UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SEB INVESTMENT MANAGEMENT AB, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. ENDO INTERNATIONAL PLC; ENDO HEALTH SOLUTIONS INC.; PAUL V. CAMPANELLI; BLAINE T. DAVIS; MATTHEW W. DAVIS; RAJIV KANISHKA LIYANAARCHCHIE DE SILVA; IVAN GERGEL; SUSAN HALL; DAVID P. HOLVECK; ALAN G. LEVIN; JULIE H. MCHUGH; SUKETU P. UPADHYAY; DANIEL A. RUDIO; ROGER H. KIMMEL; SHANE M. COOKE; JOHN J. DELUCCA; ARTHUR J. HIGGINS; NANCY J. HUTSON; MICHAEL HYATT; WILLIAM P. MONTAGUE; JILL D. SMITH; and WILLIAM F. SPENGLER, Defendants.	Civ. A. No. 2:17-CV-3711-TJS COMPLAINT – CLASS ACTION JURY TRIAL DEMANDED **ECF CASE**

AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

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Lead Plaintiff, SEB Investment Management AB ("SEB IM" or "Lead Plaintiff"), by and through its undersigned counsel, brings this action on behalf of itself and all other similarly situated investors who purchased or otherwise acquired common stock and/or ordinary shares of Endo International plc and/or Endo Health Solutions Inc. ("EHSI" and, together with Endo International plc, "Endo" or the "Company") on a United States securities exchange and/or through transactions within the United States, during the period from November 30, 2012 through June 8, 2017 (the "Class Period"),[1] including pursuant or traceable to Endo's June 2, 2015 offering of twenty-four million shares of common stock (the "June 2015 Offering"), for violations of: (i) Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), respectively, and the rules and regulations promulgated thereunder, including United States Securities and Exchange Commission ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5; and (ii) Sections 11 and 15 of the Securities Act of 1933 (the "Securities Act"), 15 U.S.C. §§ 77k and 77o (collectively, such investors are referred to herein as the "Class").

Except as to allegations specifically pertaining to Lead Plaintiff, all allegations herein are based upon the continuing investigation by Lead Plaintiff's counsel under Lead Plaintiff's supervision, which includes, but is not limited to, reviewing and analyzing: (i) Endo's public filings with the SEC; (ii) press releases and other public statements issued by Defendants (defined herein); (iii) research reports by securities and financial analysts; (iv) media and news reports concerning Endo; (v) transcripts of Endo's earnings and other investor conference calls and related presentations; (vi) regulatory filings, reports and correspondence; (vii) consultations with financial and other experts; and (viii) other publicly available information concerning Endo

[1] Effective February 28, 2014, all of Endo's outstanding common stock was converted to "ordinary shares." Lead Plaintiff refers to Endo's common stock and ordinary shares collectively herein as "common stock."

and the Defendants. Lead Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. INTRODUCTION

1. Endo is an Ireland-domiciled generics and specialty branded pharmaceutical corporation. During the Class Period, Endo earned substantial revenues from marketing and selling reformulated Opana ER to treat both chronic and acute pain. Both original Opana ER and reformulated Opana ER were "extended-release" ("ER") pain medications, which Endo claimed possessed properties that regulated the release of the drug's active ingredient over a period of time as long as twelve hours.

2. The active pain-relieving ingredient in both original Opana ER and reformulated Opana ER was oxymorphone hydrochloride – a powerful semi-synthetic opioid. Like other opioid pain medications, including OxyContin (oxycodone), Dilaudid (hydromorphone), and Vicodin (hydrocodone), Opana ER was highly-addictive and played a significant role in the ongoing opioid epidemic in the United States. Contributing to this epidemic, Endo was among the pharmaceutical companies that disseminated information from multiple, Company-controlled sources falsely claiming that opioid pain medicines (including all forms of Opana) either were not addictive or that any addictive properties could be managed – making these drugs suitable for long-term use for treating debilitating and chronic pain, and exponentially increasing sales.

3. Consumers have paid dearly for the widespread, profit-driven promotion of opioids by pharmaceutical companies like Endo. Drug overdoses were recorded as the leading cause of death for Americans under the age of 50 in 2016 and, as of June 30, 2017, drug overdose deaths were expected to exceed 66,817 for 2017, with 44,693 of those deaths attributed to opioids like oxymorphone.

4. Endo introduced the original formulation of Opana ER in 2006, and the medication was available in several different dosage strengths, ranging from 5mg up to 40mg. Ostensibly, the purpose of original Opana ER was to aid patients suffering from chronic pain in reliably managing their pain through a single pill rather than having to ingest multiple pills over the course of a day. From the time that it was introduced, original Opana ER was one of Endo's highest grossing products, earning ***hundreds of millions of dollars*** annually. By 2010, original Opana ER was Endo's second largest revenue generator, with nearly $240 million in total revenues that year, comprising 14% of Endo's overall annual revenues for 2010.

5. Less than a year after the United States Food and Drug Administration ("FDA") approved original Opana ER for sale, Endo faced stiff competition from generic manufacturers seeking to introduce their own extended-release oxymorphone medications. In this regard, Impax Laboratories, Inc. ("Impax") and others began filing applications in late 2007 seeking FDA approval for generic versions of extended-release oxymorphone hydrochloride to compete directly with Opana ER.

6. Opioid pain medications in pill form, such as Opana ER, were and are often abused by chewing, crushing or grinding and snorting, or by manipulating the product for intravenous ("IV") injection. These facts, combined with Endo's desire to stifle competition from generic drug manufacturers and fortify the Company's monopoly position in the extended-release oxymorphone market, led Endo to develop a new formulation of Opana ER that would purportedly possess properties deterring such abuse. As alleged in detail herein, in pursuing their revenue-maximizing objective during the Class Period, the Exchange Act Defendants (defined *infra* at ¶ 36) disregarded patient safety and misrepresented and omitted material facts concerning reformulated Opana ER's safety, attributes, and sustainability, including by claiming

that reformulated Opana ER had a safety profile superior to both original Opana ER and other manufacturers' generic alternatives. The Exchange Act Defendants' misrepresentations and omissions of material fact in their public statements concerning reformulated Opana ER created and/or maintained artificial inflation in the price of Endo common stock during the Class Period. Unbeknownst to Endo investors, reformulated Opana ER was far ***less safe*** than original Opana ER and the generic oxymorphone medications based upon original Opana ER, and was not effective in deterring abuse.

7. The purported "safety advantages" of reformulated Opana ER presented the only possibility for Endo to extend the life of its Opana ER patents and maintain market exclusivity for the drug. Drug development and approval, however, take time, and Endo needed to stave off generics manufacturers until the Company could obtain FDA approval of reformulated Opana ER.

8. To this end, Endo aggressively defended its patents for original Opana ER in court proceedings against generic manufacturers, which included making significant payments to settle these lawsuits on terms that delayed generic versions of original Opana ER from coming to market—conduct that the Federal Trade Commission ("FTC") has characterized as improper "pay-for-delay" settlements. For example, in January 2008, Endo sued Impax—the first company to submit an application for generic approval of the 5mg, 10mg, 20mg, 30mg, and 40mg dosages of original Opana ER—for patent infringement. By law, Endo's lawsuit delayed the FDA's review of Impax's generic application for thirty months. Impax's first filer status also meant that it would enjoy a limited exclusivity period over subsequent generic filers for the same dosage strengths. Thus, so long as Endo could delay Impax's generic oxymorphone drug coming to market, the Company effectively deferred all generic filers at those dosage strengths as well.

9. Strategically, just weeks after the FDA tentatively approved Impax's application for generic original Opana ER (following the thirty-month stay), and with its new drug application ("NDA") for reformulated Opana ER about to be filed, Endo settled with Impax. Pursuant to this settlement, Impax agreed to further delay bringing its generic version of original Opana ER to market until January 1, 2013. This settlement also served to delay other generic manufacturers from coming to market and, ostensibly, provide just enough time for Endo to gain FDA approval of and bring reformulated Opana ER to market.

10. Contemporaneously with this heated competition from generic manufacturers to sell their own versions of original Opana ER, there was an emerging public health crisis stemming from the intranasal abuse of Opana ER and other semi-synthetic opioids. By 2012, it was becoming apparent that prescription opioids like Opana ER were contributing to the deaths of tens of thousands of people each year, through intentional or accidental abuse and misuse. Original Opana ER, in particular, was highly susceptible to abuse and misuse, including by crushing, cutting or grinding and snorting the drug, chewing, and injection. These methods all compromised the extended-release feature of the drug and permitted abusers to gain immediate release of high doses of oxymorphone, which presented a severe risk of fatal overdose caused by respiratory depression.

11. Seizing on public concern over the intranasal abuse of prescription opioids, Endo filed its NDA for reformulated Opana ER on July 7, 2010. Endo heralded the new Opana ER formulation as "crush-resistant" and sought an abuse-deterrent label from the FDA to set its new formulation apart from original Opana ER, and to better compete with other opioid products. The FDA approved the NDA on December 9, 2011, but declined the Company's request to include language describing the drug's purportedly crush-resistant and abuse-deterrent properties

on the drug's label, concluding that the available data was inadequate to support such labeling at that time. Endo began marketing the drug in February 2012.

12. Undeterred by the FDA's initial refusal to approve an abuse-deterrent label, Endo sought to emphasize the purported safety features of reformulated Opana ER to preserve market exclusivity and profits for its Opana ER franchise. At the time it began marketing reformulated Opana ER, Endo started phasing out supplies of the original formulation, and notified the FDA on May 31, 2012, that it had discontinued original Opana ER for "***safety reasons***." On August 10, 2012, Endo filed a "Citizen Petition" with the FDA formally asking it to determine that Endo withdrew original Opana ER for safety reasons. In support of this petition, the Company claimed that reformulated Opana ER offered safety advantages over the original formulation and that the FDA should therefore also suspend or withdraw all applications for generic versions of the original formulation for safety reasons as well.

13. If Endo had prevailed on its Citizen Petition before year-end (given Impax's pending generic oxymorphone hydrochloride launch on January 1, 2013), the Company would have successfully fended off generic competition, leaving reformulated Opana ER alone on the market without any generic competition for the most popular dosage strengths.

14. As 2012 came to an end, however, the FDA still had not acted on Endo's Citizen Petition. Doubling down on its profit preservation efforts, Endo sued the FDA for its alleged failure to timely determine whether Endo removed original Opana ER from the market for safety reasons. The court promptly dismissed Endo's lawsuit. Consequently, Impax was permitted to begin selling its generic version of original Opana ER on or about January 1, 2013. As the FDA recognized in connection with this litigation, "***Endo's true interest in expedited FDA consideration stem[med] from business concerns rather than protection of the public health***."

Moreover, the FDA contended that Endo's Citizen Petition was nothing more than "***a thinly-veiled attempt to maintain its market-share and block generic competition*** . . . ."

15. The very next month, Endo filed a supplemental new drug application ("sNDA") with the FDA, again seeking abuse-deterrent labeling for reformulated Opana ER. The Exchange Act Defendants also continued to tout the safety benefits and prospects of reformulated Opana ER, claiming that "the company continues to believe that sufficient evidence exists to support a determination by FDA that the old formulation of OPANA® ER was discontinued for reasons of safety, which serves the public health."

16. On May 10, 2013, the FDA denied both Endo's Citizen Petition and the Company's renewed request for abuse-deterrent labeling, stating that original Opana ER was not withdrawn from sale for reasons of safety or effectiveness. The FDA further stated that the post-marketing data Endo submitted in support of its request for abuse-deterrent labeling was (as Endo acknowledged) "preliminary" and "inconclusive."

17. With no further ammunition to stop its generic competitors, Endo focused its efforts on trying to maintain – as much as possible – the lucrative revenue stream from what Defendants heralded on May 7, 2013, as Endo's "***primary product***," by making materially false or misleading statements concerning the safety, attributes and sustainability of reformulated Opana ER. Central to Endo's revised strategy was the Company's claim that available data demonstrated that reformulated Opana ER was effectively deterring abuse and that the Company was working to obtain additional data demonstrating that reformulated Opana ER was safer than the original formulation and more effective at preventing abuse.

18. Contrary to the Exchange Act Defendants' statements, however, reformulated Opana ER failed to deter abuse, as it remained subject to abuse by grinding and snorting,

chewing, and injection. Moreover, the very properties that supposedly made reformulated Opana ER safer (i.e., its purported ability to deter abuse by crushing and snorting) actually rendered the drug deadly when manipulated for IV abuse. At the times that the Exchange Act Defendants made their materially false or misleading statements, data available to the Exchange Act Defendants, including Endo's NDA studies, as well as post-marketing study data, demonstrated that reformulated Opana ER was associated with ***increased rates of abuse through injection and caused deaths and a number of serious health risks not associated with other opioids***. Among the health hazards that reformulated Opana ER presented when abused by injection was thrombotic thrombocytopenic purpura ("TTP"), a rare coagulation disorder that causes microscopic clots to form in small blood vessels. Beginning no later than the third quarter of 2013, Endo knew from data sources it sponsored that the abuse of reformulated Opana ER was shifting from crushing and snorting to injection – a much more dangerous method of abuse. Notwithstanding this data, which was fully available to the Company, Endo continued to make materially false or misleading statements indicating that the Company was collecting the data required to submit a successful application for abuse-deterrent labeling. When provided to the FDA, however, Endo's data ultimately led the FDA to demand that Endo withdraw reformulated Opana ER from the market because the risks that it presented outweighed any benefits.

19. The truth about reformulated Opana ER's actual safety risks and prospects gradually emerged during the Class Period. For example, on January 10, 2017, the FDA announced that it was convening an advisory committee (the "Advisory Committee") to review post-marketing abuse data and the overall risk/benefit profile of reformulated Opana ER. Then, on March 9, 2017, the FDA disseminated a Briefing Document in advance of the Advisory Committee meeting concerning reformulated Opana ER to be held on March 13-14, 2017. This

Briefing Document reflected the FDA's concern that Endo's post-marketing abuse data was "compelling" evidence of the ***lack of safety*** of the reformulated drug because "the reformulation caused a shift in non-oral routes [of abuse] from predominately nasal to predominately injection." The FDA further noted that the lack of safety was highlighted by the number of reports of thrombotic microangiopathy ("TMA"), a spectrum of clinical syndromes leading to microvascular thrombosis, including TTP. On March 14, 2017, the Advisory Committee voted 18-8 that the risks associated with reformulated Opana ER outweighed its benefits. Finally, on June 8, 2017, the FDA demanded that Endo voluntarily withdraw reformulated Opana ER from the market in light of the serious health risks that the drug presented.

20. As a result of the conduct alleged herein, Lead Plaintiff and other members of the Class purchased Endo common stock at artificially inflated prices during the Class Period, including in a $2.3 billion offering of Endo common stock completed in June 2015, and suffered significant losses and damages as the truth gradually emerged. On behalf of itself and all other Class members, Lead Plaintiff seeks to recover damages caused by the Defendants' misrepresentations and omissions of material facts concerning the safety, efficacy, and sustainability of reformulated Opana ER.

II. JURISDICTION AND VENUE

21. The Exchange Act claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5. The Securities Act claims asserted herein arise under Sections 11 and 15 of the Securities Act, 15 U.S.C. §§ 77k and 77o. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and Section 22 of the Securities Act, 15 U.S.C. § 77v.

22. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. §§ 78aa, and Section 22(a) of the Securities Act, 15 U.S.C. § 77v, and 28 U.S.C. § 1391(b), because the Company conducts a substantial amount of business throughout the District, including maintaining its U.S. headquarters in this District, at 1400 Atwater Drive, Malvern, Pennsylvania.

23. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the U.S. mails, interstate telephone communications, and facilities of the national securities markets.

III. PARTIES

A. Lead Plaintiff

24. Lead Plaintiff, SEB Investment Management AB is one of the largest asset managers in the Northern Europe. Headquartered in Stockholm, Sweden (organization number 556197-3719), SEB IM offers a broad range of funds and tailored portfolios for institutional investors, as well as for retail and private banking clients. SEB IM purchased shares of Endo common stock during the Class Period as set forth in the certification attached hereto as Exhibit A. SEB IM suffered substantial losses in connection with its purchases of Endo common stock during the Class Period and traceable to the June 2015 Offering as a result of Defendants' conduct complained of herein.

B. Exchange Act Defendants

25. Defendant Endo International plc is an Ireland-domiciled generics and specialty branded pharmaceutical corporation with global headquarters located at 1st Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland, and U.S. headquarters located at 1400 Atwater Drive, Malvern, Pennsylvania 19355. Endo International plc was formed on

October 31, 2013 for the purpose of acting as the holding company for EHSI and Paladin Labs Inc. ("Paladin") pursuant to EHSI's acquisition of Paladin. The ESHI-Paladin merger was consummated on February 28, 2014, and pursuant to that transaction, Endo International plc acquired EHSI as a wholly-owned subsidiary. From the start of the Class Period through its February 28, 2014 acquisition by Endo International plc, ESHI conducted business under the name Endo Health Solutions Inc. At all relevant times, Endo's common stock traded on the NASDAQ Exchange ("NASDAQ") under the symbol "ENDP." From March 3, 2014 until March 14, 2017, Endo's common stock was also listed on the Toronto Stock Exchange ("TSX") under the symbol "ENL," but according to Endo, trading on the TSX accounted for less than 1% of the volume of Endo common stock transactions during this time. The Company's market capitalization reached a Class Period high of $18.2 billion on July 28, 2015, before falling to $2.5 billion at the close of trading on June 8, 2017, the last day of the Class Period.

26. Defendant Endo Health Solutions Inc. is a wholly-owned subsidiary of Endo International plc. Prior to the start of the Class Period, and until its acquisition by Endo International plc on February 28, 2014, Endo conducted business under the name Endo Health Solutions Inc., and EHSI's common stock was publicly traded on the NASDAQ under the symbol ENDP.

27. Defendant Paul V. Campanelli ("Campanelli") was appointed President, Chief Executive Officer and a member of Endo's Board of Directors ("Board") effective September 23, 2016. Campanelli joined Endo in 2015 in connection with its acquisition of Par Pharmaceutical Companies, Inc., as head of Endo's U.S. Generics business.

28. Defendant Blaine T. Davis ("B. Davis") has served as Senior Vice President and General Manager of Specialty Pharmaceuticals at Endo since January 2015. Prior to this role, he was Senior Vice President of Corporate Affairs at Endo.

29. Matthew W. Davis ("M. Davis"), M.D. R.Ph., has served as the Senior Vice President, Research and Development Branded Pharmaceuticals since January 3, 2017.

30. Defendant Rajiv Kanishka Liyanaarchchie De Silva ("De Silva") served as Endo's President, Chief Executive Officer, and a member of the Board from March 18, 2013 to September 22, 2016.

31. Defendant Ivan Gergel, M.D. ("Gergel") was appointed Executive Vice President, Research & Development of Endo on April 11, 2008, and served as Executive Vice President Research & Development and Chief Scientific Officer from 2011 until March 31, 2014.

32. Defendant Susan Hall, Ph.D. ("Hall") served as Endo's Executive Vice President and Chief Scientific Officer from March 10, 2014 through December 2016. In her roles, Hall was responsible for Global Branded Pharmaceutical Research & Development and enterprise-wide Quality Assurance.

33. Defendant David P. Holveck ("Holveck") served as Endo's President, Chief Executive Officer, and a member of the Board from April 1, 2008 until his retirement on December 12, 2012.

34. Defendant Alan G. Levin ("Levin") served as the Company's Chief Financial Officer from June 1, 2009 until the fall of 2013, when he left the Company.

35. Defendant Julie H. McHugh ("McHugh") served as Chief Operating Officer of Endo from March 2010 to May 29, 2013, when Endo announced her immediate departure.

36. Defendants Campanelli, B. Davis, M. Davis, De Silva, Gergel, Hall, Holveck, Levin and McHugh are collectively referred to herein as the "Individual Exchange Act Defendants." The Individual Exchange Act Defendants together with Endo are referred to herein as the "Exchange Act Defendants." The Exchange Act Defendants and the Securities Act Defendants (defined *infra* Section XIV) are collectively referred to herein as "Defendants."

IV. SUMMARY OF DEFENDANTS' FRAUD

A. Company Background

37. Endo's history can be traced back to 1920, when the Company began as a family-run pharmaceutical company called Intravenous Products of America, Inc. The Company changed its name to Endo Products in 1935. In 1970, E.I. du Pont de Nemours and Company ("DuPont") acquired Endo. In 1994, Endo was established as a separate entity within a joint venture between DuPont and Merck & Company ("Merck") and re-named Endo Laboratories L.L.C. Endo Laboratories, L.L.C. was DuPont Merck's generic division. In 1997, a private equity investment firm purchased all of Endo Laboratories L.L.C.'s generic products, along with twelve branded products, including Percocet and Percodan, and renamed the company Endo Pharmaceuticals, Inc. In 2000, Endo Pharmaceuticals, Inc. acquired Algos Pharmaceutical Corporation and became a publicly traded company with the following business segments: U.S. Branded Pharmaceuticals; U.S. Generic Pharmaceutical; and International Pharmaceuticals. On February 28, 2014, the Company reincorporated in Ireland under the name Endo International plc, but retained its U.S. headquarters in Malvern, Pennsylvania. Endo employs more than 4,600 people worldwide.

38. Endo is an active participant in the opioid market, and describes itself as a "leader in developing proprietary pain management products." Through its U.S. Branded Pharmaceuticals business, Endo markets and sells branded opioids such as Opana, Opana ER,

Percodan, Percocet, and Zydone, while its U.S. Generic Pharmaceuticals business markets and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

B. In Pursuit of Increased Profits, Endo Misrepresented the Addictiveness of Opioids

39. Opioid pain medications were developed and used over many decades for the treatment of acute pain, such as surgery-related pain, or for palliative (cancer or end-of-life) care. The reasons for such limited use were clear—for hundreds of years, the addictive properties of opioids, including opium, morphine, heroin, codeine, and other drugs originally developed from poppy seeds, have been well understood. Thus, the use of opioids was widely considered to be unsuitable for chronic pain sufferers.

40. Beginning in the late 1990s, however, Endo and other opioid manufacturers adopted a marketing strategy that sought to dispel the public and medical perception of opioids as addictive and generally unsafe for long-term use and encouraged doctors to prescribe their products more liberally and to a far broader group of patients suffering from chronic pain. To this end, over the past two decades, Endo and other companies earning revenues from distributing opioid pain medications have greatly expanded their advertising campaigns touting the benefits and downplaying the risks of their various branded opioid drugs. In particular, these manufacturers have made statements minimizing the risk of addiction and fatal overdose associated with opioids. In addition, through their own sales representatives and third parties they control, including physicians known as "key opinion leaders" ("KOLs") and ostensibly neutral and credible professional societies and patient advocacy groups ("Front Groups"), Endo and others have engaged in promotional activities and disseminated marketing materials that

falsely denied or downplayed the risks of opioids and overstated the benefits of their long-term use in treating chronic pain, such as back pain, knee pain, and migraines.

41. For example, Endo (with others) supported Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine Palliative Care at Beth Israel Medical Center in New York. Dr. Portenoy was a KOL for Endo, and was instrumental in opening the door for the regular use of prescription opioids to treat chronic pain. He served on the American Pain Society and American Academy of Pain Medicine Guidelines Committees, which endorsed the use of prescription opioids to treat chronic pain first in 1997, and again in 2009. Endo also supported the American Pain Foundation ("APF"), a leading Front Group, which issued purported "education guides" for patients, the news media, and policymakers that touted the benefits of opioids for chronic pain and trivialized the attendant risks, particularly the risk of addiction. APF also engaged in a significant multimedia campaign through radio, television, and the internet to purportedly "educate" patients about their "right" to pain treatment with opioids.

42. Further, Endo funded the Federation of State Medical Boards ("FSMB"), a trade organization representing the various state medical boards in the U.S. Since 1998, the FSMB has developed state medical board policies for the use of opioids to treat pain. The 1998 policy, entitled *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("1998 Guidelines"), was produced "in collaboration with pharmaceutical companies." With the influence of Endo and others, the 1998 Guidelines provided not only that opioids could be appropriate in limited cases after other pain treatments had failed, but also that opioids were "essential" for the treatment of chronic pain, including as a first prescription option.

43. At the center of Endo's and other opioid manufacturers' market expansion efforts was a number of statements addressing the putative efficacy and alleged minimal risks that this

class of drugs posed. Most significantly, to convince doctors and patients that opioids were safe, Endo and others sought to minimize the risks of long-term opioid use, particularly the risk of addiction. They asserted that: (i) addiction risks were insignificant because most patients would not become addicted; (ii) patients who displayed signs of addiction probably were not addicted, but instead were suffering from "pseudoaddiction," a purported condition resulting from an inadequate dosage strength that could be remedied by increasing the dosage of the applicable opioid; and (iii) those who were at the greatest risk of addiction could be readily identified and managed.

44. The statements that Endo and other companies used to earn rapidly increasing revenues have been shown to be wholly unsubstantiated. In fact, Endo has acknowledged that many were false:

- *Opioids Allegedly Not Addictive*: The Guidelines issued by the Centers for Disease Control ("CDC") in 2016 ("CDC Guidelines") specifically state that "Opioid pain medication use presents serious risks, including overdose and opioid use disorder [i.e., addiction]." The FDA agrees that opioids "have serious risks including misuse and abuse, addiction, overdose, and death." Further, the FDA acknowledged that "even appropriately prescribed opioids can lead to addiction." In a settlement with the State of New York, Endo agreed not to "make statements [in New York] . . . that most patients who take opioids do not become addicted[.]"
- *Pseudoaddiction:* The CDC Guidelines reject the concept of pseudoaddiction, noting that patients "who do not experience clinically meaningful pain relief early in treatment (i.e., within one month) are unlikely to experience pain relief with longer-term use." Endo itself has admitted as much, with one of its senior executives testifying in the State of New York's case against it that he was "not aware of any research validating the 'pseudoaddiction' concept."
- *Effective Screening*: The CDC Guidelines noted the lack of any evidence supporting a claim that those at a heightened risk for opioid addiction could be "prescreened," stating that "[n]o study evaluated the effectiveness of risk mitigation strategies . . . for improving outcomes related to overdose, addiction, abuse, or misuse."

45. On January 11, 2018, Endo announced that it had received a grand jury subpoena from federal prosecutors in Miami seeking documents related to Opana ER. The federal probe came amid a growing number of lawsuits by state and local governments concerning Endo's alleged deceptive marketing of Opana ER, and requested documents regarding product safety, overdoses, and the abuse and addictiveness of the drug.

C. The Scheme to Expand the Use of Opioids Generates Enormous Sales for Endo and Other Manufacturers–But at a Horrific Cost to Americans

46. As a result of the opioid manufacturers' marketing practices, opioids became the most prescribed class of medications in the United States, with more than 250 million opioid prescriptions each year between 2010 and 2012, according to CDC data. Sales of prescription opioids in the U.S. nearly quadrupled from 1999 to 2014. As alleged above in Section IV.B, Endo, through its sales of original Opana ER and reformulated Opana ER, profited from deceptive opioid marketing practices at the expense of the health and welfare of millions of Americans nationwide.

47. Tellingly, in an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly attributed this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of whom were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain." Indeed, the National Safety Council has concluded that, by promoting the widespread use of these medications, opioid manufacturers fueled a growing supply of prescription opioids available for illicit use or sale, and an expanding population of addicted patients who often resort to buying prescription opioids or heroin off the street when they can no longer afford or legitimately obtain opioids. According to the National Heroin Task Force data, in 2015, 80% of persons who reported using heroin indicated that they began their opioid use through prescription opioid medications.

