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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	Chapter 11
ENDO INTERNATIONAL PLC, *et al.*,	Case No. 22-22549 (JLG)
Debtors.	(Jointly Administered)
MATTHEW DUNDON, TRUSTEE OF THE ENDO GUC TRUST,	
Plaintiff,	Adv. Pro. No. 24-_____ (JLG)
v.	**COMPLAINT**
RAJIV DE SILVA, DOUGLAS S. INGRAM, ARTHUR J. HIGGINS, NANCY J. HUTSON, ROGER H. KIMMEL, WILLIAM P. MONTAGUE, TODD B. SISITSKY, JILL D. SMITH, WILLIAM F. SPENGLER, PAUL V. CAMPANELLI, SUKETU P. UPADHYAY, KAREN A. WALLACE, BRIAN LORTIE, ANTONIO R. PERA, JOSEPH BARBARITE, and JOHN DOES 1-10,	
Defendants.	

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Plaintiff Matthew Dundon, in his capacity as the trustee (the "Trustee") for the Endo GUC Trust (the "GUC Trust"), established pursuant to the *Fourth Amended Joint Chapter 11 Plan of Reorganization of Endo International plc and its Affiliated Debtors* [Dkt. No. 3849] (the "Plan") and the Endo GUC Trust Agreement, dated April 23, 2024, by and among (i) the Trustee, (ii) UMB Delaware Inc., as Delaware Trustee, (iii) Endo, Inc. and (iv) Endo International plc (the "Trust Agreement"), acting on behalf of itself and as successor-in-interest to the estates of the above-captioned debtors and debtors-in-possession (the above-captioned debtors and debtors-in-possession, collectively, the "Debtors" or "Endo" or the "Company") with respect to this litigation, respectfully alleges as follows:

NATURE OF THIS ACTION

1. Endo is a leading global pharmaceutical and medical device company that for years manufactured, marketed, and distributed a wide range of products used to treat pain, cancer, and various women's health issues, among other diseases and conditions. Fueled in particular by the promotion of its branded opioid products—which were prescribed to countless Americans—Endo's financial fortunes flourished and its stock price more than quadrupled from 2010 through 2015. On the heels of that growth, in late 2015 Endo acquired a generics pharmaceutical company by the name of Par Pharmaceutical to expand further the reach of its opioid business.

2. By the end of 2016, however, as the personal and societal damage caused by opioid abuse more clearly entered the public conscience, Endo's stock and bond prices tanked—weighed down by mounting liabilities associated not only with opioids but numerous others of its products as well. In August 2022, after already being found liable in or settling a number of major personal injury lawsuits and unable to fend off thousands of pending claims, Endo filed for bankruptcy protection. Indeed, when the Company filed for chapter 11 protection, it cited among other factors

"the litigation overhang on the Company from the thousands of lawsuits related to its marketing and sale of prescription opioids."

3. On account of significant secured-debt liabilities that Endo incurred in part to buy itself time before filing for bankruptcy, little was left for the Company's many unsecured creditors at the conclusion of its bankruptcy cases. Endo's Plan provided for payments of approximately $583 million to its many opioid creditors—a fraction of the billions of dollars of total harm the Company caused those victims.

4. But Endo's remaining unsecured creditors—including women implanted with defective vaginal mesh products and patients who developed cancer from the Company's production of the drug ranitidine—fared even worse. Those unsecured creditors, among others, were left with virtually ***no money*** to compensate them for their injuries. The principal compensation they were given instead was a right to pursue legal claims against the officers and directors of Endo whose misconduct directly and substantially contributed to the mounting national opioid crisis and depleted Endo of billions of dollars, bringing Endo to its knees and ultimately leaving it unable to compensate those it injured.

5. This fiduciary duty case, brought by the Trustee of the GUC Trust, principally highlights Defendants' unlawful conduct with respect to opioids in 2016 and later—a period of time after the harm that Endo was inflicting was well known to those executives and directors, who consistently and repeatedly chose to slow roll if not completely ignore their responsibility to mitigate further harm, ultimately exacerbating damages to the Company.

6. As described more fully below, for many years Endo manufactured and sold one of the most potent branded opioids on the market, under the name Opana—most notably, a drug called Opana ER (or Opana Extended Release). Through Par Pharmaceutical and other

subsidiaries, Endo also manufactured and/or sold potent generic opioids, including oxymorphone (generic Opana), oxycodone (generic OxyContin), hydrocodone/APAP (generic Vicodin), Endocet (generic Percocet), and two forms of fentanyl. As the opioid epidemic ravaged the country with increasing ferocity during the first two decades of this century—causing the deaths of hundreds of thousands of Americans—Defendants ignored red-flag warnings, continued to favor profits over compliance with the law, failed to act honestly, responsibly, and in good faith in the best interests of Endo, and otherwise breached their fiduciary duties.

7. At Defendants' direction, Endo continued to market Opana ER aggressively through December 2016 despite all warnings of the havoc caused by the drug. Most notably, Endo touted Opana ER as abuse deterrent and crush resistant—when it most certainly was not. At minimum, and likewise in breach of their fiduciary duties, the Defendant Directors and Officers knew that Opana ER could be and was being abused, yet took scant if any steps to prevent such abuse—in an effort to maximize Endo's profits from these dangerous products.

8. Emblematic of Defendants' improper prioritizing of profits over compliance in violation of Defendants' fiduciary duties, on a 2016 Endo "scorecard" of "Goals and Objectives," a key Endo executive ranked compliance as a "company strategic goal" near the very bottom, many rungs below "revenue," which ranked at the very top.

9. In early 2017, an independent Advisory Committee of the federal Food & Drug Administration voted 18-8 that the benefits of Opana ER "were overshadowed by the continuing public health concerns around the product's misuse, abuse and diversion," and concluded that the drug's benefits no longer outweighed its risks. Despite this vote, Endo nevertheless *continued* to sell Opana ER.

10. In an unprecedented action, in June 2017, the FDA then requested that Endo remove Opana ER from the market altogether. Although Endo reported that it would voluntarily comply with this request, at the direction of Defendants, the Company continued to sell off its supply of Opana ER, once again ignoring all red flags and putting profit over compliance with the law and public safety and failing to act in good faith, honestly and responsibly.

11. Endo executives' management of its Par Pharmaceutical generic opioid business was similarly egregious. As was true of its affiliates selling branded opioids, Par Pharmaceutical improperly prioritized profits over safety and legal compliance. More specifically, despite multiple clear warnings from a third-party Drug Enforcement Administration ("DEA") compliance auditor in both mid-2010 and again in mid-2015, Par Pharmaceutical continued to employ a non-compliant and indefensible suspicious order monitoring ("SOM") program until at least late-2016, long after Endo acquired Par Pharmaceutical. In fact, it appears that Par Pharmaceutical never reported a single suspicious order of opioids to the DEA under that SOM. And continuing into 2018, long after the SOM's replacement, Par Pharmaceutical continued to fail to report any meaningful number of suspicious orders to the DEA, notwithstanding that Par Pharmaceutical was one of the top three producers of potent generic opioids that were flooding the country at the time.

12. The damage that Defendants' misconduct inflicted on Endo—including from conduct in 2016 and 2017 alone—runs into the billions of dollars. Among other injuries attributable to Defendants' conduct, the Company pre-petition had to pay at least $240 million to resolve lawsuits addressing Endo's violations of the law with respect to its sales and marketing of Opana ER. Endo likewise paid over $140 million in settlement of class actions addressing the Company's false statements concerning Opana ER. And then in bankruptcy, Endo ended up obligated to pay over $900 million in additional Opioid-related settlements. And this is just the

tip of the liability iceberg—as evidenced by the billions of dollars of claims asserted against Endo in its bankruptcy case.

13. Every dollar of liability incurred as a result of Defendants' breaches of fiduciary duty was ultimately borne by Endo's unsecured creditors, who were left with little at the end of Endo's bankruptcy case.

14. By this lawsuit, the GUC Trust seeks to hold the Defendant Directors and Officers liable for the harm that they inflicted on Endo by breaching their fiduciary duties, including with respect to mission critical company issues and risks—principally through their failure to heed red-flag warnings, repeated practice of prioritizing profits ahead of compliance with the law, and failure to act in good faith, honestly and responsibly in the best interest of Endo and its affiliates.

JURISDICTION AND VENUE

15. The Court has subject-matter jurisdiction over this adversary proceeding under 28 U.S.C. §§ 157 and 1334 and the Standing Order of the United States District Court for the Southern District of New York (the "Southern District of New York"), which refers to the Bankruptcy Judges of the Southern District of New York all cases and proceedings arising under and related to title 11 of the United States Code (the "Bankruptcy Code"). This adversary proceeding is related to the chapter 11 bankruptcy case captioned *In re Endo International Plc, et al.*, Case No. 22-22549 (JLG), pending in this Court.

16. This adversary proceeding constitutes a "non-core" proceeding as defined in 28 U.S.C. § 157(b). Plaintiff consents to the entry of final orders and judgments by the Bankruptcy Court, pursuant to Rule 7008 of the Federal Rules of Bankruptcy Procedure.

17. This Court has personal jurisdiction over each Defendant pursuant to Rule 7004(f) of the Federal Rules of Bankruptcy Procedure, as upon information and belief all Defendants are domiciled in the United States.

18. Venue in the Southern District of New York is proper under 28 U.S.C. §§ 1408 and 1409 because this adversary proceeding arises under and in connection with cases commenced under the Bankruptcy Code.

THE PARTIES

I. THE PLAINTIFF AND THE ENDO GUC TRUST

19. Plaintiff Matthew Dundon is Trustee of the GUC Trust, a Delaware trust which was formed on April 23, 2024 pursuant to the Trust Agreement and Section 6.2 of the Plan. On April 23, 2024, the Debtors and the holders of the Trust Transferred Assets transferred to the GUC Trust all claims against the GUC Excluded Parties (each as defined in the Plan), including those against Defendants. The claims raised here are held by the GUC Trust in this capacity, as successor-in-interest to Endo.

