \$6.9 million in the fourth quarter of 2014; . . .

287. The press release quoted Defendant Babich as stating: "Subsys revenues more than doubled in 2014 over the prior year, enabling us to execute our strategy to develop important new products and new indications for Subsys to further expand our revenue stream."

288. In an earnings call held the same day, Defendant Babich stated, "[w]hile we work to bring new products to market, Subsys will continue to be our main driver of revenue in 2015. ***We believe this product's success is the result of a clinical superiority product*** coupled with a focused market penetration strategy." (Emphasis added.)

289. Defendant Babich further explained:

I think Q4 is a great indication of what we can do with the product moving forward, as well. I think that is important for folks -- our sales force expansion

was based on opportunity. We keep hitting new highs in the number of new doctors that we activate on a weekly basis. We have some very unique programs within the oncology setting that we continue to execute on and any growth that we see in this overall TIRF class is specifically coming from Subsys.

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

(Emphasis added.)

290. Insys filed its annual report with the SEC on March 3, 2015, announcing financial results for the quarter and year ended December 31, 2014, on Form 10-K (the "2014 10-K"), signed by Defendants Baker, Babich, Kapoor, Fourteau, Meyer, Tambi, Lapalme, and Stanley.

291. Regarding the Company's interactions with third party payors, the 2014 10-K stated:

Our 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. All third-party payers 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 has been, and will likely continue to be, subject to these restrictions and impediments from third-party payers, particularly pharmacy benefit managers ("PBMs") and private health insurers. We provide administrative patient support assistance, in large part through our patient services hub, which provides administrative support assistance to help patients work with their insurance companies.*

(Emphasis added.)

292. The 2014 10-K further stated:

*Patient Access:* Subsys is a Tier 3 medication available under most major commercial health insurance plans. Some third-party payors require usage and failure on cheaper generic versions of Actiq prior to providing reimbursement for

Subsys and other branded TIRF products. *We believe that physicians and payors 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 payor reimbursement is in place, we offer patients coupons to reduce out of pocket costs.

(Italic subheading in original, bold and italic emphasis added.)

293. Regarding the Company's sales and marketing practices for Subsys, the 2014 10-K stated: "[w]e commercialize Subsys through a cost-efficient commercial organization utilizing an incentive-based sales model similar to that employed by Sciele Pharma and other companies previously led by members of our board of directors, including our founder and Executive Chairman."

294. Regarding Subsys's continued growth, the 2014 10-K stated, in relevant part:

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

(Emphasis added.)

295. Attached to the 2014 10-K were SOX certifications signed by Defendants Babich and Baker, attesting to the accuracy of the 2014 10-K.

296. In response to the March 3, 2015 filings, several analysts issued positive reports regarding Insys's business prospects based on those filings, including Jefferies and JMP Securities.

297. These statements made in March 3, 2015 press release, the 2014 10-K, and during the earnings call held the same day were materially false and misleading because they failed to disclose: (1) the Sales Misconduct; (2) that the Company failed to maintain internal controls; and (3) that due to the foregoing, Defendants' statements regarding the Company's

business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***May 7, 2015 Press Release and Earnings Call***

298. On May 7, 2015, Insys issued a press release announcing its financial results for the quarter ended May 31, 2017. The press release noted the following “highlights” of the quarter, *inter alia*:

- Total net revenue increased to \$70.8 million versus \$41.6 million for the first quarter of 2014;
- Revenues from Subsys<sup>®</sup> (fentanyl sublingual spray) were \$70.5 million, up 74% compared with first quarter 2014 sales of \$40.7 million;
- Net income of \$8.0 million, or \$0.23 per basic and \$0.21 per diluted share, compared to net income of \$7.7 million, or \$0.23 per basic and \$0.21 per diluted share, for the first quarter of 2014; . . .

299. The press release quoted Defendant Babich as stating “Insys had another strong quarter, driven by our twelfth consecutive quarter of Subsys sales growth.”

300. In an earnings call held the same day, Defendant Babich reiterated the same false and misleading figures for revenue and net income in the quarter ended March 31, 2015.

301. These statements made in May 7, 2015 press release and during the earnings call held the same day were materially false and misleading because they: (1) overstated revenue for the quarter ended March 31, 2015; (2) understated the Company’s product returns by distributors, rebate obligations to third-party payers, and the Company’s overall provision for sales allowances; (3) failed to disclose that, as a result of the foregoing, the Company violated its own internal accounting policies; (4) failed to disclose the Sales Misconduct; (5) failed to disclose that the Company failed to maintain internal controls; and (6) failed to disclose that due to the foregoing, Defendants’ statements regarding the Company’s business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***1Q 2015 10-Q***

302. Insys filed its quarterly report with the SEC on May 11, 2015 announcing financial results for the quarter ended March 31, 2015, on Form 10-Q (the “1Q 2015 10-Q”), signed by Defendants Baker and Babich.

303. The 1Q 2015 10-Q stated that the Company recognized revenue when the following four criteria were satisfied:

Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

304. In regard to sales allowances, the 1Q 2015 10-Q stated:

***We recognize estimated product sales allowances as a reduction of product sales in the same period the related revenue is recognized.*** Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payors and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment.

(Emphasis added.)

305. In respect to product returns, the 1Q 2015 10-Q asserted that the Company had a reasonable basis upon which to estimate returns, and had properly recorded discounts in the accrued sales allowances:

***Product Returns.*** We allow customers to return product for credit within six months before and up to 12 months following its product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. ***We have monitored actual return history since product launch, which provides us with a basis to reasonably estimate future product returns,*** taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after its product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustments. ***The allowance for product returns is included in accrued sales allowances.***

(Italic subheading in original. Bold & italic emphasis added.)

306. With regard to rebates, the 1Q 2015 10-K asserted that they were recorded at the time revenue was recognized:

*Rebates.* We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. ***Estimated rebates are recognized as a reduction of revenue in the period the related revenue is recognized.*** The allowance for rebates is included in accrued sales allowances.

(Italic subheading in original. Bold & italic emphasis added.)

307. The above statements in the 1Q 2015 10-Q were materially false and misleading when made because Insys: (1) improperly recorded revenue before it was earned; (2) failed to reserve for product returns and rebates; (3) lacked any reasonable basis for estimating its sales allowance; (4) violated Insys's own internal accounting policies; (5) lacked the appropriate processes and controls to properly track product returns and rebates; and (6) failed to maintain internal controls. Due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

308. The 1Q 2015 10-Q reported net income of \$8 million and net revenue of \$70.8 million for the quarter ended March 31, 2015.

309. In regard to discounts, rebates and returns, the 1Q 2015 10-Q stated;

Provisions for wholesaler discounts, patient discounts, rebates and returns increased to \$8.0 million, \$17.0 million, \$8.4 million and \$0.6 million, respectively, from the sale of Subsys for the three months ended March 31, 2015, compared to \$3.8 million, \$4.1 million, \$3.7 million and \$0.1 million, respectively, from the sale of Subsys for the three months ended March 31, 2014. The increase in revenue provisions was primarily attributable to increased sales and higher volumes of patient assistance. We expect net revenue from sales of Subsys to continue to increase during the remainder of 2015 due primarily to anticipated increases in the number of prescriptions fulfilled, combined with changes in prescription strength mix.

310. The 1Q 2015 10-Q asserted that “[t]he accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles, pursuant to rules and regulations of the Securities and Exchange Commission (the “SEC”).”

311. The 1Q 2015 10-Q represented that the Company maintained adequate controls over financial reporting, stating, in relevant part:

#### **ITEM 4. CONTROLS AND PROCEDURES**

##### ***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. *Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective.*

(Emphasized headings in original, italic emphasis added.)

312. Attached to the 1Q 2015 10-Q were SOX certifications signed by Defendants Babich and Baker, attesting to the accuracy of the 1Q 2015 10-Q.

313. The statements in the 1Q 2015 10-Q were materially false and misleading, and they failed to disclose material facts necessary to make the statements made not false and

misleading. Specifically, the Individual Defendants caused to Company to improperly failed to disclose: (1) that Insys overstated revenue for the quarter ended March 31, 2015; (2) that Insys understated rebate obligations to third-party payers, product returns by distributors, and the Company's overall provisions for sales allowance; (3) that Insys overstated earnings; (4) that the Company failed to maintain internal controls; (5) that as a result of the foregoing Insys's financial statements were not in compliance with GAAP; (6) the Sales Misconduct; (7) that Subsys sales were declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of the Sales Misconduct; and (7) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***August 6, 2015 Press Release***

314. On August 6, 2015, the Insys issued a press release announcing its financial results for the three and six-month periods ended June 30, 2015. The press release noted the following "highlights" for the quarter:

- Total net revenue increased to \$77.6 million versus \$55.7 million for the second quarter of 2014;
- Revenues from Subsys<sup>®</sup> (fentanyl sublingual spray) were \$76.7 million, up 40% compared with second quarter 2014 sales of \$54.6 million;
- Net income was \$7.3 million, or \$0.10 per basic and diluted share, compared to net income of \$9.5 million, or \$0.14 per basic and \$0.13 per diluted share, for the second quarter of 2014; . . .

315. Defendant Babich was quoted as stating: "Insys had another strong quarter, driven by our thirteenth consecutive quarter of Subsys sales growth."

316. The press release reported net revenue of \$148.4 million and net income of \$15.3 million for the six months ended June 30, 2017.

317. The statements in the August 6, 2015 press release were materially false and

misleading, and they failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants improperly failed to disclose: (1) that the Company had overstated revenue; (2) that Insys understated rebate obligations to third-party payers, product returns by distributors, and the Company's overall provisions for sales allowance; (3) that Insys improperly recorded an out of period adjustment of \$834,000 during the quarter ended December 31, 2016 relating to the deductible interest portion of an accrued litigation award recognized during the quarter ended June 30, 2015, increasing income tax expense by \$834,000 in the quarter ended December 31, 2016; (4) that the Company failed to maintain internal controls; (5) that as a result of the foregoing, the Company violated its own internal accounting policies for recording revenue, rebates, sales returns, and overall sales allowances; (6) the Sales Misconduct; (7) that sales of Subsys were declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of the Sales Misconduct; and (8) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***2Q 2015 10-Q and Earnings Call***

318. On August 6, 2015, Insys filed a quarterly report for the fiscal quarter ended June 30, 2015 on Form 10-Q (the "2Q 2015 10-Q"), which was signed by Defendants Babich and Baker.

319. The 2Q 2015 10-Q stated that the Company recognized revenue when the following four criteria were satisfied:

Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

320. In regard to sales allowances, the 2Q 2015 10-Q stated:

*We recognize estimated product sales allowances as a reduction of product sales in the same period the related revenue is recognized.* Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payors and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment.

(Emphasis added.)

321. In respect to product returns, the 2Q 2015 10-Q asserted that the Company had a reasonable basis upon which to estimate returns, and had properly recorded discounts in the accrued sales allowances:

*Product Returns.* We allow customers to return product for credit beginning six months prior to and ending 12 months following the product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. ***We have monitored actual return history since product launch, which provides us with a basis to reasonably estimate future product returns,*** taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after the product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. ***The allowance for product returns is included in accrued sales allowances.***

(Italic subheading in original. Bold & italic emphasis added.)

322. With regard to rebates, the 2Q 2015 10-Q asserted that they were recorded at the time revenue was recognized:

*Rebates.* We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three

months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. ***Estimated rebates are recognized as a reduction of revenue in the period the related revenue is recognized.*** The allowance for rebates is included in accrued sales allowances.

(Italics subheading in original. Bold & italic emphasis added.)

323. The above statements in the 2Q 2015 10-Q were materially false and misleading when made because Insys: (1) improperly recorded revenue before it was earned; (2) failed to reserve for product returns and rebates; (3) lacked any reasonable basis for estimating its sales allowance; (4) violated its own internal accounting policies; (5) lacked the appropriate processes and controls to properly track product returns and rebates; and (6) failed to maintain internal controls. Due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

324. The 2Q 2015 10-Q reported net revenue of \$77.6 million and net income of \$7.3 million for the three-month period ended June 30, 2015. The filing also reported net revenue of \$148.4 million and net income of \$15.4 million for the six-month period ended June 30, 2015.

325. In regard to discounts, rebates and returns, the 2Q 2015 10-Q stated:

Provisions for wholesaler discounts, patient discounts, rebates and returns increased to \$10.0 million, \$14.4 million, \$16.8 million and \$0.6 million, respectively, from the sale of Subsys for the three months ended June 30, 2015, compared to \$5.4 million, \$5.6 million, \$6.1 million and \$1.4 million, respectively, from the sale of Subsys for the three months ended June 30, 2014.

326. The 2Q 2015 10-Q asserted that “[t]he accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles, pursuant to rules and regulations of the SEC.”

327. With regard to Insys's controls over financial reporting, the 2Q 2015 10-Q

stated:

#### **ITEM 4. CONTROLS AND PROCEDURES**

##### ***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, *our disclosure controls and procedures were effective.*

(Emphasized headings in original, italic emphasis added.)

328. Attached to the 2Q 2015 10-Q were SOX certifications signed by Defendants Babich and Baker, attesting to the accuracy of the 2Q 2015 10-Q.

329. The Company held an earnings call on August 6, 2015, during which Defendant Baker made the following statement regarding the Company's financial performance:

Total net revenue for second quarter of 2015 was \$77.6 million, which was an increase of 39% as compared with \$55.7 million for the second quarter of 2014. The key driver continues to be Subsys . . . As Mike mentioned, this was our 10<sup>th</sup> straight quarter of profitability. GAAP net income for the second quarter of 2015 was \$7.3 million or \$0.10 per diluted share compared to net income of \$9.5 million or \$0.13 per diluted share for the second quarter of 2014.

330. When an analyst asked, "what's the discounting and rebating [for Subsys] was for the quarter?" during the call, Defendant Baker responded: "we're netting approximately two-thirds of our gross revenue, and our gross-to-net for Q2 were in line and consistent with that pattern."