48. The sheer number of deaths resulting from opioid abuse and misuse is staggering. According to data recently published by the CDC, drug overdose deaths, largely the result of opioid addiction, have reached all-time highs, with more than 165,000 people in the United States dying from prescription-opioid overdoses from 1999 to 2014. The death rate is continuing to accelerate. According to CDC statistics, prescription pain relievers and heroin claimed approximately 35,000 lives in 2015 and 49,000 more in 2016, with semi-synthetic opiates such as the oxymorphone hydrochloride in Opana ER, responsible for 12,727 and 14,550 deaths, respectively.

49. The problem has grown so large that drug overdose was the leading cause of death for Americans under the age of 50 in 2016, with the number of annual deaths related to drug overdoses substantially exceeding the annual number of deaths caused by the AIDS crisis during its peak years, gun violence, and even automobile accidents. Provisional data from the CDC indicates that for the twelve months ending June 30, 2017, drug overdose deaths were expected to top 66,817, with 44,693 of those deaths attributed to opioids. The CDC noted, however, that these staggering statistics are likely ***underreported*** due to incomplete data.

D. The Development Of Original Opana ER And Its Importance To Endo

50. Original Opana ER was an extended-release formulation of oxymorphone hydrochloride—a semi-synthetic opioid originally developed more than one hundred years ago. Unlike immediate-release medications, extended-release opioids like original Opana ER have special coatings or ingredients designed to control how fast the active ingredient is released from the pill into the patient's body. Compared to an immediate-release oxymorphone hydrochloride formulation, original Opana ER was supposed to provide longer-lasting, twelve-hour pain relief that enabled a patient to take fewer pills each day. Thus, original Opana ER was designed by

Endo as part of its strategy to expand its presence in the burgeoning market for chronic pain relief that resulted from the opioid marketing scheme alleged above.

51. Endo developed Opana, in immediate-release and extended-release formulations, to "compete in the market for long-acting, strong opioids"— a $3.2 billion per year market by 2005. At the time of original Opana ER's introduction in mid-2006, its primary competitor was OxyContin, a branded oxycodone-based semi-synthetic opioid developed and sold by Purdue Pharma L.P. ("Purdue").

52. Like other opioids, original Opana ER was highly addictive and susceptible to abuse, and it became one of the medications at the epicenter of U.S. opioid crisis, contributing significantly to the alarming number of opioid-related health issues and overdose deaths currently plaguing the nation. For example, in slides presented to the FDA Advisory Committee in March 2017, the CDC noted the report of a participant in a survey it had conducted: "after they took OxyContins off the market, then they came out with the OPANAs. Which was 10 times worse than that OxyContin. With like the intensity of the withdrawals."

53. The CDC further reported from a survey participant:

> I could not find any of the OxyContins and someone came to me with an Opana, and that's how I ended up doing Opana but I had a lot of people tell me "Don't do Opana because a lot of people say you do it one time and you're hooked." You'll be sick the next day so you'll have to get another one. And that's exactly what happened. I did one that night and the next morning I woke up and I just felt, I felt terrible. And so I had to get another one. You get hooked on 'em really fast, the Opanas. Very fast.

54. In particular, original Opana ER could easily be tampered with and snorted (the most common method of abuse), chewed, or injected. When swallowed whole, its extended-release mechanisms remained intact, so that original Opana ER released immediately only 10% of its oxymorphone hydrochloride into a patient's bloodstream. However, when crushed and

taken intranasally, original Opana ER released 43% of its active ingredient immediately—a phenomenon referred to by the FDA as "dose-dumping."

55. The FDA first approved original Opana ER (NDA No. 021610) on June 22, 2006, in four dosage strengths (5mg, 10mg, 20mg, and 40mg) "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time." Following FDA approval, Endo began selling original Opana ER in late July 2006. At that time, it was the only extended-release version of oxymorphone hydrochloride on the market. The FDA subsequently approved three additional dosage strengths (7.5mg, 15mg, and 30mg), which the Company announced on March 3, 2008, and made available beginning April 1, 2008.

56. As alleged above, because of the enormous expansion in the use of opioids for treating chronic pain, original Opana ER quickly became one of Endo's best-selling drugs. Endo has acknowledged that "most of [its] total revenues come from a small number of products," and one of its key products was original Opana ER. Following modest sales of $5 million in 2006, sales of original Opana ER increased substantially. By 2010, original Opana ER was Endo's second largest revenue generator, earning nearly $240 million in total annual revenues for Endo, representing approximately 14% of Endo's overall revenues that year. Sales of original Opana ER climbed to more than $384 million in 2011, or roughly 14% of the Company's total revenues that year, and held strong at nearly $300 million in 2012, 10% of Endo's total revenues that year. During the Class Period, reformulated Opana ER remained a "significant" component of Endo's total U.S. Branded Pharmaceuticals business, generating over $197 million, $175 million, and $158 million in total revenues in 2014, 2015, and 2016, respectively.

E. Generics Threaten Original Opana ER's Dominant Market Position

57. Almost immediately after its introduction in June 2006, original Opana ER's rapid growth and increasing sales drew the attention of numerous generic manufacturers who

threatened to erode the drug's market share. Original Opana ER was an attractive target for generic drug makers for two reasons: (i) oxymorphone hydrochloride had been available for decades and initially was not meaningfully protected by any patents; and (ii) at the time of its approval, because of potential patent issues, there likely was no long-term barrier to generic competition for the original formulation of Opana ER.

58. With growing sales and limited patent protection, numerous generic drug manufacturers began preparing abbreviated new drug applications ("ANDAs") for generic versions of original Opana ER. Generic drug applications are called "abbreviated" because they generally are not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. To receive approval, a generic applicant need only demonstrate that its product is bioequivalent (i.e., performs in the same manner) to its reference listed drug ("RLD") (i.e., the approved brand name drug to which the generic is compared). By designating a single RLD as the standard to which all generic versions must be shown to be bioequivalent, the FDA avoids possible significant variations among generic drugs and their brand name counterparts. Once approved, a generic applicant may manufacture and market its generic drug product to provide a lower cost alternative to consumers.

59. When a brand name drug is covered by one or more patents, a company seeking to market a generic version of that drug before the RLD's patents expire must make a "paragraph IV certification" in its ANDA, asserting that such patents are invalid, unenforceable, and/or will not be infringed by the generic drug. Once an ANDA filer submits a paragraph IV certification, it must notify the patent holder. If the patent holder initiates a patent infringement suit against the ANDA filer within forty-five days of receiving such notice, the FDA may not approve the

ANDA until the earliest of: (i) patent expiry; (ii) district court resolution of the patent litigation in favor of the generic company; or (iii) the expiration of an automatic thirty-month stay.

60. On June 29, 2007, Impax submitted an ANDA with a paragraph IV certification to the FDA, seeking approval of its generic version of original Opana ER at 5mg, 10mg, 20mg, 30mg, and 40mg dosages. The FDA initially accepted Impax's ANDA for substantive review, but it later rescinded that acceptance due to certain deficiencies. Impax then resubmitted its ANDA and the FDA accepted the application as of November 23, 2007. On December 13, 2007, Impax notified Endo of its ANDA with a paragraph IV certification seeking approval of its generic formulation of the 5mg, 10mg, 20mg, 30mg, and 40mg strengths of original Opana ER.

61. As the first filer of an ANDA for original Opana ER 5mg, 10mg, 20mg, 30mg, and 40mg strengths containing a paragraph IV certification, Impax received first-filer exclusivity for those dosage strengths—meaning that other approved generic versions of original Opana ER were precluded from entering the market until 180 days after Impax's generic launch. Given Impax's first-filer status, if Endo delayed Impax's entry, Endo would effectively delay all generics from entering the market for these dosages of original Opana ER.

62. By 2010, no fewer than six companies had submitted ANDAs seeking approval to market a generic version of original Opana ER, including Impax, Actavis South Atlantic LLC, and Watson Pharmaceuticals, Inc.

F. Endo Embarks On A Multi-Pronged Strategy to Protect Its Market Position And Extend Its Patent Exclusivity

63. Cognizant of generic ANDA filers coming down the pike, and against the backdrop of the spiraling opioid crisis alleged above, Endo also began developing a new formulation of original Opana ER that purported to be crush-resistant and thus abuse-deterrent. Endo intended to replace original Opana ER with a patent-protected reformulated version,

effectively extending the drug's market exclusivity—it just needed to stave off generic competition long enough to develop the drug and obtain FDA approval.

1. Endo Sues Generic Manufacturers to Delay Their Market Entry

64. On January 25, 2008, Endo sued Impax for allegedly infringing two of Endo's original Opana ER patents, triggering the automatic thirty-month stay of FDA approval with respect to Impax's ANDA for generic original Opana ER.

65. Litigation between Impax and Endo ensued, and the drug makers settled in 2010. Pursuant to the settlement, among other things, Impax agreed to delay launching its generic version of original Opana ER until January 1, 2013. The FTC later investigated this agreement and brought suit against Endo and Impax, alleging that their settlement was an unlawful "pay-for-delay" agreement in violation of federal antitrust laws. Because of Impax's first-filer status, Endo's settlement with Impax effectively precluded all other generic manufacturers that filed ANDAs after Impax on the same dosage strengths of generic original Opana ER from coming to market until the third quarter of 2013. Further, as alleged below in ¶¶ 80-108, as 2013 drew near, Endo again sought to prevent Impax from selling its generic version of original Opana ER altogether by arguing that safety considerations should preclude its competitors from marketing generic original Opana ER. These arguments failed.

2. Endo Seeks FDA Approval of Reformulated Opana ER

66. In July 2010, Endo submitted an NDA for reformulated Opana ER. Endo stated that the purpose behind the reformulation was to make Opana ER resistant to physical and chemical manipulation and, therefore, abuse-deterrent, and Endo sought labeling identifying such properties. According to Endo, the new formulation provided resistance to crushing, which was expected to deter abuse. Reformulated Opana ER, however, had the same active ingredient (oxymorphone hydrochloride) as original Opana ER, and like the original formulation, was an

extended-release pill. The only difference was that reformulated Opana ER was designed with INTAC®, a polyethylene oxide containing matrix manufactured by Grünenthal GmbH ("Grünenthal") that purportedly made the tablets more difficult to crush, and would form a viscous gel when in contact with liquids, rendering the product more difficult to abuse intranasally and intravenously, but which was inadequate, as alleged herein.

67. To expedite the approval of its submission, Endo attempted to "support [] the efficacy and safety" of reformulated Opana ER "based entirely on bioequivalence to [original Opana ER]." To support its claim of efficacy and safety, Endo relied on: (i) bioequivalence studies comparing reformulated Opana ER to the original formulation; (ii) a clinical pharmacokinetic (bioavailability) study ("Study 108"); (iii) human abuse potential studies ("Study 109"); (iv) two bench top attractiveness studies ("Study 901" and "Study 902"); and (v) *in vitro* manipulation and chemical extraction studies, which were designed to assess the potentially abuse-deterrent properties of the new formulation, including an alleged reduction in the potential for the drug to be tampered with and the ability of the drug's extended-release features to be compromised through tampering or improper use.

68. Study 108, was an *in vivo* bioavailability study comparing reformulated Opana ER taken intact and after physical tampering (i.e., cutting, crushing, and grinding) with crushed original Opana ER. The goal of the study was to understand whether the abuse-deterrent features of the new product could withstand physical tampering. While the data showed that reformulated Opana ER seemed to resist crushing forces from a pill crusher, Study 108 showed that tampering with reformulated Opana ER by grinding, cutting, and chewing was possible and that such tampering compromised the drug's extend release feature, allowing an abuser to obtain the full impact of the drug immediately.

69. Study 109, was an *in vivo* human abuse potential and drug-liking study comparing reformulated Opana ER taken intact and after chewing. The objectives of Study 109 were to evaluate the relative bioavailability and subjective effects produced following oral administration (i.e., swallowing) of intact and chewed reformulated Opana ER to recreational prescription opioid users. Study 109 showed that chewing reformulated Opana ER tablets was possible and compromised the controlled release mechanism of the drug and produced positive subjective effects significantly higher than those produced by ingesting intact reformulated Opana ER. Study 109 thus revealed similar positive subjective effects after chewing original Opana ER and Opana IR.

70. Endo did not publish an abstract of Study 108 or Study 109 on its website until after the New York Attorney General ("NYAG") highlighted these studies in its settlement with Endo over its deceptive marketing practices with respect to reformulated Opana ER. As revealed by the NYAG, following its investigation into Endo's marketing of reformulated Opana ER, which concluded in March 2016, Endo similarly failed to mention Study 108 or Study 109 in its reformulated Opana ER "managed care dossier" (the "Dossier"), which it distributed to formulary committees of health plans and pharmacy benefit managers to encourage them to include reformulated Opana ER in their formularies. While Endo's Vice President for Pharmacovigilance and Risk Management testified to the NYAG that the Dossier is intended to be a complete compendium of all research on the drug, Studies 108 and 109 were conspicuously absent from that file.

71. Studies 901 and 902 were conducted between December 2009 and February 2010 to test Endo's claims that reformulated Opana ER was tamper-resistant. Study 901 assessed whether individuals claiming to have experience in manipulating pharmaceutical opioid products

could convert reformulated Opana ER into a form amenable to intravenous administration or intranasal administration, and whether they would be willing to inject the tampered product. Two of the study endpoints—that reformulated Opana ER would be less extractable than original Opana ER, and that it would take less time to extract the drug from original Opana ER than reformulated Opana ER—were not met. Indeed, FDA reviewers concluded in a December 22, 2010 review, that both formulations behaved "similarly" under the study conditions with respect to extraction volume, concentration, and percent yield of oxymorphone after manipulation.

72. Study 902 tested the feasibility of manipulating reformulated Opana ER into a form suitable for intranasal administration. While it demonstrated a difficulty in forming an intranasal preparation under certain circumstances, according to FDA reviewers, neither Study 902, nor the *in vitro* studies, addressed the grinding of reformulated Opana ER tablets for possible abuse by intranasal administration.

73. Additionally, Endo submitted *in vitro* manipulation and chemical extraction studies designed to assess the tamper-resistant characteristics of reformulated Opana ER by evaluating changes in the rate of release of the drug if misused either intentionally or unintentionally. These studies evaluated the extractability of the drug from the new formulation under the effects of pH, temperature, alcohol concentration, solvent volume, and polarity at various exposure times in combination with agitation or disruption or destruction of the drug product, including from being "crushed" or cut. FDA reviewers noted that reformulated Opana ER did not demonstrate superior resistance to tampering, as evidenced by a 60% increase in the dissolution of reformulated Opana ER in one hour after tampering compared to intact tablets. Significantly, one of the *in vitro* studies showed that it might actually be easier to prepare reformulated Opana ER for injection, compared to the original formulation.

3. The FDA Approves Reformulated Opana ER, but Denies Abuse-Deterrent Labeling for the Drug

74. Based on the foregoing data, FDA reviewers noted that reformulated Opana ER "may provide an incremental improvement in tamper resistance for those wishing to snort the drug, and a similarly incremental improvement in preventing over-dosage in a patient who attempts to crush the pills," but that "concerns have been raised regarding the [redacted] tamper-resistant features of this product's formulation" because the product can still be cut or chewed. "[P]erhaps most importantly," FDA reviewers noted that "after chewing [redacted] the product acts like an immediate-release oxymorphone pill and this places certain patient populations, particularly the elderly and/or cognitively impaired, at high risk of overdose."

75. Further, FDA reviewers noted the limitations of the findings regarding reformulated Opana ER's resistance to crushing in supporting conclusions regarding reformulated Opana ER's resistance to abuse by snorting, as neither the *in vitro* studies, nor Study 902, addressed the grinding of reformulated Opana ER tablets for possible abuse by intranasal administration. Therefore, FDA reviewers concluded that reformulated Opana ER only provided "limited" resistance to physical and chemical manipulation for abuse.

76. In light of their findings, FDA reviewers were "concerned that any reference to the product's incremental improvement in tamper resistance could be misleading" and recommended that: (i) reformulated Opana ER's "product label not include language asserting that [it] provides resistance to crushing," as well as other things that were, and remain, redacted from public view; and (ii) Endo conduct a study to determine if ground reformulated Opana ER could be administered intranasally.

77. As revealed by the NYAG in March 2016, commenting on these findings, Endo's Director of Project Management acknowledged in an October 2011 email to Grünenthal, the

manufacturer of the INTAC technology that Endo included in reformulated Opana ER to purportedly serve as an abuse-deterrent, that:

> We already demonstrated that ***there was little difference between [Original and Reformulated Opana ER]*** in Study 108 when both products were ground. FDA deemed that there was no difference and this contributed to their statement that we had not shown an incremental benefit. The chewing study (109) showed the same thing ***no real difference*** which the FDA used to claim no incremental benefit.

78. On December 9, 2011, the FDA approved reformulated Opana ER, finding that it was safe and effective for the management of severe pain that requires daily opioid treatment and for which alternative treatments are ineffective. However, consistent with the findings of the reviewers, the FDA denied Endo's request for labeling describing the purported abuse deterrent properties of the reformulated drug, having concluded that the available data were inadequate to support such labeling.

79. Nevertheless, Endo soldiered on with its plan to block generics, while at the same time misleading investors as to the prospects of overcoming the FDA's concerns and obtaining approval for abuse-deterrent language on the product's label.

4. Endo Withdraws Original Opana ER and Seeks an FDA Ruling that Such Withdrawal Was for Safety Reasons

80. Endo began selling reformulated Opana ER in late February 2012. The success of reformulated Opana ER hinged on whether Endo could introduce the product and convert original Opana ER users to the reformulated, patented product before Endo faced significant generic competition.

81. As revealed by the FTC's review of Endo's internal documents in connection with its ongoing administrative proceeding against Impax related to the improper pay-for-delay settlement with Endo over generic original Opana ER (*see In the Matter of Impax Laboratories, Inc.*, Docket No. 9373), launching reformulated Opana ER ahead of generic entry was the "most

important criteria for maximum asset value, as this w[ould] allow Endo to convert from one branded product to another." Endo's internal forecasts further showed that if Endo launched reformulated Opana ER before any generic oxymorphone hydrochloride ER product launched, then Endo's sales of reformulated Opana ER would be expected to remain steady, with FY2016 peak sales for reformulated Opana ER forecasted at more than $199 million annually without generic competition. Conversely, if Endo launched reformulated Opana ER *after* generic oxymorphone hydrochloride ER came to market and generics were not removed, Endo's sales of reformulated Opana ER would be decimated, with 2016 peak sales forecasted at a mere $10 million. Therefore, according to the FTC, if Endo successfully launched reformulated Opana ER before generics and successfully deferred their entry, it could expect to convert virtually the entire Opana ER franchise to its reformulated product, and preclude substitution for generic formulations. Alternatively, if Endo only launched reformulated Opana ER at the same time as the generics, it would only be expected to capture, at most, 30% to 32% of original Opana ER sales.

82. To this end, Endo planned to remove the original formulation of Opana ER from the market and argue that it had removed the product for safety reasons. If successful, this maneuver would prohibit generics versions citing original Opana ER as its RLD from being sold, thereby maintaining Endo's Opana ER monopoly (for the most common doses).

83. On May 31, 2012, Endo notified the FDA that it decided to discontinue original Opana ER "for safety reasons," and on June 14, 2012, the Company issued a press release announcing the completion of its transition from original Opana ER to the reformulated version "designed to be crush-resistant."

a. Endo's Citizen Petition

84. Endo erroneously believed that the FDA would promptly agree, *sua sponte*, that Endo withdrew original Opana ER for safety reasons, and take action to withdraw all previously-approved generics referencing original Opana ER. The FDA, however, remained silent and on August 10, 2012, Endo made a final plea to the FDA to block these generics from coming to market by filing a Citizen Petition formally seeking action from the FDA.

85. Endo's Citizen Petition asserted that original Opana ER was discontinued from sale "for reasons of safety" and replaced by reformulated Opana ER. Specifically, Endo contended that reformulated Opana ER offered "safety advantages" over original Opana ER because it was "resistant to crushing by common methods and tools employed by abusers of prescription opioids . . . [and] is less likely to be chewed or crushed even in situations where there is no intent for abuse. . . ." Reformulated Opana ER, Endo asserted, "reduces the risk of an immediate release of a potentially lethal dose of oxymorphone in these situations." Further, Endo claimed that reformulated Opana ER has "resistance to aqueous extraction (i.e., poor syringeability)." In making these claims, Endo initially relied solely on the data submitted in 2010, in support of the reformulated Opana ER NDA. In its Citizen Petition, Endo requested that the FDA: (i) determine that original Opana ER was discontinued for reasons of safety, such that it could no longer serve as a RLD for any ANDA applicant; (ii) refuse to approve any pending ANDA for a generic version of the original Opana ER approved under NDA No. 021610; and (iii) suspend and withdraw the approval of any ANDA referencing original Opana ER as the RLD.

86. On October 26, 2012, the CDC issued a public health alert on reformulated Opana ER after observing a cluster of TTP-like illnesses associated with patients who had abused reformulated Opana ER by injecting the drug for non-medical reasons. TTP is a serious illness

that leads to blood clotting within the capillaries and has a high fatality rate if not treated. According to the CDC, twelve incidents of TTP-like symptoms following injection of reformulated Opana ER for non-medical reasons had been identified in Tennessee starting in February 2012—when the drug first entered the market.

b. The November 13, 2012 Citizen Petition Supplement—Endo Lies About Reformulated Opana ER Abuse

87. On November 13, 2012, Endo supplemented its Citizen Petition with post-marketing surveillance data concerning the abuse rates of oxymorphone products since the introduction of reformulated Opana ER, which Endo contended demonstrated the safety advantages provided by the reformulation and supported a finding that original Opana ER was withdrawn for safety reasons.

88. This new data came from post-marketing reports Endo received on: (i) February 22, May 18, August 31, and November 2, 2012, from the National Addictions Vigilance Intervention and Prevention Program ("NAVIPPRO"), a national program that Endo helped found in 2005 as the first industry sponsor, which performs surveillance of substance abuse; and (ii) on October 30, 2012, from the Researched Abuse Diversion and Addiction-Related Surveillance System ("RADARS"), which provides surveillance data to meet the needs of pharmaceutical companies, policy makers, regulatory agencies, medical/public health officials, and the public in addressing the concerns of prescription drug abuse. According to Endo, "this important new safety information indicates that the [sic] reformulated Opana ER is having the desired effect on the rates and routes of abuse of the product." Further, Endo claimed that introduction of reformulated Opana ER resulted in "significant reductions" in the proportion of abusers who reported crushing and snorting reformulated Opana ER, compared to original Opana ER.

89. Endo also made comparisons to reformulated OxyContin as support for the Company's contention that reformulated Opana ER provided safety benefits over the original formulation. Specifically, Endo noted that original Opana ER abuse increased after introduction of a crush-resistant formulation of OxyContin in 2010, and that "[t]he introduction of crush-resistant formulation of Opana ER caused a dramatic decrease in the rates of abuse" of original Opana ER, presenting a "significant environmental change."

90. As a result, Endo claimed, "these data suggest that public harm will result with the availability of additional [generic] products approved prior to the introduction of [reformulated] Opana ER."

91. The NAVIPPRO and RADARS reports that Endo submitted were never made public; only Endo's self-serving summary of the data was provided.

92. As alleged in more detail below, the FDA ultimately concluded that, contrary to Endo's assertions, the available data did not support Endo's claims that reformulated Opana ER provided a meaningful safety benefit over original Opana ER in terms of its ability to deter abuse.

c. Desperate, Endo Sues the FDA to Compel a Citizen Petition Decision before Impax's Generic Oxymorphone Would Come to Market

93. On November 30, 2012, Endo filed a lawsuit against the FDA, *Endo Pharm., Inc. v. U.S. FDA et al.*, No. 1:12-cv-01936-RBW (D.D.C.), seeking an injunction and mandamus order requiring the FDA to rule on Endo's Citizen Petition by December 31, 2012—i.e., prior to Impax's generic version of original Opana ER coming to market under the terms of the companies' prior settlement agreement—and revealing its actual motivation for withdrawing original Opana ER. The FDA saw right through Endo's scheme, and responded in court filings that, "***Endo's true interest in expedited FDA consideration stem[s] from business concerns***

rather than protection of the public health" and argued that "Endo's self-inflicted December 31 deadline [was] ***a thinly-veiled attempt to maintain its market-share and block generic competition*** . . . ."

94. The FDA prevailed. On December 19, 2012, the court found that no grounds existed to compel an earlier decision by the FDA on Endo's Citizen Petition and dismissed Endo's lawsuit. As a result, Impax's generic version of original Opana ER came to the market on or about January 1, 2013.

d. Endo Reapplies for Abuse-Deterrent Labeling and Lies about Reformulated Opana ER Abuse

95. Despite this defeat, the Exchange Act Defendants continued to misrepresent and conceal facts concerning reformulated Opana ER's purported safety advantages, abuse-deterrent properties, and prospects. On February 15, 2013, Endo submitted a new sNDA for reformulated Opana ER, asking the FDA for a second time to approve abuse-deterrent language on the drug's label. The sNDA relied on: (i) the same studies upon which Endo previously relied when seeking approval of reformulated Opana ER, the results of which were determined by the FDA to be inadequate to support abuse-deterrent language on the drug's label; and (ii) the same "preliminary" and "inconclusive" post-marketing data Endo submitted in support of its Citizen Petition.

96. Further, the Exchange Act Defendants falsely touted Endo's prospects for winning its Citizen Petition and blocking generic competition, based on post-marketing surveillance data reflecting abuse rates of the drug. For example, in response to a question posed during the Company's fourth quarter and full year 2012 earnings call on February 28, 2013 concerning why the Company was confident that the FDA would remove generic oxymorphone products by granting Endo's Citizen Petition, Defendant Gergel stated, "***we think the***

epidemiological surveillance data that we're getting in is very supportive of what we expect these abuse deterrent formulations should do."

97. Shortly thereafter, at a healthcare analyst conference, Defendant Levin claimed that "there is a very strong real world evidence that says these new formulations of oxymorphone [including reformulated Opana ER] have had a meaningful impact in terms of abuser behavior," that Endo saw "a 59% reduction in abuse from the new formulation of OPANA tamper-resistant versus the classic formulation" and that Endo now had "data for the fourth quarter that would indicate that that percentage is close to 80% on our fourth quarter 2012 to fourth-quarter 2011 comparison or full-year comparison for those 12 quarters." In sum, Defendant Levin stated, "the data seem to demonstrate that we have put a safer version of our formulation out at [sic] the market."

98. As alleged below, the FDA ultimately concluded there was no legitimate basis for these statements by the Exchange Act Defendants—and Endo knew it. Indeed, in an internal document obtained by the NYAG, a consultant to Endo reported to the Company in February 2013, "after reviewing national data from substance abuse treatment facilities, that '***[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant***,' and that there were reports of ***higher levels of abuse of reformulated Opana ER via injection***."

e. The March 21, 2013 Supplement—Endo Continues to Lie About Reformulated Opana ER Abuse

99. On March 21, 2013, Endo filed a second supplement to its Citizen Petition to provide the FDA with additional preliminary, interim analyses of ongoing epidemiological studies. The March 21, 2013 Supplement repeated Endo's earlier claims that the data submitted via the November 13, 2012 Supplement demonstrated that reformulated Opana ER was "***having***

the intended effect on the abuse rates and routes of administration of the product, as reported abuse rates appear to be significantly lower after the introduction of [reformulated] Opana® ER," and compounded this misinformation by claiming that additional analyses demonstrated that "***this trend is continuing***." In making this claim, Endo relied upon new analyses from NAVIPPRO and RADARS, received on February 5 and 10, 2013, respectively. Again, neither of these reports was made public.

100. Endo claimed that these new analyses showed "not only a reduction in abuse through both intended and unintended routes of administration since the introduction of crush-resistant Opana® ER, but also an increase in abuse of non-crush-resistant oxymorphone hydrochloride products on the market since the introduction of Opana® ER CRF [reformulated Opana ER]."