II. ENDO PLC AND ITS AFFILIATES

20. During the time periods relevant to this complaint, Endo operated a specialty biopharmaceutical business that produced and sold both generic and branded products, including opioids. Endo's most well-known branded opioid product was Opana, a highly potent opioid analgesic whose active ingredient was oxymorphone—a substance that is three times more potent than morphine. A significant proportion—nearly 10%—of Endo's $24 billion in revenues between 2007 and 2016 came from sales of Opana. Endo also sold substantial quantities of generic opioids, and during this time period the Company was among the very top manufacturers of opioids nationwide based on market share.

21. Endo International plc ("Endo plc") was an Irish public limited company and was the publicly-traded, ultimate parent of Endo's global enterprise. Endo plc was a holding company that conducted business through its operating subsidiaries and was the ultimate parent of each Debtor in the Chapter 11 Cases. As represented in Endo's First Day Declaration, affidavits filed

in opioid litigation, and filings with the Securities & Exchange Commission, Endo plc is headquartered in, and its principal place of business is, Dublin, Ireland. The Board of Endo plc had ultimate oversight and other responsibility for and directed the activities of all Endo subsidiaries. Endo plc was named as a defendant in litigation in the United States on account of its role in overseeing the manufacture, distribution, marketing, and sale of the Company's opioid products and its contribution to the opioid crisis.

22. Endo Health Solutions Inc. ("Endo Health Solutions") was incorporated in Delaware with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions focused on developing, manufacturing, marketing and distributing the Company's branded and generic products, including Opana ER. In addition, Endo Health Solutions hired executives involved in the marketing and/or sale of the Company's branded products, including opioids. Like Endo plc, Endo Health Solutions was named as a defendant in litigation on account of its role in the distribution, marketing and sale of the Company's opioid products, including Opana ER, and its contribution to the opioid crisis. In February 2024, Endo Health Solutions pleaded guilty to federal charges of violating the federal Food, Drug & Cosmetic Act by introducing misbranded drugs into interstate commerce. The federal government also (i) levied a criminal fine of over $1 billion and an additional $450 million in criminal forfeiture, and (ii) entered into a civil settlement providing for recognition by Endo Health Solutions of a $475 million unsecured claim.

23. Endo Pharmaceuticals, Inc. ("Endo Pharmaceuticals") was incorporated in Delaware with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals was involved in the manufacture, distribution, marketing, and sale of the Company's branded and generic opioid products, [redacted]. It too was named as a defendant in litigation on account of

its role in the distribution, marketing, and sale of the Company's opioid products, including Opana ER and its contribution to the opioid crisis.

24. Par Pharmaceutical Holdings, Inc. ("PPHI") was incorporated in Delaware with its principal place of business in Chestnut Ridge, New York. PPHI was acquired by Endo plc in September 2015 and during the relevant time period was an operating company of Endo plc.

25. Par Pharmaceutical Companies, Inc. ("PPCI") was incorporated in Delaware with its principal place of business in Chestnut Ridge, New York. PPCI is a wholly owned subsidiary of PPHI. Like Endo plc, Endo Health Solutions, and Endo Pharmaceuticals, PPCI was named as a defendant in litigation on account of its role in the distribution, marketing, and sale of generic opioid products, and contribution to the opioid crisis.

26. Par Pharmaceutical, Inc. ("PPI") was incorporated in Delaware with its principal place of business in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly owned subsidiary of PPCI. It too was named as a defendant in litigation on account of its role in the distribution, marketing, and sale of generic opioid products, and contribution to the opioid crisis. PPHI, PPCI, and PPI are collectively referred to here as "Par Pharmaceutical."

27. On August 16, 2022, the Debtors—which included Endo plc, Endo Health Solutions, Endo Pharmaceuticals, and Par Pharmaceutical—filed for chapter 11 bankruptcy protection, citing among other factors the number of opioid cases filed against Endo and its affiliates. The Debtors had collectively been named as defendants in over 3,500 lawsuits concerning their sale and marketing of opioid products, including the marketing and promotion of Opana and Opana ER. Pursuant to a settlement between the Debtors, the Ad Hoc First Lien Group, and the Official Committee of Unsecured Creditors (the "UCC"), as memorialized in the Trust

Agreement and Section 6.2 of the Plan, the Debtors contributed to the GUC Trust, among other claims, the claims at issue in this case.

28. The Court confirmed the Plan on March 19, 2024, and the Plan became effective on April 23, 2024 (the "Effective Date"). [Dkt. No. 4212]. The GUC Trust came into existence on the Effective Date, and now brings this action.

III. THE DEFENDANT DIRECTORS AND OFFICERS OF ENDO

A. Endo plc Director Defendants

29. The individual Defendants listed below were directors of Endo plc during the relevant period, and are referenced in the complaint as the "Endo plc Director Defendants."

30. Defendant Rajiv De Silva served as a Director and as President and CEO of Endo plc from February 2014 to September 2016.

31. Defendant Douglas S. Ingram served as a Director of Endo plc from May 2016 to November 2017. During his tenure on Endo plc's Board of Directors, Mr. Ingram served as a member of the Compensation Committee, the Operations Committee, [redacted].

32. Defendant Arthur J. Higgins served as a Director of Endo plc from February 2014 to March 2017. He served as a member of the Endo plc Operations Committee [redacted] from about 2014 through 2017.

33. Defendant Nancy J. Hutson served as a Director of Endo plc from February 2014 to April 2024.

34. Defendant Roger H. Kimmel served as a Director and Chair of the Board of Directors of Endo plc from February 2014 to June 2021. He served as Chair of the Corporate Governance Committee and the Nominating Committee, and as a member of [redacted], the Audit Committee, the Nominating Committee, the Compensation Committee, and

the Corporate Governance Committee. Mr. Kimmel also served as a member or alternate member of the Operations Committee [redacted].

35. Defendant William P. Montague served as a Director of Endo plc from February 2014 to April 2024.

36. Defendant Todd B. Sisitsky served as a Director of Endo plc from May 2016 to June 2019. During his tenure on Endo plc's Board of Directors, Mr. Sisitsky served as Chair of the Nominating Committee, and as a member of [redacted], the Nominating Committee, the Compensation Committee, and the Corporate Governance Committee.

37. Defendant Jill D. Smith served as a Director of Endo plc from February 2014 to June 2018. During her tenure on Endo's Board of Directors, Ms. Smith served as a member of the Audit Committee, the Nominating Committee, and the Corporate Governance Committee. Ms. Smith served as a member of the Operations Committee from at least 2014 through 2018. [redacted]

38. Defendant William F. Spengler served as a Director of Endo plc from February 2014 to June 2017. During his tenure on Endo plc's Board of Directors, Mr. Spengler served as Chair the Audit Committee, and as a member of the Audit Committee, and as an alternate on the Compensation Committee.

39. The Board of Endo plc had ultimate oversight and other responsibility for and directed the activities of all Endo subsidiaries.

B. Endo Health Solutions Director And Officer Defendants

40. The individual Defendants listed below were directors and/or officers of Endo Health Solutions during the relevant period, and are referenced in the complaint as "Endo Health Solutions Director and/or Officer Defendants."

41. Defendant Paul V. Campanelli served as a Director and as President and Chief Executive Officer of Endo Health Solutions beginning in 2016, through 2019.

42. Defendant Rajiv De Silva, a Director of Endo plc, also served as a Director of Endo Health Solutions and as President and Chief Executive Officer of Endo Health Solutions during 2015 until late 2016. On that basis, he is named as well as an Endo Health Solutions Director and/or Officer Defendant.

43. Defendant Suketu P. Upadhyay served as a Director and as Executive Vice President and Chief Financial Officer of Endo Health Solutions at least during the years 2015 and 2016.

44. Defendant Karen A. Wallace served as a Director of Endo Health Solutions during the years 2016 and 2017.

C. Endo Pharmaceuticals Director And Officer Defendants

45. The individual Defendants listed below were directors and/or officers of Endo Pharmaceuticals during the relevant period, and are referenced in the complaint as "Endo Pharmaceuticals Director and/or Officer Defendants."

46. Defendant Paul V. Campanelli, also a Director of Endo Health Solutions, served as a Director and President and Chief Executive Officer of Endo Pharmaceuticals during 2016. On that basis, he is named as well as an Endo Pharmaceuticals Director and/or Officer Defendant.

47. Defendant Rajiv De Silva, also a Director of Endo plc and Endo Health Solutions, served as a Director and as President and CEO of Endo Pharmaceuticals from 2013 until

at least 2016. On that basis, he is named as well as an Endo Pharmaceuticals Director and/or Officer Defendant.

48. Defendant Brian Lortie served as President of Branded Pharmaceuticals of Endo Pharmaceuticals from 2014 to 2016. Prior to that during his tenure at of Endo Pharmaceuticals, he served in the roles of Senior Vice President Branded Pharmaceuticals and Senior Vice President Pain Business.

49. Defendant Suketu P. Upadhyay, also a Director and Officer of Endo Health Solutions, served as a Director and as Executive Vice President and Chief Financial Officer of Endo Pharmaceuticals during 2015 and 2016. On that basis, he is named as well as an Endo Pharmaceuticals Director and/or Officer Defendant.

D. Par Pharmaceutical Director And Officer Defendants

50. The individual Defendants listed below were directors and/or officers of Par Pharmaceutical during the relevant period, and are referenced in the complaint as "Par Pharmaceutical Director and/or Officer Defendants."