331. The statements in 2Q 2015 10-Q and earnings call were materially false and misleading, and they failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants improperly failed to disclose: (1) that Insys overstated revenue; (2) that Insys understated rebate obligations to third-party payers,

product returns by distributors, and the Company's overall provisions for sales allowance; (3) that Insys overstated earnings; (4) that the Company failed to maintain internal controls; (5) that as a result of the foregoing Insys's financial statements were not in compliance with GAAP; (6) the Sales Misconduct; (7) that sales of Subsys were declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of the Sales Misconduct; and (8) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***November 5, 2015 Press Release***

332. On November 5, 2015, Insys issued a press release announcing its financial results for the three and nine-month periods ended September 30, 2015. The press release noted the following "highlights" for the quarter:

- Total net revenue increased to \$91.3 million compared to \$58.3 million for the third quarter of 2014;
- Revenue from Subsys<sup>®</sup> (fentanyl sublingual spray) was \$91.1 million, up 57% compared with third quarter 2014 revenue of \$58.2 million;
- Net income was \$26.1 million, or \$0.36 per basic and \$0.34 per diluted share, compared to net income of \$11.5 million, or \$0.17 per basic and \$0.16 per diluted share, for the third quarter of 2014; . . .

333. The Company also reported net revenue of \$239.7 million and net income of \$41.5 million for the nine months ended September 30, 2015.

334. The statements in the November 5, 2015 press release were materially false and misleading, and they failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants improperly failed to disclose: (1) that the Company had overstated revenue; (2) that Insys understated rebate obligations to third-

party payers, product returns by distributors, and the Company's overall provisions for sales allowance; (3) that the Company failed to maintain internal controls; (4) that as a result of the foregoing, the Company violated its own internal accounting policies for recording revenue, rebates, sales returns, and overall sales allowances; (5) the Sales Misconduct; (6) that sales of Subsys were declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of the Sales Misconduct; and (7) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

### ***3Q 2015 10-Q and Earnings Call***

335. On November 5, 2015, Insys filed a quarterly report for the fiscal quarter ended September 30, 2015 on Form 10-Q (the "3Q 2015 10-Q"), which was signed by Defendants Kapoor and Baker.

336. The 3Q 2015 10-Q stated that the Company recognized revenue when the following four criteria were satisfied:

Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

337. In regard to sales allowances, the 3Q 2015 10-Q stated:

***We recognize estimated product sales allowances as a reduction of product sales in the same period the related revenue is recognized.*** Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payors and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment.

(Emphasis added.)

338. In respect to product returns, the 3Q 2015 10-Q asserted that the Company had a reasonable basis upon which to estimate returns, and had properly recorded discounts in the accrued sales allowances:

*Product Returns.* We allow customers to return product for credit beginning six months prior to, and ending 12 months following, the product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. ***We have monitored actual return history since product launch, which provides us with a basis to reasonably estimate future product returns,*** taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after the product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. ***The allowance for product returns is included in accrued sales allowances***

(Italic subheading in original. Bold & italic emphasis added.)

339. With regard to rebates, the 3Q 2015 10-K asserted that they were recorded at the time revenue was recognized:

*Rebates.* We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. ***Estimated rebates are recognized as a reduction of revenue in the period the related revenue is recognized.*** The allowance for rebates is included in accrued sales allowances.

(Italic subheading in original. Bold & italic emphasis added.)

340. The above statements in the 3Q 2015 10-Q were materially false and misleading when made because Insys: (1) improperly recorded revenue before it was earned; (2) failed to reserve for product returns and rebates; (3) lacked any reasonable basis for estimating its sales

allowance; (4) violated Insys's own internal accounting policies; (5) lacked the appropriate processes and controls to properly track product returns and rebates; and (6) failed to maintain internal controls. Due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

341. In regard to discounts, rebates and returns, the 3Q 2015 10-Q stated:

Provisions for wholesaler discounts, patient discounts, rebates and returns increased to \$10.0 million, \$13.1 million, \$16.6 million and \$1.3 million, respectively, from the sale of Subsys for the three months ended September 30, 2015, compared to \$6.3 million, \$12.3 million, \$7.3 million and \$0.2 million, respectively, from the sale of Subsys for the three months ended September 30, 2014.

342. The Company held an earnings call on November 5, 2015, during which Defendant Baker made the following statements regarding the Company's financial performance:

Insys achieved a record quarter with total net revenue of \$91.3 million, which was an increase of 57% compared with the \$58.3 million we reported in the third quarter of 2014 . . .

GAAP net income for the third quarter of 2015 was \$26.1 million or \$0.34 per diluted share, compared to net income of \$11.5 million or \$0.16 per diluted share for the third quarter of 2014. Non-GAAP adjusted net income per diluted share for the third quarter of 2015 with \$0.50 compared to \$0.32 per diluted share for the third quarter of 2014.

343. In response to an analyst question regarding Subsys' growth outlook, Defendant Kapoor stated: "we look forward to growth of Subsys, maybe not as fast as has been in the past, but still it will be a growth product for us."

344. The 3Q 2015 10-Q stated that: "[t]he accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles, pursuant to rules and regulations of the SEC."

345. With regard to Insys's controls over financial reporting, the 3Q 2015 10-Q stated:

**ITEM 4. CONTROLS AND PROCEDURES**

***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, *our disclosure controls and procedures were effective.*

(Emphasized headings in original, italic emphasis added.)

346. Attached to the 3Q 2015 10-Q were SOX certifications signed by Defendants Kapoor and Baker, attesting to the accuracy of the 3Q 2015 10-Q.

347. The referenced statements in 3Q 2015 10-Q and earnings call were materially false and misleading, and they failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants improperly failed to disclose: (1) that Insys overstated revenue; (2) that Insys understated rebate obligations to third-party payers, product returns by distributors, and the Company's overall provisions for sales allowance; (3) that Insys overstated earnings; (4) that the Company failed to maintain internal controls; (5) that as a result of the foregoing, Insys's financial statements were not in compliance with GAAP; (6) the Sales Misconduct; (7) that sales of Subsys were declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result the Sales Misconduct; and (8) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***November 23, 2015 Issue Statement***

348. On November 23, 2015, the Company released an Issue Statement regarding Subsys and TIRF-REMS:

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

(Emphasis added.)

349. These statements were materially false and misleading because they failed to disclose: (1) the Sales Misconduct; (2) that due to the Sales Misconduct, prescribing decisions were being driven by the Sales Misconduct, not “clinical attributes of Subsys,”; (3) that due to the Sales Misconduct, the compliance program was ineffective; (4) that the Company failed to maintain internal controls; and (5) that due to the foregoing, Defendants’ statements regarding the Company’s business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***January 25, 2016 Press Release***

350. On January 25, 2016 the Individual Defendants cause Insys to issue a press release relating to the IRC in response to an *SIRF* article published on the same day. The press release stated that: “***Insys rejects the recent media reports’ account of the Company’s practices as misleading and unreliable***, especially in light of the biased agenda held by the individuals who made these misrepresentations.” (Emphasis added.) Regarding its practice of helping patients gain access to Subsys through, the IRC, among other things, the Company

stated that “*Insys requires its Patient Services Center personnel undergo specific training on applicable laws and regulations and continues to strive to comply with applicable laws and regulations through its compliance policies and procedures.*” (Emphasis added.)

351. These statements were materially false and misleading because they failed to disclose: (1) the Sales Misconduct; (2) that the Company failed to maintain internal controls; and (3) that due to the foregoing, Defendants’ statements regarding the Company’s business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***February 23, 2016 Press Release***

352. On February 23, 2016, Insys issued a press release announcing its financial results for the three and twelve-month periods ended December 31, 2015. The press release noted the following “highlights” for the quarter:

- Total net revenue increased to \$91.1 million, compared to \$66.5 million for the fourth quarter of 2014;
- Revenue from Subsys<sup>®</sup> (fentanyl sublingual spray) was \$91.1 million, up 38% compared with fourth quarter 2014 revenue of \$66.1 million;
- Net income was \$17.0 million, or \$0.24 per basic and \$0.22 per diluted share, compared to net income of \$9.3 million, or \$0.13 per basic and diluted share, for the fourth quarter of 2014; . . .

353. The press release quoted Defendant Kapoor as stating: “2015 was another year of solid growth coupled with steady R&D progress.”

354. The Company also reported the following financial results for 2015:

Net revenue for the year ended December 31, 2015 was \$330.8 million compared to \$222.1 million for the year ended December 31, 2014, an increase of 49%.

Gross margin for 2015 was 91%, compared with 90% for 2014.

\* \* \*

Net income for 2015 was \$58.5 million, or \$0.82 per basic and \$0.77 per diluted share, compared to net income of \$38.0 million, or \$0.55 per basic and \$0.52 per diluted share, for 2014. Non-GAAP adjusted net income, which adjusts for non-cash stock compensation expense and non-cash income tax expense, was \$104.2 million, or \$1.38 per diluted share, compared to \$78.7 million, or \$1.07 per diluted share, in the prior year. The reconciliation of net income to Non-GAAP adjusted net income is included at the end of this press release.

355. The statements in the February 23, 2016 press release were materially false and misleading, and they failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants improperly failed to disclose: (1) that the Company had overstated revenue; (2) that Insys understated rebate obligations to third-party payers, product returns by distributors, and the Company's overall provisions for sales allowance; (3) that the Company failed to maintain internal controls; (4) that as a result of the foregoing, the Company violated its own internal accounting policies for recording revenue, rebates, sales returns, and overall sales allowances; (5) the Sales Misconduct; (6) that sales of Subsys were declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of the Sales Misconduct; and (7) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***2015 10-K and Earnings Call***

356. On February 29, 2016, Insys filed an annual report for the fiscal quarter and year ended December 31, 2015 on Form 10-K (the "2015 10-K") providing the Company's quarterly financial results and position. The 2015 10-K was signed by Defendants Kapoor, Baker, Fourteau, Meyer, Tambi, Lapalme, and Stanley.

357. The 2015 10-K stated that the Company recognized revenue when the following four criteria were satisfied:

Revenue is recognized when (i) persuasive evidence of an arrangement exists,

(ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

358. In regard to sales allowances, the 2015 10-K stated:

*We recognize estimated product sales allowances as a reduction of product sales in the same period the related revenue is recognized.* Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payors and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment.

(Emphasis added.)

359. In respect to product returns, the 2015 10-K asserted that the Company had a reasonable basis upon which to estimate returns, and had properly recorded discounts in the accrued sales allowances:

*Product Returns.* We allow customers to return product for credit on returned product that is within six months before and up to 12 months following its product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. *We have monitored actual product sold through to patient prescriptions since product launch, which provides us with a basis to reasonably estimate future product returns,* taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after its product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustments. *The allowance for product returns is included in accrued sales allowances.*

(Italic subheading in original. Bold & italic emphasis added.)

360. With regard to rebates, the 3Q 2015 10-K asserted that they were recorded at the time revenue was recognized:

*Rebates.* We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. ***Estimated rebates are recognized as a reduction of revenue in the period the related revenue is recognized.*** The allowance for rebates is included in accrued sales allowances.

(Italic subheading in original. Bold & italic emphasis added.)

361. The above statements in the 2015 10-K and earnings call were materially false and misleading when made because Insys: (1) improperly recorded revenue before it was earned; (2) failed to adequately reserve for product returns and rebates; (3) lacked any reasonable basis for estimating its sales allowance; (4) violated Insys's own internal accounting policies; (5) lacked the appropriate processes and controls to properly track product returns and rebates; and (6) failed to maintain internal controls. Due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

362. The 2015 10-K reported net revenue of \$330.8 million and net income of \$58.5 million for the year ended December 31, 2015:

***Net Revenue.*** Net revenue increased \$108.7 million, or 49%, to \$330.8 million for the year ended December 31, 2015, compared to \$222.1 million for the year ended December 31, 2014. **The increase in net revenue was primarily attributable to the \$109.9 million, or 50%, increase in net revenue of Subsys to \$329.5 million for the year ended December 31, 2015** compared to \$219.5 million for the year ended December 31, 2014. **The increase in Subsys revenue is primarily as a result of a 30% increase in shipments to pharmaceutical wholesalers and retailers for the year ended December 31, 2015** as compared to the year ended December 31, 2014, as well as a 20% 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.

\* \* \*

We expect net revenue from sales of Subsys to continue to increase during 2016 due primarily to anticipated increases in unit prices and in the number of prescriptions fulfilled, combined with changes in prescription strength mix.

(Emphasized subheading in original, bold emphasis added.)

363. In regard to discounts, rebates, and returns, the 2015 10-K stated:

Provisions for wholesaler discounts, patient discounts, rebates and returns increased to \$36.8 million, \$61.0 million, \$63.0 million and \$3.3 million, respectively, or 33.2% on a combined basis of gross revenue from the sale of Subsys for the year ended December 31, 2014, compared to \$22.4 million, \$36.5 million, \$24.4 million and \$2.8 million, respectively, or 39.2% on a combined basis of gross revenue from the sale of Subsys for the year ended December 31, 2013. The increase in revenue provisions as a percentage of gross revenue was primarily attributable to an increase in the issuance of patient discount credits and rebate claims from managed care organizations and government programs.

364. The 2015 10-K further reported revenue allowance of \$39.1 million, rebates of \$22.4 million and returns of \$3.2 million.