101. Endo claimed that the NAVIPPRO data—comprising an interim descriptive analysis of overall abuse and abuse via specific routes of administration for reformulated Opana ER and comparator opioids—showed that the introduction of reformulated Opana ER "***coincided with significantly lower levels of abuse***" between April 1, 2012 and December 31, 2012, as compared to original Opana ER during the January 1, 2011 through December 31, 2011 time period. Further, Endo claimed that "abuse rates by route of administration" showed that "***the percentage of abuse of [reformulated] Opana® ER [] by nasal insufflation, or snorting, during the time period of the study was 74% lower than previously observed for original formulation Opana® ER***."

102. Contrary to Endo's representations, the FDA ultimately concluded that the post-marketing surveillance data Endo relied upon was inconclusive, of limited duration, and suffered from numerous other flaws (including small sample sizes, likely misclassification of drug

exposure, and possible artificially elevated baseline abuse rates for original Opana ER), such that it was impossible to draw meaningful conclusions therefrom.

f. The FDA Approves Abuse-Deterrent Labeling for Reformulated OxyContin and Grants Purdue's Citizen Petition Finding Original OxyContin Was Withdrawn for Reasons of Safety

103. On April 16, 2013, the FDA approved a sNDA for reformulated OxyContin, approving changes to the product labeling that described certain abuse-deterrent properties of that reformulated product.

104. Two days later, the FDA granted the Citizen Petition submitted by Purdue (maker of OxyContin) seeking a determination that original OxyContin was withdrawn for reasons of safety, in favor of its abuse-deterrent formulation. In granting the OxyContin Citizen Petition, the FDA reviewed and made findings with respect to OxyContin's ability to deter abuse through various routes, including intranasal abuse and intravenous abuse. Specifically, the FDA found:

> The data show that, when compared to original OxyContin, reformulated OxyContin has an increased ability to resist crushing, breaking, and dissolution using a variety of tools and solvents. The data also demonstrate that, when subjected to an aqueous environment, reformulated OxyContin gradually forms a viscous hydrogel. The data also indicate that insufflation of finely crushed reformulated OxyContin was associated with lower "liking" compared to finely crushed original OxyContin in recreational opioid users with a history of intranasal drug abuse. FDA concludes, based on these data and our review of all data and information available to the Agency at this time, that the physicochemical properties of reformulated OxyContin are expected to make abuse via injection difficult and are expected to reduce abuse via the intranasal route. In addition, reformulated OxyContin also may deter certain types of misuse in therapeutic contexts.
>
> ***Additional postmarketing studies*** intended to assess the impact of reformulated OxyContin on abuse and misuse in the community also have been conducted; some of these are still ongoing. FDA has reviewed the available data from these studies and has concluded that they ***suggest, but do not confirm, a reduction in non-oral abuse***.

g. The April 23, 2013 Supplement—Endo Falsely Claims That Reformulated Opana ER is "Virtually Identical" to Reformulated OxyContin

105. On April 23, 2013, Endo supplemented its Citizen Petition a third time, in an attempt to piggyback on the FDA's recent decision regarding the OxyContin Citizen Petition, which determined that original OxyContin was withdrawn for safety reasons in favor of the reformulated (crush-resistant) OxyContin (which the FDA also permitted to have an abuse-deterrent label), by "illustrat[ing] the similarities between Original Opana® ER and Original OxyContin®."

106. Specifically, Endo sought to persuade the FDA that it should grant Endo's Citizen Petition for the same reasons it recently granted a similar petition for Purdue's reformulated OxyContin, by claiming that reformulated Opana ER and reformulated OxyContin "ha[d] virtually identical abuse-deterrent properties," and "similar physicochemical properties" as well.

107. Contrary to Defendants' assertions that the purported similarities between reformulated Opana ER and reformulated OxyContin provided a basis to grant Endo's Citizen Petition, the two drugs had markedly different abuse-deterrent properties and associated safety data. Further, preliminary data from reformulated Opana ER's post-marketing investigations had significant limitations and were not as mature as the OxyContin post-marketing investigations. Moreover, unlike OxyContin, where the original formulation posed an increased risk for abuse by injection and the reformulated version had physiochemical properties expected to make abuse by injection difficult, including that when subjected to an aqueous environment it gradually formed a viscous hydrogel that resisted passage through a needle, the FDA noted in responding to Endo's Citizen Petition, that reformulated Opana ER "can be readily prepared for injection."

108. The FDA later chided Endo's attempt to ride reformulated OxyContin's coattails, stating that its determination about whether a drug was removed for reasons of safety "must be

made on a case-by-case basis" and that, "[a]ccordingly, any attempt by Endo to draw parallels between [reformulated OxyContin] and [reformulated Opana ER] and thereby make assumptions regarding the regulatory implications for Opana ER is misplaced."

h. FDA Denies Endo's Citizen Petition and sNDA for Abuse-Deterrent Labeling

109. On May 10, 2013, the FDA ***denied*** Endo's Citizen Petition and its sNDA requesting abuse-deterrent labeling. In its denial letter, the FDA concluded that there was "insufficient" data to conclude that: (i) original Opana ER has an increased potential for abuse compared to reformulated Opana ER; or (ii) the benefits of original Opana ER no longer outweighed its risks, including in light of the new formulation. Therefore, the FDA could not reach the conclusion that original Opana ER was withdrawn for reasons of safety or effectiveness. In reaching this decision, the FDA relied upon the data Endo submitted in support of its NDA, as well as the post-marketing data Endo submitted through its Citizen Petition and supplements.

110. The FDA also reiterated some of its earlier comments on Endo's NDA data, that it made when approving the drug stating that, "while there [wa]s an increased ability of [reformulated Opana ER] to resist crushing relative to [original Opana ER], data from *in vitro* and pharmacokinetic studies show that [reformulated Opana ER's] extended-release features can be compromised, causing the product to 'dose dump,' when subjected to other forms of manipulation such as cutting, grinding, or chewing, followed by swallowing." The FDA further noted that reformulated Opana ER "can be prepared for insufflation (snorting) using commonly available tools and methods" and "can more easily be prepared for injection than [original Opana ER]," "despite Endo's claims that [reformulated Opana ER] tablets have 'resistance to aqueous extraction (i.e., poor syringeability).'"

111. Regarding the post-marketing data Endo submitted, the FDA found that the data was "preliminary" (as Endo acknowledged) and "inconclusive," as they included, at most, only nine months of data following the introduction of reformulated Opana ER, and suffered from "significant additional deficiencies (including small sample sizes, likely misclassification of drug exposure, and possibly artificially elevated [original Opana ER] baseline abuse rates), such that it [wa]s not possible to draw meaningful conclusions based on them." Further, the FDA stated, "if one were to treat the available data as a reliable indicator of abuse rates despite the data limitations noted [], one of the post-marketing investigations suggests the troubling possibility that a higher (and rising) percentage of [reformulated Opana ER] abuse is occurring via injection than was the case with [original Opana ER]." As the FDA explained, "abuse via injection is highly dangerous, and injection of [reformulated Opana ER] in particular has been associated with a serious thrombotic thrombocytopenic purpura (TTP)-like illness"—an "association" that the FDA's review had not revealed "with any other opioid analgesic."

112. Lastly, based on a lack of evidence, the FDA rejected Endo's claims that reformulated Opana ER and reformulated OxyContin have "virtually identical" abuse-deterrent properties.

113. The price of Endo common stock declined in response to this new information, falling by $1.95 per share (or 5.28%) from its closing price of $36.92 per share on May 9, 2013, to close at $34.97 per share on May 10, 2013. The price of Endo common stock continued to decline by another $1.26 per share (or 3.60%) as the market digested this news, closing at $33.71 per share May 13, 2013.

G. After The Denial Of The Citizen Petition, Endo Falsely Reassures Investors That Reformulated Opana ER Remained Commercially Viable And That It Could Eventually Obtain An Abuse-Deterrent Label

114. No longer able to block generic competition, Endo's only remaining strategy for its Opana ER franchise was to seek to maintain at least some market position for reformulated Opana ER, despite the safety concerns being raised, and to pursue further studies in order to convince investors that Endo would obtain abuse-deterrent labeling from the FDA. All-the-while, Defendants concealed that available data, especially in combination with data submitted in support of the reformulated Opana ER NDA and Endo's Citizen Petition, showed that the drug did not deter abuse, was increasingly abused by injection, and caused a number of serious, life-threatening adverse events related to such abuse. All of the foregoing rendered the drug ***less safe*** than its original formulation, and eventually caused the FDA to require Endo to withdraw the product from the market.

115. For example, following the FDA's denial of Endo's Citizen Petition, and throughout the remainder of 2013, Defendants favorably cited their "***active***" clinical program to "***support a label change***" for reformulated Opana ER, and Defendants' "***improved expectations***" for reformulated Opana ER heading into 2014. By November 2013, Defendants anticipated resubmitting data to the FDA "***later next year with potential outcomes in 2015***."

116. Defendants reiterated this unrealistic outcome several months later, stating in February 2014 that the "clinical program that we are pursuing in conjunction with the dialogue with FDA" would hopefully allow Endo to reapply—a third time—for abuse-deterrent labeling, and that Endo could have "***a stronger label***" ***by 2015***, and once again consider reformulated Opana ER a growth asset. Throughout 2014, Defendants continued to tout their progress on a clinical trial program for reformulated Opana ER ***to support a label change application***, as well as their expectation to file data "by the end of the year or in early 2015."

1. Contemporaneously Available Data from Endo's Clinical Program Predicted a Rise in Intravenous Abuse for the Drug and Contradicted Endo's Statements Concerning Reformulated Opana ER's Abuse-Deterrent Efficacy

117. After the FDA denied its Citizen Petition and sNDA, Endo commenced a clinical program in support of its abuse-deterrent label change application that consisted of Studies 113 and 114.

118. Study 113, completed on January 8, 2014, was a randomized, double-blind ascending dose, placebo-controlled study designed to assess the safety and dose response relationship of intranasal oxymorphone hydrochloride powder (i.e., the original Opana ER) for producing subjective and reinforcing effects (i.e., measurements for abuse propensity), and to determine the dosage to be used in Study 114. Study 113 concluded that reformulated Opana ER 7.5mg was the optimal dosage to study intranasal abuse in Study 114.

119. Study 114, completed on September 4, 2014 to which Endo referred as the "insufflation study," showed that intranasal administration of reformulated Opana ER 7.5mg produced statistically significant reductions in all four subjective measures compared to intranasal administration of the original Opana ER, oxymorphone hydrochloride 7.5mg. These results supported a possible deterrent effect of reformulated Opana ER for intranasal abuse. However, when considered in conjunction with the findings from Endo's Opana ER NDA pharmacology and *in vitro* studies (which showed that reformulated Opana ER could be tampered with and injected)—the potential for reformulated Opana ER to deter intranasal abuse shown in the Study 114 data coincided with a shift abuse from intranasal abuse to abuse by injection.

2. Defendants Misrepresent the Results of the Insufflation Study and Epidemiological Data Required to Obtain an Abuse-Deterrent Label Change

120. Immediately after the insufflation study concluded, Defendants made material misrepresentations and omitted material facts concerning the results of the study. Despite key differences between reformulated Opana ER and reformulated OxyContin, Defendant De Silva boasted, "***I can tell you that, based on our initial review of the data, we expect it to support our hypothesis that the product is similar to OxyContin in terms of its abuse deterrent potential***." Defendants' statements, which were designed to reassure investors regarding the future commercial prospects for reformulated Opana ER, were materially misleading because they concealed that other data demonstrated that reformulated Opana ER did not deter abuse and, in conjunction with Endo's pharmacology and *in vitro* NDA studies, indicated a shift in the route of abuse of reformulated Opana ER from intranasal abuse to abuse by injection. Further, Defendants misrepresented the similarities between reformulated Opana ER and reformulated OxyContin in terms of their ability to deter abuse.

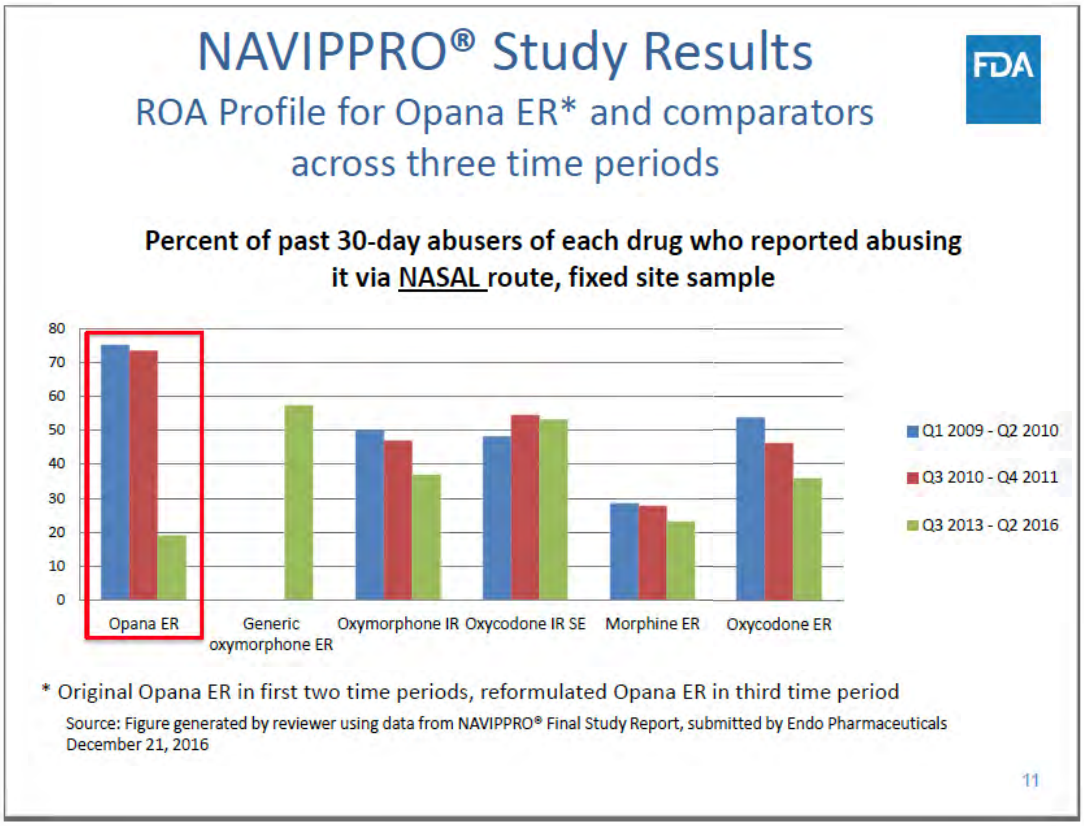
121. Defendants also misrepresented Endo's prospects for obtaining abuse-deterrent labeling for reformulated Opana ER, in light of the mounting epidemiological data, to which Endo had access, which showed an increase in IV abuse with reformulated Opana ER.

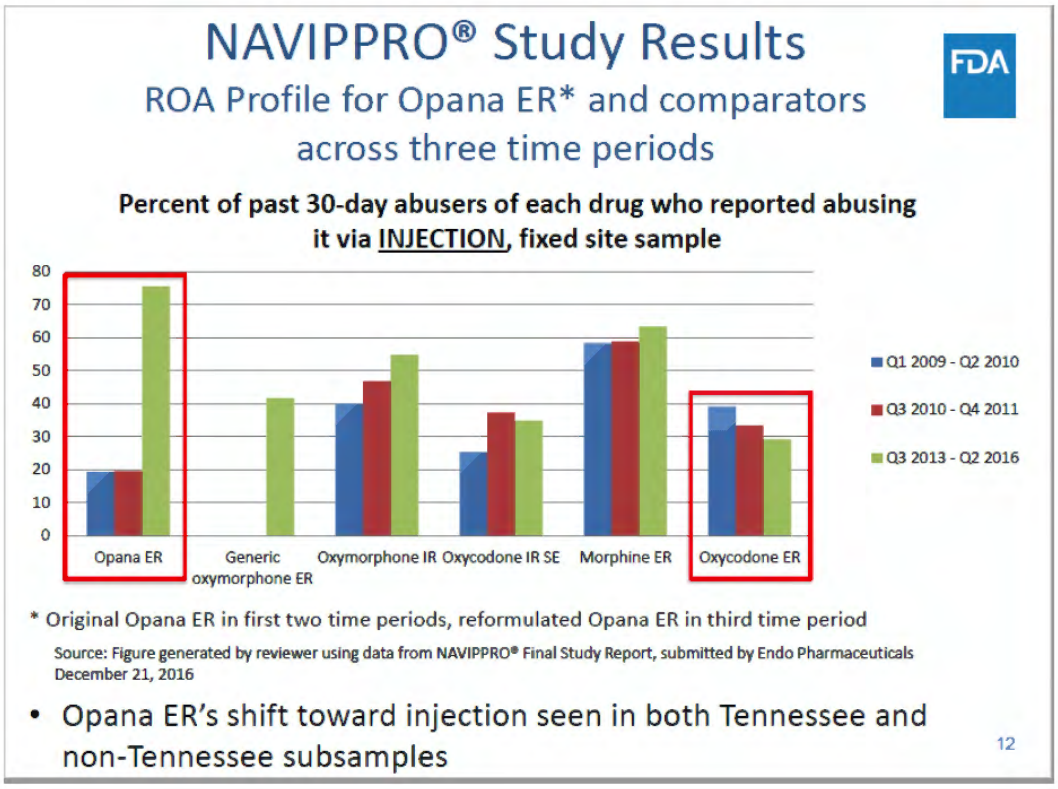
3. Material Adverse Trends in Reformulated Opana ER Abuse Observed in Endo's Ongoing Epidemiological Studies Did Not Support An Abuse-Deterrent Label Claim And Demonstrated That Reformulated Opana ER Was Affirmatively Unsafe

122. Post-marketing epidemiological data collected, used and analyzed for reformulated Opana ER showed material adverse trends in reformulated Opana ER abuse, including: (i) a shift from intranasal abuse (most commonly observed for original Opana ER) to intravenous abuse, since introduction of reformulated Opana ER; (ii) an increase in the rate of

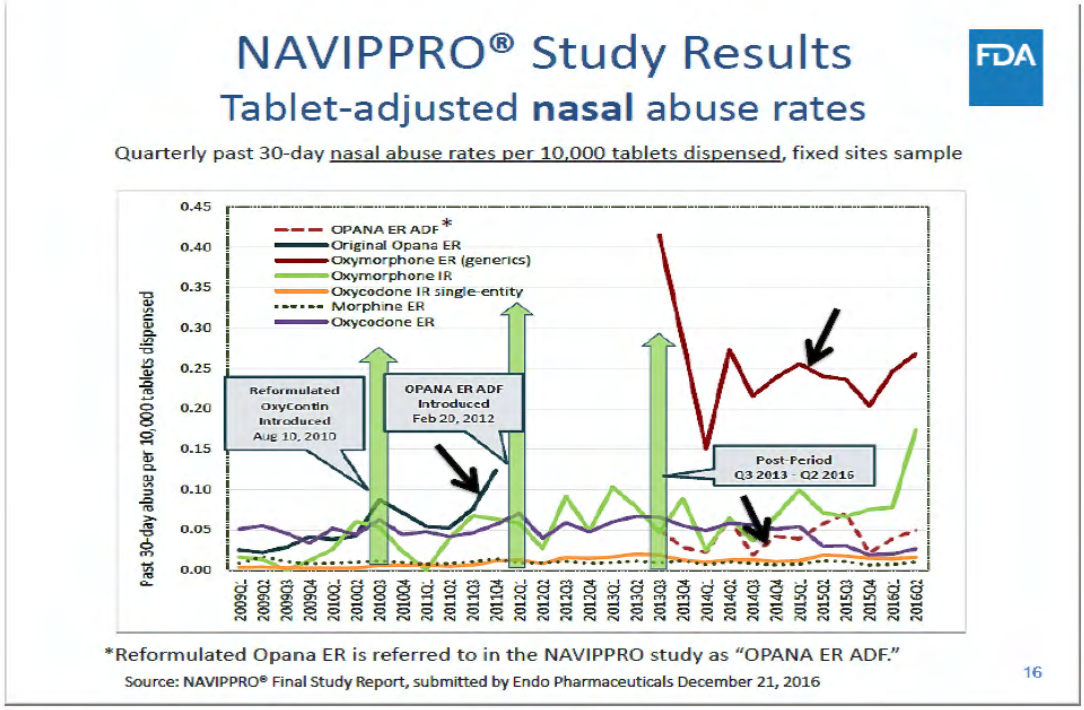
intravenous abuse; and (iii) an increase in serious adverse events associated with reformulated Opana ER injection abuse, including TMA and TTP.

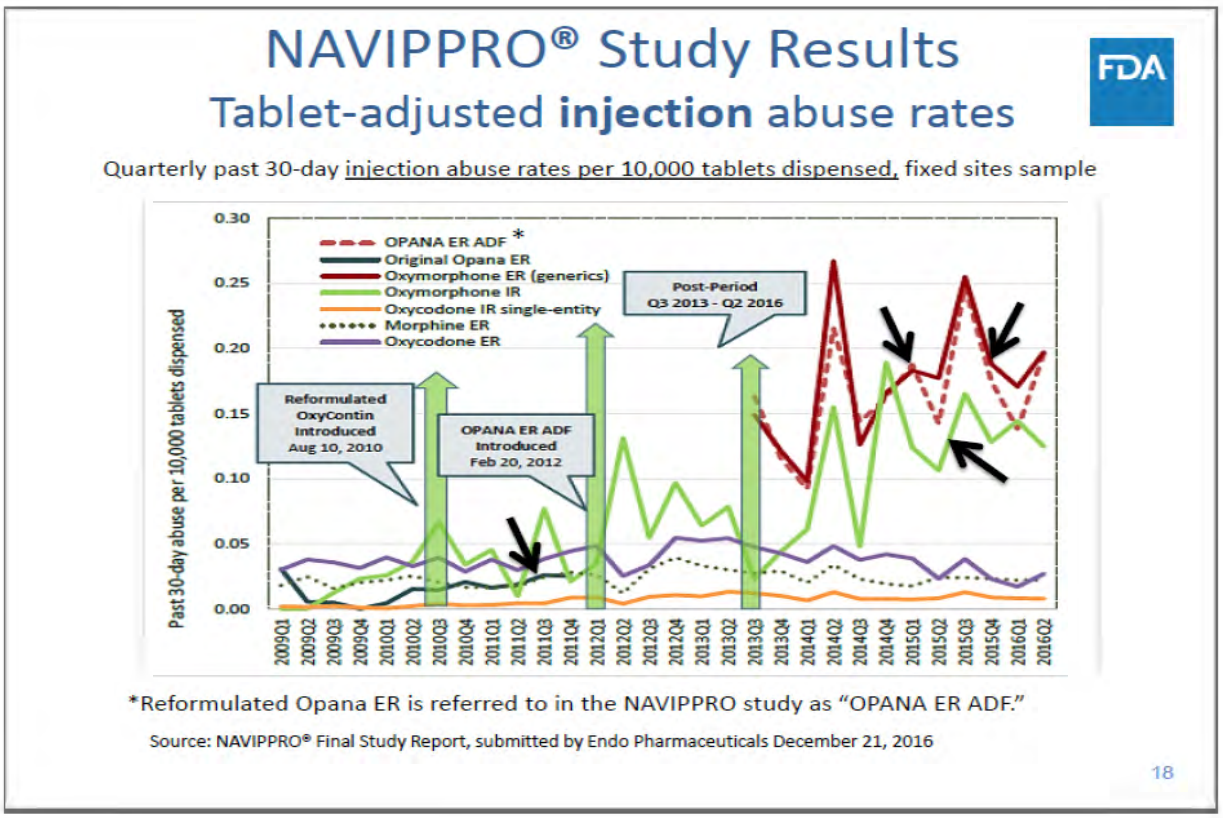
123. For example, NAVIPPRO data, which Endo used and analyzed, showed a significant shift in the route of abuse for reformulated Opana ER, from intranasal abuse to intravenous abuse, following introduction of the reformulation and further showed that this shift occurred beginning, at the latest, in the third quarter of 2013, immediately after the FDA rejected Endo's Citizen Petition:





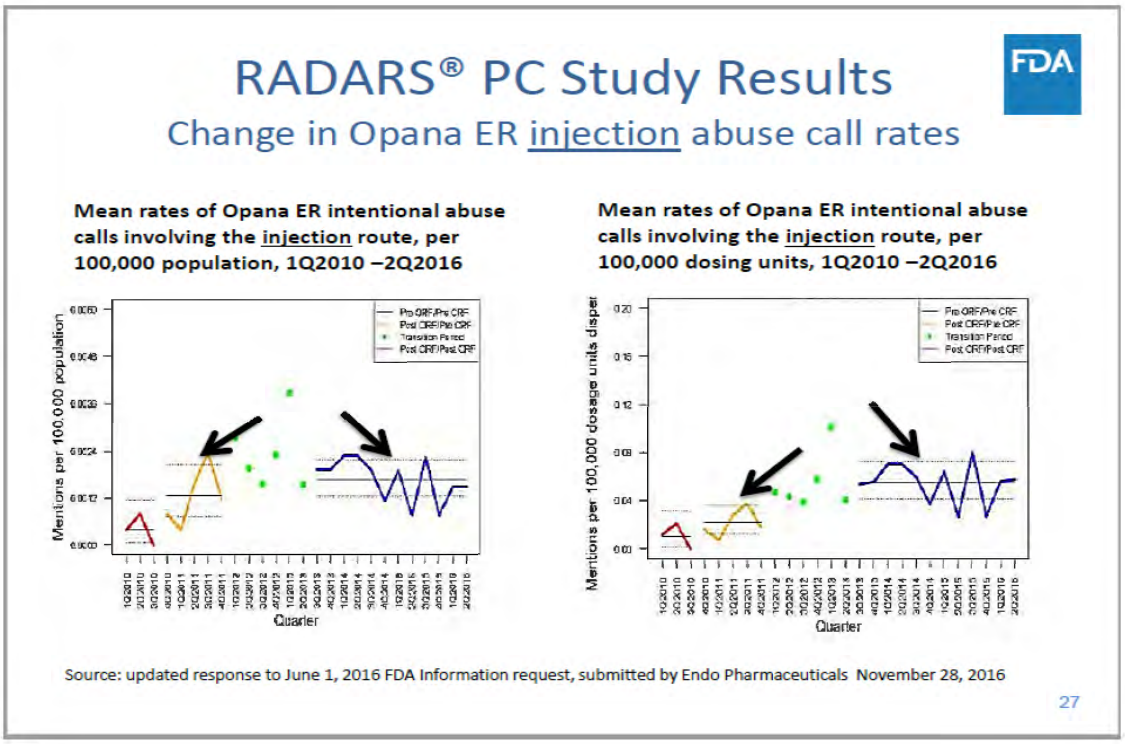
124. The NAVIPPRO data, which Endo used and analyzed, also showed a decline in nasal abuse prevalence for reformulated Opana ER, following introduction of the reformulation, but an enormous increase in intravenous abuse beginning in 2013:





125. This data clearly showed that, after the introduction of reformulated Opana ER, there was an obvious shift among abusers of the drug, from snorting to much more dangerous IV abuse, beginning in 2013. In particular, this data showed that, as compared to original Opana ER, injection abuse rates for reformulated Opana ER were nearly five times higher than rates for intranasal abuse.

126. Data from RADARS, which Endo used and analyzed, likewise showed a marked increase in reformulated Opana ER abuse via injection following the introduction of the reformulated product:



127. Based upon RADARS data, the FDA concluded that, following Opana ER's reformulation:

- There was a shift in reformulated Opana ER abuse calls from inhalation/nasal abuse calls, to injection abuse calls;
- Utilization-adjusted reformulated Opana ER injection abuse call rates (i.e., the number of abuse cases for a given amount of drug dispensed from pharmacies within the study coverage area) increased significantly; and
- Utilization-adjusted reformulated Opana ER abuse call rates were higher than other opioids analyzed.