51. Defendant Paul V. Campanelli, also a Director of Endo Health Solutions and Endo Pharmaceuticals, served as Par Pharmaceutical's Chief Operating Officer from January 2010 to September 2012, as its Chief Executive Officer from 2012 through at least 2019, other than while serving as its President from late 2015 to 2016. He also served as a Director of PPHI, PPCI, and/or PPI, from September 2012 through at least 2019. On that basis, he is named as well as a Par Pharmaceutical Director and Officer Defendant.

52. Defendant Rajiv De Silva, also a Director of Endo plc, Endo Health Solutions, and Endo Pharmaceuticals, served as a Director and CEO of PPI, starting in March 2016. On that basis, he is named as well as a Par Pharmaceutical Director and/or Officer Defendant.

53. Defendant Suketu P. Upadhyay, also a Director and Officer of Endo Health Solutions and Endo Pharmaceuticals, served as a Director and as Executive Vice President and Chief Financial Officer of Par Pharmaceutical, Inc., during 2016. On that basis, he is named as well as a Par Pharmaceutical Director and/or Officer Defendant.

54. Defendant Antonio R. Pera served as Director of PPHI and PPI in 2016, as Chief Commercial Officer of PPHI, PPCI, and/or PPI from 2014 until at least 2016, and as President of PPHI and PPI in 2016. During these years, he led Par Pharmaceutical's sales and marketing organization.

55. Defendant Joseph Barbarite served as Senior Vice President Global Quality and Compliance of PPCI, PPI, and upon information and belief PPHI from at least 2010 until at least 2016.

* * *

56. Defendants John Does 1-10 served as Directors and/or Officers of Endo plc and/or at least one of its affiliates during at least some portion of the period beginning in 2015 and at least through 2016.

57. The Trust continues to investigate potential claims for breach of fiduciary duty and otherwise.

58. Pursuant to Fed. R. Civ. P. 44.1, Irish substantive law may apply to claims against Defendants who were directors of Endo plc, and Delaware substantive law may apply to claims against Defendants who were directors and/or officers of Endo Health Solutions, Endo Pharmaceuticals and/or Par Pharmaceutical.

FACTS

I. ENDO AND OPANA ER

A. Endo: One Of The Country's Largest Opioids Manufacturers

59. Through the date of its bankruptcy filing in August 2022, Endo had been a publicly-traded global manufacturer of specialty and generic pharmaceutical drugs and medical products. Although the Company's history can be traced back to the 1920s, Endo commenced current operations in 1997 by acquiring from The DuPont Merck Pharmaceutical Company certain pharmaceutical products, along with related rights and assets.

60. Endo had four principal operating segments: (i) branded pharmaceuticals; (ii) sterile injectables; (iii) generic pharmaceuticals; and (iv) international pharmaceuticals.

61. Historically, Endo has been one of the largest manufacturers of opioids in the United States. Endo's opioid portfolio has included the following products:

a. Opana (oxymorphone hydrochloride), Opana IR (oxymorphone hydrochloride), and Opana ER (oxymorphone hydrochloride extended release). These are Schedule II opioid agonist tablets first approved by the FDA in 2006. Opana, and particularly Opana ER, was Endo's most well-known branded opioid product and was a focus of Endo's marketing efforts.

b. Percodan (oxycodone hydrochloride and aspirin). Percodan is a Schedule II opioid agonist tablet first approved by the FDA in 1950 and first marketed by Endo in 2004.

c. Percocet/Endocet (oxycodone hydrochloride and acetaminophen). This product is a Schedule II opioid agonist tablet approved by the FDA in 1999 and marketed by Endo since 2006.

B. Endo's Long, Dark History With Oxymorphone And Defendants' Marketing And Sale Of Opana ER Despite Knowledge Of Its Dangers And Abuse

1. History

62. Opana ER was not the first oxymorphone product that Endo invented, manufactured, promoted and then withdrew from the market after rampant abuse. In 1959, Endo launched Numorphan, an immediate release oxymorphone product that became the precursor to

Opana. By the 1960s, just a few years after Numorphan was released into the market, concerns arose that its tablets were being abused via injection. The pills were known as "blues" and had the ability to produce an extreme high. By 1971, Endo stopped marketing and distributing Numorphan immediate release and by 1982 had voluntarily withdrawn Numorphan from the market altogether—citing commercial reasons, but amid public concerns of rampant abuse.

63. Two and a half decades later though, Endo renamed one of its Numorphan products "Opana" and re-released into the market this highly addictive oxymorphone tablet.

64. Opana ER—oxymorphone hydrochloride extended-release tablets—was first approved by the FDA in 2006 for the management of moderate-to-severe pain when a continuous opioid analgesic was needed for an extended period of time. Opana ER's main and active ingredient, oxymorphone, is an opioid analgesic three times more potent than morphine. A single Opana ER tablet also contained far more morphine milligram equivalents than contained in otherwise comparable, so-called "immediate-release" prescription opioids—creating enormous potential for abuse.

65. In its original formulation, Opana ER could be easily crushed or dissolved in water to cause the release of all 12 hours' worth of opioids at once, producing an intense high and greatly increasing the risk of addiction and overdose from even a single use. This characteristic resulted in the rampant abuse of Opana ER.

66. In response to the public concerns regarding the abuse of its original formulation, Endo developed a reformulation of Opana ER ("Reformulated Opana ER"), which the FDA approved in 2011. The FDA, however, declined Endo's request to include in product labeling a description of its purported abuse-deterrent properties. Critically, that was because the FDA found that the drug did *not* actually meet the agency's standards for consideration as abuse-deterrent.

67. At the same time, in assessing Reformulated Opana ER, the FDA issued a statement in 2013 concluding, among other things, that:

a. While there was "an increased ability of the reformulated version of Opana ER to resist crushing relative to the original formulation, study data showed that the reformulated version's extended-release features can be compromised when subjected to other forms of manipulation, such as cutting, grinding, or chewing, followed by swallowing";

b. "Reformulated Opana ER can be readily prepared for injection, despite Endo's claim that these tablets have 'resistance to aqueous extraction (i.e., poor syringeability).' It also appears that reformulated Opana ER can be prepared for snorting using commonly available tools and methods"; and

c. One of Endo's postmarketing investigations "suggests the troubling possibility that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation."

68. Almost immediately, individuals began abusing Reformulated Opana ER. The most common method for doing so was via injection. That made Reformulated Opana ER even less safe than the original formulation. Among other things, injection introduced the risks of HIV and Hepatitis C, and, in Reformulated Opana ER's specific case, the rare blood-clotting disorder thrombotic thrombocytopenic purpura ("TTP"), which can cause kidney failure. [redacted] Indeed, Endo was aware that contemporaneous data showed that between October 2012 and March 2014, 64% of individuals who abused Reformulated Opana ER did so by injection—a significant increase from the 36% who had abused the old formulation by injection. Reformulated Opana ER was so widely abused that by 2012 Opana ER had surpassed abuse rates of Purdue Pharma's notorious opioid product OxyContin. FDA data further demonstrated that per dosing unit, Reformulated Opana ER had four times as many incidents of intentional abuse of OxyContin between 2013 and 2016.

69. In 2014 and 2015, Reformulated Opana ER was so popular among individuals who had become addicted to opioids that the drug sold on the street for as much as $100 to $150 per pill.

70. The systematic abuse of Opana ER occurred against the backdrop of a public health crisis developing across the country characterized by widespread addiction, diversion, and overdoses caused by opioids. This public health crisis is often referred to as the "opioid epidemic."

71. The number of opioid overdose deaths in the United States has increased tenfold since 1999. From 1999 to 2022, more than 720,000 people died from an overdose involving an opioid, and over 75% of the 106,699 reported drug overdose deaths in 2022 involved an opioid. Even these striking statistics do not adequately capture the full scale of the harm caused by opioids. The figures likewise do not measure the many thousands more whose lives have been forever changed by addiction, families who have lost loved ones, and the children born with neonatal abstinence syndrome.

2. Defendants' Knowledge

72. From the outset and continuing into 2018, Endo and its directors and officers, including but not limited to Defendants here, were aware of (i) the risk of addiction that Endo's opioid products posed to the general public, and (ii) the prospect of abuse of Opana ER.

73. [redacted]

74. [redacted]

[redacted]

75. [redacted]

[redacted]

76. Endo plc's Board was repeatedly informed of the abuse and misuse of its opioid products over the years. [redacted]

77. Similarly, [redacted]

78. In 2012, Endo—upon information and belief, [redacted]—had established an "Opana ER Risk Management Committee." During Committee meetings, participants discussed statistics concerning the abuse and misuse of Reformulated Opana ER, along with the diversion of Endo's opioid products. In addition, despite the importance of monitoring suspicious orders, it appears that the committee discussed Endo's suspicious order monitoring system only sporadically, noting that the program was "limited" and in need of an upgrade. Despite increasingly alarming reports of abuse, on information and belief the Opana ER Risk Management Committee was never reconvened after 2014.

79. [redacted]

80. Despite Defendants' knowledge of the extensive abuse of Opana ER, their financial goals for their flagship product never wavered, and they took scant if any steps to prevent such abuse.

3. Marketing

81. At the time of Opana's entry into the opioid market, the medical consensus was that use of opioids should be narrowly tailored. Opioids were to be used only for short-term acute pain, for cancer, or for end-of-life pain. Opioids were seen as possessing addictive properties that would not be conducive to long-term use, and inappropriate for treating less severe chronic pain conditions.

82. One way to increase revenues was to expand the potential patient pool. To that end, Endo implemented a marketing campaign designed among other things to convince medical professionals and patients that Endo's opioids, including Opana ER, could be prescribed safely in high doses for a broad variety of pain ailments, and could improve patients' quality of life by providing continuous pain relief. These practices expanded the prescription and use of non-medically necessary opioid products, which in turn led to even more abuse and diversion.