	<b>Wholesale Discounts <sup>(1)</sup></b>	<b>Patient Discount Programs</b>	<b>Rebates</b>	<b>Returns</b>	<b>Total</b>
Balance at December 31, 2014	\$ 5,418	\$ 2,227	\$ 7,910	\$ 1,159	\$ 16,714
Provision related to current period sales	36,849	60,991	63,402	3,158	164,400
Provisions related to sales made in prior years	-	-	(367)	138	(229)
Payment and credits related to sales made in current period	(30,480)	(53,848)	(41,030)	-	(125,358)
Payment and credits related to sales made in prior periods	(5,418)	(2,227)	(7,543)	(1,257)	(16,445)
Balance at December 31, 2015	<u>\$ 6,369</u>	<u>\$ 7,143</u>	<u>\$ 22,372</u>	<u>\$ 3,198</u>	<u>\$ 39,082</u>

(1) Includes wholesaler discounts, prompt pay discounts, stocking allowances and government chargebacks.

365. The Company held an earnings call on February 23, 2016, during which Defendant Baker made the following statements regarding the Company's financial performance:

Insys achieved a solid fourth quarter, with total net revenue of \$91.1 million, an increase of 37%, as compared with \$66.5 million for the fourth quarter of 2014. We generated adjusted EBITDA of \$39.3 million in the quarter. GAAP net income for the fourth quarter of 2015 was \$17 million, or \$0.22 per diluted share, compared to net income of \$9.3 million, or \$0.13 per diluted share for the fourth quarter of 2014. Non-GAAP adjusted net income per diluted share for the fourth quarter of 2015 was \$0.36, compared to \$0.26 per diluted share for the fourth quarter of 2014.

366. In response to an analyst's question during the call regarding the decline Subsys prescriptions, Defendant Baker attributed the decline to seasonality:

Q: "Can you give us an idea of how many the Subsys scripts are down fourth quarter to first? And second is you're cutting back the marketing expenses for Subsys, and you indicated some loss of market share, which is very contrary to what the recent history has been. Is that because of Optum, or are there other reasons that you might be losing market share?"

A: "I think to comment on your expenses, marketing expenses, we believe that we are spending wisely, and there's some readjustment on our expenditure on the speaker program, which speaker programs are heavily weighted when you launch a product and as time goes on, they tend to slow down, and that's what we did. We don't think that has anything to do with the market share. ***On the decline, I think what seasonally in the first quarter, a lot of plans go through reauthorization and things like that, so it has some impact on the script, just because of the seasonality in the first quarter.***

So I'm sure we're having some impact from that, some impact from Optum, some impact from the TIRF category, and I don't have to tell you that the publicity, the onslaught of sometimes misinformation have as well. So it's a combination of all of those factors. We are very conscious about it. We are very focused on it and we're working very hard on it. Our challenge as a team, a management team is to stabilize and change the trajectory of Subsys, and I can assure you that is job one in this Company. We meet every day, all of the management team address the

issues of Subsys, and address them right away.”

(Emphasis added.)

367. The 2015 10-K included a letter from Insys’s auditor, which stated that:

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Insys Therapeutics, Inc. at December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

368. With regard to change in Insys’s internal controls over financial reporting, the 2015 10-K revealed that Insys lacked adequate internal controls regarding “accounting for stock option awards,” stating, in relevant part:

During the quarterly period ending December 31, 2015, we identified a material weakness in our internal control over financial reporting regarding the accounting for stock option awards. ***There were no other changes in our internal control over financial reporting*** as such term is defined in Exchange Act Rules 13a–15(f) and 15d–15(f) that occurred during the quarterly period ended December 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

(Emphasis added.)

369. However, despite noting that there were no other changes in internal controls, the 2015 10-K did not disclose that the Company did not have adequate internal controls over financial reporting relating to sales rebates and returns.

370. With respect to the material weakness in accounting for stock option awards, the 2015 10-K stated:

While we expect to take the measures necessary to address the underlying causes of this material weakness, we cannot at this time estimate how long it will take and our efforts may not prove to be successful in remediating this material weakness. While we have not incurred and do not expect to incur material expenses specifically related to the remediation of this material weakness, actual expenses may exceed our current estimates and overall costs of compiling the system and processing documentation necessary to assess the effectiveness of our internal control over financial reporting may be material.

371. Attached to the 2015 10-K were SOX certifications signed by Defendants Kapoor and Baker, attesting to the accuracy of the 2015 10-K.

372. The referenced statements in 2015 10-K and earnings call were materially false and misleading, and they failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants improperly failed to disclose: (1) that Insys overstated revenue; (2) that Insys understated rebate obligations to third-party payers, product returns by distributors, and the Company's overall provisions for sales allowance; (3) that Insys overstated earnings; (4) that the Company failed to maintain internal controls; (5) that as a result of the foregoing, Insys's financial statements were not in compliance with GAAP; (6) that Insys improperly recorded an out-of-period adjustment related to a stock option modification during the three months ended March 31, 2016 that related to the fourth quarter of 2015, resulting in a restated \$1.5 million increase in operating expenses during the three months ended December 31, 2015; (7) the Sales Misconduct; (8) that sales of Subsys were declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of the Sales Misconduct; and (9) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***2016 Proxy Statement***

373. Insys filed a Schedule 14A with the SEC on April 20, 2016 (the "2016 Proxy Statement"). Plaintiff's allegations with respect to the misleading statements in the 2016 Proxy Statement are based solely on negligence; they are not based on any allegation of reckless or knowing conduct by or on behalf of the Individual Defendants, and they do not allege and do not sound in fraud. Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to

these allegations and related claims.

374. The 2016 Proxy Statement stated that:

We have adopted a Code of Business Conduct and Ethics that applies to employees, officers and directors, including our executive management team, such as our Chief Executive Officer and Chief Financial Officer. This Code of Business Conduct and Ethics is posted on our website at [www.insysrx.com](http://www.insysrx.com) (the contents of such website are not incorporated into this proxy statement). We intend to satisfy the requirements under Item 5.05 of Form 8-K regarding disclosure of amendments to, or waivers from, provisions of the Code of Business Conduct and Ethics by posting such information on our website.

We also have compliance and ethics policies applicable to our employees designed to prevent and detect violations of our Code of Business and Ethics Conduct, as well other internal policies and the law. A major goal of the compliance and ethics program is to promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law. In this regard, we have established avenues for parties external to the Insys Therapeutics to raise compliance and ethics concerns with respect to our employees, directors and third parties doing business with the Company.

375. The 2016 Proxy Statement was false and misleading because, despite assertions to the contrary, its Code of Conduct was not followed, resulting in—and evidenced by—the Sales Misconduct.

376. The Individual Defendants also caused the 2016 Proxy Statement to be false and misleading with regard to executive compensation in that they purported to employ “pay-for-performance” elements, while failing to disclose that the Company’s revenues and profits, and therefore its financial performance, were based on the Sales Misconduct and therefore any compensation based on the Company’s financial performance was artificially inflated.

377. The 2016 Proxy Statement also failed to disclose that the Company: (1) failed to maintain a proper “tone at the top” resulting in premature recording of revenue, overstatement of earnings, the failure to properly account for sales allowances, and GAAP violations; (2) engaged in the Sales Misconduct; and (3) had not maintained adequate internal controls.

*April 28, 2016 Press Release*

378. On April 28, 2016, Insys issued a press release announcing its financial results for the three-month period ended March 31, 2016. The press release noted the following “highlights” for the quarter:

- Total net revenue decreased to \$62.0 million, compared to \$70.8 million for the first quarter of 2015;
- Revenue from Subsys<sup>®</sup> (fentanyl sublingual spray) was \$62.0, down 12% compared with first quarter 2015 revenue of \$70.5 million;
- Net income was \$2.4 million, or \$0.03 per basic and \$0.03 per diluted share, compared to net income of \$8.0 million, or \$0.11 per basic and \$0.11 per diluted share, for the first quarter of 2015; . . .

379. The press release asserted that: “[t]he [Q1] results reflect a decline in Subsys demand, as Subsys prescription volumes were down, as well as a reduction in Subsys wholesale channel inventory levels.”

380. The statements in the April 28, 2016 press release were materially false and misleading, and they failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants improperly failed to disclose: (1) that the Company had overstated revenue; (2) that Insys understated rebate obligations to third-party payers, product returns by distributors, and the Company’s overall provisions for sales allowance; (3) that the Company overstated earnings; (4) that Insys improperly recorded an out-of-period adjustment related to a stock option modification during the three months ended March 31, 2016 that related to the fourth quarter of 2015, resulting in a restated \$1.5 million increase in operating expenses during the three months ended December 31, 2015; (5) that the Company failed to maintain internal controls; (6) that as a result of the foregoing, the Company violated its own internal accounting policies for recording revenue, rebates, sales returns, and overall sales allowances; (7) the Sales Misconduct; (8) that sales of Subsys were declining as a

result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of the Sales Misconduct; and (9) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***1Q 2016 10-Q and Earnings Call***

381. On May 5, 2016, Insys filed a quarterly report for the fiscal quarter ended March 31, 2016 on Form 10-Q (the "1Q 2016 10-Q"), which was signed by Defendants Kapoor and Baker.

382. The 1Q 2016 10-Q stated that the Company recognized revenue when the following four criteria were satisfied:

Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

383. In regard to sales allowances, the 1Q 2016 10-Q stated:

***We recognize estimated product sales allowances as a reduction of product sales in the same period the related revenue is recognized.*** Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payors and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment.

(Emphasis added.)

384. In respect to product returns, the 1Q 2016 10-Q asserted that the Company had a reasonable basis upon which to estimate returns, and had properly recorded discounts in the accrued sales allowances:

***Product Returns.*** We allow customers to return product for credit beginning six months prior to, and ending 12 months following, the product expiration date. The

shelf life of Subsys is currently 36 months from the date of manufacture. ***We have monitored actual return history since product launch, which provides us with a basis to reasonably estimate future product returns***, taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after the product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. ***The allowance for product returns is included in accrued sales allowances.***

(Italic subheading in original. Bold & italic emphasis added.)

385. With regard to rebates, the 1Q 2016 10-Q asserted that they were recorded at the time revenue was recognized:

***Rebates.*** We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. ***The allowance for rebates is included in accrued sales allowances.***

(Italic subheading in original. Bold & italic emphasis added.)

386. The above statements in the 1Q 2016 10-Q were materially false and misleading when made because Insys: (1) improperly recorded revenue before it was earned; (2) failed to reserve for product returns and rebates; (3) lacked any reasonable basis for estimating its sales allowance; (4) violated Insys's own internal accounting policies; (5) lacked the appropriate processes and controls to properly track product returns and rebates; and (6) failed to maintain internal controls. Due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

387. The 1Q 2016 10-Q reported net revenue of \$62.0 million and net income of \$2.4 million in the quarter ended March 31, 2016.

388. In regard to discounts, rebates and returns, the 1Q 2016 10-Q stated:

Provisions for wholesaler discounts, patient discounts, rebates, and returns decreased to \$6.4 million, \$16.1 million, \$7.2 million and (\$0.5) million, respectively, or 32.0% on a combined basis of gross revenue from the sale of Subsys for the three months ended March 31, 2016, compared to \$8.0 million, \$17.0 million, \$8.4 million and \$0.6 million, respectively, or 32.4% on a combined basis of gross revenue from the sale of Subsys for the three months ended March 31, 2015. The decrease in product sales allowances was primarily attributable to decreased sales, lower volumes of patient assistance, and lower rebate rates due to recent price increases.

389. The Company held an earnings call on May 5, 2016, during which Defendant Baker made the following statements regarding the Company's financial performance:

Let me give just a little bit of color with respect to kind of our current situation with Subsys. What we saw in the first quarter of 2016, a market decline in Subsys scripts, about a 23% decline in scripts in Q1 of 2016 relative to Q4 of 2015, and about a 31% decline in revenue due to some deleveraging in the wholesale inventory channel. ***We have seen recently what we believe stabilization in Subsys script trends.*** Our market share in the TIRF class has maintained in the mid-40% range, but there has been a decline in the overall TIRF class. ***But, given the most recent 12-week trend that we've observed, we believe that those trends have stabilized.***

And so, whereas we reported about \$62 million in Q1 of 2016 with about a \$7 million de-lever in the channel ***puts us on a roughly \$70 million per quarter revenue run rate for Subsys currently.*** We were profitable at the \$62 million revenue for Q1, all the while reaffirming our commitment to advancing our pipeline and maintaining profitability . . .

(Emphasis added.)

390. In response to an analyst question regarding payer coverage for Subsys, Defendant Baker admitted that third-party payors were exhibiting increased reluctance to reimburse for Subsys:

Q: “[C]an you discuss what payer coverage looks like for this year? Maybe compare that with last year?”

A: “Yes, so, as I think the market is well aware, we had -- when we launched Subsys we had contracted with Optum, we were the preferred product on the Optum formulary in the TIRF class. In exchange for that placement, we were paying a very substantial rebate, and we made a decision, it was a financially-driven decision, to terminate our contract with Optum. As we’ve played that out here, effective January 1, it’s been actually a net positive for us financially to no longer be paying that rebate to Optum. We are under contract with CVS, Cigna, and maintain good payer relationships with them.

You know, the payer landscape in 2016 has been -- and I think it’s not unique to our product or even to our class, *I think it’s across-the-board, payers are – they seem to be digging their heels in a little bit in 2016, making it difficult for patients to get reimbursed, especially for specialty-type products such as Subsys.* But, we remain committed to, as we always have, patient access. And so, to the extent that the payers are uncooperative, we continue to partner with physicians and patients to ensure that they have access to the medication that they need and continue to maintain dialogue with the payer community to remind them of the medical needs that are being served for the patients that they have a contract with. And so, we’re on the forefront of managing those payer relationships, as well as again primary focus is on ensuring that the patients get access to the care that they need.”

(Emphasis added.)

391. The same analyst later asked about the volume of off-label Subsys prescriptions that had been written and whether those numbers were decreasing in light of continued regulatory and third-party pressures. Defendant Baker responded:

Yes, there have been some studies conducted, that the FDA has asked the REMS, specifically, as a class-wide REMS, to conduct. And there has been *an observed level of off-label use in the category...* think it’s been -- *based on what I’ve seen, fairly consistent.* At least since Subsys has been on the market.”