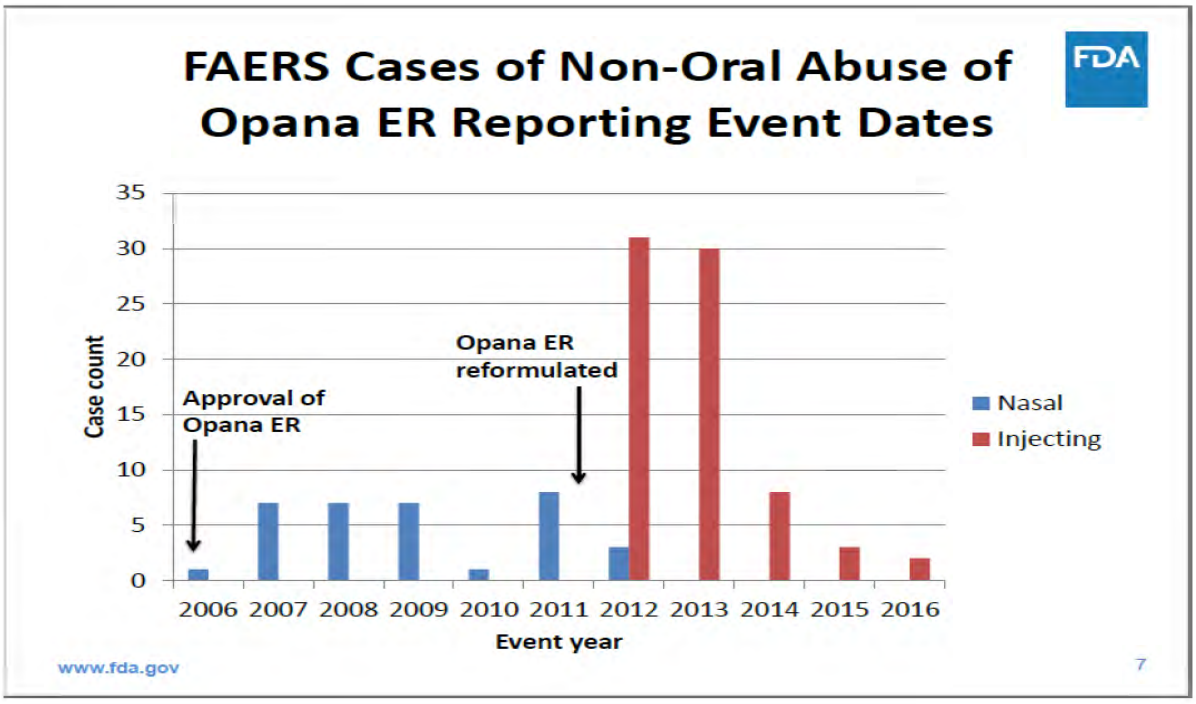
128. Notwithstanding the data from these ongoing studies, in May 2015, Defendants highlighted that Endo would meet with the FDA in June 2015 to review the Company's data to date. At this time, Endo claimed that, while the timing of its sNDA submission would depend on how much epidemiological data was required, the Defendants believed Endo already had "***sufficient and robust enough data***" to support an abuse-deterrent labeling decision. Following Endo's meeting with the FDA, in August 2015, Defendant De Silva touted "***the momentum we***

have generated with the FDA," boasting that "***we left that meeting with more optimism than before***" and that Endo "***now expect[ed] to submit a supplemental request for labeling that will potentially add abuse deterrent formulation claims***."

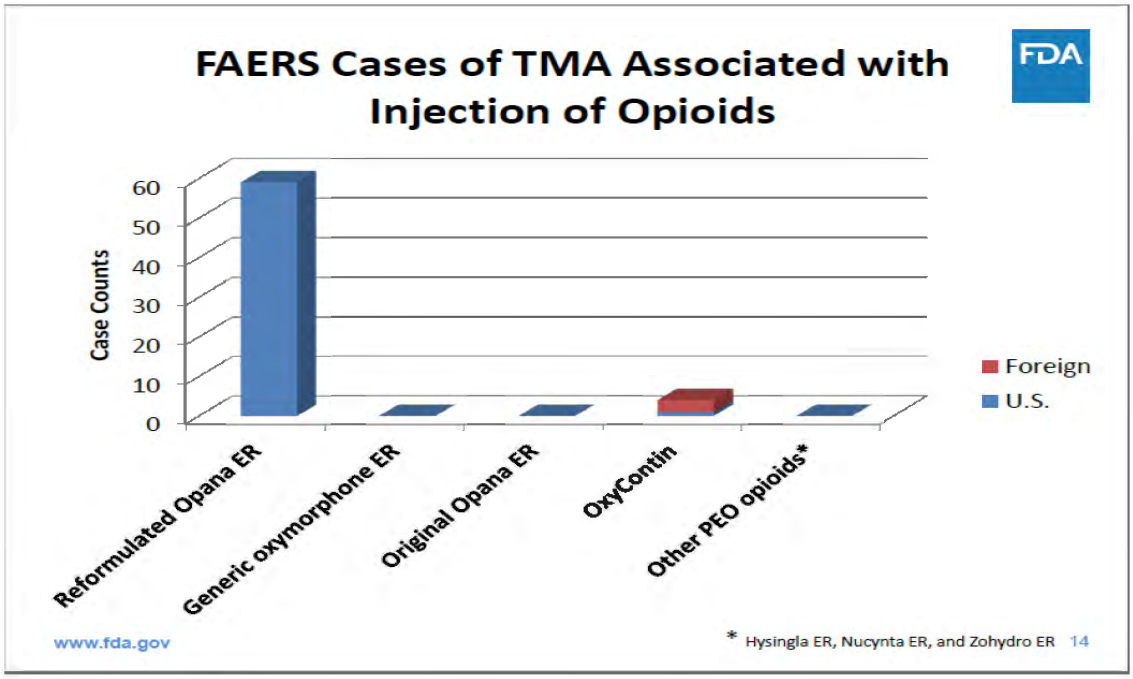
129. In addition, Defendants falsely claimed that the final results of Endo's insufflation study were "***positive as we would've expected, because it's basically the same kind of construct that OxyContin had***," when in fact, there were material differences between reformulated Opana ER and reformulated OxyContin, and data from the insufflation study demonstrated that reformulated Opana ER did not show improved resistance to abuse by crushing and snorting.

4. Data Reported to the FAERS System Demonstrated a Rise in Abuse of Reformulated Opana ER by Injection and Associated Events of TMA—Raising Substantial Questions about the Commercial Viability of the Drug

130. Data reported to the FDA's Adverse Event Report System ("FAERS") database also demonstrated a significant rise in the rate of abuse after the introduction of reformulated Opana ER to the market, as reflected in the following chart:



131. FAERS data also revealed fifty-nine cases of TMA associated with reformulated Opana ER use between December 2011 and June 2016. This serious adverse effect was unique to intravenous abuse of reformulated Opana ER:



5. Reformulated Opana ER Leads to HIV Outbreak in Indiana

132. On April 24, 2015, the CDC issued a public health alert announcing its investigation into a cluster of HIV-infections reported in Indiana associated with individuals who abused reformulated Opana ER intravenously. The CDC Alert stated that:

> From November 2014 to January 2015, ISDH [Indiana State Department of Health] identified 11 new HIV infections in a rural southeastern county where fewer than 5 infections have been identified annually in the past. As of April 21, 2015, an on-going investigation by ISDH with assistance from CDC has identified 135 persons with newly diagnosed HIV infections in a community of 4,200 people; 84% were also HCV infected. Among 112 persons interviewed thus far, 108 (96%) injected drugs; all reported dissolving and injecting tablets of the prescription-type opioid oxymorphone (OPANA® ER) using shared drug preparation and injection equipment.

6. Despite Substantial Information Available to it Regarding the Safety Issues Presented by Reformulated Opana ER, Endo Re-submits its Abuse-Deterrent Label sNDA, Reassuring Investors About the Future of the Drug

133. Despite the accumulated pre-approval and post-marketing study results and data, alleged herein, including Endo's NDA studies, and existing NAVIPPRO, RADARS and FAERS data, on January 29, 2016, Endo re-submitted its sNDA requesting a label change to identify reformulated Opana ER's purported intranasal abuse-deterrent properties and a description of studies supporting the same (as alleged above at ¶ 109, in 2013 FDA declined to approve Endo's sNDA following its original submission in 2012). To support its 2016 sNDA, Endo relied on data from: (i) its insufflation study; and (ii) the ongoing post-marketing epidemiological studies based upon the NAVIPPRO and RADARS data. Thereafter, Defendants continued to misrepresent and omit material facts regarding the prospects of obtaining abuse-deterrent labeling for reformulated Opana ER based on its submission.

134. On June 16, 2016, the FDA announced that it would convene an Advisory Committee in the fall of 2016, to review Endo's data and to obtain input on the patterns of abuse and reports of serious illness associated with intravenous abuse of reformulated Opana ER in connection with Endo's application for abuse-deterrent labeling.

135. Just two months later, however, on August 12, 2016, Endo announced the sudden withdrawal of its sNDA "based on an August 11, 2016 discussion" with the FDA, but continued to misled investors about reformulated Opana ER's prospects, stating that the Company would continue to collect data.

136. As the FDA subsequently revealed (on March 9, 2017), based on preliminary analyses of the data Endo submitted in support of its January 29, 2016 sNDA, the FDA was concerned that some of these data suggested that reformulated Opana ER may be less safe than

original Opana ER. As a result, the FDA requested, and Endo agreed to participate in, an FDA Advisory Committee meeting to publicly discuss the abuse-related safety concerns surrounding reformulated Opana ER, following submission and FDA review of an additional year of post-marketing data.

H. The Truth About Reformulated Opana ER's Safety, Attributes, And Sustainability Continues to Emerge Through A Number Of 2017 Disclosures From The FDA

137. On January 10, 2017, the FDA announced that a Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee (the "Advisory Committee") would be held to discuss pre- and post-marketing data concerning the abuse of reformulated Opana ER, the overall risk-benefit of the product, and abuse of generic versions of the opioid (the "January 2017 FDA Notice").

138. In an official statement issued the next day, the FDA provided additional detail regarding the Advisory Committee meeting. The FDA stated that the Advisory Committee would hold a Joint Meeting to discuss: (i) "safety issues for [reformulated Opana ER]"; (ii) "pre- and post-marketing data about the abuse of Opana ER, and the overall risk-benefit of this product"; and (iii) "abuse of generic oxymorphone ER and oxymorphone immediate-release (IR) products."

139. The price of Endo common stock declined in response to this information, falling by $1.10 per share (or 6.70%) from its January 9, 2017 closing price of $16.41 per share, to close at $15.31 per share on January 10, 2017. Endo's share price continued to decline by another $1.30 per share (or 8.49%), to close at $14.01 per share on January 11, 2017.

140. Defendants, as part of their scheme to protect reformulated Opana ER, downplayed the importance of the Advisory Committee meeting. For example, when asked during Endo's February 28, 2017 earnings call for his thoughts on the upcoming panel on

reformulated Opana ER, including: (i) what he thought the FDA's "end game" was; (ii) what his "level of concern" was; and (iii) whether analysts should "be concerned about a potential, that the product is removed from the market," Defendant Campanelli noted that the Advisory Committee meeting was to discuss "all oxymorphone products. So it's not just OPANA ER," and stated that "our studies to date support the safety and efficacy for the intended use of OPANA."

141. On March 9, 2017, the FDA published its briefing documents in advance of the Advisory Committee meeting, which included the FDA's preliminary views on the safety and abuse-deterrent properties of reformulated Opana ER, to be discussed by the Advisory Committee. Among other things, the briefing document reflected the FDA's concern that Endo's post-marketing abuse data presented a "compelling" case that "the reformulation caused a shift in non-oral routes from predominately nasal to predominately injection," particularly in light of the number of reports of TMA and TTP associated with reformulated Opana ER.

142. The FDA observed that the results of Endo's insufflation study, "coupled with results from [its NDA] physical manipulation and extraction studies [i.e., Studies 108 and 109], as well as the pharmacological properties of oxymorphone, provide support for the abuse of OPANA ER . . . through the intranasal (IN) and intravenous (IV) routes, as observed in epidemiological studies."

143. The FDA also found that Endo's ongoing epidemiological studies, specifically the NAVIPPRO studies, showed that: (i) "overall abuse of Opana ER was significantly higher in the post period [after reformulation] compared to that of original Opana ER in the pre period [before reformulation]"; and (ii) "there was a significant increase in injection from the pre to the post period." The FDA further noted that epidemiological data indicate that: (i) reformulated Opana

ER is "commonly abused by non-oral routes[,]" including through insufflation and also was "commonly abused by injection"; (ii) "intravenous injection is an important route of abuse for reformulated OPANA ER"; and (iii) "the difficulties associated with abuse of OPANA ER by oral administration and insufflation . . . may contribute to a higher proportion of individuals abusing reformulated OPANA ER by injection than the other routes."

144. Similarly, the FDA observed that the FAERS reports demonstrated that "[n]asal abuse was primarily reported before reformulation and intravenous abuse was primarily reported after reformulation" and concluded that "[t]hese findings are qualitatively consistent with a shift from nasal to intravenous abuse of Opana ER following its reformulation."

145. In response to this news, the price of Endo common stock fell by $0.27 per share (or 2.5%) from its closing price of $10.80 per share on March 8, 2017, to close at $10.53 per share on March 9, 2017.

146. On March 14, 2017, following the two-day FDA Advisory Committee meeting convened to discuss reformulated Opana ER, committee members voted, 18-8, with one abstention, that the benefits of reformulated Opana ER did not outweigh its risks, with a number of committee members recommending that the drug be removed from the market.

147. Analysts promptly issued reports noting the uncertainty regarding reformulated Opana ER's prospects following the Advisory Committee meeting. For example, in a March 15, 2017 report, RBC analysts noted that "FDA AdCom on OPANA ER adds uncertainty," while analysts from Susquehanna Financial Group similarly stated in a March 15, 2017 report that "a surprise vote against the risk/benefit profile of Opana ER adds an unhelpful question mark for ENDP's 2018 earnings." In a March 15, 2017 report, Morgan Stanley commented that the FDA's vote "could lead to regulatory restrictions or, in a worst-case scenario, withdrawal from

the market," but that "it is unclear if FDA will demand product withdrawal." This Morgan Stanley report further stated that, "it was made clear during voting that a vote against branded Opana ER was not necessarily a vote for withdrawal, so it is unclear if FDA will take action to have it withdrawn from the market."

148. In response to this information, the price of Endo common stock declined by $0.45 per share (or 4.22%), from its closing price of $10.67 per share on March 13, 2017, to close at $10.22 per share on March 14, 2017.

149. On June 8, 2017, after the close of market, the full truth concerning reformulated Opana ER's safety, attributes, and sustainability was laid bare, when the FDA announced that it had asked Endo to voluntarily withdraw reformulated Opana ER from the market. Specifically, the FDA stated:

> Today, the U.S. Food and Drug Administration requested that Endo Pharmaceuticals remove its opioid pain medication, reformulated Opana ER (oxymorphone hydrochloride), from the market. After careful consideration, the agency is seeking removal based on its concern that the benefits of the drug may no longer outweigh its risks. This is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse.
>
> "We are facing an opioid epidemic – a public health crisis, and we must take all necessary steps to reduce the scope of opioid misuse and abuse," said FDA Commissioner Scott Gottlieb, M.D. "We will continue to take regulatory steps when we see situations where an opioid product's risks outweigh its benefits, not only for its intended patient population but also in regard to its potential for misuse and abuse."
>
> The FDA's decision is based on a review of all available postmarketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation. Injection abuse of reformulated Opana ER has been associated with a serious outbreak of HIV and hepatitis C, as well as cases of a serious blood disorder (thrombotic microangiopathy). This decision follows a March 2017 FDA advisory committee meeting where a group of independent experts voted 18-8 that the benefits of reformulated Opana ER no longer outweigh its risks.

> Opana ER was first approved in 2006 for the management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. In 2012, Endo replaced the original formulation of Opana ER with a new formulation intended to make the drug resistant to physical and chemical manipulation for abuse by snorting or injecting. While the product met the regulatory standards for approval, the FDA determined that the data did not show that the reformulation could be expected to meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for Opana ER. ***Now, with more information about the risks of the reformulated product, the agency is taking steps to remove the reformulated Opana ER from the market.***
>
> "The abuse and manipulation of reformulated Opana ER by injection has resulted in a serious disease outbreak. When we determined that the product had dangerous unintended consequences, we made a decision to request its withdrawal from the market," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "This action will protect the public from further potential for misuse and abuse of this product."
>
> The FDA has requested that the company voluntarily remove reformulated Opana ER from the market. Should the company choose not to remove the product, the agency intends to take steps to formally require its removal by withdrawing approval. In the interim, the FDA is making health care professionals and others aware of the particularly serious risks associated with the abuse of this product.

150. In response to this news, the price of Endo common stock declined by $2.29 per share (or 16.62%), from its closing price of $13.78 per share on June 8, 2017, to close at $11.49 per share on June 9, 2017.

151. Due to pressure by the FDA, on July 6, 2017, Endo announced that it decided to remove reformulated Opana ER from the market.

V. DEFENDANTS' PRE-CLASS PERIOD MISSTATEMENTS AND OMISSIONS

152. Even prior to the start of the Class Period, Defendants misrepresented and omitted material facts regarding the safety, attributes, and sustainability of reformulated Opana ER, including its purported "crush-resistant" and "abuse-deterrent" properties, the prospects of FDA-labeling concerning the same, and the prospects of generic formulations of original Opana ER impacting Endo's market share.

153. For example, in its Citizen Petition to the FDA dated August 10, 2012 (made public on September 11, 2012), Endo stated the following in support of its claim that it withdrew original Opana ER for "safety reasons":

> Opana® ER CRF offers resistance to crushing, which can deter abuse where recreational and experienced abusers attempt to crush the tablets for ingestion or further manipulation. The tablets also offer resistance in situations of misuse – for example, where patients or healthcare providers attempt to crush tablets to facilitate swallowing or gastric tube administration, where patients intentionally or unintentionally attempt to chew the tablets to facilitate swallowing or where children unintentionally chew the tablets prior to accidental ingestion.
>
> * * *
>
> Because ***Opana® ER presents a greater risk of abuse, misuse and diversion than Opana® ER CRF***, Endo discontinued Opana® ER from sale for safety reasons within the meaning of FDC Act § 505(j)(7)(C) and 21 C.F.R. § 314.161.
>
> ***Opana® ER CRF provides safety advantages over Opana ® ER***. It is resistant to crushing by common methods and tools employed by abusers of prescription opioids. The presence of both Opana® ER CRF and generic, non-crush-resistant oxymorphone formulations on the market simultaneously would allow abuse or diversion to continue, limiting the potential benefits that can be provided by Opana ® ER CRF. Furthermore, Opana ER CRF is less likely to be chewed or crushed even in situations where there is no intent for abuse, such as where patients inadvertently chew the tablets, or where caregivers attempt to crush the tablets for easier administration with food or by gastric tubes, or where children accidentally gain access to the tablets. The new formulation reduces the risk of an immediate release of a potentially lethal dose of oxymorphone in these situations.
>
> * * *
>
> ***Opana® ER CRF provides safety advantages over Opana® ER based on the in vitro and bioavailability data and studies involving experienced opioid abusers provided by Endo to FDA***. The sudden and dramatic increase in abuse and overdose of non-crush-resistant oxymorphone formulations following the introduction of a tamper-resistant formulation of OxyContin also demonstrate that these formulations are less safe than Opana® ER CRF.

154. On November 13, 2012, Endo supplemented its Citizen Petition with data from post-marketing surveillance reports that Endo claimed indicated that reformulated Opana ER was "having the desired effect on the rates and routes of abuse of the product" and showed

"significant reductions" in the reported rates of abuse and proportion of abusers who reported crushing and snorting reformulated Opana ER, compared to the original formulation.

155. Contrary to Defendants' representations, the post-marketing surveillance data Endo relied on did not support its claim that introduction of reformulated Opana ER was having the intended effect on the abuse rates and routes of administration of the product, and did not show that reformulated Opana ER was deterring abuse. Specifically, the data was of limited duration, and suffered from numerous other flaws (including small sample sizes, likely misclassification of drug exposure, and possible artificially elevated baseline abuse rates for original Opana ER), making it impossible to draw meaningful conclusions therefrom. Moreover, even if one accepted the data as a reliable indicator of abuse rates, one of the post-marketing studies showed a potentially higher percentage of reformulated Opana ER abuse via injection, and a significant number of incidences of TMA, TTP, and other serious adverse events associated with this form of abuse, which information Defendants concealed from the public. As such, the data did not support Endo's claim that reformulated Opana ER provided safety benefits compared to the original formulation.

VI. THE EXCHANGE ACT DEFENDANTS' FALSE OR MISLEADING STATEMENTS DURING THE CLASS PERIOD

156. During the Class Period, the Exchange Act Defendants misrepresented and omitted material facts regarding the safety, attributes, and sustainability of reformulated Opana ER, including: (i) its safety advantages over original Opana ER due to its purported "crush-resistant" and abuse-deterrent properties; and (ii) the Company's prospects for obtaining data sufficient to demonstrate reformulated Opana ER's abuse-deterrent effects (in support of an abuse-deterrent label), including based on post-marketing studies. Contrary to the Exchange Act Defendants' representations, reformulated Opana ER was actually ***less safe*** than the original

formulation. In fact, the very properties that purportedly rendered the drug abuse-deterrent were driving a shift in the route of abuse compared to original Opana ER, from intranasal abuse to intravenous abuse, resulting in a number of serious health problems, including TMA and TTP.

A. The Exchange Act Defendants' Misrepresentations and Omissions in 2012 and 2013

157. The Class Period begins on November 30, 2012, when, after receiving no response from the FDA to its Citizen Petition, Endo filed a lawsuit against the FDA seeking an injunction and a mandamus order "requiring FDA to determine forthwith and without further delay and, in any event, by no later than December 31, 2012, whether Endo withdrew Original Formulation Opana® ER for safety reasons"—i.e., before Impax's generic version of original Opana ER would come on the market under the terms of the companies' prior settlement agreement. In a November 30, 2012 press release announcing the lawsuit, Endo claimed that the surveillance data submitted in support of Endo's Citizen Petition "***show [a] dramatic decrease in abuse rates of reformulated OPANA® ER designed to be crush-resistant when compared to non-tamper resistant formulation***." Elaborating further on the data, Endo stated that:

> Endo reformulated OPANA ER to a version ***designed to be crush-resistant*** and launched this reformulated version in March 2012. ***Current data monitoring abuse rates show a substantial decrease in abuse since the launch of the reformulated product***, while simultaneously showing a more than 122 percent increase in abuse rates of the 7.5mg and 15mg non-tamper resistant extended release oxymorphone HCl.
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> * * *
>
> Since its launch, Endo has collected surveillance data on the rates of abuse of oxymorphone HCl from two national programs - the first includes surveillance of substance abusers and the second collects data from U.S. Poison Control Centers. ***The data show a 59 percent drop in abuse rates of the reformulated OPANA ER which is designed to be crush-resistant***. The same data demonstrate a 122 percent increase in abuse rates of non-tamper resistant extended-release oxymorphone HCl.

158. Based on this data, Defendant Holveck represented in the November 30, 2012 press release that, "[s]ufficient evidence exists to support the determination that the old formulation of OPANA ER was discontinued for reasons of safety."

159. Endo repeated these statements in a Form 8-K filed with the SEC on December 3, 2012, to which the Company attached a copy of the November 30, 2012 press release.

160. The statements alleged above in ¶¶ 157-59 characterizing reformulated Opana ER as tamper-resistant, because it was "designed to be crush-resistant," and touting post-marketing surveillance data as demonstrating "a substantial decrease in abuse since the launch of the reformulated product," were materially false or misleading at the time the time they were made because Defendants knew or recklessly disregarded that the very properties that purportedly rendered the drug crush-resistant actually made it ***less safe***, as reformulated Opana ER could be abused by injection, and the post-marketing data demonstrated that it was *increasingly* being abused by injection, and that the safety risks associated with reformulated Opana ER abuse were so severe that they would require the drug's withdrawal. In particular:

- Studies conducted in 2009 and 2010 showed that reformulated Opana ER was not "crush-resistant" or tamper-resistant, but rather could be manipulated through crushing, grinding, chewing, snorting and injection, and had the potential to shift the route of abuse to the most dangerous method—intravenous abuse (*see* ¶¶ 67-69 and 71-73);

- Post-marketing surveillance data submitted in support of Endo's Citizen Petition was inconclusive, of limited duration, and suffered from numerous other flaws (including small sample sizes, likely misclassification of drug exposure, and possible artificially elevated baseline abuse rates for original Opana ER), making it impossible to draw meaningful conclusions therefrom. As such, it did not support the conclusion that reformulated Opana ER resulted in a decrease in abuse rates compared to original Opana ER. Therefore, generic versions of original Opana ER were no more likely to lead to abuse and misuse than reformulated Opana ER (*see* ¶¶ 87-92, 98-99, 102, 109-12); and

- Post-marketing data submitted in support of Endo's Citizen Petition indicated an increasing percentage of reformulated Opana ER abuse due to injection, compared to original Opana ER (*see* ¶¶ 110-11).

161. On December 11, 2012, Endo announced that its subsidiary, "Endo Health Solutions Launche[d] 7.5mg and 15mg Strengths of Reformulated, ***Designed to be Crush-Resistant, OPANA® ER***." In the press release, Defendants stated:

> As Endo reported in November, ***surveillance data collected by national independent sources through the third quarter of 2012 suggest that the introduction of reformulated OPANA ER designed to be crush-resistant in February reduced abuse rates of the product when compared to the non-crush-resistant version that Endo discontinued in May***. Additionally, rates of abuse for the non-crush-resistant 7.5mg and 15mg oxymorphone HCl tablets marketed by Actavis appear to have increased more than 122 percent since Endo launched its reformulated OPANA ER version.

162. The statements alleged above in ¶ 161 characterizing reformulated Opana ER as tamper-resistant, because it was "designed to be crush-resistant," and touting post-marketing data as demonstrating "reduced abuse rates," were materially false or misleading for the reasons alleged above at ¶ 160.

163. On January 3, 2013, following the District Court's dismissal of Endo's lawsuit against the FDA for an expedited decision on the Company's Citizen Petition, Endo issued a press release, stating, "[c]onsistent with its Citizens Petition, the company continues to believe ***that sufficient evidence exists to support a determination by FDA that the old formulation of OPANA® ER was discontinued for reasons of safety***, which serves the public health."

164. Endo repeated these statements in a Form 8-K filed with the SEC the next day, to which the Company attached a copy of the January 3, 2013 press release.

165. The statements alleged above in ¶¶ 163-64 touting reformulated Opana ER post-marketing safety data as "sufficient evidence" that reformulated Opana ER was safer than original Opana ER were materially false or misleading for the reasons alleged above at ¶ 160.

166. On January 7, 2013, Endo participated in the J.P. Morgan Healthcare Conference. In a Form 8-K filed with the SEC that day, Endo attached the slides to be presented. The presentation slides asserted that Endo "continue[s] to believe that ***surveillance data supports removal of old formulation brand and generics from market for reasons of safety***."

167. The statements alleged above in ¶ 166 touting reformulated Opana ER post-marketing safety data as supporting the conclusion that reformulated Opana ER was safer than original Opana ER were materially false or misleading for the reasons alleged above at ¶ 160.