83. Endo, through Defendants, engaged in misleading marketing that among other things overstated the benefits of opioid products and understated the risks to users and targeted and compensated physicians known to prescribe large quantities of opioids. As set forth below, this conduct continued through 2016.

84. Endo engaged in several deceptive marketing tactics to boost sales of its opioid products while understating or misrepresenting their risks.

85. Most notably, Endo falsely marketed Reformulated Opana ER as abuse-deterrent, even though (i) the FDA had explicitly rejected Endo's request to include that claim in the drug's label, and (ii) Defendants had known that its opioid products were addictive and carried high risks of abuse.

86. Examples of deceptive marketing statements made by Endo during the active marketing period of Opana ER include the following:

- Failing to disclose the FDA's labeling denial on the Opana ER website or other written marketing communications concerning Opana ER.
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- Failing to inform health care providers and potential users that Opana ER was not abuse deterrent or crush resistant.

87. [redacted] (ii) [redacted] and (iii) the FDA's findings that Reformulated Opana ER was easier to inject than original Opana ER. Further, upon

Endo's announcement in July 2017 that the Company would withdraw Reformulated Opana ER, *see* paragraphs 114-16 below, [redacted]

88. [redacted]

89. Endo disseminated these deceptive messages through websites, publications and "Key Opinion Leaders." Although the FDA rejected the "abuse deterrent formulation" label for Reformulated Opana ER in 2011, [redacted]

90. Consistent with Endo's overall messaging, Endo's securities filings repeatedly touted Opana ER as "crush resistant" and "designed to be crush resistant." The filings likewise omitted any disclosure of those features of Opana ER that made the product less safe.

91. Endo also employed a network of sales representatives to encourage physicians to prescribe Endo's opioid products, including via "detailing"—in-person visits to potential and

actual prescribers. Targeting prescribers was core to Endo's sales proposition. Numerous 10-Ks—signed by Defendants De Silva and Upadhyay—acknowledged that growth in sales of its opioid products was attributable to its "promotional efforts through physician targeting." [redacted] further pushing those representatives to detail prescribers.

92. [redacted]

93. The Sales Force Blitz, a targeted sales campaign, was an attempt to increase sales of Opana ER by assigning more sales representatives to promote the product to prescribers via "targeting" the "sweet spot of doc[tors]" amenable to prescribing the drug in greater quantities. [redacted]

94. [redacted]— creating a significant incentive for these sales representatives to convince doctors to prescribe Opana ER, regardless of the risks involved.

95. The Sales Force Blitz was effective. Opana ER sales, which had been plummeting since the introduction of Reformulated Opana ER in 2012 on account of generic oxymorphone competition, began to level off.

96. [redacted] for a product called Belbuca, an opioid based buprenorphine film used to treat long-acting pain. Endo had purchased the rights to sell Belbuca via a licensing agreement with BioDelivery Sciences International. By February 2016, the Belbuca launch was underway.

97. [redacted]

98. [redacted]

II. MISCONDUCT IN 2016 AND FORWARD

99. [redacted] Presumably by "educating" healthcare professionals, Endo was effectively urging its sales representatives to advise potential "targets" that Opana ER contained abuse deterrent

properties that the original formulation or generic formulation did not—even though the FDA had specifically stated that Reformulated Opana ER was not abuse deterrent.

100. Endo continued to promote Opana ER in this deceptive manner throughout 2016.

101. [redacted]

102. [redacted]

103. Even with the June 2016 change, however, Defendants' wrongful conduct effectively continued at least through the end of 2016. On information and belief based on the absence of evidence to the contrary, Endo did nothing—and delivered no message—designed to disabuse health care providers of the prior false messages concerning Opana ER that Endo had pressed *for years*. Endo did not, for example, instruct sales representatives to inform health care providers that the abuse-deterrent, crush-resistant message previously delivered was false and/or misleading.

104. Significantly, the changes described in paragraph 102 above were occasioned not by any change in Endo's marketing strategy or concern over the impact of its false or misleading marketing of Opana ER.

105. Rather, in March 2016 Endo Health Solutions and Endo Pharmaceuticals entered into an Assurance of Discontinuance with the New York State Attorney General concerning their improper marketing practices for Opana ER.

106. The Assurance of Discontinuance stated that "The Attorney General found that Endo improperly marketed Opana ER to be crush resistant, when Endo's own studies showed that the pill could be crushed and ground."

107. The Assurance of Discontinuance also stated that its investigation "revealed that Endo had no meaningful program in place to ensure that its sales representatives were not encouraging health care providers engaged in abuse and diversion to write more prescriptions for Opana ER."

108. As part of the settlement with the New York State Attorney General, Endo agreed to "stop improperly marketing Opana ER as being crush resistant."

109. Yet as far as the Trustee can tell, and as set forth at paragraph 102 above Endo did not deliver new instructions to its sales representatives until June 2016. And as set forth at paragraph 103 above, there were no instructions given to sales representatives to inform health care providers that *prior* messages concerning Opana ER as abuse deterrent or crush resistant were false.

110. In September 2016, Endo received a report from a Florida detective describing an "Opana sales and use ring," and stating that 50 people had been arrested and two people had died. This email chain reached all the way to Defendant Campanelli. On the same day that Endo received this report, the Endo Northeast Leadership team received an email stressing that "it is very important that our teams are selling Opana ER on every call." Endo's leadership received several similar reports while the Company continued to promote Reformulated Opana ER.

111. [redacted] and consequently cut the sales force and personal promotion of Belbuca and Opana ER in December 2016. Endo ceased promoting the products not because of concern over the abuse of Opana ER, but rather only when it became clear that there was no longer a short-term economic benefit in such targeted promotion.

112. On March 13 and 14, 2017, an independent FDA advisory committee determined by an 18-8 vote that the benefits of Reformulated Opana ER no longer outweighed its risks. Members of the advisory committee found that any benefits of Reformulated Opana ER "were overshadowed by the continuing public health concerns around the product's misuse, abuse, and diversion."

113. Even though Endo stopped actively marketing Opana ER, it nevertheless continued selling Opana ER.

114. In an unprecedented action, in June 2017 FDA requested that Endo remove Opana ER from the market.

115. It was only then, on July 6, 2017, that Endo reported that the Company would voluntarily remove Opana ER from the market.

116. [redacted] In response to this update, the Endo Board appears to have principally focused on the economic hit that Endo would suffer. [redacted]

117. Upon deciding to withdraw Reformulated Opana ER from the market, and once again putting profits over compliance, Endo took steps to ensure that the Company would make money on its remaining Opana ER inventory. [redacted]

118. At minimum, Defendant Campanelli and likely other Defendants were aware of this strategy to offload Reformulated Opana ER.

119. [redacted] Endo's residual sales of Opana ER continued into 2018.

120. Through the launch of Opana ER in 2006 until sales ceased—including from 2016 forward—Endo realized hundreds of millions of dollars through the sale of Opana ER, a drug which the Company was fully aware was being seriously abused.

III. GUILTY PLEA AND CIVIL SETTLEMENT

121. In February 2024, Endo Health Solutions and the United States entered into a "global resolution" of the federal government's criminal and civil investigations into the sales and marketing of Opana ER. As part of the settlement, Endo Health Solutions agreed to plead guilty to violating the Federal Food, Drug & Cosmetic Act by "caus[ing] the introduction and delivery for introduction into interstate commerce of Opana ER, a drug that was misbranded in that the drug's labeling lacked adequate directions for use."

122. As part of its guilty plea, Endo Health solutions "admit[ted] that it is responsible for the acts of its employees and agents, described below, and admits the following facts:

> In February 2012, ENDO submitted proposed promotion materials for reformulated Opana ER to FDA for advisory review. In April 2012, FDA sent ENDO a marketing claims review letter stating that claims and representations in the proposed promotion materials suggesting that reformulated Opana ER offered any therapeutic advantage over the original formulation—including claims of "mechanical stability," "mechanical strength," and "obstacle[s]" or "resistance to crushing by tools"—"ha[ve] not been demonstrated by substantial evidence or clinical experience" and "misleadingly minimize the risks associated with Opana ER by suggesting that the new formulation . . . confers some form of abuse deterrence properties when this has not been demonstrated by substantial evidence." The FDA concluded: 'We are especially concerned from a public health perspective because the presence of this information in the detail aid could result in health care practitioners or patients thinking that the new formulation is safer than the old formulation, when this is not the case.'
>
> ENDO hired hundreds of sales representatives to conduct in-person marketing of Opana ER and reformulated Opana ER (known in the industry as "detailing") of healthcare providers. ENDO's analyses showed that its detailing of healthcare providers was effective at increasing the drug's sales, which is a finding generally consistent with the effect of detailing efforts for branded pharmaceuticals in the industry.
>
> Despite FDA's guidance to ENDO, from April 2012 through May 2013, certain ENDO sales representatives marketed reformulated Opana ER to prescribers by touting Opana ER's purported abuse deterrence, crush resistance and/or tamper resistance. Moreover, certain ENDO sales managers were aware that certain sales representatives were making claims regarding reformulated Opana ER's purported abuse deterrence, crush resistance, and/or tamper resistance during sales calls.
>
> In January 2013, ENDO supplied its sales representatives with demonstration cards that contained sample rods of the INTAC technology used in reformulated Opana ER. Some ENDO sales representatives improperly hit the demonstration rods with hammers and conducted other demonstrations with sample rods to attempt to convey the message that reformulated Opana ER was, in fact, crush proof, tamper resistant, and/or abuse deterrent until May 2013.