(Emphasis added.)

392. The 1Q 2016 10-Q stated that: “[t]he accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles, pursuant to rules and regulations of the SEC.”

393. With regard to Insys’s controls over financial reporting, the 1Q 2016 10-Q stated:

#### ITEM 4. CONTROLS AND PROCEDURES

##### *Evaluation of Disclosure Controls and Procedures*

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, and in light of the unremediated material weakness in the design and operation of our internal control over financial reporting relating specifically to the lack of effective policies and procedures, and effective reviews by personnel at an appropriate level, for accounting for stock options awards in accordance with GAAP, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, *our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were not effective. To address this material weakness, we have taken steps to address the underlying causes of the material weakness as described further below under “Remediation Efforts to Address Material Weakness in Internal Control over Financial Reporting.” Accordingly, we believe that the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q do fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.*

(Emphasized headings in original, italic emphasis added.)

394. Attached to the 1Q 2016 10-Q were SOX certifications signed by Defendants Kapoor and Baker, attesting to the accuracy of the 1Q 2016 10-Q.

395. The above-referenced statements from the 1Q 2016 10-Q and earnings call were materially false and misleading, and they failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants improperly failed to disclose: (1) that Insys overstated revenue; (2) that Insys understated rebate obligations to third-party payers, product returns by distributors, and the Company’s overall provisions for sales allowance; (3) that Insys overstated earnings; (4) that Insys improperly recorded an out-of-period adjustment related to a stock option modification during the three months ended March 31, 2016 that related to the fourth quarter of 2015, resulting in a restated \$1.5 million increase in operating expenses during the three months ended December 31, 2015; (5) that the Company

failed to maintain internal controls; (6) that as a result of the foregoing, Insys's financial statements were not in compliance with GAAP; (7) the Sales Misconduct; (8) that sales of Subsys were declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of the Sales Misconduct; and (9) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***August 3, 2016 Press Release and Earnings Call***

396. On August 3, 2016, Insys issued a press release announcing its financial results for the three-month period ended June 30, 2016. The press release noted the following "highlights" for the quarter:

- Total net revenue was \$67.1 million, compared to \$77.6 million for the second quarter of 2015;
- Net income totaled \$4.4 million, or \$0.06 per basic and \$0.06 per diluted share, compared to net income of \$7.3 million, or \$0.10 per basic and \$0.10 per diluted share, for the second quarter of 2015; . . .

397. The press release asserted that the quarterly "results reflect a decline in Subsys prescription volumes due to softness in overall demand in the TIRF category, including Subsys, and continued pressure from third-party payers."

398. The Company held an earnings call on August 3, 2016, during which Defendant Baker made the following statements regarding the Company's financial performance:

Despite recent challenges, Insys remains profitable with a strong, debt-free balance sheet. We reported total net revenue of \$67.1 million for the second quarter of 2016, which was a decrease of 13.5% from the \$77.6 million in the quarter a year ago. As expected, SUBSYS prescription trends experienced softness in the second quarter of 2016. ***The decline in SUBSYS revenue was a reflection of the heightened publicity surrounding the national opioid epidemic and the resulting sensitivity by some health care providers who prescribe opioids.*** This sensitivity has affected the entire TIRF class. At current prescription levels, we expect to remain profitable and to continue to fund our R&D efforts.

GAAP net income for the second quarter of 2016 was \$4.4 million, or \$0.06 per diluted share, compared to net income of \$7.3 million, or \$0.10 per diluted share, for the second quarter of 2015. Non-GAAP adjusted net income per diluted share for the second quarter of 2016 was \$0.13 compared to \$0.21 per diluted share for the second quarter of 2015. Gross margin was 90.7% for the second quarter of 2016, compared with 89.3% for the comparable period in 2015.

(Emphasis added.)

399. During the call, Defendant Kapoor stated that Insys “does not track [the percent of Subsys patients who are cancer versus non-cancer] because [the Company] leave[s] it up to the physicians.”

400. During the call, the following exchange took place between an analyst and Defendants Baker and Kapoor regarding revenue reimbursements and Insys’s market share:

Q: “[C]an you just talk about how we should think about the gross to net on SUBSYS through the back half of the year?”

A: “Our Q2 gross to net roughly -- is coming in at rough -- or netting roughly 60%. Historically, we had been at about two-thirds that we had netted. And, again, I think the continued pressure from third-party payers has required us to step in and provide a little more support. We expect, David, that that will continue to be a challenge as we move throughout the balance of 2016, and we expect there to be further downward pressure on our revenue as a result of that as we move throughout the balance of the year and into 2017.”

401. Defendant Kapoor added:

“And *we are confident that we can maintain the market share*, which we believe is very important to us.

\* \* \*

So there’s a lot of activity that is going on in the SUBSYS space from us, and we believe we are the only company out there in TIRF market that’s doing any research. So we think that eventually all that is going to help our SUBSYS sales. And, therefore, it’s important for us to maintain the market share we have. And we believe we have the best product in the space with the features we have and the acceptability by the CPEs and the patients is huge. And so we will stay competitive.”

(Emphasis added.)

402. The above-referenced statements from the August 3, 2016 press release and earnings call were materially false and misleading, and they failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants improperly failed to disclose: (1) that the Company had overstated revenue; (2) that Insys understated rebate obligations to third-party payers, product returns by distributors, and the Company's overall provisions for sales allowance; (3) that the Company overstated earnings; (4) that the Company failed to maintain internal controls; (5) that as a result of the foregoing, the Company violated its own internal accounting policies for recording revenue, rebates, sales returns, and overall sales allowances; (6) the Sales Misconduct; (7) that sales of Subsys were declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of the Sales Misconduct; and (8) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***2Q 2016 10-Q***

403. On August 5, 2016, Insys filed a quarterly report for the fiscal quarter ended June 30, 2016 on Form 10-Q (the "2Q 2016 10-Q"), which was signed by Defendants Kapoor and Baker.

404. The 2Q 2016 10-Q stated that the Company recognized revenue when the following four criteria were satisfied:

Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

405. In regard to sales allowances, the 2Q 2016 10-Q stated:

***We recognize estimated product sales allowances as a reduction of product sales in the same period the related revenue is recognized.*** Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-

party payors and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment.

(Emphasis added.)

406. In respect to product returns, the 2Q 2016 10-Q asserted that the Company had a reasonable basis upon which to estimate returns, and had properly recorded discounts in the accrued sales allowances:

*Product Returns.* We allow customers to return product for credit beginning six months prior to, and ending 12 months following, the product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. ***We have monitored actual return history since product launch, which provides us with a basis to reasonably estimate future product returns,*** taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after the product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product.

Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. ***The allowance for product returns is included in accrued sales allowances.***

(Italic subheading in original. Bold & italic emphasis added.)

407. With regard to rebates, the 2Q 2016 10-Q asserted that they were recorded at the time revenue was recognized:

*Rebates.* We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated

levels of inventory in the distribution channel. ***The allowance for rebates is included in accrued sales allowances.***

(Italic subheading in original. Bold & italic emphasis added.)

408. The above statements in the 2Q 2016 10-Q were materially false and misleading when made because Insys: (1) improperly recorded revenue before it was earned; (2) failed to reserve for product returns and rebates; (3) lacked any reasonable basis for estimating its sales allowance; (4) violated Insys's own internal accounting policies; (5) lacked the appropriate processes and controls to properly track product returns and rebates; and (6) failed to maintain internal controls. Due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

409. The 2Q 2016 10-Q reported net revenue of \$67.1 million and net income of \$4.4 million in the quarter ended March 31, 2016, and net revenue of \$129.1 million and net income of \$6.8 million in the six months ended March 31, 2016,

410. In regard to discounts, rebates and returns, the 2Q 2016 10-Q stated:

Provisions for patient discounts, wholesaler discounts, rebates, and returns were \$24.1 million \$7.8 million, \$12.6 million and \$0.5 million, respectively, or 40.1% on a combined basis of gross revenue from the sale of Subsys for the three months ended June 30, 2016, compared to \$14.4 million, \$10.0 million, \$16.8 million and \$0.6 million, respectively, or 35.3% on a combined basis of gross revenue from the sale of Subsys for the three months ended June 30, 2015.

411. The 2Q 2016 10-Q stated that: "[t]he accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles, pursuant to rules and regulations of the SEC."

412. With regard to Insys's controls over financial reporting, the 2Q 2016 10-Q stated:

#### ITEM 4. CONTROLS AND PROCEDURES

##### *Evaluation of Disclosure Controls and Procedures*

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, and *in light of the unremediated material weakness in the design and operation of our internal control over financial reporting relating specifically to the lack of effective policies and procedures, and effective reviews by personnel at an appropriate level, for accounting for stock options awards in accordance with GAAP*, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, *our disclosure controls and procedures were not effective*. To address this material weakness, we have taken steps to address the underlying causes of the material weakness as described further below under “Remediation Efforts to Address Material Weakness in Internal Control over Financial Reporting.” Accordingly, *we believe that the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q do fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented*.

(Emphasized headings in original, italic emphasis added.)

413. Attached to the 2Q 2016 10-Q were SOX certifications signed by Defendants Kapoor and Baker, attesting to the accuracy of the 2Q 2016 10-Q.

414. The above-referenced statements in the 2Q 2016 10-were materially false and misleading, and they failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants improperly failed to disclose: (1) that Insys overstated revenue; (2) that Insys understated rebate obligations to third-party payers, product returns by distributors, and the Company’s overall provisions for sales allowance; (3) that Insys overstated earnings; (4) that the Company failed to maintain internal controls; (5) that as a result of the foregoing, Insys’s financial statements were not in compliance with GAAP; (6) the Sales Misconduct; (7) that sales of Subsys were declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of the Sales Misconduct; and

(8) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***November 3, 2016 Press Release and Earnings Call***

415. On November 3, 2016, Insys issued a press release announcing its financial results for the three-month period ended June 30, 2016. The press release noted the following "highlights" for the quarter:

- Total net revenue was \$55.2 million, compared to \$91.3 million for the third quarter of 2015;
- Net income totaled \$190,000, or \$0.00 per basic and \$0.00 per diluted share, compared to net income of \$26.1 million, or \$0.36 per basic and \$0.34 per diluted share, for the third quarter of 2015; . . .

416. The press release quoted Defendant Kapoor, who stated, in relevant part:

Although Subsys volumes declined in the quarter, we are pleased to have maintained a mid-40% market share and believe the product will continue to provide a solid financial foundation for growth and to support our R&D efforts . . . We remain excited about our pipeline and believe that both our spray and cannabinoid platform products will provide opportunities for future growth[.]

417. The press release attributed the decreased revenue to "a decline in Subsys prescription volumes due to softness in overall demand in the TIRF category, including Subsys, and continued pressure from third-party payers."

418. The press release reported net revenue of \$184.3 million and net income of \$7 million for the nine-month period ended September 30, 2016.

419. The Company held an earnings call on November 3, 2016, during which Defendant Baker made the following statements regarding the Company's financial performance:

[W]e reported net revenue of \$55.2 million for the third quarter of 2016, which was a decrease from the \$91.3 million in the year ago quarter. As expected, Subsys prescription trends experienced softness in the third quarter of 2016. ***The decline in Subsys revenue is the result of ongoing and heightened publicity surrounding the national opioid epidemic and continuing governmental and regulatory scrutiny of the Company and of the Transmucosal Immediate-Release Fentanyl or TIRF class, resulting in sensitivity by some healthcare providers to prescribe and dispense TIRF medications.***

\* \* \*

GAAP net income for the third quarter of 2016 was \$190,000 or \$0.00 per diluted share compared to net income of \$26 million or \$0.34 per diluted share for the third quarter of 2015. Non-GAAP adjusted net income per diluted share for the third quarter of 2016 was \$0.07 compared to \$0.50 per diluted share for the third quarter of 2015.

(Emphasis added.)

420. During the call, in response to an analyst's question regarding "gross net spreads for Subsys going forward" and "continued pressure on the overall TIRF market due to greater physician sensitivity to opioids," Defendant Kapoor attributed the decline in Subsys prescriptions to trends in the overall TIRF market:

So with respect to the gross to nets, what we saw here in the third quarter was roughly 50% gross to net, which is the most challenged our gross to nets have ever been. ***We expect that as we move forward we're going to be able to make slight improvements to our gross to nets.*** With respect to the TIRF class overall there has been a lot of pressure on the class. There have been significant declines in the class. If you go back to when the REMS was implemented, about four years ago the TIRF class was roughly 10,000 per month. Today, the class is down to about 6,200 scripts per month. We continue to maintain our share in the mid-40% range. So as the class goes kind of that's how Subsys goes. So we expect that there will be continued pressure on the class but we also believe that over time we are going to be able to see growth again in the TIRF class.

(Emphasis added.)

421. During the call, Defendant Vetticaden represented that Insys was "committed to the appropriate use of opioids" and was under "a moral imperative to contribute to solutions to address this opioid epidemic." Defendant Vetticaden continued, stating that "one of our

principal areas of expertise is in drug development and it is through these efforts that we believe we will be able to offer potential solutions to address some of the concerns associated with the opioid epidemic.”

422. The above-referenced statements the November 3, 2016 press release and earnings call were materially false and misleading, and they failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants improperly failed to disclose that: (1) the Company had overstated revenue; (2) Insys understated rebate obligations to third-party payers, product returns by distributors, and the Company’s overall provisions for sales allowance; (3) the Company overstated earnings; (4) the Company failed to maintain internal controls; (5) as a result of the foregoing, the Company violated its own internal accounting policies for recording revenue, rebates, sales returns, and overall sales allowances; (6) the Sales Misconduct; (7) sales of Subsys were declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of the Sales Misconduct; and (8) due to the foregoing, Defendants’ statements regarding the Company’s business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***3Q 2016 10-Q***

423. On November 3, 2016, Insys filed a quarterly report for the fiscal quarter ended September 30, 2016 on Form 10-Q (the “3Q 2016 10-Q”), which was signed by Defendants Kapoor and Baker.