168. On February 28, 2013, Endo issued a press release announcing its fourth quarter 2012 financial results and its 2013 financial guidance, and filed a Form 8-K with the SEC that same day, attaching a copy of the press release. In the press release and Form 8-K, Defendants stated:

> As captured in our amended Citizen's Petition in Nov 2012, Endo submitted emerging safety data that demonstrate that ***the introduction in the first quarter of 2012 of the reformulated OPANA ER designed to be crush-resistant, is reducing rates of abuse***. ***Comparisons of abuse rates for OPANA ER, from the third quarter of 2011 through the third quarter of 2012, demonstrate that the reported rate of abuse of the reformulated OPANA ER was reduced by 59 percent, based on the total number of prescriptions dispensed, versus the rate observed for the non-crush-resistant formulation of OPANA ER, which is no longer being manufactured by the company***.
>
> * * *
>
> The company further assumes no generic competition thereafter due to the anticipated outcome of an FDA decision in late May 2013 that could remove generic formulations of extended release oxymorphone from the market. Consistent with its Citizens Petition, the company continues to believe that ***sufficient evidence exists to support a determination by FDA that the old formulation of OPANA® ER was discontinued for reasons of safety***, which serves the public health.

169. The statements alleged above in ¶ 168 touting post-marketing data as demonstrating "reduc[ed] rates of abuse" for reformulated Opana ER, and as supporting the

conclusion that reformulated Opana ER was safer than original Opana ER, were materially false or misleading for the reasons alleged above at ¶ 160.

170. On February 28, 2013, Endo also held its quarterly earnings call with analysts. During the call, Defendants reiterated their expectations of no generic competition after the first six months of 2013, based on their assumption that Endo would succeed on its Citizen Petition. Commenting on the Company's "growth drivers" for 2013, Defendant McHugh stated that, "***we have an additional quarter of surveillance data that indicates our abuse deterrent formulation of Opana ER is abused or misused at a rate that is 80% lower than the generic versions of extended release oxymorphone that were on the market in 2012***."

171. During the question and answer portion of the call, when asked "[w]hat makes the company confident that the FDA will remove the non-abuse deterrent Oxymorphone products in May," Defendant Gergel stated, "***We think the epidemiological surveillance data that we're getting in is very supportive of what we expect these abuse deterrent formulations should do i[n] supporting our original contention in this regard***."

172. In another exchange with the same analyst regarding whether Endo "ha[d] a sense of how much data they [the FDA] [would] need before they would be willing to change that label to get comfortable with the abuse deterrent property," Defendant Gergel responded:

> I think, obviously the data is coming in. ***It's all going in the right direction. It's saying what we expected it would say and it's pretty consistent, not just for our product***, but also for Oxycontin, so and I don't think it's a surprise there, ***intuitively one would expect these abuse deterrent formulations to lower rates of abuse and that's what we're seeing***. From our perspective, as I said, ***the data is very encouraging and it's reasonably robust***.

173. In yet another exchange during the February 28, 2013 conference call regarding the surveillance data comparing abuse rates for the purportedly abuse-deterrent reformulated Opana ER to non-abuse-deterrent generic formulations, Defendant Gergel stated that:

> We're familiar of course. Look, we based our data on both the N[AVIPPRO] work and the RADAR[S] systems which are established systems, which are clearly recognized by FDA as the go to bodies if you like, and our data, I went through it a bit earlier on this call, but I think it's pretty compelling data. We compare, ***when we look at comparisons between our current formulation and generic formulations on the market, we see a difference in abuse rates. We saw differences in abuse rates when we first brought our product to market*** so I think we very much stand by our data. ***It's robust and compelling***.

174. Moreover, Defendants Gergel and B. Davis had the following exchange with an analyst regarding an earlier CDC report of side effects with patients who injected reformulated Opana ER and whether the FDA's views had changed in light of these side effects, given the agency's comments about side effects from injection abuse at the time of approval:

> Shibani Malhotra, Analyst: The CDC has issued some warnings or reports of serious side effects with patients who are trying to inject and able to inject OPANA ER. And the reason I ask is during the Remoxy panel a few years ago, the FDA seemed to be obsessed with necrosis in dog tissue with some Remoxy injections and the whole focus was on the fact that abuse ultimately will find ways to abuse. So how do you see or how do you think the FDA views that changed on that if at that all given the side effects of injecting OPANA ER?
>
> Ivan Gergel, CSO: Well, so we designed the OPANA crush resistant formulation to be crush resistant to avoid primarily the nasal route of abuse and clearly, ***we're looking into this data, but it's in a very, very distinct area of the country*** and obviously, we've had discussions with the FDA about that and we continue to look at the data.
>
> Blaine Davis – SVP Corporate Affairs: And again just to comment a little further, remember some of the most common forms of abuse related to the old formulation are precisely why the development pathway relative to the new formulation or crush-resistant formulation of OPANA were pursued. ***The data that we've collected in those two surveillance databases clearly show a significant reduction in abuse by those methods*** which I think is some of the most important characteristic of the data that we've generated so far.

175. The statements alleged above in ¶¶ 170-74 touting post-marketing data as demonstrating reduced abuse rates for reformulated Opana ER, and as supporting the conclusion that reformulated Opana ER was safer than original Opana ER were materially false or misleading for the reasons alleged above at ¶ 160.

176. On March 1, 2013, Endo filed its Annual Report on Form 10-K with the SEC (the "2012 Form 10-K"). In the 2012 Form 10-K, Endo continued to mischaracterize reformulated Opana ER as "crush-resistant" and "designed to be crush-resistant," while concealing that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, including that it could still be abused by injection and, as post-marketing data indicated, it was increasingly being abused by injection, as alleged above at ¶ 160.

177. On March 6, 2013 Endo participated in the Cowen Health Care Conference. In connection with the conference, Endo filed a Form 8-K with the SEC that day, attaching the slides to be presented. The slides continued to tout reformulated Opana ER's purported "***Crush-Resistant Formulation (CRF)***." In addition, the slides represented that Endo "***continue[d] to believe that surveillance data supports removal of old formulation brand and generics from market for reasons of safety***."

178. The statements alleged above in ¶ 177 concerning reformulated Opana ER's purported resistance to crushing and representing that reformulated Opana ER was safer than original Opana ER were materially false or misleading for the reasons alleged above at ¶ 160.

179. During the question and answer portion of the March 6, 2013 Cowen Health Care Conference, Defendant Levin stated the following, in response to a question on Endo's post-marketing safety data for reformulated Opana ER:

> I think there are a couple of things with regard to the data that are helpful to bear in mind with regard to what we've seen so far. First, the data was pulled from the [NAVIPPRO] and RADARS' databases. These are databases that the FDA uses and has good confidence in being indicative of live market use of opioid products. So we're pleased and I think FDA is comfortable with these databases as well. The data that we provided showed a couple of things when we filed our Citizens [sic] Petition Amendment in November of last year. One, it clearly showed that with the advent of a tamper-resistant formulation of OxyContin in 2010, abusers began to move into the non-tamper resistant formulation of OPANA ER that existed at that time. ***Secondly, it clearly showed that abusers moved out of the***

> ***tamper-resistant formulation of oxymorphone when we introduced crush-resistant Opana ER in 2012.*** And third, it clearly showed that for the crushable versions of generic oxymorphone that existed, once we introduced our tamper-resistant formulation, abusers moved into those crushable formulations. ***So there is a very strong real world evidence that says that these new formulations of oxymorphone have had a meaningful impact in terms of abuser behavior. We also saw a 59% reduction in abuse from the new formulation of Opana tamper-resistant versus the classic formulation*** that reflected in-takes from substance abuse clinics and adverse event reporting, both of which were part of the NAVIP[P]RO and RADARS' databases. ***And we've now gotten data for the fourth quarter that would indicate that, that percentage is close to 80% on our fourth-quarter 2012 to fourth-quarter 2011 comparison or full-year comparison for those 12 quarters. So, again, the data seems to demonstrate that we have put a safer version of our formulation out at the market*** and that is all part of the dialog that we're having with the FDA now.

180. The statements alleged above in ¶ 179 touting Endo's post-marketing data as demonstrating reduced abuse rates for reformulated Opana ER, and as supporting the conclusion that reformulated Opana ER was safer than original Opana ER were materially false or misleading for the reasons alleged above at ¶ 160.

181. On March 21, 2013, Endo supplemented its Citizen Petition again, to provide the FDA with ongoing epidemiology study data that it claimed "***demonstrate[ed] that the introduction of crush-resistant [reformulated] Opana® ER [] is having the intended effect on abuse rates and routes of administration, supporting Endo's decision to withdraw [original] Opana® ER [] for safety reasons***."

182. The March 21, 2013 Supplement repeated Defendants' prior misrepresentations that the data submitted via the November 13, 2012 Supplement demonstrated that reformulated Opana ER was "***having the intended effect on the abuse rates and routes of administration of the product, as reported abuse rates appear to be significantly lower after the introduction of [reformulated] Opana® ER***," and compounded this misinformation by claiming that "***[t]his trend is continuing***." In making this claim, Defendants relied upon new analyses from NAVIPPRO and RADARS, received on February 5 and 10, 2013, respectively.

183. In the March 21, 2013 Supplement, Endo claimed that the NAVIPPRO data showed that the introduction of reformulated Opana ER "***coincided with significantly lower levels of abuse***" in the April 1, 2012 through December 31, 2012 time period, as compared to original Opana during the January 1, 2011 through December 31, 2011 time period. Further, Endo claimed that "abuse rates by route of administration" showed that "***the percentage of abuse of [reformulated] Opana® ER [] by nasal insufflation, or snorting, during the time period of the study was 74% lower than previously observed for original formulation Opana® ER***."

184. The statements alleged above in ¶¶ 181-83 touting post-marketing data as demonstrating reduced abuse rates for reformulated Opana ER, and as supporting the conclusion that reformulated Opana ER was safer than original Opana ER, were materially false or misleading for the reasons alleged above at ¶ 160.

185. On April 23, 2013, Endo filed a third supplement to its Citizen Petition, publicly claiming that the "***similarities between Original Opana® ER and Original OxyContin® [] require[d] the FDA to make the same determination***" for Endo's Citizen Petition that it had for Purdue's Citizen Petition concerning OxyContin.

186. Endo further claimed that "***crush-resistant Opana® ER has virtually the same abuse-deterrent properties as reformulated OxyContin®***," including that: (i) like reformulated OxyContin, when compared to original Opana ER, reformulated Opana ER "has an increased ability to resist crushing, breaking, and dissolution using a variety of tools and solvents," and that "when subjected to an aqueous environment it gradually forms a viscous hydrogel"; (ii) like original OxyContin, original Opana ER was reformulated with properties "intended to make the tablet more difficult to manipulate"; and (iii) "***[s]imilar to reformulated OxyContin®, Crush-Resistant Opana® ER has dramatically reduced abuse rates compared to Original Opana®***

ER," including that, like reformulated OxyContin, the available data from post-marketing studies suggest a reduction in non-oral abuse for reformulated Opana ER. Endo also claimed that the abuse risks of original Opana ER "mirror[ed]" and were "virtually identical" to those of original OxyContin.

187. Endo also claimed that, "***given the similarities between Original OxyContin® and Original Opana® ER***, including their abuse potential, abuse risks, respective histories of abuse, and the similar abuse-deterrent properties and impact on abuse rates of their respective new formulations," the FDA should decide the petitions consistently to protect the public health.

188. The statements alleged above in ¶¶ 185-87 touting post-marketing data as demonstrating reduced abuse rates for reformulated Opana ER, and as supporting the conclusion that reformulated Opana ER was safer than original Opana ER were materially false or misleading for the reasons alleged above at ¶ 160.

189. In addition, Endo's statements alleged above at ¶¶ 185-87 touting the purported similarities between reformulated Opana ER and reformulated OxyContin, including as supportive of Endo's Citizen Petition, were materially false or misleading because the two drugs were not "virtually identical" and had markedly different abuse-deterrent properties and associated safety data. Among other things, *in vitro*, pharmacokinetic, available clinical abuse potential, and post-marketing data for OxyContin showed that original OxyContin posed an increased potential for intranasal abuse compared to reformulated OxyContin, whereas data showed that reformulated Opana ER could still be prepared for insufflation (snorting) using commonly available tools and methods. Further, unlike reformulated OxyContin, which deterred abuse by injection when subjected to an aqueous environment by forming a viscous hydrogel that

resisted passage through a needle, reformulated Opana ER could be "readily prepared for injection."

190. On May 7, 2013, Endo issued a press release again touting the surveillance data submitted in support of its Citizen Petition, stating that:

> In Nov. 2012, the company supplemented this Citizen Petition to include emerging safety data that the company believes suggests that the first quarter 2012 ***introduction of the reformulated OPANA ER designed to be crush-resistant is substantially reducing rates of abuse***. More recent data from an ongoing epidemiology study were submitted to the Citizen Petition docket in March 2013. These data indicate that per 100,000 prescriptions dispensed, the past 30-day abuse rate of crush-resistant OPANA ER was 79 percent lower than the abuse rate of generic versions of extended-release oxymorphone that were on the market in 2012.

191. The May 7, 2013 press release further stated that Endo's assumptions for 2013 financial guidance included its assumption of "no generic competition" after May 2013, in light of the anticipated outcome on its Citizen Petition. In this regard, the Exchange Act Defendants further reiterated that "the company continues to believe that ***sufficient evidence exists to support a determination by FDA that the old formulation of OPANA ER was discontinued for reasons of safety***, which served the public health."

192. Endo repeated these statements in a Form 8-K filed that same day, to which the Company attached a copy of the May 7, 2013 press release.

193. The statements alleged above in ¶¶ 190-92 touting post-marketing data as demonstrating reduced abuse rates for reformulated Opana ER, and as supporting the conclusion that reformulated Opana ER was safer than original Opana ER were materially false or misleading for the reasons alleged above at ¶ 160.

194. Endo also filed its quarterly report on Form 10-Q on May 7, 2013. The 1Q13 Form 10-Q continued to characterize reformulated Opana ER as "crush-resistant" and "designed to be crush-resistant," while concealing that the very properties that purportedly rendered the

drug crush-resistant actually made it less safe, including that it could still be abused by injection and, as post-marketing data indicated, it was increasingly being abused by injection, as alleged above at ¶ 160.

195. The 1Q13 Form 10-Q also touted the similarities between reformulated Opana ER and reformulated OxyContin, stating:

> In April 2013, the FDA announced that it had determined that the original OxyContin ® extended-release tablets marketed by a competitor, which were withdrawn from the market in August 2010 upon the launch of the reformulated OxyContin®, were withdrawn for reasons of safety or effectiveness. The FDA further stated that it would not accept or approve any ANDAs that rely upon the approval of original OxyContin®, precluding the pending generic OxyContin ® applicants to come to market. While uncertainty remains with respect to how the FDA will respond to our August 13, 2012 Citizen Petition on Opana ® ER, ***we believe our situation shares many similarities to the original OxyContin®***. However, there can be no assurance that a similar determination will be made for Opana ® ER. The FDA is expected to respond to this Citizen Petition on May 10, 2013.

196. The statements alleged above in ¶ 195 likening reformulated Opana ER to reformulated OxyContin were materially false or misleading for the reasons alleged above at ¶ 189.

197. Endo also held its first quarter 2013 earnings call with analysts and investors on May 7, 2013. During the question and answer portion of the call, Defendant De Silva represented that, "[a]s we look forward to the future, ***OPANA is going to be the primary product for our ful[l] organization***."

198. Further, when asked about Endo's April 23, 2013 supplement to its Citizen Petition, Defendant De Silva stated, "the main gist of that supplement was to point out the similarities between the OPANA ER situation and OxyContin with respect to the recent decision that FDA took." Defendant De Silva further stated that:

> We believe that we have a very strong facts on our side. If you look at our filings over the course of the last year, ***surveillance data alone shows that there's been a***

> ***very sharp decrease in abuse of the brand with the launch of the abuse deterrent product.*** Depending on which time period it look looks at it's – it could be an almost 60% reduction. So, we do believe that we have a very strong data on our side. Obviously, every company has a slightly different twist on it. But I do think that the way that the FDA looked at OxyContin, we certainly applaud that decision. ***We merely wanted to point out one more time, the similarities between the two situations*** with FDA as they deliberated on our own file.

199. The statements alleged above in ¶¶ 197-98 touting post-marketing data as supporting the conclusion that reformulated Opana ER was safer than original Opana ER, as well as the statements likening reformulated Opana ER to reformulated OxyContin, were materially false or misleading for the reasons alleged above at ¶¶ 160 and 189.

200. On May 10, 2013, the FDA denied Endo's Citizen Petition, finding that original Opana ER was ***not*** withdrawn from the market for reasons of safety. In addition, the FDA issued a complete response to Endo's sNDA requesting the addition of labeling language describing the purported abuse-deterrent properties of reformulated Opana ER. In a Company press release issued later that day, Defendant De Silva expressed Endo's disappointment and disagreement with the decision, and reiterated that the Company "presented FDA data collected from an ongoing epidemiology study that indicate that per 100,000 prescriptions dispensed, the past 30-day abuse rate of crush-resistant OPANA ER was 79 percent lower than the abuse rate of generic versions of extended-release oxymorphone that were on the market in 2012."

201. Defendant De Silva's statements alleged above at ¶ 200 continued to conceal material information regarding the safety, attributes and prospects of reformulated Opana ER, as set forth herein, for the reasons alleged above at ¶ 160.

202. On August 6, 2013, Endo filed its quarterly report on Form 10-Q for the second quarter of 2013. The 2Q13 Form 10-Q continued to tout Endo's "crush-resistant" and "designed to be crush-resistant" reformulation of Opana ER, while concealing that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, including that it could

still be abused by injection and, as post-marketing data indicated, that it was increasingly being abused by injection, as alleged above at ¶ 160.

203. On November 5, 2013, Endo filed its quarterly report on Form 10-Q with the SEC for the third quarter of 2013. The 3Q13 Form 10-Q continued to tout Endo's "crush-resistant" and "designed to be crush-resistant" reformulation of Opana ER, while concealing that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, including that it could still be abused by injection and, as post-marketing data demonstrated, it was increasingly being abused by injection, and that the safety risks associated with reformulated Opana ER abuse were so severe that they would require the drug's withdrawal, as alleged at ¶ 160. In addition, by no later than the third quarter of 2013:

- Endo's post-marketing experience with reformulated Opana ER, including as set forth in reports by NAVIPPRO and RADARS, and as reflected in FAERS data, showed a dramatic shift in the route of abuse of Opana ER from intranasal abuse (with original Opana ER) to much more dangerous intravenous abuse (with reformulated Opana ER), as well as an *increase* in the rate of abuse by injection for reformulated Opana ER, compared to its original formulation (*see* ¶¶ 123-27; 141-44); and

- Endo's post-marketing experience with reformulated Opana ER also showed that intravenous abuse of reformulated Opana ER caused an increasing number of serious adverse events (associated with its abuse by injection), in particular, instances of TTP, a rare coagulation disorder that causes microscopic clots to form in small blood vessels, that was not observed before introduction of the reformulation (*see* ¶¶ 130-31).

204. On November 12, 2013, Defendant De Silva participated in the Credit Suisse Healthcare Conference on behalf of Endo, during which he stated, "I would say ***we've had improved expectations both in OPANA*** as well as Voltaren Gel." He explained that, "***the clinical program that [sic] we will hopefully be able to resubmit data to the FDA in support of a potential relabeling on the product some time later next year with potential outcomes in 2015***."

205. The statement alleged above in ¶ 204 touting Endo's "improved expectations" and prospects for reformulated Opana ER, including regarding the potential for relabeling reformulated Opana ER as abuse-deterrent, was materially false or misleading for the reasons alleged above at ¶¶ 160 and 203.

B. The Exchange Act Defendants' Misrepresentations and Omissions in 2014

206. On February 28, 2014, Endo held its quarterly earnings call to discuss the Company's fourth quarter and full year financial 2013 financial results. During the question and answer portion of the call, in response to the question "what are your latest thoughts on . . . your ability to stabilize or perhaps even return Opana to share growth," Defendant De Silva stated, "***we have [a]n active clinical program that we are pursuing in conjunction with the dialogue with the FDA which would hopefully allow us to apply for a label change sometime in the recent future - near future . . . And if all goes well, we may have a situation in 2015 with a stronger label where we could look at this brand again as a growth asset*** . . . ."

207. The statements alleged above in ¶ 206 touting Endo's prospects for resubmitting an abuse-deterrent label application for reformulated Opana ER were materially false or misleading for the reasons alleged above at ¶¶ 160 and 203.

208. On March 3, 2014, Endo filed its annual report on Form 10-K with the SEC (the "2013 Form 10-K"). The 2013 Form 10-K continued to tout Endo's "crush-resistant" and "designed to be crush-resistant" reformulation of Opana ER, while concealing that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, including that it could still be abused by injection and, as post-marketing data demonstrated, it was increasingly being abused by injection, as alleged above at ¶¶ 160 and 203.

209. Endo's 2013 Form 10-K also failed to disclose, in violation of Item 303 of Regulation S-K, material adverse safety trends associated with reformulated Opana ER observed

in post-marketing data by no later than 3Q13, as alleged above at ¶¶ 123-31, 141-44, 160, and 203 including: (i) a shift in the route of abuse from intranasal abuse to intravenous abuse; (ii) an increase in the rate of abuse by injection; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

210. On May 1, 2014, Endo held its quarterly earnings call with analysts to discuss its first quarter 2014 financial results. During the call, Defendant De Silva stated, "***we are making progress on our clinical trial program for OPANA ER in support of the label change application***."

211. During the question and answer portion of the call, when asked for "an update on the insufflation study on OPANA ER, where that stands, and the chances of someday ending up with a label that has more abuse deterrent language," Defendant De Silva stated, "***we are making progress in three fronts with Opana***," including that "***we are engaged in a clinical program, so we have agreed [on] a protocol for the insufflation study with FDA. And we have begun the study itself. . . . and if all goes well, we will be able to file our data with the FDA by the end of the year, or early in 2015***." Defendant De Silva further stated that "***we also need to continue to provide evidence from the epidemiology databases as well. So we are cautiously optimistic***."

212. The statements alleged above in ¶¶ 210-11 touting Endo's progress towards resubmitting an abuse-deterrent label change application for reformulated Opana ER, were materially false or misleading for the reasons alleged above at ¶¶ 160 and 203.

213. On May 9, 2014, Endo filed its quarterly report on Form 10-Q for the first quarter of 2014. The 1Q14 Form 10-Q continued to tout Endo's "crush-resistant" and "designed to be crush-resistant" reformulation of Opana ER while concealing that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, including that could still

be abused by injection and, as post-marketing data demonstrated, it was increasingly being abused by injection, as alleged above at ¶¶ 160 and 203.

214. Endo's 1Q14 Form 10-Q also failed to disclose, in violation of Item 303 of Regulation S-K, material adverse safety trends associated with reformulated Opana ER observed in post-marketing data by no later than 3Q13, as alleged above at ¶¶ 123-31, 141-44, 160, and 203, including: (i) a shift in the route of abuse from intranasal abuse to intravenous abuse; (ii) an increase in the rate of abuse by injection; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

215. On August 4, 2014, Endo filed its quarterly report on Form 10-Q for the second quarter of 2014. The 2Q14 Form 10-Q continued to tout Endo's "crush-resistant" and "designed to be crush-resistant" reformulation of Opana ER, while concealing that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, including that it could still be abused by injection and, as post-marketing data demonstrated, it was increasingly being abused by injection, as alleged above at ¶¶ 160 and 203.

216. Endo's 2Q14 Form 10-Q also failed to disclose, in violation of Item 303 of Regulation S-K, material adverse safety trends associated with reformulated Opana ER observed in post-marketing data by no later than 3Q13, as alleged above at ¶¶ 123-31, 141-44, 160, and 203, including: (i) a shift in the route of abuse from intranasal abuse to intravenous abuse; (ii) an increase in the rate of abuse by injection; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

217. On November 10, 2014, Endo filed its quarterly report on Form 10-Q for the third quarter of 2014. The 3Q14 Form 10-Q continued to tout Endo's "crush-resistant" and "designed to be crush-resistant" reformulation of Opana ER, while concealing that the very properties that

purportedly rendered the drug crush-resistant actually made it less safe, including that it could still be abused by injection and, as post-marketing data demonstrated, it was increasingly being abused by injection, as alleged above at ¶¶ 160 and 203.

218. Endo's 3Q14 Form 10-Q also failed to disclose, in violation of Item 303 of Regulation S-K, material adverse safety trends associated with reformulated Opana ER observed in post-marketing data by no later than 3Q13, as alleged above at ¶¶ 123-31, 141-44, 160, and 203, including: (i) a shift in the route of abuse from intranasal abuse to intravenous abuse; (ii) an increase in the rate of abuse by injection; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

C. The Exchange Act Defendants' Misrepresentations and Omissions in 2015

219. On January 6, 2015, Endo participated in the Goldman Sachs Healthcare Conference. During this conference, Defendant De Silva stated, "***We just concluded a[n] [insufflation] study, we have not published that data yet. But I can tell you that, based on our initial review of the data, we expect it to support our hypothesis that the product is similar to OxyContin in terms of its abuse deterrent potential***."

220. Defendants De Silva's statements alleged above in ¶ 219 touting the insufflation study data were materially false or misleading for the reasons alleged above at ¶¶ 160 and 203.

221. On March 2, 2015, Endo filed its Annual Report on Form 10-K with the SEC for fiscal year 2014 (the "2014 Form 10-K"). The 2014 Form 10-K continued to tout Endo's "crush-resistant" and "designed to be crush-resistant" reformulation of Opana ER, while concealing that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, including that could be abused by injection and, as post-marketing data demonstrated, it was increasingly being abused by injection, as alleged above at ¶¶ 160 and 203.

222. Endo's 2014 Form 10-K also failed to disclose, in violation of Item 303 of Regulation S-K, material adverse safety trends associated with reformulated Opana ER observed in post-marketing data by no later than 3Q13, as alleged above at ¶¶ 123-31, 141-44, 160, and 203, including: (i) a shift in the route of abuse from intranasal abuse to intravenous abuse; (ii) an increase in the rate of abuse by injection; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

223. On May 11, 2015, Endo filed its quarterly report on Form 10-Q for the first quarter of 2015. The 1Q15 Form 10-Q continued to tout Endo's "crush-resistant" and "designed to be crush-resistant" reformulation of Opana ER, while concealing that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, including that it could still be abused by injection and, as post-marketing data demonstrated, it was increasingly being abused by injection, as alleged above at ¶¶ 160 and 203.

224. Endo's 1Q15 Form 10-Q also failed to disclose, in violation of Item 303 of Regulation S-K, material adverse safety trends associated with reformulated Opana ER observed in post-marketing data by no later than 3Q13, as alleged above at ¶¶ 123-31, 141-44, 160, and 203, including: (i) a shift in the route of abuse from intranasal abuse to intravenous abuse; (ii) an increase in the rate of abuse by injection; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

225. Endo also held its first quarter 2015 earnings call on May 11, 2015. During the call, Defendant De Silva stated, "We continue our robust efforts to protect the OPANA ER franchise, including the promotion and development of the product, as well as the vigorous assertion of its intellectual property. We have a meeting scheduled with FDA in June to discuss the next steps in development and labeling."

226. With respect to the referenced upcoming FDA meeting in June 2015, analysts asked whether Endo had already submitted its information, and how soon after the meeting Endo expected a label change to occur. In response, Defendant De Silva stated that:

> We are in the process of completing the information, sorry, the dossier for that meeting. Corey, there's no - this has been, as you know, a multi-year ongoing dialogue with the FDA, so I'm not going to predict timing of when they might respond. ***A lot of it is going to depend on their view on how much epi data is required to make the case. So in our view, we have sufficient and robust enough data for their decision***, but they may take a different view, right? That is - that continues to be the uncertainty. That being said, we along with FDA continue to believe that some form of abuse-deterrent is in the best interest of patients.

227. Further, when asked to "provide a little bit more perspective on the OPANA ER outlook, and what to watch," Defendant De Silva stated, in relevant part, "***Our development efforts have gone well in terms of the insufflation study that we conducted and as we also talked about earlier in the call, we now have a date with FDA to discuss (technical difficulty) our insufflation study data as well as epi data, hopefully in support of relabeling***."