> In December 2016, ENDO voluntarily stopped the detailing of reformulated Opana ER by sales representatives to healthcare providers.
>
> ENDO continued to sell reformulated Opana ER until July 2017. ENDO voluntarily withdrew the product from the market after FDA requested that ENDO do so due to concerns related to intravenous abuse of the product.
>
> The FDA-approved labeling for reformulated Opana ER did not provide adequate information for healthcare providers to safely prescribe reformulated Opana ER for use as an opioid that is abuse deterrent. For example, the FDA approved labeling for reformulated Opana ER did not reflect reformulated Opana ER's purported abuse-deterrent, crush resistant, and/or tamper resistant properties that certain sales representatives conveyed to healthcare providers when marketing reformulated Opana ER (as described in paragraphs 11 and 12 above).
>
> As a result of the conduct described above, ENDO is responsible for the misbranding of reformulated Opana ER by marketing the drug in a manner designed to convey abuse deterrence, but with a label that failed to include adequate directions for use for its claimed abuse deterrence, in violation of the Federal Food, Drug, and Cosmetic Act.

123. As part of the global resolution, Endo Health Solutions agreed to a civil settlement of $475 million—an allowed unsecured claim in its bankruptcy case—to resolve its civil liability under the federal False Claims Act. The Settlement Agreement recited that "the United States contends that it has certain civil claims against Endo arising from Endo's marketing, promotion and sale, and manufacturing of Opana ER from 2011 to 2017," as alleged in the government's proof of claim filed in the bankruptcy proceeding. In that proof of claim, the federal government had alleged among other things that Endo Health Solutions had "used sales goals and sales contests to ensure that sales representatives directly marketed to these high-volume opioid prescribers, including those whom Endo had previously identified as posing risks of abuse and diversion."

124. The proof of claim also alleged that, "As a result of Endo hypertargeting high-volume opioids prescribers to begin writing Opana ER prescriptions, or to write more Opana ER

prescriptions, Endo knew that by November 2016 fewer than ten percent of all Opana ER prescribers wrote more than half of all Opana ER prescriptions."

IV. PAR PHARMACEUTICAL AND GENERIC OPIOIDS

A. Generic Opioids Manufacturers Also Significantly Contributed To The Opioid Epidemic

125. While branded opioids like OxyContin and Opana ER played a devastating role in the opioid epidemic, generic opioids also greatly contributed to the epidemic's decades-long wave of loss and suffering. As reported by the *Washington Post*, a review of DEA data and other documents establishes that Par Pharmaceutical "and other generic-pain-pill makers rushed to gain market share as the nation's deadliest drug epidemic spun out of control."

126. Par Pharmaceutical manufactured or acquired and then sold several potent generic opioids, including oxycodone (generic OxyContin), hydrocodone (generic Vicodin), Endocet (generic Percocet), and two forms of fentanyl.

127. Par Pharmaceutical sold generic opioids both in the years before and after its acquisition by Endo plc in 2015.

128. Upon information and belief, the Par Pharmaceutical Director and Officer Defendants were repeatedly informed of the abuse and misuse of the kinds of opioid products that Par Pharmaceutical sold over these years. From at least 2010 and continuing into 2018, Par Pharmaceutical and its directors and officers, including but not limited to those named as Defendants here, were aware (i) of the risk of addiction that Par Pharmaceutical opioid products posed to the general public, (ii) of the prospect of abuse and diversion of opioids that Par Pharmaceutical sold, including but not limited to oxycodone and hydrocodone, and (iii) that Par Pharmaceutical was required by regulation to maintain an appropriate suspicious order monitoring program and to report all suspicious orders to the DEA.

B. Par Pharmaceutical's Lengthy History Selling Potent Generic Opioids Without A Compliant Suspicious Order Monitoring System And Despite Repeated Warnings Of Non-Compliance

129. Despite Par Pharmaceutical's production of potent opioids during an opioid abuse epidemic, through at least late-2016—and despite a series of red flags over more than half-a-decade—the Par Pharmaceutical Director and Officer Defendants completely failed to maintain a suspicious order monitoring program that complied with DEA regulations.

1. Successive DEA Compliance Auditor Reports Repeatedly Waved Red Flags Over Par Pharmaceutical's Lack Of A Compliant SOM

130. In April 2010, a third-party DEA compliance auditor hired by Par Pharmaceutical reviewed Par Pharmaceutical's handling of controlled substances. The resulting DEA Audit Report delivered to Defendant Barbarite in May 2010 found that Par Pharmaceutical had no SOM program in place at all, in violation of 21 C.F.R. § 1301.74(b).

131. The report quoted in bold the text of 21 C.F.R. § 1301.74(b), which requires that registrants such as Par Pharmaceutical "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances" and that "[t]he registrant shall inform the Field Division Office of the [DEA] in his area of suspicious orders when discovered by the registrant." The regulation provides that the term "suspicious orders" "include[s] orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.*

132. The auditor instructed that to remedy Par Pharmaceutical's non-compliance, "a program must be instituted based on customers' sales volumes, seasonal fluctuations, etc., with a firm statistical analysis as the basis for such a program." The auditor further recommended that "the basis for . . . identifying, investigating, and clearing or reporting suspicious orders be documented in an SOP."

133. Despite the auditor's clear statement that Par Pharmaceutical "must" institute such an SOM and that it be documented in a Standard Operating Procedure ("SOP"), the company failed to do so.

134. Although the auditor first flagged in May 2010 that Par Pharmaceutical's non-compliance with the regulatory requirement that it have a SOM, it was not until nearly two years later, in April 2012, that Par Pharmaceutical first ostensibly created an SOM, embodied in Standard Operating Procedure ("SOP") No. SO002.

135. SOP No. SO002—written by Par Pharmaceutical's director of sales, rather than a compliance officer—did not comply with the regulation's requirements or the auditor's instructions for an SOM. The SOP was apparently a fig-leaf meant to give the appearance of regulatory compliance—but was not designed properly to disclose suspicious orders to Par Pharmaceutical and/or the DEA. Rather, the SOP was designed in every way to avoid disrupting sales and profits while paying no more than lip-service to regulatory compliance.

136. The SOP's monitoring procedures relied on Par Pharmaceutical's customers to self-report their usage to establish certain benchmarks that, when exceeded, could be adjusted based on a *sales* team member's interview with the customer. Most tellingly, the SOP contained no instructions at all for reporting suspicious orders to the DEA as required by the regulation.

137. An October 2012 update to SOP No. SO002 added bolded instructions for reporting to the DEA, FDA, and state board of pharmacy "Suspicious Criminal Activities," and "within three days of suspecting criminal activity." However, absent in the SOP was any definition of merely suspicious orders—defined by the regulation to include any orders of unusual size, deviating substantially from a normal pattern, or of unusual frequency—or instruction for reporting suspicious orders to the DEA.

138. Upon information and belief, Par Pharmaceutical did not consult with its DEA compliance auditor about SOP No. SO002 before its publication. In short, the so-called SOM that Par Pharmaceuticals established in April 2012 and updated in October 2012 bore all the indicia of a SOM designed in bad faith with the aim of maximizing opioid sales and profits and avoiding identification of suspicious orders or reporting of such orders to the DEA pursuant to the regulatory requirements.

139. Par Pharmaceutical waited five years until holding its next DEA compliance audit in April 2015. The auditor delivered its DEA Audit Report to Defendant Barbarite in June 2015, and—unsurprisingly—the findings with respect to the SOM (SOP NO. SO002) were damning. The auditor's verdict was that Par Pharmaceutical's procedures for monitoring and reporting suspicious orders required a total overhaul: Par Pharmaceutical's "entire approach to SOM should be [re-]evaluated."

140. The auditor warned that "Par's current SOM system as it currently operates may be difficult to explain and defend during a DEA review" and that "Par Pharma's SOM system may be difficult to defend during a DEA SOM audit." First and foremost, "[t]here is no indication that the system measures or attempts to measure order size, pattern and frequency" despite that "[t]hese are the requirements in the regulations." This second audit report again quoted the full text of 21 C.F.R. § 1301.74(b), this time with bolded emphasis on the final sentence of the regulatory provision: "**Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency**." The auditors instructed Par Pharmaceutical instead to use a "**Defensible**" SOM Model that (i) "Identifies orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency" and (ii) is "Statistically based."

141. The auditor also criticized the relegation of SOM decisions to sales team members rather than to regulatory compliance officers. The auditor was compelled to state the obvious: "Any employees that receive incentives for controlled substance orders should not be involved in evaluating either accounts or orders."

142. The auditor identified that—as a matter of utmost priority—"the requirement to report suspicious criminal activity rather than suspicious orders should be corrected as soon as possible, since it misses the point of the regulations. Suspicious orders should be reported as soon as they are identified."

143. Despite the auditor's vigorous criticism of SOP NO. SO002, Par Pharmaceutical did not implement *any* of the auditor's recommendations for its SOM. Instead, Par Pharmaceutical continued to use the very same indefensible SOM for more than another year, until late 2016.

144. In an April 2016 email, an employee in Customer Operations confirmed to a DEA Compliance specialist that, pursuant to SOP No. SO002, her group was continuing to evaluate controlled substance orders based on customer-provided information. In late October 2016, the same Customer Operations employee emailed members of the company's DEA Compliance team seeking confirmation that SOP No. SO002 should be retired. [redacted]

145. SOP No. SO002 named Sales Operations as responsible for ensuring compliance with DEA requirements and Quality Compliance as responsible for providing guidance. Defendant Pera oversaw Sales Operations from early 2014 through at least 2016, and Defendant Barbarite oversaw Quality Compliance at least from 2010 through late 2016. Upon information and belief, both Defendants Pera and Barbarite reported directly to Defendant Campanelli before

and after Endo's acquisition of Par Pharmaceutical. Upon information and belief, all three of these Defendants were responsible for Par Pharmaceutical's continued use of SOP No. SO002 despite repeated warnings from the auditor prior to Endo's acquisition of Par Pharmaceutical in 2015 and for the non-compliant SOP's continued use for a significant time after the acquisition.