424. The 3Q 2016 10-Q stated that the Company recognized revenue when the following four criteria were satisfied:

Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

425. In regard to sales allowances, the 3Q 2016 10-Q stated:

*We recognize estimated product sales allowances as a reduction of product sales in the same period the related revenue is recognized.* Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payors and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment.

(Emphasis added.)

426. In respect to product returns, the 3Q 2016 10-Q asserted that the Company had a reasonable basis upon which to estimate returns, and had properly recorded discounts in the accrued sales allowances:

*Product Returns.* We allow customers to return product for credit beginning six months prior to, and ending 12 months following, the product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. *We have monitored actual return history since product launch, which provides us with a basis to reasonably estimate future product returns,* taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after the product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. *The allowance for product returns is included in accrued sales allowances.*

(Italic subheading in original. Bold & italic emphasis added.)

427. With regard to rebates, the 3Q 2016 10-Q asserted that they were recorded at the time revenue was recognized:

*Rebates.* We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a

rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. ***The allowance for rebates is included in accrued sales allowances.***

(Italic subheading in original. Bold & italic emphasis added.)

428. The above statements in the 3Q 2016 10-Q were materially false and misleading when made because Insys: (1) improperly recorded revenue before it was earned; (2) failed to reserve for product returns and rebates; (3) lacked any reasonable basis for estimating its sales allowance; (4) violated Insys's own internal accounting policies; (5) lacked the appropriate processes and controls to properly track product returns and rebates; and (6) failed to maintain internal controls. Due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

429. The 3Q 2016 10-Q reported net revenue of \$55.2 million and net income of \$190,000 in the quarter ended September 30, 2016, and net revenue of \$184.3 million and net income of \$7 million in the nine months ended September 30, 2016,

430. In regard to discounts, rebates and returns, the 3Q 2016 10-Q stated:

Provisions for patient discounts, wholesaler discounts, rebates, and returns were \$33.6 million \$8.2 million, \$13.2 million and less than \$0.1 million, respectively, or 49.9% on a combined basis of gross revenue from the sale of Subsys for the three months ended September 30, 2016, compared to \$13.1 million, \$10.0 million, \$16.6 million and \$1.3 million, respectively, or 31.0% on a combined basis of gross revenue from the sale of Subsys for the three months ended September 30, 2015.

431. The 3Q 2016 10-Q stated that: "[t]he accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles, pursuant to rules and regulations of the SEC."

432. With regard to Insys's controls over financial reporting, the 3Q 2016 10-Q stated:

#### **ITEM 4. CONTROLS AND PROCEDURES**

##### ***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, and *in light of the unremediated material weakness in the design and operation of our internal control over financial reporting relating specifically to the lack of effective policies and procedures, and effective reviews by personnel at an appropriate level, for accounting for stock options awards in accordance with GAAP*, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, *our disclosure controls and procedures were not effective*. To address this material weakness, we have taken steps to address the underlying causes of the material weakness as described further below under "Remediation Efforts to Address Material Weakness in Internal Control over Financial Reporting." Accordingly, *we believe that the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q do fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented*.

(Emphasized headings in original, italic emphasis added.)

433. Attached to the 3Q 2016 10-Q were SOX certifications signed by Defendants Kapoor and Baker, attesting to the accuracy of the 3Q 2016 10-Q.

434. The referenced statements in the 3Q 2016 10-Q were materially false and misleading, and they failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants improperly failed to disclose: (1) that Insys overstated revenue; (2) that Insys understated rebate obligations to third-party payers, product returns by distributors, and the Company's overall provisions for sales allowance; (3) that Insys overstated earnings; (4) that the Company failed to maintain internal controls; (5) that as a result of the foregoing, Insys's financial statements were not in compliance with GAAP; (6)

the Sales Misconduct; (7) that sales of Subsys were declining as a result of third-party payers refusing to reimburse for off-label Subsys prescriptions as a result of the Sales Misconduct; and (7) that due to the foregoing, Defendants' statements regarding the Company's business, operations, and prospects were materially false, misleading, and/or lacked a reasonable basis in fact.

***2017 Proxy Statement***

435. Insys filed the 2017 Proxy Statement on April 18, 2017. Plaintiff's allegations with respect to the misleading statements in the 2017 Proxy Statements are based solely on negligence; they are not based on any allegation of reckless or knowing conduct by or on behalf of the Individual Defendants, and they do not allege and do not sound in fraud. Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to these allegations and related claims.

436. The 2017 Proxy Statement stated that:

We have adopted a Code of Business Conduct and Ethics that applies to employees, officers and directors, including our executive management team, such as our Chief Executive Officer and Chief Financial Officer. This Code of Business Conduct and Ethics is posted on our website at [www.insysrx.com](http://www.insysrx.com) (the contents of such website are not incorporated into this proxy statement) . . . We also have compliance and ethics policies applicable to our employees designed to prevent and detect violations of our Code of Business and Ethics Conduct, as well other internal policies and the law. A major goal of the compliance and ethics program is to promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law. In this regard, we have established avenues for parties external to the Insys Therapeutics to raise compliance and ethics concerns with respect to our employees, directors and third parties doing business with the Company.

437. The 2017 Proxy Statement was false and misleading because, despite assertions to the contrary, its Code of Conduct was not followed, resulting in—and evidenced by—the Sales Misconduct.

438. The Individual Defendants also caused the 2017 Proxy Statement to be false and

misleading with regard to executive compensation in that they purported to employ “pay-for-performance” elements, while failing to disclose that the Company’s revenues and profits, and therefore its financial performance, were based on the Sales Misconduct and therefore any compensation based on the Company’s financial performance was artificially inflated.

439. The 2017 Proxy Statement also failed to disclose that the Company: (1) failed to maintain a proper “tone at the top” resulting in premature recording of revenue, overstatement of earnings, the failure to properly account for sales allowances, and GAAP violations, and GAAP violations; (2) engaged in the Sales Misconduct; and (3) had not maintained adequate internal controls.

### **The Truth Emerges**

#### ***The Sales Misconduct***

440. The truth regarding the Sales Misconduct was slowly revealed through a series of SEC filings made by Insys, media reports, and civil and criminal actions filed against the Company, its insiders, and medical practitioners in the speaker program, many of which are outlined above. Examples include the following.

441. On November 27, 2014, the *New York Times* published an article entitled, “Using Doctors With Troubled Pasts to Market a Painkiller,” which revealed some of the Company’s Kickback Misconduct and Off-label Misconduct. In response, the closing price per share of Insys common stock fell 8.58%, or \$3.44, over two trading days to close at \$36.65 on December 1, 2014.

442. On May 20, 2015, it was disclosed that Drs. Ruan and Couch had been arrested and charged with conspiracy to distributed controlled substances, including Subsys. On this news, the price of Insys common stock fell by \$2.65 per share, or 4.43%, from a closing price of \$59.77 on May 19, 2015 to a closing price of \$57.12 on May 20, 2015.

443. In response to the June 23, 2015 plea agreement of Insys speaker Alfonso and a June 24, 2015 *New York Times* article regarding her guilty plea, the price of Insys common stock fell by \$5.17 per share, or 12.64%, over two trading days, from a closing price of \$40.91 on June 23, 2015, to a closing price of \$35.74 on June 25, 2015,

444. On December 3, 2015, the *SIRF* published an article entitled, “Murder Incorporated: Insys Therapeutics, Part I.” The article discussed Defendants Babich and Kapoor’s involvement in the Sales Misconduct, as well as the FCA Misconduct. It alleged that Defendant Kapoor forced out Defendant Babich in response to “intense regulatory scrutiny.” On this news, the Company’s stock price fell by 18.54%, or \$4.94, from its December 2, 2015 closing price to a close at \$26.06 per share on December 3, 2015.

445. On January 25, 2016, the *SIRF* published another article regarding Insys and Subsys entitled, “The Brotherhood of Thieves: Insys Therapeutics.” The article gave more details regarding the FCA Misconduct. On this news the price of Insys common stock declined by 4.73%, or \$1.07, from a closing price of \$22.65 on January 22, 2016 to a close at a price of \$21.58 on January 25, 2016, on heavy trading volume.

446. On December 8, 2016, the Federal Indictment was unsealed against Defendant Babich and Burlakoff. In response to that disclosure the price of Insys common stock declined 11.87%, or \$1.27, from a closing price of \$10.70 per share on December 7, 2016 to a closing price of \$9.43 per share on December 8, 2016.

447. On October 26, 2017, the Superseding Federal Indictment was unsealed, revealing new criminal charges against Defendant Kapoor in connection with the Sales Misconduct.

### ***The Accounting Issues***

448. On March 15, 2017, the Company issued a press release announcing that it

would “delay the release of its financial results for the fourth quarter and full year 2016.” This release revealed to the investing public, for the first time, that the Company’s Audit Committee had:

been conducting an independent review of the Company’s processes related to estimation of, and increases to, certain sales allowances recorded during 2016, with a potential reduction of 2015 net revenue and pre-tax income not expected to exceed \$5 million, as well as extended payment terms offered to certain customers during the third quarter of 2016.

449. The March 15, 2017 press release continued by asserting that “[t]he Company and the Audit Committee are working diligently to complete their review and the Company will make a further announcement regarding updated timing of its release of financial results and a related conference call once the review is completed.”

450. This review resulted in the Company filing a notification of late filing with the SEC on March 15, 2017 on Form 12b-25 to obtain an automatic 15-day extension of the filing deadline for its annual report for the year ended December 31, 2016 on Form 10-K.

451. On this news, the Company’s share price declined \$0.44, or 4.2%, from its closing price on March 15, 2017, to close at \$10.06 per share on March 16, 2017.

452. On March 31, 2017, the Company filed a Form 8-K with the SEC which disclosed that on March 30, 2017, the Audit Committee:

concluded, upon the recommendation of the Company’s management, that the Company’s *previously issued interim unaudited condensed consolidated financial statements* as of and for the quarters ended September 30, June 30, and March 31, 2016 and 2015, *should no longer be relied upon*, and determined that *those financial statements will be restated due to the identification of certain errors*.

(Emphasis added.)

453. The Form 8-K identified these errors as “related to the Company’s accounting for certain of its product sales allowances.”

454. Further, the Form 8-K admitted that “[t]he Company will also reverse an out-of-period adjustment related to a stock option modification previously recorded during the three months ended March 31, 2016 that related to the fourth quarter of 2015.”

455. Finally, the 8-K also reported that the Company would:

reverse an out of period adjustment of \$834,000 recorded during the three months ended December 31, 2016 that relates to the deductible interest portion of an accrued litigation award recognized during the three months ended June 30, 2015. This will now result in an increase in income tax expense of \$834,000 for the three months ended December 31, 2016 and a corresponding decrease in income tax expense for the three months ended June 30, 2015.

456. In the Company’s Form 10-K for the fiscal year ended December 31, 2016 filed with the SEC on April 3, 2017 (the “2016 10-K”), the Company admitted that that management and the independent auditor had identified “*material weaknesses in [the Company’s] internal control over financial reporting.*” These weaknesses were “related specifically to the lack of effective policies and procedures, or timely and effective reviews by personnel at an appropriate level, for accounting for the rebate component of our product sales allowances and the allowance for excess and obsolete inventory.”

457. The 2016 10-K further revealed that that “*management in the finance and accounting group did not display adequate tone at the top.*” (Emphasis added.)

458. On April 7, 2017, the Company filed with the SEC three Forms 10-Q/A providing its restated quarterly reports from the quarters ended March 31, June 30, and September 30 of the years 2015 and 2016. The Forms 10-Q/A reported a significant increase in the Company’s product sales allowance in all but the quarter ended September 30, 2016.

Values in millions, subject to rounding	Product Sales Allowance		Rebate Obligations		Net Revenue	
	Original	Restated	Original	Restated	Original	Restated
<b>Period Ended</b>						

March 31, 2015	\$15.2	\$21.3	\$8.4	\$11.5	\$70.8	\$67.7
June 30, 2015	\$17.6	\$20.4	\$16.8	\$13.4	\$77.6	\$80.2
September 30, 2015	\$25.6	\$31.9	\$16.6	\$20.1	\$91.3	\$88.5
March 31, 2016	\$25	\$29.7	\$7.2	\$8.3	\$62.0	\$60.4
June 30, 2016	\$30.4	\$31.7	\$12.6	\$9.3	\$67.1	\$69.2
September 30, 2016	\$41.8	\$41.8	\$13.2	\$11.9	\$55.2	\$57.8

459. Insys simultaneously recorded a \$3.033 million adjustment to net revenue in 2014 and a \$474,000 adjustment in 2015, both of which resulted from accounting improprieties in recording revenue from Subsys. Insys reclassified portions of the revenue and expenses to 2016, helping to offset an otherwise adverse effect of the increase in sales allowances to net revenue for 2015 and 2016: Insys increased net revenue \$3.152 million and increased net income \$4.263 million in 2016, as a result of the afore-mentioned revision and decrease to net revenue in 2014 and decrease in 2015. In addition, Insys reversed two out-of-period adjustments related to a stock option modification and the deductible interest portion of an accrued litigation award—Insys failed to recognize the \$1.5 million operating expense during the three months ended December 31, 2015, instead recognizing the expenses to the subsequent quarter.

#### **Legal Actions Against Company Insiders and Affiliates Arising From the Misconduct**

460. The wrongdoing alleged herein has led to civil and criminal charges being filed against Insys, its directors, its executive officers, its employees, and its prescribing physicians, including several members of its speaker program.

461. Between August 2013 to May 2014, Dr. Couch was paid \$75,448 as an Insys speaker. Dr. Couch was the 2nd-highest prescriber of Subsys in 2013, according to Medicare part D data, and ranked 3rd in Tricare records in 2014. On May 20, 2015, Dr. Couch was indicted for “deliberately over-prescribing controlled substances” that, among other things, led

to the death of two patients.