228. Defendant De Silva's statements alleged above in ¶¶ 225-27 touting Endo's clinical program and insufflation study (in support of abuse-deterrent labeling) and prospects for obtaining a label change for reformulated Opana ER regarding the same were materially false or misleading for the reasons alleged above at ¶¶ 160 and 203.

229. On August 10, 2015, Endo filed its quarterly report on Form 10-Q for the second quarter of 2015. The 2Q15 Form 10-Q continued to tout Endo's "crush-resistant" and "designed to be crush-resistant" reformulation of Opana ER, while concealing that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, including that it could still be abused by injection and, as post-marketing data demonstrated, it was increasingly being abused by injection, as alleged above at ¶¶ 160 and 203.

230. Endo's 2Q15 Form 10-Q also failed to disclose, in violation of Item 303 of Regulation S-K, material adverse safety trends associated with reformulated Opana ER observed in post-marketing data by no later than 3Q13, as alleged above at ¶¶ 123-31, 141-44, 160, and 203, including: (i) a shift in the route of abuse from intranasal abuse to intravenous abuse; (ii) an increase in the rate of abuse by injection; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

231. Endo also held its second quarter earnings call with analysts and investors on August 10, 2015. During the call, Defendant De Silva provided an update on reformulated Opana ER stating that, "***[f]ollowing our meeting in June with FDA, we now expect to submit a supplemental request for labeling that will potentially add abuse deterrent formulation claims***."

232. During the question and answer portion of the call, analysts asked Defendant De Silva to give "a sense of what is going on behind the scenes in [Endo's] discussion[] with [the FDA] and whether [Endo] actually believe[s] that [it was] going to get a label change" and, if so, whether it was "going to differentiate from the generics [and] have an impact on [Endo's] business." Defendant De Silva responded stating that:

> [W]e did meet with the FDA in June with respect to our complete response as well as to go through the most recent epi data that we have as well. And ***we left that meeting with more optimism than before***. But that being said, I would not say that we have a very clear view to how the FDA will look at this ***but it was clear from the meeting that we would be in a position to file for a label update as soon as we can get that data together, which will likely be the back end of this year or early in 2016***.

233. In addition, Defendant De Silva touted "the ***momentum we've generated with the FDA***" with respect to reformulated Opana ER.

234. The statements alleged above in ¶¶ 231-33 touting Endo's expectations for resubmitting an abuse-deterrent label request based on purported momentum gained with the FDA were materially false or misleading for the reasons alleged above at ¶¶ 160 and 203.

235. On November 9, 2015, Endo filed its quarterly report on Form 10-Q for the third quarter of 2015. The 3Q15 Form 10-Q continued to tout Endo's "crush-resistant" and "designed to be crush-resistant" reformulation of Opana ER, while concealing that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, including that it could still be abused by injection and, as post-marketing data demonstrated, it was increasingly being abused by injection, as alleged above at ¶¶ 160 and 203.

236. Endo's 3Q15 Form 10-Q also failed, in violation of Item 303 of Regulation S-K, to disclose material adverse safety trends associated with reformulated Opana ER observed in post-marketing data by no later than 3Q13, as alleged above at ¶¶ 123-31, 141-44, 160, and 203, including: (i) a shift in the route of abuse from intranasal abuse to intravenous abuse; (ii) an increase in the rate of abuse by injection; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

237. On November 17, 2015, Endo participated in the Stifel Nicolaus Healthcare Conference. During the question and answer portion of the conference, Defendant De Silva was asked: (i) if Endo did get the relabeling for reformulated Opana ER that it sought, whether it would then "have to go through an extra step to get the generics pulled off the market"; and (ii) whether Endo was "continuing with its epidemiological studies in the background, to be able to put information to the FDA up front as [Endo was] seeking the labeling, and asking for all of that to happen at the same time." Defendant De Silva stated:

> RAJIV DE SILVA: Sure. So the submission to the FDA will have two components to it. So one is the results of the insufflation study, which essentially

> is a so-called crushing and snorting study, which we've already conducted. ***Results are positive as we would've expected,*** because it's basically the same kind of construct that OxyContin had. ***And the second part of the submission is sufficient epidemiological data. And there's always the debate with the FDA as to what is sufficient. But our beliefs is based on our discussion with the FDA that by the end of this year we will have*** [. . .] ***[a]round two years of data, which should be sufficient for the filing***. Now [we'll] continue to collect data after that, but that's the basis of what will go into the FDA. Now in terms of the process of taking the generics off the market – so the win that we just had on the Paragraph IV [alone] will essentially leave us and Impax alone in the market for next year. And then if we are able to get a relabeling, the process of taking Impax off the market will require a (inaudible). So it is not automatic removal from the market. But we will then have the basis to remove the original NDA from the market, and then petition for the removal of the generic.

238. The statements alleged above in ¶ 237 touting Endo's clinical program and insufflation study (in support of abuse-deterrent labeling) and prospects for obtaining a label change regarding the same were materially false or misleading for the reasons alleged above at ¶¶ 160 and 203.

D. The Exchange Act Defendants' Misrepresentations and Omissions in 2016

239. On February 29, 2016, Endo filed its Annual Report on Form 10-K for fiscal year 2015 (the "2015 Form 10-K"). The 2015 Form 10-K continued to tout Endo's "crush-resistant" and "designed to be crush-resistant" reformulation of Opana ER, while concealing that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, including that it could still be abused by injection and, as post-marketing data demonstrated, it was increasingly being abused by injection, as alleged above at ¶¶ 160 and 203.

240. Endo's 2015 Form 10-K also failed to disclose, in violation of Item 303 of Regulation S-K, material adverse safety trends associated with reformulated Opana ER observed in post-marketing data by no later than 3Q13, as alleged above at ¶¶ 123-31, 141-44, 160, and 203, including: (i) a shift in the route of abuse from intranasal abuse to intravenous abuse; (ii) an

increase in the rate of abuse by injection; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

241. Endo also held its fourth quarter and full year 2015 earnings call with analysts and investors on February 29, 2016. During the call, Defendant De Silva stated, "we . . . ***are continuing to advance [Opana ER] with the recently submitted data package to the FDA that we feel could support an abuse deterrent formulation label expansion***."

242. During the question and answer portion of the February 29, 2016 call, Defendant De Silva was asked for any further information around his expectations on when Endo could hear from the FDA, and if it did receive the abuse-deterrent labeling it sought, whether it expected the old formulation generics to be removed from the market for safety. In response, Defendant De Silva stated:

> So the Opana ER submission has gone in. It was a monumental effort just because not only [sic] the inclusion of data from our insufflation study but also a lot of epi-data. The FDA set an action date of July 29 of 2016 for the file, so there is the timeframe in which we expect to hear back from them. And now even if we are successful in getting the re-labeling, it will certainly serve to help remove all the generics from the market with the exception of [Impax] that are seen, per the license to the product. And therefore, to do so would require a longer path, including a Citizen's [sic] Petition, which we certainly would undertake, but it would not be immediate.

243. The statements alleged above in ¶¶ 241-42 touting Endo's recent submission to the FDA in support of abuse-deterrent labeling and prospects for obtaining the same were materially false or misleading for the reasons alleged above at ¶¶ 160 and 203.

244. On May 6, 2016, Endo filed its quarterly report on Form 10-Q for the first quarter of 2016. The 1Q16 Form 10-Q continued to tout Endo's "crush-resistant" and "designed to be crush-resistant" reformulation of Opana ER, while concealing that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, including that it could

still be abused by injection and, as post-marketing data demonstrated, it was increasingly being abused by injection, as alleged above at ¶¶ 160 and 203.

245. Endo's 1Q16 Form 10-Q also failed to disclose, in violation of Item 303 of Regulation S-K, material adverse safety trends associated with reformulated Opana ER observed in post-marketing data by no later than 3Q13, as alleged above at ¶¶ 123-31, 141-44, 160, and 203, including: (i) a shift in the route of abuse from intranasal abuse to intravenous abuse; (ii) an increase in the rate of abuse by injection; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

246. On August 8, 2016, Endo held its second quarter 2016 earnings call. During the question and answer portion of the call, Defendant De Silva had the following exchange with an analyst:

> DONALD ELLIS, ANALYST, JMP SECURITIES: But since you traffic in the opioid market pretty significantly, what can you tell us about your current thoughts about when, how, and if there will be a meaningful transition to the opioid deterrent versions of narcotics?
>
> RAJIV DE SILVA: As you pointed out, we have had a lot of experience in heritage in the pain market, including in opioids. ***And we ourselves have done a lot of work around OPANA's reformulation, in effect to make the abuse of the product more difficult***. That being said, I think the public health environment debate around this, if you look around this, while encouraging abuse-deterrent formulations, it's still unclear at what point the entire market will shift to products that are quote-unquote abuse deterrent. So in terms of the FDA's own determination of what constitutes it, there's a lot of debate. We don't have a crystal ball, and we'd be speculating, but we certainly as we look, forward longer-term perspective one of the things that the long-acting products would transition to more abuse deterrent formulations, but is that going to happen in the short term? That is anyone's guess.

247. The statements alleged above in ¶ 246 were materially false or misleading for the reasons alleged above at ¶¶ 160 and 203.

248. On August 9, 2016, Endo filed its quarterly report on Form 10-Q for the second quarter of 2016. The 2Q16 Form 10-Q continued to tout Endo's "crush-resistant" and "designed

to be crush-resistant" reformulation of Opana ER, while concealing that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, including that it could still be abused by injection and, as post-marketing data demonstrated, it was increasingly being abused by injection, as alleged above at ¶¶ 160 and 203.

249. Endo's 2Q16 Form 10-Q also failed to disclose, in violation of Item 303 of Regulation S-K, material adverse safety trends associated with reformulated Opana ER observed in post-marketing data by no later than 3Q13, as alleged above at ¶¶ 123-31, 141-44, 160, and 203, including: (i) a shift in the route of abuse from intranasal abuse to intravenous abuse; (ii) an increase in the rate of abuse by injection; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

250. On August 12, 2016, Endo issued a press release announcing that, after discussion with the FDA, it was withdrawing its sNDA seeking specific abuse-deterrent labeling for reformulated Opana ER without prejudice to refiling—based on a conversation Endo had with the FDA just one day prior. This press release further stated:

> The Company plans to continue collecting and analyzing epidemiological data relating to OPANA® ER. Endo's financial projections for 2016 did not assume approval of the sNDA.
>
> "***We anticipate the generation of additional data and we will seek collaboration with FDA to appropriately advance OPANA® ER***," said Sue Hall, Ph.D., Executive Vice President, Chief Scientific Officer and Global Head of Research & Development and Quality at Endo.

251. The statements alleged above in ¶ 250 touting Endo's plans to continue collecting and analyzing epidemiological data relating to reformulated Opana ER, and the Company's prospects for generating the additional data required to support abuse-deterrent labeling for the drug, were materially false or misleading for the reasons alleged above at ¶¶ 160 and 203.

252. On November 8, 2016, Endo filed its quarterly report on Form 10-Q for the third quarter of 2016. The 3Q16 Form 10-Q continued to tout Endo's "crush-resistant" and "designed to be crush-resistant" reformulation of Opana ER, while concealing that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, including that it could still be abused by injection and, as post-marketing data demonstrated, it was increasingly being abused by injection, as alleged above at ¶¶ 160 and 203.

253. Endo's 2Q16 Form 10-Q also failed to disclose, in violation of Item 303 of Regulation S-K, material adverse safety trends associated with reformulated Opana ER observed in post-marketing data by no later than 3Q13, as alleged above at ¶¶ 123-31, 141-44, 160, and 203, including: (i) a shift in the route of abuse from intranasal abuse to intravenous abuse; (ii) an increase in the rate of abuse by injection; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

E. The Exchange Act Defendants' Misrepresentations and Omissions in 2017

254. On March 1, 2017, Endo filed its annual report on Form 10-K with the SEC for fiscal year 2016 (the "2016 Form 10-K"). Endo's 2016 Form 10-K, failed to disclose, in violation of Item 303 of Regulation S-K, material adverse safety trends associated with reformulated Opana ER, observed in post-marketing data by no later than 3Q13, as alleged above at ¶¶ 123-31, 141-44, 160, and 203, including: (i) a shift in the preferred route of abuse of Opana ER, from intranasal abuse (with original Opana ER) to intravenous abuse (with reformulated Opana ER); (ii) an increase in the rate of abuse by injection; and (iii) an increase in serious adverse events associated with intravenous abuse of reformulated Opana ER, which presented safety risks so severe that they would require the drug's withdrawal.

255. On March 14, 2017, the FDA voted, 18-8, with one abstention, that the benefits of reformulated Opana ER did not outweigh its risks. In a press release addressing the vote, Endo

attempted to downplay its impact on the franchise, noting that "***several of the Advisory Committee members acknowledged the role of OPANA® ER in clinical practice***" and that "***a number of Committee members expressed their preference that OPANA® ER remain on the market with additional regulatory restrictions to mitigate the risks***." The press release further stated:

> While the FDA will consider the Committee's vote, any decision regarding whether to take regulatory action rests solely with the Agency. Endo believes that OPANA® ER remains an important clinical choice for appropriate patients and will evaluate the range of available options for maintaining access for legitimate use.
>
> "Endo remains confident that the body of evidence established through clinical research demonstrates that OPANA® ER has a favorable risk-benefit profile when used as intended in appropriate patients," said Matthew W. Davis, M.D., R.Ph., Senior Vice President, Research & Development, Branded Pharmaceuticals at Endo.

256. Although, as alleged below (¶¶ 283-86), the statements alleged above at ¶ 255 partially revealed the truth regarding the risks to reformulated Opana ER, the Exchange Act Defendants continued to conceal material facts regarding the safety, attributes, and sustainability of the drug. Among other things, contrary to the Exchange Act Defendants' representations that reformulated Opana ER carried a favorable safety profile, the very properties that were intended to deter abuse were contributing to a rise in the rate of abuse by injection and caused a number of serious adverse and life-threatening events, rendering the drug unsafe and requiring its removal from the market.

257. On May 9, 2017, the Company issued a press release announcing its first quarter 2016 financial results. A copy of this press release was also attached to a Form 8-K that Endo filed with the SEC the same day. The press release and Form 8-K stated the following concerning the March 14, 2017 Advisory Committee meeting and vote:

> On March 14, 2017, the FDA's Advisory Committees voted 18 to eight, with one abstention, that the benefits of reformulated OPANA® ER no longer outweigh its risks, while ***a number of the Committee members expressed their preference that OPANA® ER remain on the market with additional regulatory restrictions***. Following the outcome of the FDA advisory committee meetings, the Company stated its belief that OPANA® ER remains an important clinical choice for appropriate patients and that Endo plans to work collaboratively with the FDA as it completes its product evaluation.

258. Endo also filed its quarterly report for the first quarter of 2017 on Form 10-Q on May 9, 2017, again making virtually identical statements:

> In March 2017, we announced that the FDA's Drug Safety and Risk Management and Anesthetic and Analgesic Drug Products Advisory Committees (the Committees) voted that the benefits of reformulated OPANA® ER (oxymorphone hydrochloride extended release) no longer outweigh its risks. While ***several of the Committee members acknowledged the role of OPANA® ER in clinical practice***, others believed its benefits are now outweighed by the continuing public health concerns around the product's misuse, abuse and diversion. ***During the Committees' discussion following the vote, a number of Committee members recommended that OPANA® ER remain on the market with additional regulatory restrictions to mitigate the risks***. The FDA convened these Committees to discuss pre- and post- marketing data about the abuse of OPANA® ER, the product's overall risk- benefit profile, as well as the abuse of generic oxymorphone ER and oxymorphone immediate- release products. While the FDA will consider the Committees' vote, any decision regarding whether to take regulatory action rests solely with the FDA.

259. The statements alleged above in ¶ 258 downplaying the significance of the Advisory Committee vote with respect to reformulated Opana ER, were materially false or misleading for the reasons alleged above at ¶¶ 160 and 203.

260. The 1Q17 Form 10-Q also failed to disclose, in violation of Item 303 of Regulation S-K, material adverse safety trends associated with reformulated Opana ER observed in post-marketing data by no later than 3Q13, as alleged above at ¶¶ 123-31, 141-44, 160, and 203, including: (i) a shift in the route of abuse from intranasal abuse to intravenous abuse; (ii) an increase in the rate of abuse by injection; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

261. Endo also held its quarterly earnings call on May 9, 2017. During the question and answer portion of the call, when asked whether Endo had "had any interaction with the FDA [] on OPANA since the Advisory Committee and the vote there," Defendant Campanelli stated:

> So I think to start out with the OPANA question, obviously we're laser focused with the FDA. While they're-- we are waiting for eventual meeting with the FDA. We clearly are in preparation on concepts and ideas that we would like to communicate and have that conversation with the FDA. But at this point in time, it's a bit premature. That has not been established. The way I kind of characterize OPANA today, it's really business as usual, right? So we're ongoing and there hasn't been any formal discussions or meetings with the FDA.

262. Similarly, when asked whether he had "any more granular detail on the timing of the discussions on the evaluation with the FDA" and whether "they [have] provided you any details on when they will complete their evaluation," Defendant Campanelli stated:

> So I'll take the OPANA question quickly. I think it would be our hope and our anticipation that a conversation or a meeting could take place before the second half. So we're hoping that it'll be shortly, right? But I think as I said, we are being a little proactive in our views on things that we had pitched at the Ad Com and things that we would want to follow up with the FDA with respect to OPANA. But as I said before, right now, today, it's business as usual on OPANA.

263. The statements alleged above in ¶¶ 261-62, which downplayed the import of the FDA Advisory Committee vote, and repeatedly touted the possibility of reformulated Opana ER remaining on the market, notwithstanding the Advisory Committee's view that its risks outweighed its benefits, were materially false or misleading because they continued to conceal material facts regarding the safety, attributes, and sustainability of reformulated Opana ER, including that, contrary to these representations that the drug carried a purported safety benefit in its ability to deter abuse, the very properties that were intended to deter abuse were contributing to a rise in the rate of abuse by injection and caused a number of serious adverse and life-threatening events, rendering the drug unsafe and requiring its removal from the market, as alleged above at ¶¶ 160 and 203.

VII. LOSS CAUSATION

264. The Exchange Act Defendants' material misrepresentations and omissions alleged herein concerning the safety, attributes, and sustainability of reformulated Opana ER caused the price of Endo common stock to be artificially inflated and/or maintained such artificial inflation in the price of Endo common stock prior to and during the Class Period, thereby operating as a fraud or deceit upon Lead Plaintiff and other putative class members who purchased or otherwise acquired Endo common stock during the Class Period.

265. In reliance upon public information disclosed by and relating to Endo and reformulated Opana ER, as well as the integrity of the market price for Endo common stock, Lead Plaintiff and other putative Class members purchased or otherwise acquired Endo common stock during the Class Period at artificially inflated prices that incorporated and reflected the Exchange Act Defendants' material misrepresentations and omissions alleged herein. Lead Plaintiff and other putative Class members suffered actual economic loss and were damaged by the Exchange Act Defendants' misrepresentations and omissions when the truth concerning reformulated Opana ER's safety, attributes, and sustainability concealed by the Exchange Act Defendants' misrepresentations and omissions was revealed through the public disclosures of new information concerning reformulated Opana ER on May 10, 2013, January 10, 2017, March 9, 2017, March 14, 2017, and June 8, 2017. These partial corrective disclosures and/or materializations of the foreseeable risks concealed by the Exchange Act Defendants' fraud caused foreseeable declines in the price of Endo common stock by removing portions of the artificial inflation in the price of Endo common stock that resulted from the Exchange Act Defendants' fraud. Moreover, the timing and magnitude of the declines in the price of Endo common stock in response to the public disclosure of new, Company-specific news on each of the foregoing days, as alleged herein, negate any inference that the losses suffered by Lead

Plaintiff and other Class members were caused by changed market conditions or other macroeconomic factors unrelated to the Exchange Act Defendants' fraud.

266. The truth about reformulated Opana ER's safety, attributes, and sustainability began to materialize and was partially revealed late in the afternoon on May 10, 2013, when the FDA posted its decision denying Endo's Citizen Petition seeking a determination that original Opana ER was withdrawn from the market for safety reasons, based on its findings that the data Endo submitted in support of its Citizen Petition was "insufficient" to support any of the following conclusions: (i) original Opana ER had an increased potential for abuse compared to reformulated Opana ER; (ii) original Opana ER's risks outweighed its benefits; and, therefore, (iii) original Opana ER was withdrawn for reasons of safety or effectiveness.

267. While the FDA cited a number of deficiencies in Endo's post-marketing surveillance data that prevented the FDA from drawing any meaningful conclusions therefrom as to reformulated Opana ER's abuse deterrence, the FDA noted that, if one were to rely on such data, "one of the post-marketing investigations suggests the troubling possibility that ***a higher (and rising) percentage of [reformulated Opana ER] abuse is occurring via injection than was the case with [original Opana ER]***." The FDA also rejected Endo's claims that reformulated Opana ER and reformulated OxyContin have "virtually identical" abuse-deterrent properties.

268. In a press release issued after the close of market on May 10, 2013, Endo responded to the FDA's Citizen Petition denial and also reported that the FDA had denied its sNDA seeking abuse-deterrent language on reformulated Opana ER's label as well. As a result, Endo also provided an estimate that its guidance for FY2013 could be negatively impacted by up to $120 million in revenues and $0.55 in EPS (subject to any cost-cutting measures).

269. These disclosures of new information concerning reformulated Opana ER directly and proximately caused a substantial decline in the price of Endo common stock by removing a portion of the artificial inflation in the price of Endo common stock caused by the Exchange Act Defendants' misrepresentations and omissions of material fact concerning reformulated Opana ER. In response to this information, the disclosure of which was a foreseeable consequence of, and within the zone of risk created by, the Exchange Act Defendants' misrepresentations and omissions of material fact concerning reformulated Opana ER, the price of Endo common stock price declined by $1.95 per share (or 5.28%) from its closing price of $36.92 per share on May 9, 2013, to close at $34.97 per share on May 10, 2013. The price of Endo common stock continued to decline by another $1.26 per share (or 3.60%) as the market digested this new information, including the information set forth in the press release that Endo issued after the close of trading on May 10, 2013, concerning reformulated Opana ER, closing at $33.71 per share on May 13, 2013.

270. Analysts attributed the declines in the prices of Endo common stock on each of these days to the FDA's denial of Endo's Citizen Petition, the FDA's Complete Response to Endo's sNDA seeking abuse-deterrent labeling for reformulated Opana ER, and Endo's reduction of its earnings guidance for reformulated Opana ER for the remainder of 2013 set forth in the Company's May 10, 2013 press release.

271. For example, on May 10, 2013, analysts from Leerink Swann noted that, according to the FDA: (i) "[a]vailable data do not support ENDP's conclusions regarding alleged safety advantages of reformulated Opana ER"; (ii) "the new formulation [of Opana ER] is still susceptible to other forms of manipulation allowing the product to 'dose dump'" and can "still be snorted and injected"; and (iii) "there are currently not sufficient data to concluded that

'old' Opana ER poses an increased potential for abuse compared to reformulated Opana ER." These analysts further noted that the "FDA's response [also] included significant criticism of ENDP's 'preliminary' post-marketing data, including small sample size, short time frame, likely misclassification of drug exposure, and having possibly 'artificially elevated baseline Opana ER abuse rates.'"

272. Moreover, J.P. Morgan issued a May 13, 2013 report describing the FDA's decision as "***clearly surprising***" and reduced its revenue estimates for reformulated Opana ER, while Jefferies issued a May 13, 2013 report lowering its price target for Endo common stock from $47.00 to $37.00 per share, and described the news as "***disappointing & material***," and the FDA's Citizen Petition denial as "scathing." Similarly, Susquehanna Financial Group issued a May 13, 2013 report in which it described the outcome as "***worse than expected***" in that the "FDA not only denied ENDP's petition on the adequacy of its post-marketing data purporting to show reduced abuse, but it went further by openly questioning the abuse-deterrent benefits of the formulation itself." Citing "key points from FDA's response," Susquehanna Financial Group further noted that "FDA concluded that [reformulated Opana ER] can still be compromised by cutting, grinding, or chewing and can be 'readily prepared for injection' (disputing ENDP's claim of 'resistance to aqueous extraction') as well as prepared for snorting."

273. RBC Capital Markets ("RBC") issued a May 12, 2013 report in which RBC reduced its price target for Endo common stock from $29.00 to $27.00 per share, and stated, "[w]e now model significant franchise erosion and note that even though Opana had only represented $3-4 to our NPV, expectations were for considerable growth and long term sustainability of the franchise." Moreover, RBC noted that "investors may question management credibility," given that "management only recently reiterated its 2013 guidance ($4.40-$4.70)

that did NOT assume Opana generics" and that the reduction in guidance post FDA decision "is the second time Endo has reduced its guidance since its October 2012 Analyst Day." RBC further stated that "we are surprised that management was so confident in the sustainability of the Opana franchise as [the] agency's eventual conclusion that Opana TR [sic] did not confer a significant safety benefit could have been pre-empted by reading the drug's medical review. We were led to believe the concerns highlighted in our note published 2/7/2013, (ENDP – Downgrading to Underperform on Increased Concerns Regarding Opana ER) were based on old data and these had since been addressed."

274. Notwithstanding the new information concerning reformulated Opana ER revealed on May 10, 2013, the full truth regarding reformulated Opana ER's safety, attributes, and sustainability was not revealed and did not materialize at that time, as the Exchange Act Defendants continued to make material misrepresentations and omit material facts regarding these matters from their public statements concerning the drug, as alleged herein at ¶¶ 202-63. As a result, Endo common stock continued to trade at artificially inflated prices.

275. Additional new information concerning the risks regarding the safety, attributes and sustainability of reformulated Opana ER further materialized and was revealed on January 10, 2017, when, minutes before the market opened, *Bloomberg* reported that the FDA scheduled an Advisory Committee meeting to review abuse data for reformulated Opana ER, as well as the overall risk-benefit profile of the drug. *Briefing.com* similarly reported that morning that the FDA scheduled an Advisory Committee meeting to discuss safety issues for reformulated Opana ER.

276. The announcement that the FDA was convening an Advisory Committee meeting to review abuse rate data for reformulated Opana ER and assess whether the benefits of the drug

outweighed its risks was a foreseeable consequence of, and within the zone of risk created by, the misrepresentations and omissions of material fact alleged herein concerning reformulated Opana ER, and partially revealed the truth concerning reformulated Opana ER's true safety risks and sustainability, including that reformulated Opana ER was more harmful than the Exchange Act Defendants represented it to be. Specifically, the FDA's decision to convene an Advisory Committee signaled that the dangers that reformulated Opana ER presented could defeat the marketability of the drug and require its removal—the first step of which was the FDA's re-assessment of the drug's risk-benefit profile to determine if its benefits continued to outweigh its safety risks in light of pre- and post-marketing data on abuse.

277. As a direct and proximate result of the disclosure of this new information concerning reformulated Opana ER, the price of Endo's common stock declined by $1.10 per share (or 6.70%) from its closing price on January 9, 2017, of $16.41 per share, to close at $15.31 per share on January 10, 2017. The price of Endo common stock declined by an additional $1.30 per share (or 8.49%) to close at $14.01 per share on January 11, 2017, removing a portion of the artificial inflation in the price of Endo common stock.

278. Despite this partial disclosure, the full risks and truth regarding the safety, attributes, and sustainability of reformulated Opana ER were not revealed by this announcement and Endo's stock price remained at artificially inflated levels. The Exchange Act Defendants also downplayed the importance of the Advisory Committee meeting. For example, when asked during Endo's February 28, 2017 earnings call for his thoughts on the upcoming panel on reformulated Opana ER, including (i) what he thought the FDA's "end-game" was, (ii) what his "level of concern" was, and (iii) whether analysts should "be concerned about a potential that the product is removed from the market," Defendant Campanelli noted that the meeting was to

discuss "all oxymorphone products. So it's not just OPANA ER," and stated that "our studies to date support the safety and efficacy for the intended use of OPANA."