146. SOP No. SO002's facial non-compliance with the requirements of 21 C.F.R. § 1301.74(b) from the start in 2012 and the auditor's formal warning in 2015 that Par Pharmaceutical continued to lack a compliant SOM were not the only red flags that Par Pharmaceutical was failing to meet the regulatory requirements.

2. The Year-After-Year Failure Of Par Pharmaceutical's SOM To Generate Notifications Of Suspicious Orders To The DEA Was Another Series Of Red Flags

147. Par Pharmaceutical's failure to report even one suspicious order to the DEA using SOP No. SO002 during peak years of the opioid epidemic while selling substantial quantities of the drugs should have itself been warning enough. From April 2012—when SOP No. SO002 came into effect—until April 2015, when the auditor first reviewed SOP No. SO002, Par Pharmaceutical was selling several forms of potent opioids in significant quantities. But during that same period, it appears that Par Pharmaceutical reported to the DEA not a single order of opioid products as suspicious.

148. From the time of the April 2015 audit—in which the auditor emphatically warned that SOP No. SO002 was not a compliant SOM—until the retirement of SOP No. SO002 in late 2016, Par Pharmaceutical continued to sell these potent opioids. But during this period too, it appears that Par Pharmaceutical made no suspicious order reports to the DEA.

149. In stark contrast, Mallinckrodt—one of Par Pharmaceutical's chief competitors in the manufacture and sale of generic opioids—reported an average of nearly 200 suspicious orders to the DEA each year between 2012 and 2017 based on its sales to *Missouri alone*. According to

a *Washington Post* analysis, Missouri was about average compared to the rest of the nation in the quantity of prescription opioids supplied to the state from 2006 to 2019.

150. Par Pharmaceutical's consistent failure to report any orders as suspicious based on its *nationwide* sales each year between April 2012 and October 2016 was yet another series of red flags waving vigorously throughout that period that Par Pharmaceutical's SOM was (i) non-compliant with the mandatory regulations, and (ii) ineffective at preventing the illegal diversion and abuse of opioids that it was selling in substantial quantities.

3. Par Pharmaceutical's Failure To Generate Notifications Of Suspicious Orders To The DEA Continued Into 2017 And 2018

151. Even after SOP No. SO002 was retired in late 2016 and continuing into 2018, Par Pharmaceutical—and Endo writ large—made few if any suspicious order reports to the DEA, with respect to its opioid sales. Indeed, Endo plc's Senior Executive of Global Supply Chain testified in a multi-district opioid litigation in which Endo plc, Endo Pharmaceuticals, Endo Health Solutions, PPI and PPCI, were all named as defendants that Endo "did not report any suspicious orders to the DEA" during that period, or as far back as 1999. The enduring paucity of suspicious order notifications constituted additional red flags to all Defendants that no Endo affiliate—including Par Pharmaceutical—had in place a compliant SOM or was satisfying its obligation to report all suspicious orders to the DEA even after Par Pharmaceutical's retirement of SOP No. SO002.

152. One such red flag following the retirement of SOP No. SO002 is a response from Endo in mid-2017 to an inquiry, from a United States Senator for Missouri serving as Ranking Member of the Committee on Homeland Security and Governmental Affairs about Endo's sales of opioids to Missouri. Endo's response acknowledged that from 2012 through mid-2017 neither Par Pharmaceutical nor Endo Pharmaceuticals identified a single schedule CII or CIII opioid order

originating in Missouri as requiring a suspicious order notification to the DEA. At the same time that Endo responded to the Senator's inquiry, DEA data obtained by the *Washington Post* shows that Par Pharmaceutical was filling orders originating in Jackson County, Missouri at a yearly rate of nearly three million doses of oxycodone and hydrocodone alone—enough to provide every resident of the county in 2017 with four doses of these potent prescription opioids.

* * *

153. Upon information and belief, the failure of Par Pharmaceutical's directors and officers to ensure a compliant and effective SOM despite the many red flags was occasioned by their prioritization of profits over compliance. And Par Pharmaceutical's failure to maintain an effective SOM and report suspicious orders played a role in litigation naming Endo plc, Endo Pharmaceuticals, Endo Health Solutions, PPI and PPCI, as defendants, in turn contributing to Endo's insolvency.

V. ENDO'S DIRECTORS AND OFFICERS HAD—AND BREACHED—A DUTY TO PROTECT ENDO, OVERSEE ITS AFFAIRS, PAY ATTENTION TO RED FLAGS AND ENSURE ENDO'S COMPLIANCE WITH ALL LAWS

154. The reference to and allegations concerning Endo in this Section V apply equally to Endo plc, Endo Health Solutions, Endo Pharmaceuticals and their directors and officers unless specifically noted otherwise.

155. As set forth below, Defendants owed fiduciary duties to Endo plc, Endo Health Solutions, and/or Endo Pharmaceuticals to (i) refrain from activities that would expose Endo to significant liabilities, (ii) properly oversee the Company's affairs, (iii) ensure the Company's compliance with all laws and regulations, (iv) ensure that opioids marketed and distributed by Endo were not endangering the public—which in turn would inevitably and materially injure the Company, (v) act in good faith and in best interests of the Company, (vi) act honestly and responsibly in relation to the conduct of the affairs of the Company, and (vii) exercise proper care,

skill, and diligence. Defendants failed in carrying out these duties and protecting the Company and its stakeholders.

156. By reason of their positions as directors, officers, and fiduciaries of Endo plc, Endo Health Solutions, and/or Endo Pharmaceuticals, and because of their ability to control its business and corporate affairs, Defendants owed fiduciary obligations of care, good faith, and loyalty, and were required to run, oversee, and manage Endo consistent with these obligations. To fulfill their responsibilities and duties, Defendants were required to supervise and manage Endo's policies and controls, and ensure compliance with various laws and regulations that applied to Endo's business.

157. [redacted]

158. As an opioid manufacturer, Endo was subject to extensive regulation and regulatory oversight from both the federal government and each of the states within which it operates. On information and belief, Endo's directors and officers were aware of their obligation to ensure Endo's compliance with laws and regulations governing to the manufacture and sale of opioid products. For example, Endo's annual reports would disclose that:

> In the United States, the development, testing, manufacture, holding, packaging, labeling, distribution, marketing, and sales of

> our products and our ongoing product development activities are subject to extensive and rigorous government regulation. The Federal Food, Drug and Cosmetic Act (FFDCA), the Controlled Substances Act and other federal and state statutes and regulations govern or influence the testing, manufacture, packaging, labeling, storage, record keeping, approval, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements can result in fines, recall or seizure of products, total or partial suspension of production and/or distribution, injunctions . . . civil penalties and criminal prosecution.

159. Endo's annual reports also disclosed that (i) "changes … in legal or regulatory interpretation," "or new legislation," "could have a material adverse effect on our business, financial condition, results of operations, and cash flows," (ii) Endo's opioid products are subject to "certain security and record keeping requirements by the . . . DEA," and (iii) these requirements are meant to "prevent loss and diversion" of these controlled substances. Variations of these disclosures appeared on every one of Endo's Form 10-Ks dating back to at least 2006, following the launch of Opana and Opana ER. Defendants Campanelli and De Silva signed certain of Endo's Form 10-Ks making these disclosures from 2015 through 2021.

160. In addition, Endo was required to comply with the statutory requirements imposed by the Comprehensive Drug Abuse Prevention and Control Act of 1970 (the "CSA"), 21 U.S.C. § 801 *et seq.*, and the regulations promulgated pursuant to the CSA, 21 C.F.R. § 1300, *et seq.* Congress enacted the CSA in 1970 to (i) promote public health by making medications available to patients, and (ii) protect public safety by abating illegal diversion of controlled substances.

161. The CSA created a "closed" chain of distribution designed and intended to prevent the diversion of legally-produced controlled substances into the illicit market. As with Par Pharmaceutical, the regulations applicable to this closed system required Endo to design and operate a system to monitor, identify, halt, and report "suspicious orders" for controlled

substances, as that term is defined in the regulation, and protect against the diversion of its products. *See* 21 C.F.R. § 1301.74(b).

162. To discharge their duties, Defendants were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the Company. Pursuant to those duties, Defendants were required among other things:

a. to exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner to make it possible to provide the highest quality performance of their business;

b. to exercise good faith to ensure that the Company was operated in a diligent, honest, and prudent manner and complied with all applicable federal and state laws, rules, regulations, and requirements; and

c. when put on notice of problems with the Company's business practices and operations, to exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

163. Endo has admitted that the Company did not meet these requirements. In his First Day Declaration in the bankruptcy proceeding, the Company's representative stated, "[t]he Debtors had limited insight into precisely where their products ended up, who used them, or whether anyone abused them contrary to their FDA-approved labeling." This statement is an admission of Endo's failure to monitor properly the problem of abuse and diversion, as required by law. In key respects, the statement is also false. As pleaded above, Defendants could not have been unaware of the extensive abuse of Opana ER unless they consciously ignored and/or improperly closed their eyes to that abuse. Despite their legal obligation to take the appropriate actions to correct this misuse, Defendants attempted to distance Endo (and themselves) from their contribution to the opioid crisis by blaming among others the doctors, themselves targeted and misled by Endo.

164. Endo misleadingly promoted Opana ER products as having a lower potential for abuse, hired sales representatives to target prescribers, utilized a speaker program to pay millions

of dollars to prescribers, and promoted misleading and harmful narratives about "pseudoaddiction." Endo maintained many of these practices at least through December 2016.