462. The same day, Dr. Ruan known internally at Insys as one of the Company's "three whales," was separately indicted for "deliberately over-prescribing controlled substances" that, among other things, led to the death of two patients. Between August 2013 to May 2014, Dr. Ruan was paid \$144,951 as an Insys speaker. According to Medicare part D data, Dr. Ruan was the 5th-highest prescriber of Subsys in 2013—he ranked 1st in Tricare records in 2014.

463. Drs. Couch and Ruan were charged in a superseding indictment on April 28, 2016 for accepting kickbacks as inducement, and in exchange for, prescribing high volumes of Subsys in the form of speaking fees. They were found guilty on February 23, 2017.

464. On June 23, 2015, Alfonso pled guilty to accepting \$83,000 in kickbacks from Insys in return for prescribing Subsys. Alfonso was the 22nd-highest Subsys prescriber in 2013, according to Medicare Part D data, and she ranked 25th in Tricare records in 2014. She was responsible for \$1.6 million in Subsys claims submitted to Medicare Part D and private insurers, and prescribed Subsys to non-cancer patients.

465. The DOJ charged Roper, a former District Manager of Insys, with violating the Anti-Kickback Statute on June 8, 2016, in connection with Kickback Misconduct in the form of speaker programs organized between October 2013 and April 2015.

466. On the same day, the DOJ charged Serrano with violating the Anti-Kickback Statute in connection with Kickback Misconduct in the form of speaker programs organized between October 2013 to June 2015.

467. The Attorney General of the State of Illinois filed a complaint against Insys for violating the Illinois Consumer Fraud and Deceptive Business Practices Act on August 25, 2016 (the "Illinois Action"). The Illinois Action alleges that the Company engaged in fraudulent and

deceptive acts and practices, including by: (1) heavily marketing to high-volume prescribers without regard to whether the prescribers treat BTCP; (2) engaging in the Kickback Misconduct; (3) marketing Subsys off-label to treat noncancer breakthrough pain; (4) implementing the “Switch Program” to market Subsys to patients prescribed competing TIRF drugs regardless of the patients’ diagnosis; (5) engaging in the FCA Misconduct; and (6) deceptively representing that the “effective dose” of Subsys was between 600 mcg and 1600 mcg in order to promote use of higher dosages, despite the existence FDA titration procedures. The Company paid \$4.45 million in connection with a final judgment and consent decree entered in the action on August 18, 2017.

468. The Department of Justice charged Jeffrey Pearlman, a District Manager of Insys, with violating the Anti-Kickback Statute on June 8, 2016, in connection with Kickback Misconduct in the form of speaker programs organized between February 2013 and December 2015. Pearlman’s ultimate indictment was announced on February 10, 2017. The indictment quotes the following email exchange, in which Pearlman told a sales representative:

What I am concerned about is you and I spoke 6 weeks ago when we were giving her this extra program and asked if her finding 1 new patient a week was a reasonable expectation 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. Keep in mind these emails are for you and me, not her. But our 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? Very simply ***when I look at return on investment as she has not motivated any new prescribers as of yet and she is not significantly increasing her own business, I am going to have tremendous difficulty justifying more programs.***

(Emphasis added.)

469. The DOJ charged Gurrieri with knowingly conspiring to devise a scheme to defraud insurers and PBMs to obtain money through fraudulent misrepresentations on October 12, 2016. An affidavit filed by the FBI Special Agent establishes that, by November 2012, Insys

and Gurrieri “knew that only approximately 30 to 33 percent of all prescriptions written for [Subsys] were receiving prior authorization. [Insys], Gurrieri, and others began planning a program to increase the percentage of successful prior authorizations.” The plan devised involved numerous fraudulent schemes, including: (1) hiding the IRC from third party payors by falsely representing that IRC employees worked for the prescribers’ office, and blocking the origin of the IRC phone call to further that false representation; (2) concocting a “spiel” about patient diagnoses that deliberately omitted the word “cancer” in order mislead agents of third party payors; (3) falsifying patient diagnosis codes to make third party payors believe patients had cancer, regardless of the patient’s diagnosis; and (4) instructing IRC employees to falsify medical records to include medications on the “cheat sheet” that the patient used in the past but that failed to alleviate the breakthrough pain. The Individual Defendants allowed the IRC fraud scheme to continue unabated until October 2016, despite having this knowledge.

470. Six senior Insys executives were indicted on December 6, 2016, including Defendant Babich, Burlakoff, Gurry (former Vice President of Managed Markets), Richard M. Simon (“Simon”) (former National Sales Director), Lee (former Regional Sales Director), and Rowan (former Regional Sales Director) (the “Indicted Defendants”). The indictment charges the Indicted Defendants with: (1) racketeering conspiracy (18 U.S.C. § 1962(d)); (2) mail fraud conspiracy (18 U.S.C. § 1349); (3) wire fraud conspiracy (18 U.S.C. § 1349); (4) and conspiracy to violate the Anti-Kickback Law (18 U.S.C. § 371), *inter alia*.

471. On December 8, 2016 the DOJ issued a press release (the “DOJ Press Release”). The DOJ Press Release describes the Federal Indictment as charging the Indicted Defendants with overseeing and facilitating “a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe a fentanyl-based pain medication [Subsys] and defraud healthcare insurers.”

472. With respect to the Kickback Misconduct, the Federal Indictment alleges Babich, Burlakoff, Simon, Lee, and Rowan conspired to carry out the Individual Defendants' criminal scheme to bribe doctors to prescribe Subsys by, *inter alia*, disguising payments to doctors as part of a robust speaker program that was designed to induce them to prescribe Subsys.

473. The Federal Indictment quotes a June 27, 2012 e-mail, entitled "Live Speaker Targets," in which Babich instructs Insys sales managers to ensure that their teams of sales representatives understood "the important nature of having one of their top targets as a speaker. It can pay big dividends for them."

474. The Federal Indictment describes how Defendant Babich used pharmacy data to identify and recruit the highest prescribers of TIRF products to prescribed Subsys through the Kickback Misconduct. The Federal Indictment quotes an email from Burlakoff to newly-hired sales reps, copying Defendant Babich:

[I]t all starts with choosing the right LOCAL speaker. Your local speaker should be your "business partner". You do not work for him, nor does he work for you. You are partners in this endeavor, if your speaker does not see it this way..... (then it is time to identify another speaker).

475. The Federal Indictment also describes other forms of Kickback Misconduct. For example, with regard to hiring sales representatives as an inducement to doctors, a September 12, 2013 e-mail received by Defendant Babich stated: "As a point of reference, Mike Babich described this hire as 'strategic' . . . This is [Practitioner #3's] . . . niece. . . . Mike understands our rational[e] for this [hire]..." The Federal Indictment further alleges that Defendant Babich approved the hire on the date the email was sent.

476. The Federal Indictment alleges that Gurry and Defendant Babich engaged in the FCA Misconduct by establishing the IRC to create perverse incentives for employees to commit fraud, ultimately achieving an approval rate of 85% for Subsys. For example, the Federal

Indictment states: “At a Company leadership meeting, [Defendant] BABICH, GURRY, AND BURLAKOFF were presented the dysphagia diagnosis [a form letter] and the procedures the Reimbursement Unit used to gain prior authorization from insurers and pharmacy benefit managers using the dysphagia diagnosis.”

477. On or about October 26, 2017, the U.S. Attorney’s Office for the District of Massachusetts issued the Superseding Federal Indictment, which superseded the Federal Indictment and added charges against Defendant Kapoor

478. Christopher Clough, a physician assistant, was indicted on March 22, 2017 for accepting kickbacks from Insys between August 2013 and October 2014. The Indictment alleges that:

Senior officials and managers of [Insys] regularly informed Company sales representatives that they should expect a ‘return on investment’ given to doctors who were part of the ISP Speaker Program and that they should inform these doctors that they would not obtain any future speaking programs if they did not prescribe more of the Fentanyl spray.

479. On October 5, 2017 the New Jersey Attorney General filed a civil complaint against Insys in connection with the FCA Misconduct. The Complaint in that action alleged:

As recently as June 2016, in response to the consulting firm’s findings, Insys Executive Vice President and former COO Daniel Brennan (“Brennan”) emailed Kapoor to relay his serious concerns about Insys’ “overall sales rep compensation” structure, as well as Insys’ hiring of subpar pharmaceutical representatives. In particular, Brennan explained that Insys is “still creating an environment of noncompliance by paying a low base salary (barely above minimum wage) and then very high ratio of incentive pay as their overall comp.”

Indeed, as Brennan explained to Kapoor, the consulting firm’s interviews of Insys’ employees revealed that they themselves found that Insys’ “compensation structure encouraged inappropriate behavior,” which Brennan assumed to mean “off label promotion and quid pro quo behavior.” In Brennan’s words, “with a potent pain product like [Subsys] ha[s], it is dangerous to have so little previous pharma experience/training.” Brennan “strongly recommended” a change in payment structure “that is more in line with industry standards and creates a more compliant behaving sales organization (important given the scrutiny we have with DOJ and media coverage of our company —both affecting our reputation and trust with customers and our internal personnel).”

After Kapoor forwarded Brennan's email to Insys Board Member Patrick Fourteau, Fourteau replied to Brennan by stating that he did "not like either the tone or the substance of [Brennan's] message."

When Kapoor responded to Brennan's email the following day, he, among other things, attempted to shift the blame from Insys to Brennan: "To be entirely honest, I am a little concerned that your email directly follows on the heels of the recent termination discussions (and actions) related to your commercial team."

480. The Company has also entered into a settlement for \$2.9 million with the State of New Hampshire in connection with an investigation into the Company's sales practices.

### **Repurchases**

481. During the period in which the Company made false and misleading statements and/or omissions, the Individual Defendants caused the Company to initiate repurchases of its common stock at artificially inflated prices that substantially damaged the Company.

482. As the Company stock was actually only worth \$9.97 per share, the price at closing on March 17, 2017, the Company overpaid over \$18.6 million in total for these repurchases.

483. According to the Company's Form 10-Q filed with the SEC on August 5, 2016, in the quarter ended June 30, 2016, the Individual Defendants caused the Company to repurchase 202,150 shares of its own common stock at an average price per share of approximately \$13.60, for a total cost to the Company of approximately \$2.7 million.

484. Due to the artificial inflation of the Company's stock price caused by misrepresentations alleged to have been made by the Individual Defendants, the Company paid on average \$3.63 more than the actual worth of each share during the quarter ended June 30, 2016. Thus, the total over payment by the Company for its repurchases of its own stock during the quarter ended June 30, 2016 was approximately \$733,804.

485. According to the Company's Form 10-Q filed with the SEC on May 5, 2016, in the quarter ended March 31, 2016, the Individual Defendants caused the Company to repurchase 640,925 shares of its own common stock at an average price per share of approximately \$20.83, for a total cost to the Company of approximately \$13.4 million.

486. Due to the artificial inflation of the Company's stock price caused by misrepresentations alleged to have been made by the Individual Defendants, the Company paid on average \$10.86 more than the actual worth of each share during the quarter ended March 31, 2016. Thus, the total over payment by the Company for its repurchases of its own stock during the quarter ended March 31, 2016 was approximately \$7 million.

487. According to the Company's Form 10-K filed with the SEC on February 29, 2016, in the quarter ended December 31, 2015, the Individual Defendants caused the Company to repurchase 560,200 shares of its own common stock at an average price per share of approximately \$29.45, for a total cost to the Company of approximately \$16.5 million.

488. Due to the artificial inflation of the Company's stock price caused by misrepresentations alleged to have been made by the Individual Defendants, the Company paid on average \$19.48 more than the actual worth of each share during the quarter ended December 31, 2015. Thus, the total over payment by the Company for its repurchases of its own stock during the quarter ended December 31, 2015 was approximately \$11 million.

489. In total, the Company overpaid an aggregate amount of approximately \$18.6 million for repurchases of its own stock during the period of time in which the Company made false and misleading statements and omissions.

#### **Summary of Individual Defendants' Misconduct**

490. In breach of their fiduciary duties, the Individual Defendants willfully or recklessly caused or permitted the Company to engage in an illegal sale and promotion scheme

for its lead product, Subys, resulting in the Sales Misconduct.

491. In breach of their fiduciary duties, the Individual Defendants willfully or recklessly caused or permitted the Company to make the false and misleading statements and omissions of material fact to the investing public as set forth above. Specifically, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements that failed to disclose that, *inter alia*: (1) the Company failed to maintain a proper “tone at the top” resulting in premature recording of revenue, overstatement of earnings, the failure to properly account for sales allowances, and GAAP violations; (2) the Company engaged in the Sales Misconduct; (3) the Company’s revenues were artificially inflated as a result of the Sales Misconduct; (4) the Company failed to maintain internal controls; and (5) a result of the foregoing, statements about the Company’s business, operations and prospects were materially false and misleading and lacked a reasonable basis at all relevant times.

492. The Individual Defendants also failed to correct and/or caused the Company to fail to correct the foregoing false and misleading statements and omissions of material fact, rendering them personally liable to the Company for breaching their fiduciary duties.

493. The Individual Defendants moreover breached their fiduciary duties by allowing Defendant Babich to be awarded with a \$10 million severance package, which was unjust in light of his involvement in the misconduct discussed herein.

494. Additionally, while the Individual Defendants caused the Company’s stock to be artificially inflated, the Individual Defendants caused the Company to overpay for repurchases of Company stock, and five of the Individual Defendants benefitted themselves by engaging in insider sales.

495. Lastly, the Individual Defendants breached their fiduciary duties by causing the

Company to fail to maintain internal controls.

**DAMAGES TO INSYS**

496. As a direct and proximate result of the Individual Defendants' conduct, Insys is losing and expending, and will lose and expend, many millions of dollars.