279. On March 9, 2017, the FDA published its briefing documents in advance of the Advisory Committee meeting, which included the FDA's preliminary views on the safety and effectiveness of the abuse-deterrent properties of reformulated Opana ER, to be discussed by the Advisory Committee. Among other things, the briefing documents reflected the FDA's view that Endo's post-marketing abuse data presented a "compelling" picture that "the reformulation caused a shift in non-oral routes [of abuse] from predominately nasal to predominately injection," particularly in light of the number of reports of TMA, a spectrum of clinical syndromes leading to microvascular thrombosis, including TTP.

280. Analysts took note of these disclosures. For example, Piper Jaffray issued a report on March 9, 2017 noting "that [the] FDA expresse[d] clear skepticism regarding ENDP's post-marketing (i.e., abuse) data" but also stated that it was "compelling" that those abusing reformulated Opana ER were increasingly doing so through injection. As a result, Piper Jaffray concluded that "we [can] easily envision an outcome next week that results in more restrictive labeling," but "would be surprised to see the [FDA] panel recommend an outright removal of ENDP's product."

281. As a direct and proximate result of this disclosure of new information revealing a portion of the relevant truth concealed by the Exchange Act Defendants' misrepresentations and omissions of material facts concerning reformulated Opana ER, the price of Endo common stock declined by $0.27 per share (or 2.5%) from its closing price of $10.80 per share on March 8, 2017, to close at $10.53 per share on March 9, 2017, removing a portion of the artificial inflation in the price of Endo common stock.

282. Despite this partial disclosure of previously concealed and/or misrepresented material information concerning reformulated Opana ER, the full risks and truth regarding the safety, attributes, and sustainability of reformulated Opana ER were not revealed by this announcement and Endo's stock price remained at artificially inflated levels.

283. On March 14, 2017, following the two-day FDA Advisory Committee meeting convened to discuss reformulated Opana ER, committee members voted, 18-8, with one abstention, that the benefits of reformulated Opana ER did not outweigh its risks. Moreover, a number of committee members recommended that the drug be removed from the market.

284. As a direct and proximate result of this disclosure of new information revealing a portion of the relevant truth concealed by the Exchange Act Defendants' misrepresentations and omissions of material facts concerning reformulated Opana ER, the price of Endo common stock declined by $0.45 per share (or 4.22%), from its closing price of $10.67 per share on March 13, 2017, to close at $10.22 per share on March 14, 2017. Securities analysts attributed this decline in the price of Endo common stock to the new information concerning reformulated Opana ER disclosed on March 14, 2017. For example, William Blair stated in a report issued on March 14, 2017 that shares of Endo were "down over 4% after the vote," while Susquehanna Financial Group noted in a report issued on March 15, 2017 that "yesterday's 4% decline came on top of recent underperformance for which Opana uncertainty appears a significant factor."

285. Despite this partial disclosure of previously concealed and/or misrepresented material information concerning reformulated Opana ER, the full risks and truth regarding the safety, attributes, and sustainability of reformulated Opana ER were not revealed by this announcement and Endo's stock price remained at artificially inflated levels. In this regard, Endo downplayed the significance of the Advisory Committee's observations and

recommendations, stating in a press release Endo issued on March 14, 2017 that, "[w]hile several of the Advisory Committee members acknowledged the role of Opana ER in clinical practice, others believed its benefits are now overshadowed by the continuing public health concerns around the product's misuse, abuse and diversion" and that "a number of Committee members expressed their preference that Opana ER remain on the market with additional regulatory restrictions to mitigate the risks."

286. In connection with the foregoing, analysts issued reports in which they noted, for example, that Endo had stressed that the Advisory Committee only made recommendations to the FDA, and it remained uncertain what actions the FDA would take with respect to reformulated Opana ER. For example, RBC noted in a report issued on March 15, 2017 that "FDA AdCom on [reformulated] OPANA ER adds uncertainty," while Susquehanna Financial Group similarly stated in a report issued on March 15, 2017 that "a surprise vote against the risk/benefit profile of [reformulated] Opana ER adds an unhelpful question mark for ENDP's 2018 earnings." Morgan Stanley commented in a report issued on March 15, 2017 that the FDA's vote "could lead to regulatory restrictions or, in a worst-case scenario, withdrawal from the market," but that "it is unclear if FDA will demand product withdrawal." This Morgan Stanley report further stated that, "it was made clear during voting that a vote against branded [reformulated] Opana ER was not necessarily a vote for withdrawal, so it is unclear if FDA will take action to have it withdrawn from the market."

287. On June 8, 2017, the FDA issued a press release publicly demanding that Endo voluntarily withdraw reformulated Opana ER from the market "based on its concern that the benefits of the drug may no longer outweigh its risks." According to the FDA's press release, it sought removal "due to the public health consequences of abuse."

288. The FDA's demand that Endo withdraw reformulated Opana ER from the market based upon the safety risks that the drug presented was a foreseeable consequence of, and within the zone of risk created by, the Exchange Act Defendants' materially false or misleading statements concerning the safety, attributes, and sustainability of reformulated Opana ER. Moreover, the FDA's June 8, 2017 announcement revealed new information that was previously concealed by the Exchange Act Defendants' materially false or misleading statements. This disclosure revealed the relevant remaining truth concealed and/or obscured by the Exchange Act Defendants' prior materially false or misleading statements concerning reformulated Opana ER.

289. As a direct and proximate result of this final partial corrective disclosure and/or materialization of the foreseeable risks concealed by the Exchange Act Defendants' fraud, the price of Endo common stock declined by $2.29 per share (or 16.62%) from its closing price of $13.78 per share on June 8, 2017 to close at $11.49 per share on June 9, 2017. In response to this new information concerning reformulated Opana ER, securities analyst BMO capital markets issued a report on June 8, 2017 stating, "we're surprised the FDA has requested complete removal of the product as opposed to implementing additional restrictions for it" and that the "loss of earnings and cash flow due to a withdrawal would clearly be disappointing." Deutsche Bank Markets Research similarly stated in a report issued on June 8, 2017 that, "[i]n a surprising development, the FDA has requested that ENDP remove its reformulated Opana ER (~4% of revenue) from the market due to concerns about the potential consequences of abusing the drug via the IV route."

290. The material misrepresentations and omissions alleged above caused the prices of Endo common stock to be artificially inflated, and/or maintained such artificial inflation, throughout the Class Period. Lead Plaintiff and other Class members purchased or otherwise

acquired Endo common stock at prices that were artificially inflated as a result of the Exchange Act Defendants' misrepresentations and omissions of material fact alleged herein.

291. The Exchange Act Defendants' wrongful conduct directly and proximately caused the damages suffered by Lead Plaintiff and other Class members. Throughout the Class Period, the prices at which Lead Plaintiff and other Class members purchased Endo common stock were artificially inflated as a result of the Exchange Act Defendants' materially false or misleading statements concerning reformulated Opana ER's safety, attributes, and sustainability. Had the Exchange Act Defendants disclosed complete, accurate, and truthful information concerning these matters during the Class Period, Lead Plaintiff and other Class members would not have purchased or otherwise acquired Endo common stock at the artificially inflated prices that they paid. It was entirely foreseeable to the Exchange Act Defendants that misrepresenting and concealing these material facts and risks from the public would cause the price of Endo common stock to be artificially inflated. It was also foreseeable that the ultimate disclosure of this information, and/or the materialization of the risks concealed by the Exchange Act Defendants' material misstatements and omissions, would cause the price of Endo common stock to decline, as the inflation resulting from the Exchange Act Defendants' earlier materially false or misleading statements was removed from the price of Endo common stock.

292. Accordingly, the Exchange Act Defendants' conduct, as alleged herein, proximately caused foreseeable losses to Lead Plaintiff and to the other members of the Class who purchased or otherwise acquired Endo common stock during the Class Period.

293. The economic losses, i.e., damages, suffered by Lead Plaintiff and other Class members are direct and foreseeable results of: (i) the Exchange Act Defendants' materially false or misleading statements and omissions of material fact, which caused the price of Endo

common stock to be artificially inflated, and/or maintained such artificial inflation; and (ii) the subsequent significant decline in the price of Endo common stock when the truth was gradually revealed and/or the risks previously concealed by the Exchange Act Defendants' fraud gradually materialized on May 10, 2013, January 10, 2017, March 9, 2017, March 14, 2017 and June 8, 2017, removing portions of the artificial inflation from the price of Endo common stock.

VIII. ADDITIONAL ALLEGATIONS OF SCIENTER

294. The Exchange Act Defendants were active and culpable participants in the fraud alleged herein, as evidenced by their knowing or reckless issuance and/or ultimate authority over the materially false or misleading statements alleged herein. Each of the Individual Exchange Act Defendants acted with scienter in that each knew or recklessly disregarded that each of his or her respective public statements alleged in Section VI above was materially false or misleading when made, and knowingly or recklessly participated or acquiesced in the issuance or dissemination of each such statement as a primary violator of Section 10(b) of the Exchange Act. In addition to the specific facts alleged above, including in Section IV, the Exchange Act Defendants' scienter is further evidenced by the following facts:

A. The Exchange Act Defendants' Responsibility for the Alleged Misstatements

295. As executive officers of the Company, each of the Individual Exchange Act Defendants was responsible for and had a substantial role in issuing the material misrepresentations and omissions alleged herein. Among other things, each Individual Exchange Act Defendant was directly quoted in press releases and/or made public statements during the Company's earnings calls and industry conferences on behalf of Endo.

B. The Exchange Act Defendants' Receipt of and/or Access to Information Undermining Their Public Statements

296. Each of the Exchange Act Defendants also received and/or had access to detailed information concerning the business operations and financial condition of the Company, including information regarding the safety, attributes, and sustainability of reformulated Opana ER. Moreover, each of the Individual Exchange Act Defendants was a senior executive of Endo and, thus, had access to all relevant information concerning the business operations and financial condition of the Company.

297. Each of the Exchange Act Defendants also had access to information discussed at monthly Risk Evaluation and Mitigation Strategy ("REMS") meetings, at which reformulated Opana ER's post-marketing safety data was discussed, as Endo's REMS program was mandated by the FDA. The FDA's approval of reformulated Opana ER mandated an REMS to ensure safe use of the drug, which included a schedule of REMS assessments. In July 2012, the FDA approved a class-wide REMS for all extended-release and long-acting opioids, including reformulated Opana ER, which again included a schedule for REMS assessments. Endo's REMS at the time of reformulated Opana ER was approved was consistent with the class-wide REMS approved in July 2012. The REMS required assessments to be submitted to the FDA at six and twelve months after the initial approval date (July 9, 2012), and annually thereafter.

298. All REMS assessments were required to include information on the status of any post-approval study or clinical trial required or otherwise undertaken to investigate a safety issue, including whether any difficulties were encountered completing any such study or clinical trial. In addition, for each of its annual assessments beginning on July 9, 2014, Endo was required to report, among other information, the results of: (i) an evaluation of patients' understanding of the serious risks of reformulated Opana ER, including based on surveys collected; (ii) surveillance

for misuse, abuse, overdose, addiction, and death, including information on changes in abuse, misuse, overdose, addiction, and death for different risk groups; and (iii) drug utilization patterns.

299. Public statements made by the Exchange Act Defendants during the Class Period also give rise to a strong inference that each had detailed knowledge of or access to the material facts and information that they misrepresented or concealed. The vast majority of the Exchange Act Defendants' misrepresentations pertain to reformulated Opana ER and concern data regarding the abuse of the drug, and the Individual Exchange Act Defendants made statements and answered questions regarding these subjects during earnings calls and investor conferences during the Class Period. In that regard, each of the Exchange Act Defendants is presumed to have knowledge of and/or access to the information about which he or she made public statements, and each Individual Exchange Act Defendant controlled the contents of his or her statements made on behalf of the Company during the Class Period.

300. In addition, as Endo's CEO and CFO, Defendants De Silva, Holveck, Campanelli, and Levin were each provided with, or had access to, copies of the SEC filings alleged herein to be false or misleading prior to, or shortly after, their issuance, and had the ability and opportunity to prevent their issuance or to cause them to be corrected. As CEO and CFO, Defendants De Silva, Holveck, Campanelli, and Levin each signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") and Exchange Act Rule 13a-14(a) in connection with Endo's Forms 10-Q and Forms 10-K filed with the SEC during the Class Period. As signatories of both: (i) the SOX certification representing that "the information contained in th[e] [SEC filings] fairly presents, in all material respects, the financial condition and results of operations of Endo"; and (ii) the Rule 13a-14(a) certification representing that the Company's SEC filings did "not contain any untrue

statement of a material fact or omit to state a material fact necessary to make the statements made . . . not misleading," Defendants De Silva, Holveck, Campanelli, and Levin each had a duty to monitor any conduct or information that threatened to undermine the veracity of the representations made in these filings, including all material facts concerning reformulated Opana ER and Endo's business.

C. NAVIPPRO, RADARS and FAERS Data Showed That Abuse of Reformulated Opana ER by Injection was Escalating

301. Shortly after the introduction of reformulated Opana ER, the Exchange Act Defendants used and analyzed data from multiple sources, including NAVIPPRO (the national program that Endo helped found and sponsored), RADARS, and FAERS, that clearly showed that the introduction of reformulated Opana ER corresponded with: (i) a shift in the route of abuse commonly associated with the drug, from intranasal abuse for original Opana ER, to intravenous abuse for reformulated Opana ER; (ii) an increase in the rate of intravenous abuse of reformulated Opana ER; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

302. Specifically, the Exchange Act Defendants used and analyzed NAVIPPRO data, and regularly received reports from NAVIPPRO, which showed that, beginning in 2013, intravenous abuse of reformulated Opana ER increased. The NAVIPPRO data also demonstrated a significant shift in the route of abuse for Opana ER, from intranasal abuse to intravenous abuse, and further showed that this shift had occurred, at the latest, by the third quarter of 2013.

303. The Exchange Act Defendants also had used and analyzed RADARS data, and regularly received reports from RADARS, which showed that following Opana ER's reformulation: (i) there was a shift in Opana ER abuse calls from inhalation/nasal abuse calls to

injection abuse calls; (ii) utilization-adjusted Opana ER injection abuse call rates increased significantly; and (iii) utilization-adjusted Opana ER abuse call rates were higher than other opioids analyzed.

304. The Exchange Act Defendants also had access to FAERS data, which showed that ***fifty-nine*** cases of TMA were reported with reformulated Opana ER between the time of the drug's approval on December 9, 2011 and June 1, 2016. These cases resulted from intravenous abuse of reformulated Opana ER, as reported to FAERS. Notably, FAERS data showed ***zero*** reports of cases of TMA prior to the approval of reformulated Opana ER.

305. As a result of the Exchange Act Defendants' use and analysis of, and/or access to, the corroborative data from these independent sources, the Exchange Act Defendants knew or recklessly disregarded that reformulated Opana ER caused a rise in intravenous abuse of the drug, and associated health hazards.

D. Core Operations

306. Opana ER was a core product for the Company, a chief revenue generator, and a key driver of Endo's earnings during the Class Period. Indeed, Endo admits that during the Class Period, "most of [its] total revenues come from a small number of products," one of which was Opana ER.

307. By 2010, Opana ER was Endo's second largest revenue generator, earning nearly $240 million in total annual revenues for Endo, representing approximately 14% of Endo's overall revenues that year. Sales of Opana ER climbed to more than $384 million in 2011, or roughly 14% of the Company's total revenues that year, and held strong at nearly $300 million in 2012, 11% of Endo's total revenues that year. Sales from reformulated Opana ER similarly represented 11% of total revenues in 2013, at $227 million. In total, Opana ER generated approximately $1 billion in revenues for Endo from 2010 to 2013.

308. Reformulated Opana ER remained a "significant" component of Endo's total U.S. Branded Pharmaceuticals business throughout the remainder of the Class Period, generating approximately $198 million, 176 million, and $159 million in total revenues for Endo in 2014, 2015 and 2016, respectively. Reflecting this reality, Defendant De Silva proclaimed on May 7, 2013 that reformulated Opana ER was Endo's "***primary product***."

309. Opana ER also was a critical aspect of Endo's business because Endo relied heavily on Opana ER revenues to fund new research and development, including the development of compounds for palliative and curative treatment of cancer, and tamper resistant formulations of other currently available long and short acting opioids.

IX. THE FRAUD-ON-THE-MARKET PRESUMPTION OF RELIANCE APPLIES TO THE EXCHANGE ACT CLAIMS

310. At all relevant times, the market for Endo common stock was open and efficient for the following reasons, among others: (i) Endo common stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market, under the ticker symbol "ENDP"; (ii) as a registered and regulated issuer of securities, Endo filed periodic public reports with the SEC, in addition to the Company's frequent voluntary dissemination of information; (iii) Endo regularly communicated with investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts, and other similar reporting services; and (iv) Endo was followed by numerous securities analysts employed by major brokerage firms, including Morgan Stanley, Piper Jaffray, RBC Capital Markets, William Blair, Susquehanna Financial Group, and others, who wrote reports that were distributed

to those brokerage firms' sales force and certain of their customers, and that were publicly available and entered the public marketplace.

311. As a result of the foregoing, the market for Endo common stock promptly digested current information regarding Endo from publicly available sources and the prices of Endo's common stock reflected such information. Based upon the materially false or misleading statements and omissions of material fact alleged herein, Endo common stock traded at prices in excess of its true value during the Class Period.

312. The material misrepresentations and omissions alleged herein would induce a reasonable investor to misjudge the value of Endo common stock.

313. Lead Plaintiff and other members of the putative Class, purchased or otherwise acquired Endo common stock relying upon the integrity of the market price of Endo common stock and other market information relating to Endo.

314. Lead Plaintiff and other members of the putative Class purchased or otherwise acquired Endo common stock without knowledge of the misrepresented or omitted facts, between the time that the Exchange Act Defendants made the material misrepresentations and omissions and the time that the full truth was revealed, during which period the Exchange Act Defendants' misrepresentations and omissions artificially inflated the price of Endo common stock and/or maintained such artificial inflation.

315. Under these circumstances, Lead Plaintiff and other members of the Class, as purchasers or acquirers of Endo common stock at artificially inflated prices during the Class Period, suffered similar injuries and a presumption of reliance under the fraud-on-the-market doctrine applies.

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

X. THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE ARE INAPPLICABLE

317. The Private Securities Litigation Reform Act's statutory safe harbor and/or the "bespeaks caution doctrine" applicable to forward-looking statements under certain circumstances do not apply to any of the materially false or misleading statements alleged herein.

318. None of the statements complained of herein was a forward-looking statement. Rather, each was a historical statement or a statement of purportedly current facts and conditions at the time each statement was made.

319. To the extent that any materially false or misleading statement alleged herein, or any portion thereof, can be construed as forward-looking, such statement was a mixed statement of present and/or historical facts and future intent, and is not entitled to safe harbor protection with respect to the part of the statement that refers to the present and/or past.

320. To the extent that any materially false or misleading statement alleged herein, or any portions thereof, may be construed as forward-looking, such statement was not accompanied by meaningful cautionary language identifying important facts that could cause actual results to

differ materially from those in the statement or portion thereof. As alleged above in detail, given the then-existing facts contradicting Defendants' statements, any generalized risk disclosures made by Defendants were not sufficient to insulate Defendants from liability for their materially false or misleading statements.

321. To the extent that the statutory safe harbor may apply to any materially false or misleading statement alleged herein, or a portion thereof, Defendants are liable for any such false or misleading statement because at the time such statement was made, the speaker knew the statement was false or misleading, or the statement was authorized and approved by an executive officer of Endo who knew that such statement was false or misleading.

XI. CLASS ACTION ALLEGATIONS

322. Lead Plaintiff brings this action as a class action pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3) on behalf of itself and a class consisting of all persons who purchased or otherwise acquired Endo publicly traded common stock during the period from November 30, 2012 through June 8, 2017, inclusive (the "Class"), including shares of common stock sold in the June 2015 Offering, and who were damaged thereby. Excluded from the Class are: (i) the Exchange Act Defendants and the Securities Act Defendants (as alleged herein); (ii) present or former executive officers and directors of Endo during the Class Period, and members of their immediate families (as defined in 17 C.F.R. § 229.404, Instructions (1)(a)(iii) and (1)(b)(ii))); (iii) any of the foregoing entities' and individual's legal representatives, heirs, successors or assigns; and (iv) any entity in which the Exchange Act Defendants or the Securities Act Defendants have or had a controlling interest, or any affiliate of Endo. For the avoidance of doubt, "affiliates" are persons or entities that directly, or indirectly through one or more intermediaries, control, are controlled by or are under common control with one of the Exchange Act Defendants or the Securities Act Defendants.

323. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Endo common stock actively traded on the NASDAQ. As of February 2, 2018, Endo had more than 223 million shares of common stock outstanding. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that there are at least thousands of members of the proposed Class. Class members who purchased Endo common stock may be identified from records maintained by Endo or its transfer agent(s), and may be notified of this class action using a form of notice similar to that customarily used in securities class actions.

324. Lead Plaintiff's claims are typical of other Class members' claims, as all members of the Class were similarly affected by the Exchange Act Defendants' and the Securities Act Defendants' respective wrongful conduct in violation of federal laws that are complained of herein.

325. Lead Plaintiff will fairly and adequately protect other Class members' interests and has retained competent counsel experienced in class actions and securities litigation. Lead Plaintiff has no interests that are adverse or antagonistic to the interests of other Class members.

326. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of fact and law common to the Class are:

a) whether the federal securities laws were violated by the respective acts of the Exchange Act Defendants and the Securities Act Defendants as alleged herein;

b) whether respective statements made by the Exchange Act Defendants and the Securities Act Defendants to the investing public during the Class Period were

materially false or misleading;

c) whether the respective statements made by the Exchange Act Defendants and the Securities Act Defendants omitted material facts required to be stated, or necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

d) the extent of injuries sustained by members of the Class and the appropriate measurement of damages.

327. A class action is superior to all other available methods for the fair and efficient adjudication of this action because joinder of all Class members is impracticable. Additionally, the damages suffered by some individual Class members may be relatively small so that the burden and expense of individual litigation make it impracticable for such members to individually redress the wrong done to them based upon the misconduct alleged herein. There will be no difficulty in managing this action as a class action.

328. The prosecution of separate actions by individual Class members would create the risk of inconsistent or varying adjudications with respect to the individual Class members, which would establish incompatible standards of conduct for the Exchange Act Defendants and the Securities Act Defendants, or adjudications with respect to individual Class members that would, as a practical matter, be dispositive of the interests of the other members not parties to the adjudications or substantially impair their ability to protect their interests.

329. The Exchange Act Defendants and the Securities Act Defendants have acted on grounds generally applicable to the Class with respect to the matters complained of herein, thereby making appropriate the relief sought herein with respect to the Class as a whole.

XII. COUNT I: VIOLATION OF SECTION 10(B) OF THE EXCHANGE ACT AND RULE 10B-5 (AGAINST ALL DEFENDANTS)

330. This claim is brought by Lead Plaintiff on behalf of itself and all other members of the Class against the Exchange Act Defendants pursuant to and for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

331. In support of this claim, Lead Plaintiff repeats and re-alleges each allegation set forth above as if fully alleged herein.

332. During the Class Period, the Exchange Act Defendants used the means and instrumentalities of interstate commerce, the U.S. mails, and the facilities of the national securities exchanges to make materially false or misleading statements alleged herein to: (i) deceive the investing public, including Lead Plaintiff and all other members of the Class; (ii) cause the market price of Endo common stock to trade above its true value; and (iii) cause Lead Plaintiff and all other members of the Class, during the Class Period, to purchase or otherwise acquire Endo common stock at artificially inflated prices. In furtherance of their unlawful scheme, plan, or course of conduct, the Exchange Act Defendants took the actions alleged herein.

333. While in possession of material adverse, non-public information, the Exchange Act Defendants, individually and in concert, directly or indirectly, by the use of means and instrumentalities of interstate commerce, the U.S. mails, and the facilities of a national securities exchange, knowingly and/or recklessly: (i) employed devices, schemes, and artifices to defraud; (ii) made false or misleading statements of material fact and/or failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and (iii) engaged in acts, practices, and a course of business that

operated as a fraud or deceit upon the purchasers of the Company's common stock, including Lead Plaintiff and other Class members, in an effort to inflate and/or maintain artificially high market prices for Endo common stock, in violation of Section 10(b) and Rule 10b-5. The Exchange Act Defendants are alleged as primary participants in the wrongful conduct alleged herein.

334. Each of the Exchange Act Defendants is liable as a participant in a fraudulent scheme or course of conduct that operated as a fraud or deceit on purchasers of Endo common stock during the Class Period by knowingly or recklessly disseminating materially false or misleading statements and/or concealing adverse facts. The scheme: (i) deceived the investing public regarding Endo's business, operations, growth prospects, management, and the value of Endo common stock; and (ii) caused Lead Plaintiff and the other members of the Class to acquire Endo common stock at artificially inflated prices during the Class Period. Each of the Individual Exchange Act Defendants during his or her tenure with the Company was involved in drafting, producing, reviewing, and/or disseminating the statements at issue in this case, approved or ratified these statements, and knew or recklessly disregarded that these materially false or misleading statements were being issued regarding the Company.

335. In addition to the duties of full disclosure imposed on the Exchange Act Defendants as a result of making affirmative statements and reports to the investing public, the Exchange Act Defendants also had a duty to disclose information required to update and/or correct their prior statements, misstatements, and/or omissions, and to update any statements or omissions that had become false or misleading as a result of intervening events. Further, the Exchange Act Defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC,

including accurate and truthful information with respect to the Company's operations, so that the market price of Endo common stock would be based on truthful, complete, and accurate information.

336. The Exchange Act Defendants also had a duty to disclose the material adverse trends in reformulated Opana ER abuse rates, including a rise in injection abuse and related serious adverse events, that became known to them through post-marketing data, under Item 303 of Regulation S-K, 17 C.F.R. § 229.303. Such disclosures were required to be made in Endo's Annual Reports on Form 10-K and in its Quarterly Reports on Form 10-Q.

337. Each of the Exchange Act Defendants acted with knowledge or a reckless disregard for the truth of the misrepresented and omitted facts alleged herein, in that each failed to disclose such facts, even though such facts were readily available to him or her, if not known. The Exchange Act Defendants' material misrepresentations and omissions were made knowingly and/or recklessly, for the purpose and effect of concealing the truth with respect to reformulated Opana ER from the investing public and supporting the artificially inflated price of its common stock.

338. The dissemination of the materially false or misleading information and failure to disclose material facts, as alleged above, artificially inflated and/or maintained artificial inflation already in the market price of Endo common stock during the Class Period. Relying upon the materially false or misleading statements made by the Exchange Act Defendants, the efficiency and integrity of the market in which the Company's common stock trades, and upon the absence of material adverse information that was known to or recklessly disregarded by the Exchange Act Defendants but not disclosed by the Exchange Act Defendants, Lead Plaintiff and the other members of the putative Class purchased or otherwise acquired Endo common stock during the

Class Period at prices that they did not know were artificially inflated. As the previously misrepresented and/or concealed material facts emerged, the price of Endo common stock declined, causing Lead Plaintiff and putative class members to suffer losses as a direct and proximate result of the Exchange Act Defendants' wrongful conduct alleged herein, in connection with their purchases and/or acquisitions of Endo common stock during the Class Period. These declines and the preceding disclosures are alleged above in ¶¶ 264-293.