165. Defendants were aware—or had reason to know—that numerous prescribers and clinics detailed by its sales representatives were operating pill mills. Yet Endo allowed these sales representatives to continue to detail them. [redacted]

166. Moreover, even though the FDA had rejected Endo's request to allow the Company to market Reformulated Opana ER as abuse deterrent, [redacted].

167. Defendants oversaw the deployment of its sales representatives and received detailed information about their performance. [redacted]

[redacted]

168. Endo executives also received information concerning certain problematic sales practices. [redacted] Failure to give healthcare providers information as part of Endo's anti-abuse and anti-diversion efforts also increased the likelihood that Endo's opioids would be overprescribed and abused or diverted. [redacted]

169. [redacted]

[redacted] Notwithstanding the warnings of Endo leadership, it appears that nothing material was done to correct the systemic failures.

170. [redacted] The Board meeting minutes do not reflect that any action was undertaken by the Board to remedy these "compliance issues."

171. Underscoring Defendants' misplaced priorities in violation of their fiduciary duties, in March 2016—after Endo executed the Assurance of Discontinuance with the New York State Attorney General—[redacted]

VI. PAR PHARMACEUTICAL'S DIRECTORS AND OFFICERS HAD—AND BREACHED—A DUTY TO PROTECT PAR PHARMACEUTICAL, OVERSEE ITS AFFAIRS, PAY ATTENTION TO RED FLAGS AND ENSURE PAR PHARMACEUTICAL'S COMPLIANCE WITH ALL LAWS

172. Defendants Par Pharmaceutical Directors and Officers owed fiduciary duties to Par Pharmaceutical to (i) refrain from activities that would expose Par Pharmaceutical to significant liabilities, (ii) properly oversee Par Pharmaceutical's affairs, (iii) ensure Par Pharmaceutical's compliance with all laws and regulations, (iv) ensure that opioids distributed by Par

Pharmaceutical were not endangering the public—which in turn would inevitably and materially injure Par Pharmaceutical, (v) act in good faith and in best interests of Par Pharmaceutical, (vi) act honestly and responsibly in relation to the conduct of the affairs of Par Pharmaceutical, and (vi) exercise proper care, skill, and diligence. Defendants Par Pharmaceutical Directors and Officers failed in carrying out these duties and protecting Par Pharmaceutical and its stakeholders.

173. By reason of their positions as directors, officers, and fiduciaries of Par Pharmaceutical, and because of their ability to control its business and corporate affairs, Defendants Par Pharmaceutical Directors and Officers owed fiduciary obligations of care, good faith, and loyalty, and were required to run, oversee, and manage Par Pharmaceutical consistent with these obligations. To fulfill their responsibilities and duties, Defendants were required to supervise and manage Par Pharmaceutical's policies and controls, and ensure compliance with various laws and regulations that applied to Par Pharmaceutical's business.

174. As an opioid manufacturer, Par Pharmaceutical was subject to extensive regulation and regulatory oversight from both the federal government and each of the states within which it operates. On information and belief, Par Pharmaceutical's directors and officers were aware of their obligation to ensure Par Pharmaceutical's compliance with laws and regulations governing to the manufacture and sale of opioid products. For example, prior to Par Pharmaceutical's 2015 acquisition by Endo plc, PPCI's annual reports would disclose that:

> The development, manufacturing, sales, marketing and distribution of our products are subject to extensive regulation by the U.S. federal government, principally the FDA, and, as applicable, the Drug Enforcement Agency, FTC and state and local governments. For both currently marketed and future products, failure to comply with applicable regulatory requirements can, among other things, result in suspension of regulatory approval and possible civil and criminal sanctions. Regulations, enforcement positions, statutes and legal interpretations applicable to the pharmaceutical industry are constantly evolving and are not always clear. Significant changes in

> regulations, enforcement positions, statutes and legal interpretations could have a material adverse effect on our financial condition and results of operations.
>
> . . . .
>
> The FDCA, the Controlled Substances Act and other federal statutes and regulations govern the development, testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, import and export, and advertising and promotion of our products. Non-compliance with applicable regulations can result in judicially and/or administratively imposed sanctions, including the initiation of product seizures, injunctions, fines and criminal prosecutions.

Variations of these disclosures appeared on every one of PPCI's Form 10-Ks dating back to least 2010. Defendant Campanelli signed certain of Par Pharmaceutical's SEC filings making these disclosures from 2014 through 2015.

175. As described in Section V above with respect to other Endo entities, Par Pharmaceutical too was required to comply with the statutory requirements imposed by the CSA, the regulations promulgated pursuant thereto, including 21 C.F.R. § 1301.74(b), which required Par Pharmaceutical to design and operate an SOM system to monitor, identify, halt, and report "suspicious orders" for controlled substances, as that term is defined in the regulation, and protect against the diversion of its products.

176. To discharge their duties, Defendants were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the Company. Pursuant to those duties, Defendants were required among other things:

a. to exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner to make it possible to provide the highest quality performance of their business;

b. to exercise good faith to ensure that the Company was operated in a diligent, honest, and prudent manner and complied with all applicable federal and state laws, rules, regulations, and requirements; and

c. when put on notice of problems with the Company's business practices and operations, to exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

177. Endo's admission that the Company did not meet these requirements, described in paragraph 163 above, includes Par Pharmaceutical. Endo thus admitted Par Pharmaceutical's failure to monitor properly the problem of abuse and diversion, as required by law. As pleaded above, Defendants Par Pharmaceutical Directors and Officers could not have been unaware of the extensive abuse of the opioids produced and/or distributed by Par Pharmaceutical unless they consciously ignored and/or improperly closed their eyes to that abuse. Despite their legal obligations to effectuate a compliant SOM and to report suspicious orders to the DEA, these Defendants continued to maintain a non-compliant SOM through at least late 2016, and failed to report any suspicious orders to the DEA while using that non-compliant SOM. All this in the face of repeated red flags over the course of over six years.

178. As pleaded in greater detail in paragraphs 130-32 above, Par Pharmaceutical's DEA compliance auditor informed Defendant Barbarite in 2010 that Par Pharmaceutical lacked an SOM as required by 21 C.F.R. § 1301.74(b).

179. Par Pharmaceutical did not create an SOP for an SOM until two years after the auditor flagged the non-compliance. And the procedures it did establish in SOP No. SO002 do not reflect a good faith effort at compliance, and instead prioritized sales and profits over even basic compliance. These misplaced priorities are evidenced in among other things (i) the authorship of the SOP (a sales director), (ii) the SOP's locus of the primary responsibility for DEA compliance in the Sales organization rather than Compliance, (iii) the reliance on customer's self-reported information, (iv) a failure even to attempt to measure the indicia of suspicious orders explicitly identified in the regulation (order size, pattern, and frequency), and (v) the absence of any direction to report suspicious orders to the DEA.

180. The SOM was also demonstrably ineffective. Between 2012 and mid-2017, another producer of generic opioids was, in an average state, reporting nearly 200 suspicious orders to the DEA each year. In contrast, Par Pharmaceutical reported no suspicious orders *nationwide* to the DEA even during the height of the opioid crisis when Par Pharmaceutical was selling potent opioids across the country. Defendants Par Pharmaceutical Directors and Officers were aware—or had reason to know—that opioids like the ones it sold were being diverted and abused on a massive scale. For example, Defendant Campanelli admitted in deposition testimony in a multi-district litigation in which both PPI and PPCI were Defendants that the opioid abuse epidemic had "resonated" with him by at least 2015. Given Par Pharmaceutical's failure to report any suspicious orders to the DEA while using SOP No. SO002 as its SOM, these Defendants were aware or should have known that Par Pharmaceutical—as one of the very largest sources of opioids flooding the country—was not maintaining an appropriate or compliant suspicious order monitoring program.

181. In mid-2015, the Par Pharmaceutical's DEA compliance auditor informed Defendant Barbarite that the SOM established in SOP No. SO002—for which the organizations directly overseen by Mr. Barbarite and Defendant Pera were responsible—was indefensible and entirely "misses the point of the regulations."

182. Defendants Par Pharmaceutical Directors and Officers failed to take any action to remedy this glaring non-compliance, through at least late 2016 when SOP No. SO002 was retired—still in the same form as that condemned by the auditor. Par Pharmaceutical continued to fail to report a single suspicious order of opioids to the DEA prior to its retirement of SOP No. SO002.

183. Even after the retirement of SOP No. SO002, Defendants Par Pharmaceutical Directors and Officers continued to ignore red flags that the replacement SOM was also non-

compliant. Continuing into 2018, Par Pharmaceutical did not report any meaningful number of suspicious orders of opioids to the DEA in spite of its position as one of the top three manufacturer-sellers of generic opioids in the nation during the opioid abuse epidemic.

184. Upon information and belief, Defendants Par Pharmaceutical Directors and Officers failed to act to establish a compliant SOM and report suspicious orders to the DEA on account of their misplaced priorities in violation of their fiduciary duties, placing sales and profits far above even rudimentary compliance with the law.

VII. THE DAMAGE TO ENDO INFLICTED BY DEFENDANTS' MISCONDUCT

185. On account of Defendants' misconduct and breaches of fiduciary duty, Endo and its affiliates suffered damages currently estimated at close to $2 billion. These damages were primarily borne by Endo's unsecured creditors who received cents on the dollar for each of their claims on account of Endo's bankruptcy—which was largely driven by its opioid liability.