497. Such expenditures include, but are not limited to, the cost incurred as a result of the SEC investigation and legal fees and payments associated with the Securities Class Actions filed against the Company and four of the Individual Defendants; the settlements entered into with the ODOJ, the State of Illinois, and State of New Hampshire; the anticipated \$150 million liability in connection with the DOJ Investigation;<sup>14</sup> and amounts paid to outside lawyers, accountants, and investigators in connection thereto.

498. Such losses include the \$10 million in severance that Defendant Babich unjustly received following his involvement in the misconduct discussed herein, particularly the facilitation of the Sales Misconduct.

499. Such losses include those caused by the loss of key executive officers and directors.

500. Such losses include the Company's overpayment by approximately \$18.6 million for repurchases of its own stock during the period when the Company's stock price was artificially inflated due to the false and misleading statements discussed herein.

501. Such costs include, but are not limited to, excessive compensation and benefits paid to the Individual Defendants who breached their fiduciary duties to the Company.

502. As a direct and proximate result of the Individual Defendants' conduct, Insys has also suffered and will continue to suffer a loss of reputation and goodwill, and a "liar's

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<sup>14</sup> As reported in the Company' Form 10-K for the fiscal year ended December 31, 2017 filed with the SEC on March 12, 2018.

discount” that will plague the Company’s stock in the future due to the Company’s misrepresentations and the Individual Defendants’ breaches of fiduciary duties and unjust enrichment.

### **DERIVATIVE ALLEGATIONS**

503. Plaintiff brings this action derivatively and for the benefit of Insys to redress injuries suffered, and to be suffered, as a result of the Individual Defendants’ breaches of their fiduciary duties as directors and/or officers of Insys, gross mismanagement, abuse of control, waste of corporate assets, unjust enrichment, and violations of Sections 14(a), 10(b) and 20(a) of the Exchange Act, as well as the aiding and abetting thereof.

504. Insys is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

505. Plaintiff is, and has been at all relevant times, an Insys shareholder. Plaintiff will adequately and fairly represent the interests of Insys in enforcing and prosecuting its rights, and, to that end, has retained competent counsel, experienced in derivative litigation, to enforce and prosecute this action.

### **DEMAND FUTILITY ALLEGATIONS**

506. Plaintiff incorporates by reference and re-alleges each and every allegation stated above as if fully set forth herein.

507. A pre-suit demand on the Board of Insys is futile and, therefore, excused. At the time of filing of this action, the Board consists of six individuals: Individual Defendants Meyer and Lapalme (collectively, the “Director-Defendants”), and non-parties Saeed Motahari (“Motahari”), Rohit Vishnoi, Trudy Vanhove, and Vaseem Mahboob (collectively, with the Director-Defendants, the “Directors”). Plaintiff only needs to allege demand futility as to three of the six Directors who are on the Board at the time this action is commenced.

508. Demand is excused as to all of the Director-Defendants because each one of them faces, individually and collectively, a substantial likelihood of liability as a result of the schemes they engaged in knowingly or recklessly, to make and/or cause the Company to engage in the Sales Misconduct, to fail to comply with federal law in the marketing and sale of Subsys, to fail to maintain adequate internal controls to ensure compliance with the law, to make the false and misleading statements and omissions of material fact while two of them engaged in insider sales based on material non-public information, netting proceeds of about \$1.9 million, and, at the same time, to cause the Company to overpay \$18.6 million for repurchases of its own stock, all of which renders the Director-Defendants unable to impartially investigate the charges and decide whether to pursue action against themselves and the other perpetrators of the scheme.

509. In complete abdication of their fiduciary duties, the Director-Defendants either knowingly or recklessly participated in or allowed the Sales Misconduct and made and/or caused the Company to make the materially false and misleading statements alleged herein. The fraudulent schemes were intended to make the Company appear more profitable and attractive to investors. While investors were duped into believing the fraud perpetrated by the Individual Defendants, five of the Individual Defendants, two of whom are Directors, collectively sold about \$15.3 million worth of Company stock at artificially inflated prices based on inside material information.

510. As a result of the foregoing, the Director-Defendants breached their fiduciary duties, face a substantial likelihood of liability, are not disinterested, and demand upon them is futile, and thus excused.

511. Additional reasons that demand on Defendant Meyer is futile follow. Defendant Meyer is the Chairman of the Board, a position he has occupied since January 2017. Defendant

Meyer has served as a company director since 2010. Defendant Meyer receives lavish compensation, including \$306,428 in the fiscal year ended December 31, 2016. Defendant Meyer's large Company stock holding, worth over \$2 million on March 15, 2017, reveals his interest in keeping the Company's stock price as high as possible. As Chairman of the Board and a long-time Company director, Defendant Meyer conducted little, if any, oversight of the Company's internal controls and of the scheme to engage in the Sales Misconduct and to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the schemes, and consciously disregarded his duties to protect corporate assets. Defendant Meyer was a member of the Board throughout the period that the Sales Misconduct occurred and was present at numerous board meetings where evidence of the Sales Misconduct was presented, thus, he faces a substantial likelihood of liability in this action. Defendant Meyer was ultimately responsible for the false and misleading statements and omissions that were made, including those contained in the SEC filings referenced herein, as he signed both the 2014 10-K and 2015 10-K. Additionally, he is liable for causing the Company to fail to disclose that, *inter alia*: (1) the Company failed to maintain a proper "tone at the top" resulting in premature recording of revenue, overstatement of earnings, the failure to properly account for sales allowances, and GAAP violations; (2) the Company engaged in the Sales Misconduct; (3) the Company's revenues were artificially inflated as a result of the Sales Misconduct; (4) the Company failed to maintain internal controls; and (5) a result of the foregoing, statements about the Company's business, operations and prospects were materially false and misleading and lacked a reasonable basis at all relevant times. His insider sales before the fraud was exposed, which yielded over \$1.3 million in proceeds, demonstrate his motive in facilitating and participating in the fraud. Thus, for these reasons, too, Defendant Meyer breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or

disinterested, and thus demand upon him is futile and, therefore, excused.

512. Additional reasons that demand on Defendant Lapalme is futile follow. Defendant Lapalme has served as a Company director since 2011. Defendant Lapalme receives lavish compensation, including \$299,428 in the fiscal year ended June 30, 2017. His large Company stock holding, worth approximately \$1.8 million before the fraud was exposed, reveals his interest in keeping the Company's stock price as high as possible. As a long-time Company Director, Defendant Lapalme conducted little, if any, oversight of the Company's internal controls and of the scheme to engage in the Sales Misconduct and to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the schemes, and consciously disregarded his duties to protect corporate assets. Defendant Lapalme was a member of the Board throughout the period that the Sales Misconduct occurred and was present at numerous board meetings where evidence of the Sales Misconduct was presented, thus, he faces a substantial likelihood of liability in this action. Defendant Lapalme also was the maker of many of the false statements and omissions of material fact that are alleged herein, as he signed both the 2014 10-K and 2015 10-K. He is liable for causing the Company to fail to disclose that, *inter alia*: (1) the Company failed to maintain a proper "tone at the top" resulting in premature recording of revenue, overstatement of earnings, the failure to properly account for sales allowances, and GAAP violations; (2) the Company engaged in the Sales Misconduct; (3) the Company's revenues were artificially inflated as a result of the Sales Misconduct; (4) the Company failed to maintain internal controls; and (5) a result of the foregoing, statements about the Company's business, operations and prospects were materially false and misleading and lacked a reasonable basis at all relevant times. Thus, for these reasons, too, Defendant Lapalme breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him

is futile and, therefore, excused.

513. Additional reasons that demand on non-party Motahari is futile follow. Motahari serves as Insys's President and CEO, and is, thus, as the Company admits, a non-independent director under NASDAQ Listing Rules. He receives lavish compensation, including an annual base salary of \$675,000, 100% bonus eligibility and a guaranteed cash bonus of \$540,000 for fiscal year 2017. Thus, for these reasons, Motahari is not independent, and thus demand upon him is futile and, therefore, excused.

514. Additional reasons that demand on the Board is futile follow.

515. As described above, two of the Directors on the Board directly engaged in insider trading, in violation of federal law and the Company's Code of Conduct. Defendant Meyer engaged in insider sales executed during the period when the Company's stock price was artificially inflated due to the false and misleading statements alleged herein. Therefore, demand in this case is futile as to him, and excused.

516. Additionally, each one of the Director-Defendants, individually and collectively, faces a substantial likelihood of liability as a result of their intentional or reckless approval of the unnecessary and harmful repurchases that caused the Company to overpay by \$18.6 million for its own common stock during the period in which the false and misleading statements were made. The Director-Defendants, as alleged herein, were aware or should have been aware of the misinformation being spread by the Company and yet approved the repurchases. Thus, the Directors breached their fiduciary duties, face a substantial likelihood of liability, are not disinterested, and demand upon them is futile, and thus excused.

517. All of the directors are beholden to Defendant Kapoor by virtue of Defendant Kapoor's 67.1% controlling interest in Insys.<sup>15</sup> As the majority shareholder, the Directors serve at the whim of Defendant Kapoor. As Defendant Kapoor faces a substantial likelihood of liability in the Securities Class Actions and the Superseding Federal Indictment and granting a demand might hamper the Company's efforts to settle or defend the Securities Class Actions and Defendant Kapoor's efforts to settle or defend the Superseding Federal Indictment, the Directors are not able to consider a demand with independence. Defendant Kapoor exercised extensive hands on control of Insys and its Board as Company founder, and its President, CEO and Chairman of the Board during parts of the Relevant Period, during which time the Company engaged in the Sales Misconduct, in violation of the law. He was intimately involved with the day to day running of the Company, including the daily tracking of Subsys prescriptions. When regulators began to scrutinize the Company, Defendant Kapoor fired Defendant Babich, and then had the Compensation Committee delegate the responsibility to determine Defendant Babich's severance to him as CEO. Defendant Kapoor's conduct has demonstrated both his contempt for the law and the control he exercises over the Board of Insys. Thus, the remaining Directors are unable to evaluate a demand with independence, and therefore, demand is excused.

518. Defendants Meyer and Lapalme demonstrated how beholden they are to Defendant Kapoor when they permitted Defendant Kapoor to become the Company's CEO, and then delegated to him the authority to negotiate Defendant Babich's severance.

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<sup>15</sup> According to the Company's Form 10-K filed with the SEC on March 12, 2018, "After Dr. Kapoor's indictment, he agreed to put his ownership in our common stock in a trust to be controlled independently, which was executed on February 27, 2018 and filed with the Securities and Exchange Commission on a Current Report of Form 8-K filed on February 28, 2018."

519. Defendant Lapalme has previously worked on boards controlled by Defendant Kapoor: he was a director of Sciele Pharma from 2000 to 2008, a company Kapoor founded and controlled for many years. Defendant Kapoor served as a director of Sciele Pharma from 1996 to 2006. During that time, and during the time Defendant Lapalme acted as a director of Sciele Pharma, Defendant Kapoor was Sciele Pharma's largest stockholder, with his holdings declining over time from 50.3% in 2000 to 15% in 2006.

520. Defendant Meyer has served on the board of directors of Akorn, Inc. ("Akorn") since June 2009. Defendant Kapoor owned 25.3% of Akorn's common stock as of March 2, 2017 and served as the company's Chairman of the board of directors until his resignation on October 30, 2017.

521. Defendants Meyer and Lapalme were all present at meetings where the Board received information about the Company's illegal marketing schemes, including the Sales Misconduct. With this knowledge, they approved the Sales Misconduct, causing the Company to violate the law, thus breaching the duty of loyalty. Further, they were members of the Board during the time that the Company failed to implement a compliance program that complied with the OIG guidelines, or act in the face of numerous red flags, including the receipt of the HHS Subpoena, numerous news articles regarding the Sales Misconduct, the Securities Class Actions, and criminal suits against the Company, its employees and executives, and members of Insys's speaker program.

522. Defendants Meyer and Lapalme were members of the Board during the time that it failed to, despite resolving to do so, have a functioning Special Committee. As members of the Special Committee, Defendants Meyer is especially culpable for this failure.

523. Insys has been, and will continue to be, exposed to significant losses due to the wrongdoing complained of herein, yet the Directors have not filed any lawsuits against

themselves or others who were responsible for that wrongful conduct to attempt to recover for Insys any part of the damages Insys suffered, and will continue to suffer, thereby. Thus, any demand on the Directors would be futile.

524. The Individual Defendants' conduct described herein and summarized above, including the decision for the Company to engage in the repurchases of its own stock, could not have been the product of legitimate business judgment as it was based on bad faith and intentional, reckless, or disloyal misconduct. Thus, none of the Directors can claim exculpation from their violations of duty pursuant to the Company's charter (to the extent such a provision exists). As a majority of the Directors face a substantial likelihood of liability, such Directors are self-interested in the transactions challenged herein and cannot be presumed to be capable of exercising independent and disinterested judgment about whether to pursue this action on behalf of the shareholders of the Company. Accordingly, demand is excused as being futile.

525. The acts complained of herein constitute violations of fiduciary duties owed by Insys's officers and directors, and these acts are incapable of ratification.

526. The Directors may also be protected against personal liability for their acts of mismanagement and breaches of fiduciary duty alleged herein by directors' and officers' liability insurance if they caused the Company to purchase it for their protection with corporate funds, i.e., monies belonging to the stockholders of Insys. If there is a directors' and officers' liability insurance policy covering the Directors, it may contain provisions that eliminate coverage for any action brought directly by the Company against the Directors, known as, *inter alia*, the "insured-versus-insured exclusion." As a result, if the Directors were to sue themselves or certain of the officers of Insys, there would be no directors' and officers' insurance protection. Accordingly, the Directors cannot be expected to bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage, if

such an insurance policy exists, will provide a basis for the Company to effectuate a recovery. Thus, demand on the Directors is futile and, therefore, excused.