339. At the time of the material misrepresentations and omissions alleged herein, Lead Plaintiff and other putative Class members were ignorant of their falsity and believed them to be true. Had Lead Plaintiff and the other putative class members known the relevant truth regarding the safety, attributes, and sustainability of reformulated Opana ER, which was misrepresented and/or concealed by the Exchange Act Defendants, Lead Plaintiff and the other putative Class members would not have purchased or otherwise acquired Endo common stock at the artificially inflated prices paid.

340. By virtue of the foregoing, the Exchange Act Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. As a direct and proximate result of the Exchange Act Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages attributable to the fraud alleged herein, in connection with their purchases and/or acquisitions of Endo common stock during the Class Period.

341. This action was filed within two years of discovery of the fraud alleged herein, and within five years of Lead Plaintiff's purchases of Endo common stock giving rise to this cause of action.

XIII. COUNT II: VIOLATION OF SECTION 20(A) OF THE EXCHANGE ACT (AGAINST THE INDIVIDUAL DEFENDANTS)

342. This claim is brought by Lead Plaintiff on behalf of itself and all other members of the Class against the Individual Exchange Act Defendants pursuant to and for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

343. In support of this claim, Lead Plaintiff repeats and re-alleges each allegation set forth above as if fully alleged herein.

344. During the Class Period, each of the Individual Exchange Act Defendants was a controlling person of Endo within the meaning of Section 20(a) of the Exchange Act as alleged herein. Each of the Individual Exchange Act Defendants was a high-level executive or officer of Endo. By virtue of his or her respective high-level positions within Endo, each of the Individual Exchange Act Defendants directly participated in the management of the Company, and was directly involved in the day-to-day operations of the Company at the highest levels. In particular, each of the Individual Exchange Act Defendants had direct and supervisory involvement in the day-to-day operations of the Company or the matters that are the subject of the alleged misrepresentations and omissions and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

345. As high-level executives of the Company, each of the Individual Exchange Act Defendants was privy, and had regular access, to confidential and proprietary information concerning the Company, its business, operations, performance, financial statements, and financial condition, growth, and future prospects. Each of the Individual Exchange Act Defendants had access to such information through internal corporate documents and information, conversations, and connections with other corporate officers and employees,

attendance at management meetings and/or meetings of the Company's Board of Directors and committees thereof, as well as reports and other information provided to them in connection therewith, during his or her respective tenure with the Company.

346. By virtue of their high-level positions, each of the Individual Exchange Act Defendants participated in the material misrepresentations and omissions made by or on behalf of the Company and disseminated to the investing public, and/or was provided with or had access to copies of the Company's reports, press releases, public filings and other statements alleged herein to have been misleading, both prior to and/or shortly after such statements were publicly disseminated, and had the ability to prevent the issuance of such statements or to cause such statements to be corrected.

347. As such, each of the Individual Exchange Act Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the statements that Lead Plaintiff contends herein were materially false or misleading.

348. As executive officers of a publicly-held company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ and governed by federal securities laws, each of the Individual Exchange Act Defendants had a duty to disseminate prompt, accurate, and truthful information with respect to the Company's business, operations, growth, financial statements, and financial condition, and to correct or update any previously issued statements that became materially misleading or untrue so that the market prices of the Company's publicly traded common stock would be based on accurate information. Each of the Individual Exchange Act Defendants violated these requirements and obligations during the Class Period.

349. Each of the Individual Exchange Act Defendants, because of his or her position of control and authority as an executive officer of Endo: (i) was able to, and did, control the content of the Company's SEC filings, press releases, and other public statements that Endo issued during the Class Period; (ii) was provided with copies of the statements at issue in this action before they were made to the public; and (iii) had the ability to prevent their issuance or cause them to be corrected. Accordingly, each of the Individual Exchange Act Defendants is responsible for the accuracy of the materially false or misleading public statements alleged herein.

350. Each of the Individual Exchange Act Defendants, because of his or her position of control and authority as an executive officer of Endo, had access to the adverse undisclosed information alleged herein concerning Endo's business, operations, and financial statements, through access to internal corporate documents, conversations with other Endo officers and employees, attendance at Endo management meetings, and via reports and other information received in connection therewith, and knew or recklessly disregarded that these adverse undisclosed facts rendered the representations made by or about Endo materially false or misleading.

351. As alleged above, Endo violated Section 10(b) and Rule 10b-5, promulgated thereunder, by its acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons of Endo, each of the Individual Exchange Act Defendants is liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as Endo is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, to Lead Plaintiff and other members of the Class who purchased or otherwise acquired Endo common stock during the Class Period at artificially inflated prices.

XIV. VIOLATIONS OF THE SECURITIES ACT

352. Lead Plaintiff asserts negligence and/or strict liability based claims under Sections 11 of the Securities Act, 15 U.S.C. 77k and 77o against the Securities Act Defendants (defined *infra*), based upon untrue statements and omissions of material fact made in the offering materials publicly disseminated in connection with Endo's June 2, 2015 public offering of Endo common stock (the "June 2015 Offering"), including the Registration Statement on Form S-3 and prospectus dated June 2, 2015 (the "Registration Statement"), the preliminary prospectus supplement on Form 424B5 dated June 3, 2015, and the final prospectus supplement on Form 424B5 dated June 8, 2015 (collectively, the "Offering Materials").

353. For purposes of this Count, Lead Plaintiff expressly excludes and disclaims any allegation that could be construed as alleging or sounding in fraud or intentional or reckless misconduct. This claim is based solely on negligence and/or strict liability.

A. Additional Securities Act Defendants

354. Defendant Suketu P. Upadhyay ("Upadhyay") was Endo's CFO and Executive Vice President from September 23, 2013 to November 22, 2016. Defendant Upadhyay signed the Registration Statement issued in connection with the June 2015 Offering.

355. Defendant Daniel A. Rudio ("Rudio") has been the Chief Accounting Officer and Controller of Endo since April 1, 2011. Defendant Rudio served as VP of Endo from April 1, 2011 until March 10, 2017, when he became Senior Vice President. Defendant Rudio signed the Registration Statement issued in connection with the June 2015 Offering.

356. Defendant Roger H. Kimmel ("Kimmel") has served as Chairman of Endo's Board since May 30, 2007. Defendant Kimmel signed the Registration Statement issued in connection with the June 2015 Offering.

357. Defendant Shane M. Cooke ("Cooke") has been a member of the Board since July 30, 2014. Defendant Cooke signed the Registration Statement issued in connection with the June 2015 Offering.

358. Defendant John J. Delucca ("Delucca") was a member of the Board from February 2014 through June 9, 2015. Defendant Delucca signed the Registration Statement issued in connection with the June 2015 Offering.

359. Defendant Arthur J. Higgins ("Higgins") was a member of the Board from December 2013 through March 31, 2017. Defendant Higgins signed the Registration Statement issued in connection with the June 2015 Offering.

360. Defendant Nancy J. Hutson, Ph.D., ("Hutson") has been a member of the Board since February 2014. Defendant Huston signed the Registration Statement issued in connection with the June 2015 Offering.

361. Defendant Michael Hyatt ("Hyatt") has been a member of the Board since February 2014. Defendant Hyatt signed the Registration Statement issued in connection with the June 2015 Offering.

362. Defendant William P. Montague ("Montague") been a member of the Board since February 2014. Defendant Montague signed the Registration Statement issued in connection with the June 2015 Offering.

363. Defendant Jill D. Smith ("Smith") has been a member of the Board since February 2014. Defendant Smith signed the Registration Statement issued in connection with the June 2015 Offering.

364. Defendant William F. Spengler ("Spengler") was a member of the Board from 2008 through June 8, 2017. Defendant Spengler signed the Registration Statement issued in connection with the June 2015 Offering.

365. Defendants De Silva, Upadhyay, Rudio, Kimmel, Cooke, Delucca, Higgins, Hutson, Hyatt, Montague, Smith, and Spengler are collectively referred to herein as the "Individual Securities Act Defendants." Together with Endo, the Individual Securities Act Defendants are referred to herein as the "Securities Act Defendants."

B. June 2015 Offering

366. On June 2, 2015, Endo filed the Registration Statement with the SEC and announced that it was commencing a $1.75 billion offering of Endo common stock.

367. On June 3, 2015, the Company filed a prospectus supplement on Form 424B5 with the SEC.

368. On June 4, 2015, Endo increased the offering size to 24,024,025 shares of common stock, and priced the offering at $83.25 per share, as reflected in its final prospectus supplement for the offering on Form 424B5.

369. On June 10, 2015, Endo announced the closing of the offering, and reported that the Company had issued 27,627,628 shares of common stock (including 3,603,603 shares sold to underwriters as an overallotment) at a price of $83.25, for aggregate gross proceeds of approximately $2.3 billion.

C. The Offering Materials Failed to Disclose Data Showing a Rise in IV Abuse With Reformulated Opana ER

370. The Offering Materials incorporated by reference, *inter alia*, Endo's: (i) 2014 Form 10-K; and (ii) 1Q15 Form 10-Q.

371. In the 2014 Form 10-K and 1Q15 Form 10-Q incorporated by reference into the Offering Materials, the Securities Act Defendants touted the "crush-resistant" and "designed to be crush-resistant" formulation of Opana ER, while omitting that the very properties that purportedly rendered the drug crush-resistant actually made it less safe, as reformulated Opana ER could be abused by injection, and the post-marketing data demonstrated that it was *increasingly* being abused by injection, and that the safety risks associated with reformulated Opana ER abuse were so severe that they would require the drug's withdrawal. In particular:

- Studies conducted in 2009 and 2010 showed that reformulated Opana ER was not "crush-resistant" or tamper-resistant, but rather could be manipulated through crushing, grinding, chewing, snorting and injection, and had the potential to shift the route of abuse to the most dangerous method—intravenous abuse (*see* ¶¶ 67-69 and 71-73);

- Post-marketing surveillance data submitted in support of Endo's Citizen Petition was inconclusive, of limited duration, and suffered from numerous other flaws (including small sample sizes, likely misclassification of drug exposure, and possible artificially elevated baseline abuse rates for original Opana ER), making it impossible to draw meaningful conclusions therefrom. As such, it did not support the conclusion that reformulated Opana ER resulted in a decrease in abuse rates compared to original Opana ER. Therefore, generic versions of original Opana ER were no more likely to lead to abuse and misuse than reformulated Opana ER (*see* ¶¶ 87-92, 98-99, 102, 109-12);

- Post-marketing data submitted in support of Endo's Citizen Petition indicated an increasing percentage of reformulated Opana ER abuse due to injection, compared to original Opana ER (¶¶ 110-11)

- By no later than the third quarter of 2013, Endo's post-marketing experience with reformulated Opana ER, including as set forth in reports by NAVIPPRO and RADARS, and as reflected in FAERS data, showed a dramatic shift in the route of abuse of Opana ER from intranasal abuse (with original Opana ER) to much more dangerous intravenous abuse (with reformulated Opana ER), as well as an *increase* in the rate of abuse by injection for reformulated Opana ER, compared to its original formulation (*see* ¶¶ 123-27; 141-44); and

- By no later than the third quarter of 2013, Endo's post-marketing experience with reformulated Opana ER also showed that intravenous abuse of reformulated Opana ER caused an increasing number of serious adverse events (associated with its abuse by injection), in particular, instances of TTP,

> a rare coagulation disorder that causes microscopic clots to form in small blood vessels, that was not observed before introduction of the reformulation (*see* ¶¶ 130-31).

372. Endo's 2014 Form 10-K and 1Q15 Form 10-Q incorporated into the Offering Materials also failed to disclose, in violation of Item 303, material adverse safety trends in abuse rates associated with reformulated Opana ER observed in post-marketing data, as alleged above at ¶¶ 123-31, 141-44, and 371, including: (i) a shift in the route of abuse from intranasal abuse to intravenous abuse; (ii) an increase in the rate of abuse by injection; and (iii) a rise in serious adverse events associated with IV abuse of reformulated Opana ER, such as TTP and TMA.

373. The Offering Materials also failed to disclose the most significant risk factors that rendered the offering speculative or risky in violation of Item 503 of Regulation S-K, 17 C.F.R. § 229.503 ("Item 503"); namely that the Company faced a material risk of regulatory action with respect to reformulated Opana ER, in that the FDA would require the drug's removal from the market on account of the material adverse safety risks and trends in intravenous abuse rates observed with the drug in post-marketing safety data.

XV. COUNT III: VIOLATION OF SECTION 11 OF THE SECURITIES ACT (AGAINST THE SECURITIES ACT DEFENDANTS)

374. Lead Plaintiff repeats and re-alleges the allegations set forth above in ¶¶ 352-73, as if fully alleged herein.

375. Lead Plaintiff brings this claim against the Securities Act Defendants pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of itself and all other Class members who purchased Endo common stock pursuant or traceable to the Registration Statement issued in connection with the June 2015 Offering.

376. Lead Plaintiff expressly excludes and disclaims any allegation that could be construed as alleging or sounding in fraud or intentional or reckless misconduct. This claim is based solely on negligence and/or strict liability.

377. The Offering Materials contained untrue statements of material fact and omitted material facts required to be stated in order to make the statements contained therein not misleading, as alleged more fully above in ¶ 370-73.

378. The Offering Materials also failed to disclose material adverse trends, in violation of Item 303, including the increase in reformulated Opana ER abuse by injection and related serious adverse events and failed to disclose the most significant risk factors that rendered the offering speculative or risky, in violation of Item 503, namely that the Company faced a material risk of regulatory action with respect to reformulated Opana ER, in that the FDA would require the drug's removal from the market on account of the material adverse safety risks and trends in intravenous abuse rates observed with the drug in post-marketing safety data.

379. As issuer of the common stock issued in connection with the June 2015 Offering Endo is strictly liable to the members of the Class for the untrue statements and omissions of material fact contained therein.

380. Each of the Securities Act Defendants acted negligently in connection with the June 2015 Offering, in that that each of the Securities Act Defendants failed to undertake a reasonable investigation and/or lacked reasonable grounds for the belief that the statements contained in the Registration Statement were true, and/or were not misleading based upon the omission of any material fact, and are therefore liable to Lead Plaintiff and the other members of the Class who purchased shares of Endo common stock pursuant or traceable to the Registration Statement.

381. Each of the Securities Act Defendants signed the Registration Statement either personally or through an attorney-in-fact and/or caused its issuance. Each Securities Act Defendant had a duty to undertake a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the Registration Statement, including the statements set forth in all materials incorporated by reference into the Registration Statement, and to ensure that all such statements were true and accurate and that there were no omissions of material fact that were required to be disclosed to prevent any of the statements therein from being misleading. By virtue of each of the Securities Act Defendants' failure to exercise reasonable care, the Offering Materials contained untrue statements and omissions of material facts necessary to make the statements contained therein not misleading.

382. Lead Plaintiff and other Class members have sustained damages in connection with their purchases of Endo common stock pursuant or traceable to the Registration Statement for the June 2015 Offering. The value of Endo common stock has declined substantially subsequent to and due to the Securities Act Defendants' violations.

383. At the time of their purchases of Endo common stock pursuant or traceable to the Registration Statement for the June 2015 Offering, Lead Plaintiff and other members of the Class did not know the true facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the disclosures alleged herein.

384. The Defendants named in this Count, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

385. Lead Plaintiff has standing to bring this claim under Section 11 of the Securities Act on behalf of itself and all other Class members that purchased Endo common stock pursuant

or traceable to the Registration Statement for the June 2015 Offering. Moreover, Lead Plaintiff's purchases of Endo common stock during the Class Period implicate the same set of concerns as the conduct that Lead Plaintiff alleges to have caused injury to itself and to other members of the Class who purchased shares of Endo common stock pursuant or traceable to the Registration Statement for the June 2015 Offering.

386. This claim is brought within the applicable statute of limitations because less than one year has elapsed from the time that Lead Plaintiff and the other members of the Class who purchased shares of Endo common stock pursuant or traceable to the Registration Statement for the June 2015 Offering discovered or reasonably could have discovered the facts upon which this Count is based and the time that this claim was first brought. Less than three years have elapsed from the time that the shares of Endo common stock were sold in the June 2015 Offering pursuant to the Registration Statement.

387. By reason of the foregoing, the Securities Act Defendants named in this Count have violated Section 11 of the Securities Act.

XVI. COUNT IV: FOR VIOLATION OF SECTION 15 OF THE SECURITIES ACT AGAINST THE INDIVIDUAL SECURITIES ACT DEFENDANTS

388. Lead Plaintiff repeats and re-alleges the allegations above in ¶¶ 352-87. This claim is based solely on the Individual Securities Act Defendants' negligence.

389. This claim is asserted against the Individual Securities Act Defendants for violations of Section 15 of the Securities Act, 15 U.S.C. § 77o, on behalf of Lead Plaintiff and all other members of the Class who purchased shares of Endo common stock pursuant or traceable to the Registration Statement for the June 2015 Offering. This claim is premised upon Endo's primary violation of Section 11 of the Securities Act alleged above in Count III.

390. At all times relevant to this claim, each of the Individual Securities Act Defendants was a controlling person of Endo within the meaning of Section 15 of the Securities Act. At the time of the June 2015 Offering, each of the Individual Securities Act Defendants was an officer or director of Endo. As such, each participated in the day to day operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of Endo's business affairs, including the registration of its securities.

391. Each of the Individual Securities Act Defendants also signed the Offering Materials or caused them to be signed and, thus, had the power to control the contents of the Offering Materials before they were disseminated to the public.

392. As officers and directors of Endo and as signatories to the Registration Statement, each of the Individual Securities Act Defendants had a duty to disseminate accurate and truthful information with respect to Endo's business, financial condition, and results of operations, including its proposed sale of common stock. By virtue of signing the Registration Statement, each of the Individual Securities Act Defendants also participated in the preparation and/or dissemination of the Offering Materials, and otherwise participated in the process necessary to conduct the June 2015 Offering.

393. Because of their respective positions of control and authority as officers and directors of Endo, and as signatories to the Offering Materials, each of the Individual Securities Act Defendants was able to, and did, control the contents of the Offering Materials, which contained material misrepresentations and omissions of material fact.

394. By reason of the aforementioned conduct, each of the Individual Securities Act Defendants is liable under Section 15 of the Securities Act jointly and severally with, and to the

same extent as, Endo is liable under Section 11 of the Securities Act, in connection with the June 2015 Offering.

XVII. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff prays for relief and judgment, including:

A. Awarding compensatory damages against all Exchange Act Defendants and Securities Act Defendants, jointly and severally, for all damages sustained as a result of the Exchange Act and the Securities Act Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon, as allowed by law;

B. Awarding extraordinary, equitable, and/or injunctive relief as permitted by law (including, but not limited to, rescission);

C. Awarding Lead Plaintiff its costs and expenses incurred in this Action, including reasonable counsel fees and expert fees; and

D. Awarding such other and further relief as may be just and proper.

XVIII. JURY TRIAL DEMANDED

Lead Plaintiff hereby demands a trial by jury.

Dated: February 5, 2018

Respectfully submitted,

KESSLER TOPAZ MELTZER & CHECK LLP

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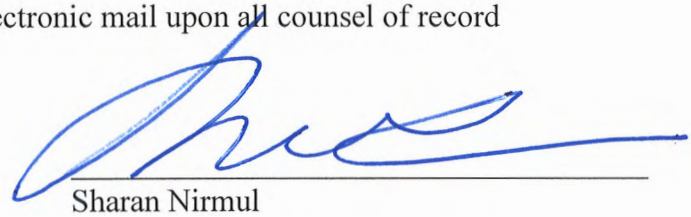
Counsel for Lead Plaintiff SEB Investment Management AB

CERTIFICATE OF SERVICE

I hereby certify that on February 5, 2018, a true and correct copy of the foregoing was hand delivered to the Clerk of the Court to be electronically filed, will be available for viewing and downloading from the ECF system, and will be served by operation of the Court's electronic filing system (CM/ECF) and electronic mail upon all counsel of record

Dated: February 5, 2018



Sharan Nirmul

EXHIBIT A

CERTIFICATION

SEB Investment Management AB ("SEB Investment Management" or "Plaintiff"), on behalf of the Funds listed in the attached Schedule A, declares, as to the claims asserted under the federal securities laws, that:

1. Plaintiff did not purchase the securities that are the subject of this action at the direction of Plaintiff's counsel or in order to participate in any private action.

2. Plaintiff is willing to serve as a representative party on behalf of the Class, including providing testimony at deposition and trial, if necessary.

3. Plaintiff's Class Period purchase and sale transactions in Endo International plc (formerly Endo Health Solutions Inc.) securities that are the subject of this action are reflected in the attached Schedule A.

4. SEB Investment Management has full power and authority to bring suit to recover for investment losses on behalf of its Funds.

5. Plaintiff has fully reviewed the Amended Complaint for Violations of the Federal Securities Laws and has authorized its filing.

6. I, Hans Ek, Deputy Chief Executive Officer, am authorized to make legal decisions on behalf of SEB Investment Management.

7. Plaintiff intends to actively monitor and vigorously pursue this action for the benefit of the Class.

8. Plaintiff will endeavor to provide fair and adequate representation to the Class and work directly with Class counsel to obtain the largest recovery for the Class consistent with good faith and sound judgment.

9. During the three years prior to the date of this Certification and presently, Plaintiff has served as representative party in a class action filed under the federal securities laws only in the instant action, *Bier v. Endo International, PLC, et al.*, No. 17-3711 (E.D. Pa.).

10. Other than the instant action, Plaintiff has not sought to serve as a representative party for a class action filed under the federal securities laws during the three years prior to the date of this Certification.

11. Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond Plaintiff's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the Court.

I declare under penalty of perjury of the laws of the United States of America that the foregoing is true and correct.

Executed this 5th day of February 2018.

For and on behalf of
SEB Investment Management AB

By: _____
Name: Hans Ek
Title: Deputy Chief Executive Officer

SCHEDULE A

SEB Fund 3 - SEB U.S. Index Fund

Buy/Sell	Date	Quantity of Common stock/ Ordinary Shares	Price
Buy	1/26/2015	5,700	$79.15
Buy	7/2/2015	1,900	$82.02
Sell	8/24/2015	1,200	$73.45
Sell	2/9/2016	600	$52.22
Sell	2/28/2017	5,800	$13.65

SEB Fund 3 - SEB Ethical Global Index Fund

Buy/Sell	Date	Quantity of Common stock/ Ordinary Shares	Price
Buy	5/30/2014	5,100	$70.59
Buy	8/28/2014	3,900	$64.02
Buy	4/15/2015	2,600	$95.92
Buy	9/22/2015	5,100	$75.78
Sell	5/20/2016	16,700	$15.44

SEB Concept Biotechnology

Buy/Sell	Date	Quantity of Common stock/ Ordinary Shares	Price
Buy	4/2/2013	20,600	$31.91
Buy	4/3/2013	11,900	$33.29
Buy	4/4/2013	39,400	$33.70
Buy	4/9/2013	3,700	$34.98
Buy	4/18/2013	3,600	$35.75
Buy	4/29/2013	4,000	$36.45
Buy	5/13/2013	12,800	$33.71
Buy	5/14/2013	7,200	$33.74
Buy	6/24/2013	19,300	$37.19
Buy	7/9/2013	4,600	$39.28
Buy	7/15/2013	6,900	$39.10
Buy	8/2/2013	10,300	$39.21
Buy	8/19/2013	3,500	$37.39
Buy	9/3/2013	6,400	$41.83
Buy	9/12/2013	6,500	$43.70
Buy	9/23/2013	5,200	$45.51

Buy	10/21/2013	8,500	$44.46
Buy	10/30/2013	6,300	$44.40
Buy	11/18/2013	7,400	$64.20
Buy	11/22/2013	5,000	$65.07
Buy	11/27/2013	5,000	$67.08
Buy	12/2/2013	3,200	$67.01
Buy	1/23/2014	6,700	$66.76
Buy	1/27/2014	24,100	$64.67
Buy	2/5/2014	4,000	$68.65
Buy	2/24/2014	5,800	$77.64
Buy	2/27/2014	5,900	$79.50
Buy	3/6/2014	7,200	$76.27
Buy	6/2/2014	15,800	$70.31
Buy	7/2/2014	12,900	$69.43
Buy	7/8/2014	11,300	$66.88
Buy	8/12/2014	11,600	$61.42
Buy	8/21/2014	16,500	$63.55
Buy	8/22/2014	3,400	$63.72
Buy	8/27/2014	2,200	$65.00
Buy	9/3/2014	10,700	$62.93
Buy	9/5/2014	6,600	$63.94
Buy	9/15/2014	4,000	$64.61
Buy	9/22/2014	6,600	$66.16
Buy	9/26/2014	5,400	$69.95
Buy	10/1/2014	4,100	$68.10
Buy	10/22/2014	14,600	$63.19
Buy	10/23/2014	3,800	$64.66
Buy	10/29/2014	15,200	$65.74
Buy	10/30/2014	5,600	$66.29
Buy	11/4/2014	5,600	$68.67
Buy	11/13/2014	2,500	$67.45
Buy	12/2/2014	5,800	$70.64
Buy	12/4/2014	4,700	$70.69
Buy	1/13/2015	6,600	$79.49
Buy	1/20/2015	11,800	$81.04
Buy *	1/29/2015	61,277	$81.64
Buy	2/2/2015	11,900	$80.12
Buy	2/23/2015	8,800	$84.94
Buy	3/9/2015	9,900	$89.54
Buy	3/10/2015	14,700	$89.31
Buy	3/12/2015	6,200	$90.50
Buy	3/24/2015	11,900	$89.88
Buy	6/2/2015	3,600	$83.86
Buy	6/24/2015	4,900	$82.78
Buy	7/29/2015	27,400	$86.90
Buy	10/23/2015	21,400	$55.97

Buy	7/20/2016	41,200	$17.64
Buy	8/22/2016	100,300	$22.98
Buy	1/25/2017	48,400	$11.92
Buy	5/2/2017	9,600	$11.78
Sell	8/26/2013	5,400	$39.30
Sell	9/5/2013	10,400	$43.05
Sell	10/8/2013	5,100	$44.15
Sell	10/10/2013	4,600	$44.67
Sell	11/12/2013	17,200	$63.55
Sell	3/14/2014	5,100	$71.69
Sell	3/25/2014	1,800	$68.51
Sell	3/26/2014	3,800	$68.42
Sell	3/27/2014	3,300	$64.62
Sell	3/28/2014	4,800	$67.45
Sell	4/1/2014	8,000	$68.10
Sell	4/9/2014	4,300	$61.90
Sell	4/11/2014	1,600	$57.33
Sell	4/28/2014	10,000	$60.52
Sell	10/14/2014	7,800	$61.10
Sell	10/17/2014	6,000	$61.62
Sell	11/28/2014	7,100	$73.17
Sell	1/12/2015	27,400	$77.86
Sell	2/11/2015	68,500	$81.47
Sell	3/26/2015	8,200	$87.81
Sell	3/27/2015	9,500	$90.04
Sell	4/10/2015	6,400	$94.18
Sell	4/17/2015	3,800	$93.34
Sell	4/28/2015	11,800	$87.83
Sell	5/4/2015	12,200	$86.32
Sell	5/7/2015	11,700	$86.33
Sell	5/12/2015	5,100	$84.60
Sell	8/24/2015	9,300	$73.45
Sell	9/1/2015	7,200	$74.38
Sell	9/30/2015	7,600	$69.28
Sell	10/15/2015	6,700	$66.60
Sell	1/7/2016	3,200	$56.36
Sell	1/15/2016	14,000	$52.53
Sell	2/8/2016	10,400	$50.65
Sell	2/11/2016	10,700	$48.49
Sell	9/12/2016	12,400	$20.80
Sell	11/8/2016	21,000	$14.25
Sell	11/17/2016	49,800	$17.20
Sell	12/21/2016	17,300	$15.75
Sell	2/22/2017	118,500	$13.21

* Shares received in connection with Endo International plc's acquisition of Auxilium Pharmaceuticals, Inc. are priced at closing price on the date of receipt.