186. The damages suffered by Endo on account of Defendants' misconduct reduced recoveries of unsecured creditors dollar-for-dollar. These damages include but are by no means limited to the following payments made by Endo to settle various suits and actions, and the corresponding legal costs that the Company accrued in defending these claims:

a. $344 million paid in legal fees in defending opioid lawsuits;

b. $242 million in pre-bankruptcy, opioid-related settlements, including but not limited to settlements with:

   i. New York: $200,000 (March 2016);

   ii. County of Cuyahoga, Ohio and the State of Ohio: $10 million (September 2019);

   iii. Oklahoma: $8.75 million (January 2020);

   iv. The State of New York, Nassau County, New York, and Suffolk County, New York: $50 million (September 2021);

v. Texas: $63 million (December 2021);

vi. Florida: $65 million (January 2022);

vii. West Virginia: $26 million (March 2022);

c. $200 million paid to Department of Justice in the bankruptcy;[1]

d. $273.6 million paid to state opioid claimants in bankruptcy;[2]

e. $89.2 million paid to private opioid plaintiffs in bankruptcy;[3]

f. $240 million paid in other professional fees during bankruptcy (as of July 2023).

g. $82.5 million paid in settling a securities class action brought against Endo and other director and officer defendants (approved December 2019); and

h. $63.4 million paid in settling another securities class action brought against Endo and other director and officer defendants (approved October 2021).

CLAIMS FOR RELIEF

First Claim For Relief: Breach Of Fiduciary Duty Against The Directors Of Endo International plc Under Irish Law

187. The Trustee repeats and realleges the allegations set forth in each of the paragraphs above.

188. Each of the Endo plc Director Defendants owed fiduciary duties of loyalty and care under the Irish Companies Act and otherwise. These duties included the obligation to (i) act in good faith in the best interest of the Company, (ii) act honestly and responsibly in relation to the conduct of the affairs of the Company, (iii) exercise his or her powers only for purposes allowed by law, and (iv) exercise the care, skill, and diligence which would be exercised in the same circumstances by a reasonable person having the knowledge and experience reasonably expected of a person in the same circumstances and with the knowledge and experience possessed by the

[1] The stated amount of the settlement was $364.9 million, to be paid over a period of years.
[2] The stated amount of the settlement was $460 million, to be paid over a period of years.
[3] The stated amount of the settlement was $119.2 million, to be paid over a period of years.

director. In addition, the Endo plc Director Defendants had specific fiduciary duties set out in Endo's corporate governance documents.

189. Among other things, and as set forth above, the Endo plc Director Defendants breached their duties to Endo of loyalty and/or care by:

- Failing to act honestly, responsibly and in good faith in the interests of Endo.
- Causing—or ignoring red flags and failing to prevent—Endo's unlawful sales and marketing practices, which involved mismarketing Opana ER, exaggerating its benefits, and downplaying its risks, thus causing widespread addiction, harm, and death and exposing Endo to hundreds of millions of dollars of liability.
- Repeatedly and systematically prioritizing profits over compliance with the law.

190. By incurring the financial obligations and penalties described above, Endo has been damaged substantially as a direct and proximate result of the breaches of fiduciary duty by the Endo plc Director Defendants.

191. For these reasons, judgment should be entered against each of the Endo plc Director Defendants in an amount to be determined at trial.

Second Claim For Relief: Breach Of Fiduciary Duty Against The Directors Of Endo Health Solutions And Endo Pharmaceuticals Under Delaware Law

192. The Trustee repeats and realleges the allegations set forth in each of the paragraphs above.

193. Each of the Directors of Endo Health Solutions and Endo Pharmaceuticals named as Defendants owed fiduciary duties of loyalty and care to those respective entities. These duties included the obligation to (i) ensure that Endo complied with applicable laws and regulations, (ii) sell opioid products in a legal and ethical manner, (iii) observe and respond appropriately to "red flags" in promoting Opana ER, and (iv) not promote profits over compliance with the law.

194. Among other things, and as set forth above, the Defendant Directors of Endo Health Solutions and Endo Pharmaceuticals breached their duties to those respective entities:

- Causing—or ignoring red flags and failing to prevent—Endo's unlawful sales and marketing practices, which involved mismarketing Opana ER, exaggerating its benefits, and downplaying its risks, thus causing widespread addiction, harm, and death and exposing Endo to hundreds of millions of dollars of liability.

- Repeatedly and systematically prioritizing profits over compliance with the law.

195. By incurring the financial obligations and penalties described above, Endo has been damaged substantially as a direct and proximate result of the breaches of fiduciary duty by the Defendant Directors of Endo Health Solutions and Endo Pharmaceuticals.

196. For these reasons, judgment should be entered against each of the Defendant Directors of Endo Health Solutions and Endo Pharmaceuticals in an amount to be determined at trial.

Third Claim For Relief: Breach Of Fiduciary Duty Against The Officers Of Endo Health Solutions And Endo Pharmaceuticals Under Delaware Law

197. The Trustee repeats and realleges the allegations set forth in each of the paragraphs above.

198. Each of the Officers of Endo Health Solutions and Endo Pharmaceuticals named as Defendants owed fiduciary duties of loyalty and care to those respective entities. These duties included the obligation to (i) ensure that Endo complied with applicable laws and regulations, (ii) sell opioid products in a legal and ethical manner, (iii) observe and respond appropriately to "red flags" in promoting Opana ER, and (iv) not promote profits over compliance with the law.

199. Among other things, and as set forth above, the Defendant Officers of Endo Health Solutions and Endo Pharmaceuticals breached their duties to those respective entities by:

- Causing—or ignoring red flags and failing to prevent—Endo's unlawful sales and marketing practices, which involved mismarketing Opana ER, exaggerating its benefits, and downplaying its risks, thus causing widespread addiction, harm, and death and exposing Endo to hundreds of millions of dollars of liability.

- Repeatedly and systematically prioritizing profits over compliance with the law.

- Acting in a reckless and/or grossly negligent manner with respect to both red flags and compliance issues and the interests of Endo Health Solutions and Endo Pharmaceuticals.

200. As officers of Endo Health Solutions and Endo Pharmaceuticals, these Defendants are not entitled to any exculpation under 8 Del. C. § 102(b)(7).

201. By incurring the financial obligations and penalties described above, Endo has been damaged substantially as a direct and proximate result of the breaches of fiduciary duty by the Defendant Officers of Endo Health Solutions and Endo Pharmaceuticals.

202. For these reasons, judgment should be entered against each of the Defendant Officers of Endo Health Solutions and Endo Pharmaceuticals in an amount to be determined at trial.

Fourth Claim For Relief: Breach Of Fiduciary Duty Against The Directors Of Par Pharmaceutical Under Delaware Law

203. The Trustee repeats and realleges the allegations set forth in each of the paragraphs above.

204. Each of the Directors of Par Pharmaceutical named as Defendants owed fiduciary duties of loyalty and care to Par Pharmaceutical. These duties included the obligation to (i) ensure that Par Pharmaceutical complied with applicable laws and regulations, (ii) sell opioid products in a legal and ethical manner, (iii) observe and respond appropriately to "red flags" in distributing generic opioids, and (iv) not promote profits over compliance with the law.

205. Among other things, and as set forth above, the Defendant Directors of Par Pharmaceutical breached their duties to Par Pharmaceutical by:

- Causing—or ignoring red flags and failing to prevent—Par Pharmaceutical's unlawful sales practices, which involved failing to establish and maintain a compliant suspicious order monitoring program, and exposing Par Pharmaceutical to hundreds of millions of dollars of liability.

- Repeatedly and systematically prioritizing profits over compliance with the law.

206. By incurring the financial obligations and penalties described above, Par Pharmaceutical has been damaged substantially as a direct and proximate result of the breaches of fiduciary duty by the Defendant Directors of Par Pharmaceutical.

207. For these reasons, judgment should be entered against each of the Defendant Directors of Par Pharmaceutical in an amount to be determined at trial.

Fifth Claim For Relief: Breach Of Fiduciary Duty Against The Officers Of Par Pharmaceutical Under Delaware Law

208. The Trustee repeats and realleges the allegations set forth in each of the paragraphs above.

209. Each of the Officers of Par Pharmaceutical named as Defendants owed fiduciary duties of loyalty and care to Par Pharmaceutical. These duties included the obligation to (i) ensure that Par Pharmaceutical complied with applicable laws and regulations, (ii) sell opioid products in a legal and ethical manner, (iii) observe and respond appropriately to "red flags" in distributing generic opioids, and (iv) not promote profits over compliance with the law.

210. Among other things, and as set forth above, the Defendant Officers of Par Pharmaceutical breached their duties to Par Pharmaceutical by:

- Causing—or ignoring red flags and failing to prevent—Par Pharmaceutical's unlawful sales practices, which involved failing to establish and maintain a compliant suspicious order monitoring program, and exposing Par Pharmaceutical to hundreds of millions of dollars of liability.
- Repeatedly and systematically prioritizing profits over compliance with the law.
- Acting in a reckless and/or grossly negligent manner with respect to both red flags and compliance issues and the interests of Par Pharmaceutical.

211. As officers of Par Pharmaceutical, these Defendants are not entitled to any exculpation under 8 Del. C. § 102(b)(7).

212. By incurring the financial obligations and penalties described above, Par Pharmaceutical has been damaged substantially as a direct and proximate result of the breaches of fiduciary duty by the Defendant Officers of Par Pharmaceutical.

213. For these reasons, judgment should be entered against each of the Defendant Officers of Par Pharmaceutical in an amount to be determined at trial.

RESERVATION OF RIGHTS

214. The Trustee reserves the right, to the extent permitted under the Bankruptcy Code, the Federal Rules of Civil or Bankruptcy Procedure, or by agreement, to assert any claims relating to the subject matter of this action or otherwise relating to the Debtors and their estates against any third party.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment against Defendants as follows:

a. awarding damages in an amount to be determined at trial;

b. awarding attorneys' fees, costs, and other expenses incurred in this action;

c. awarding pre- and post-judgment interest at the maximum rate permitted by law; and

d. awarding such other and further relief as the Court deems just and proper.

Dated: New York, New York
July 24, 2024

KRAMER LEVIN NAFTALIS & FRANKEL LLP

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