527. If there is no directors' and officers' liability insurance, then the Directors will not cause Insys to sue the Individual Defendants named herein, since, if they did, they would face a large uninsured individual liability. Accordingly, demand is futile in that event, as well.

528. Thus, for all of the reasons set forth above, all of the Directors, and, if not all of them, at least three of them, cannot consider a demand with disinterestedness and independence. Consequently, a demand upon the Board is excused as futile.

### **FIRST CLAIM**

#### **Against Individual Defendants for Violations of Section 14(a) of the Exchange Act**

529. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

530. The Section 14(a) Exchange Act claims alleged herein are based solely on negligence. They are not based on any allegation of reckless or knowing conduct by or on behalf of the Individual Defendants. The Section 14(a) claims alleged herein do not allege and do not sound in fraud. Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to these nonfraud claims.

531. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that “[i]t shall be unlawful for any person, by use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use

of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 12 of this title [15 U.S.C. § 78I].”

532. Rule 14a-9, promulgated pursuant to § 14(a) of the Exchange Act, provides that no proxy statement shall contain “any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.” 17 C.F.R. §240.14a-9.

533. Under the direction and watch of the Directors, the 2016 and 2017 Proxy Statements failed to disclose that the Company: (1) failed to maintain a proper “tone at the top” resulting in premature recording of revenue, overstatement of earnings, the failure to properly account for sales allowances, and GAAP violations; (2) engaged in the Sales Misconduct; and (3) had not maintained adequate internal controls.

534. The Individual Defendants also caused the 2016 and 2017 Proxy Statements to be false and misleading with regard to executive compensation in that they purported to employ “pay-for-performance” elements while failing to disclose that the Company’s revenues and profits, and therefore its financial performance, were based on unsound maintenance and safety protocols and therefore any compensation based on the Company’s financial performance was artificially inflated.

535. The 2016 and 2017 Proxy Statements also made reference to the Company’s Code Conduct. The Code required the Company and Individual Defendants to abide by relevant laws and statutes, and not engage in off-label marketing. By engaging in the Sales Misconduct, the Individual Defendants violated the Code of Conduct. The 2016 and 2017 Proxy Statements failed to disclose these violations and also failed to disclose that the terms of the Code Conduct were being violated.

536. In the exercise of reasonable care, the Individual Defendants should have known that by misrepresenting or failing to disclose the foregoing material facts, the statements contained in the 2016 and 2017 Proxy Statements were materially false and misleading. The misrepresentations and omissions were material to Plaintiff in voting on the matters set forth for shareholder determination in the 2016 and 2017 Proxy Statements, including but not limited to, election of directors, ratification of an independent auditor, and the approval of officer compensation.

537. The Company was damaged as a result of the Individual Defendants' material misrepresentations and omissions in the 2016 and 2017 Proxy Statements.

### **SECOND CLAIM**

#### **Against Individual Defendants for Violations of Section 10(b) and Rule 10b-5 of the Exchange Act**

538. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

539. The Individual Defendants participated in a scheme to defraud with the purpose and effect of defrauding Insys. Not only is Insys now defending claims that it violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, but the Company itself is also one of the largest victims of the unlawful scheme perpetrated upon Insys by the Individual Defendants. With the price of its common stock trading at artificially-inflated prices due to the Individual Defendants' misconduct, the Individual Defendants caused the Company to repurchase tens of millions of dollars of its own shares on the open market at artificially-inflated prices, damaging Insys by millions of dollars.

540. During the Relevant Period, the Individual Defendants also individually and in concert, directly and indirectly, by the use and means of instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct

designed to falsify the Company's press releases, public statements made in conference calls, and periodic and current reports filed with the SEC.

541. The Individual Defendants employed devices, schemes and artifices to defraud while in possession of adverse, material, non-public information and engaged in acts, practices and a course of conduct that included the making of, or participation in the making of, untrue and/or misleading statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Insys not misleading.

542. The Individual Defendants, as top executives and directors of the Company, are liable as direct participants in the wrongs complained of herein. Through their positions of control and authority as directors and officers of the Company, the Individual Defendants were able to and did control the conduct complained of herein and the content of the public statements disseminated by Insys. The Individual Defendants acted with scienter during the Relevant Period, in that they either had actual knowledge of the schemes and the misrepresentations and/or omissions of material facts set forth herein or acted with reckless disregard for the truth in that they failed to ascertain and to disclose the true facts, even though such facts were available to them. The Individual Defendants were the top executives of the Company, or received direct briefings from them, and were therefore directly responsible for the schemes set forth herein and for the false and misleading statements and/or omissions disseminated to the public through press releases, conference calls, and filings with the SEC.

543. In addition to each of the Individual Defendants approving the issuance of the Company's false and misleading statements while they were serving as a senior executive and/or director of the Company, as members of the Board, each of the Individual Defendants then serving as a director would have signed the Company's false and misleading Form 10-K's filed with the SEC during the False Statements Relevant Period, including Defendants Baker,

Babich, Kapoor, Fourteau, Meyer, Tambi, Lapalme, and Stanley, who signed the 2014 10-K, and Defendants Kapoor, Baker, Fourteau, Meyer, Tambi, Lapalme, and Stanley, who signed the 2015 10-K.

544. By virtue of the foregoing, the Individual Defendants have violated § 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

545. Plaintiff on behalf of Insys has no adequate remedy at law.

### **THIRD CLAIM**

#### **Against the Individual Defendants for Violations of Section 20(a) of the Securities Exchange Act of 1934**

546. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

547. The Individual Defendants, by virtue of their positions with Insys and their specific acts, were, at the time of the wrongs alleged herein, controlling persons of Insys and each of its officers and directors who made the false and misleading statements alleged herein within the meaning of § 20(a) of the Exchange Act. The Individual Defendants had the power and influence and exercised the same to cause Insys to engage in the illegal conduct and practices complained of herein.

548. Plaintiff, on behalf of Insys, has no adequate remedy at law.

### **FOURTH CLAIM**

#### **Against the Individual Defendants for Breach of Fiduciary Duties**

549. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

550. Each Individual Defendant owed to the Company the duty to exercise candor,

good faith, and loyalty in the management and administration of Insys's business and affairs.

551. Each of the Individual Defendants violated and breached his fiduciary duties of candor, good faith, loyalty, reasonable inquiry, oversight, and supervision.

552. The Individual Defendants' conduct set forth herein was due to their intentional, reckless, or negligent breach of the fiduciary duties they owed to the Company, as alleged herein. The Individual Defendants intentionally, recklessly, or negligently breached or disregarded their fiduciary duties to protect the rights and interests of Insys.

553. In breach of their fiduciary duties, the Individual Defendants either engaged in, or caused the Company to engage in, the Sales Misconduct.

554. The Individual Defendants also breached their fiduciary duties by causing the Company to fail to maintain internal controls.

555. In further breach of their fiduciary duties owed to Insys, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements of material fact. Specifically, Defendants failed to disclose that, *inter alia*: (1) the Company failed to maintain a proper "tone at the top" resulting in premature recording of revenue, overstatement of earnings, the failure to properly account for sales allowances, and GAAP violations; (2) the Company engaged in the Sales Misconduct; (3) the Company's revenues were artificially inflated as a result of the Sales Misconduct; (4) the Company failed to maintain internal controls; and (5) a result of the foregoing, statements about the Company's business, operations and prospects were materially false and misleading and lacked a reasonable basis at all relevant times.

556. The Individual Defendants failed to correct and/or caused the Company to fail to correct the false and misleading statements and omissions of material fact referenced herein, rendering them personally liable to the Company for breaching their fiduciary duties.

557. In breach of their fiduciary duties, five of the Individual Defendants engaged in lucrative insider sales while the price of the Company's common stock was artificially inflated due to the false and misleading statements of material fact discussed herein. Moreover, while the price of the Company's stock was artificially inflated, the Individual Defendants, in further breach of their fiduciary duties, caused the Company to engage in repurchasing its own stock.

558. In breach of their fiduciary duties, the Individual Defendants delegated the responsibilities of the Compensation Committee to Defendant Kapoor, allowing Defendant Kapoor to negotiate Defendant Babich's \$10 million severance package, which was unjustified and constituted a further breach in light of Defendant Babich's involvement in the misconduct discussed herein.

559. The Individual Defendants had actual or constructive knowledge that the Company issued materially false and misleading statements, and they failed to correct the Company's public statements. The Individual Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth, in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and omissions were committed knowingly or recklessly and for the purpose and effect of artificially inflating the price of Insys's securities and disguising insider sales.

560. The Individual Defendants had actual or constructive knowledge that they had caused the Company to improperly engage in the fraudulent schemes set forth herein and to fail to maintain adequate internal controls. The Individual Defendants had actual knowledge that the Company was engaging in the fraudulent schemes set forth herein, and that internal controls were not adequately maintained, or acted with reckless disregard for the truth, in that they caused the Company to improperly engage in the fraudulent schemes and to fail to maintain

adequate internal controls, even though such facts were available to them. Such improper conduct was committed knowingly or recklessly and for the purpose and effect of artificially inflating the price of Insys's securities and engaging in insider sales.

561. These actions were not a good-faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

562. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Insys has sustained and continues to sustain significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

563. Plaintiff, on behalf of Insys, has no adequate remedy at law.

#### **FIFTH CLAIM**

##### **Against Individual Defendants for Unjust Enrichment**

564. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

565. By their wrongful acts and false and misleading statements and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Insys.

566. The Individual Defendants either benefitted financially from the improper conduct and their making lucrative insider sales and received unjustly lucrative bonuses tied to the false and misleading statements, or received bonuses, stock options, or similar compensation from Insys that was tied to the performance or artificially inflated valuation of Insys, or received compensation that was unjust in light of the Individual Defendants' bad faith conduct.

567. Defendant Babich, in particular, was unjustly enriched by the \$10 million in unjustified severance which he received, despite his role in the misconduct discussed herein.

568. Plaintiff, as a shareholder and a representative of Insys, seeks restitution from the Individual Defendants and seeks an order from this Court disgorging all profits—including from insider sales, benefits, and other compensation (including any performance-based or valuation-based compensation)—obtained by the Individual Defendants due to their wrongful conduct and breach of their fiduciary duties.

569. Plaintiff, on behalf of Insys, has no adequate remedy at law.

### **SIXTH CLAIM**

#### **Against Individual Defendants for Abuse of Control**

570. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

571. The Individual Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Insys, for which they are legally responsible.

572. As a direct and proximate result of the Individual Defendants' abuse of control, Insys has sustained significant damages. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations of candor, good faith, and loyalty, Insys has sustained and continues to sustain significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

573. Plaintiff, on behalf of Insys, has no adequate remedy at law.

### **SEVENTH CLAIM**

#### **Against Individual Defendants for Gross Mismanagement**

574. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

575. By their actions alleged herein, the Individual Defendants, either directly or

through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of Insys in a manner consistent with the operations of a publicly-held corporation.

576. As a direct and proximate result of the Individual Defendants' gross mismanagement and breaches of duty alleged herein, Insys has sustained and will continue to sustain significant damages.

577. As a result of the misconduct and breaches of duty alleged herein, the Individual Defendants are liable to the Company.

578. Plaintiff, on behalf of Insys, has no adequate remedy at law.

### **EIGHTH CLAIM**

#### **Against Individual Defendants for Waste of Corporate Assets**

579. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

580. As a result of the foregoing, and by failing to properly consider the interests of the Company and its public shareholders, Defendants have caused Insys to waste valuable corporate assets and to incur many millions of dollars of legal liability and/or costs to defend unlawful actions. In addition, the Individual Defendants caused the Company to repurchase shares of its own common stock at artificially inflated prices and approve severance and compensation packages that were unjustified in light of the misconduct discussed herein, thereby wasting the Company's assets. Particularly, the Individual Defendants caused Insys to waste valuable corporate assets by awarding Defendant Babich \$10 million in unjustified severance.

581. As a result of the waste of corporate assets, the Individual Defendants are each

liable to the Company.

582. Plaintiff, on behalf of Insys, has no adequate remedy at law.

**PRAYER FOR RELIEF**

FOR THESE REASONS, Plaintiff demands judgment in the Company's favor against all of the Individual Defendants as follows:

(a) Declaring that Plaintiff may maintain this action on behalf of Insys, and that Plaintiff is an adequate representative of the Company;

(b) Declaring that the Individual Defendants have breached and/or aided and abetted the breach of their fiduciary duties to Insys;

(c) Determining and awarding to Insys the damages sustained by it as a result of the violations set forth above from each of the Individual Defendants, jointly and severally, together with pre-judgment and post-judgment interest thereon;

(d) Directing Insys and the Individual Defendants to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect Insys and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote the following resolutions for amendments to the Company's Bylaws or Articles of Incorporation and the following actions as may be necessary to ensure proper corporate governance policies:

1. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the board;
2. a provision to permit the shareholders of Insys to nominate at least four candidates for election to the board;

3. a proposal to ensure the establishment of effective oversight of compliance with applicable laws, rules, and regulations;
- (e) Awarding Insys restitution from Individual Defendants, and each of them;
- (f) Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' and experts' fees, costs, and expenses; and
- (g) Granting such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

Dated: August 6, 2018.

**THE ROSEN LAW FIRM, P.A.**

/s/ Phillip Kim

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*Counsel for Plaintiff*

**VERIFICATION**

I, Hamid Ravansari, am a plaintiff in the within action. I have reviewed the allegations made in this shareholder derivative complaint, know the contents thereof, and authorize its filing. To those allegations of which I have personal knowledge, I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely upon my counsel and their investigation and believe them to be true.

I declare under penalty of perjury that the foregoing is true and correct. Executed this th day of July, 2018.

10/07/2018 03:56:34

DocuSigned by:  
*Hamid Ravansari*  
\_\_\_\_\_  
Hamid Ravansari