NEW YORK STATE
DEPARTMENT OF FINANCIAL SERVICES
ONE STATE STREET
NEW YORK, NEW YORK 10004

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In the Matter of:

ENDO INTERNATIONAL, PLC.,
ENDO HEALTH SOLUTIONS, INC.,
ENDO PHARMACEUTICALS, INC., and
PAR PHARMACEUTICAL COMPANIES, INC.,

Respondents.

No. 2020-0022-C

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STATEMENT OF CHARGES AND NOTICE OF HEARING

TO THE ABOVE-NAMED RESPONDENTS:

PLEASE TAKE NOTICE that a hearing will be held at the office of the New York State Department of Financial Services, One State Street, New York, New York 10004, 6th Floor, on the 26th day of October, 2020, at 10:00 a.m., and continuing thereafter day to day, as determined by the Department, before a Hearing Officer to be appointed by the Superintendent of Financial Servics, to determine whether RESPONDENTS have violated Section 403 of the New York Insurance Law and/or Section 408(a)(1)(A) of the New York Financial Services Law and whether civil monetary penalties shall be imposed and other appropriate relief granted as a result of such violation(s).

I.

OVERVIEW

1. The opioid epidemic has caused a devastating public health crisis in the United States. The human cost of that crisis has been profound, with more than 400,000 deaths linked to opioid-related drug abuse since 1997. The financial cost has been debilitating, with costs to the U.S. economy estimated in the hundreds of billions of dollars.

2. The crisis was created and fueled, in part, by greed. Entities and individuals at multiple levels of the opioid supply chain enjoyed huge profits as the drugs they sold both destroyed lives and dramatically increased the cost of health care in America.

3. These entities and individuals were well aware that opioids were highly addictive and subject to abuse, and, as a result, were generally appropriate only for cancer pain, short-term pain relief (such as immediately after surgery or trauma) or palliative (end of life) care.

4. Despite knowing that the long-term use of opioids for chronic pain treatment could lead to addiction and abuse, these entities and individuals took steps to expand the market for their pills into areas of treatment that they knew to be unsafe.

5. To do so, among many other things, the entities and individuals misrepresented the safety and efficacy of their drugs in marketing materials and in communications to healthcare professionals. They downplayed the addictive nature of their products and actively promoted a discredited theory of "pseudoaddiction." They paid prominent doctors, advocacy groups, and professional associations vast sums of money to promote the use of opioids in areas that were not medically responsible. Moreover, they chose to look the other way when faced with blatant signs of over-prescription, abuse, and illegal diversion.

6. These efforts to expand the opioid market were fabulously successful. Despite the fact that there were no material changes in the circumstances under which opioids were medically indicated, the sales of opioids increased dramatically.

7. The consequences of this explosion of opioids on the market were as predictable as they were tragic. In every community, in every walk of life, Americans became addicted to these powerful drugs. When they could no longer obtain "legitimate" prescriptions from their doctor, they often turned to illicit sources, including "pill mills" where unscrupulous healthcare providers would hand out opioid prescriptions, for cash, on demand. And when the opioid medications themselves became too expensive or too difficult to obtain, many victims turned to street-level drugs to feed their habit, including heroin and fentanyl-laced narcotics.

8. This addiction cycle has not only destroyed countless families and lives, but it has also resulted in a tremendous increase in healthcare costs, including claims paid by commercial health insurers. In addition to billions of dollars in unnecessary opioid prescriptions, healthcare costs related to treatment of opioid addiction and abuse have skyrocketed. From 2007 to 2014, for example, private insurance claims related to opioid dependence diagnoses rose more than 3000% nationally, and nearly 500% in New York State. Over just the past 10 years, the dramatic rise in additional claims paid by commercial health insurers in the State of New York as a direct result of the opioid crisis led to, in turn, New York consumers of commercial health insurance overpaying an estimated $1.8 billion in premiums.

9. One study has estimated that opioid overdose patients add approximately $11.3 billion to the U.S. healthcare system each year — or approximately 1% of all expenditures. In 2015, the Centers for Disease Control and Prevention ("CDC") estimated that healthcare costs directly related to opioid abuse on the whole totaled $28 billion in that year alone. That year, the

average costs for private payors for a patient with an opioid abuse or dependence diagnosis was more than 550% higher — an increase of almost $16,000 — than the average per-patient cost based on all patients' claims.

10. These costs have ultimately been handed down to consumers who have been made to pay higher premiums for health insurance products.

11. Indeed, New Yorkers spend more on average than the rest of the country on health insurance. Per-person spending on health care was about 3% higher than the national average in 2013. By 2017, that gap increased to approximately 12%. The average annual rate of growth in per-person spending from 2013 to 2017 was 6.2% in New York, compared with a 3.9% national rate. A large degree of this increase in spending has been due to prescription drugs, whose costs constitute a high proportion of this growth. Indeed, compared with other categories of healthcare costs, prescription drugs have experienced the largest spending growth in New York as well as nationally, with rates of 40% and 29% respectively.

12. This enforcement action seeks to make Respondents accountable for the harm caused by the opioid crisis and incurred by the New York insurance industry and consumers of private commercial health insurance policies.

II.

THE ROLE AND JURISDICTION OF THE DEPARTMENT OF FINANCIAL SERVICES

13. The New York State Department of Financial Services (the "Department") is the sole insurance regulator in the State of New York, including with respect to commercial health insurance plans through which more than five million New Yorkers obtain their vital health insurance coverage. As such, among other things, the Department licenses health insurance companies, conducts examinations thereof, and reviews and approves insurance rates.

14. The Superintendent of the Department also bears the responsibility of ensuring the safety and soundness of New York's insurance industry and to promote the reduction and elimination of fraud, criminal abuse, and unethical conduct with respect to insurance institutions and their customers.

15. The Superintendent has the authority to conduct investigations, to bring enforcement proceedings, and to levy monetary penalties against parties who have engaged in wrongdoing in violation of the relevant laws and regulations.

16. In particular, pursuant to Section 403 of the New York Insurance Law, the Superintendent has the authority to levy civil penalties upon any person who has committed a fraudulent insurance act, as defined in Section 176.05 of the New York Penal Law, up to $5,000 and the amount of the claim — per fraudulent claim.

17. Under New York Penal Law Section 176.05, a fraudulent insurance act is an act "committed by any person who, knowingly and with intent to defraud presents [or] causes to be presented . . . to or by an insurer . . . or any agent thereof: . . . a claim for payment, services or other benefit pursuant to [a health insurance] policy, contract or plan that he or she knows to: (a) contain materially false information concerning any material fact thereto; or (b) conceal, for the purpose of misleading, information concerning any fact material thereto . . . ."

18. In addition, under Sections 404 and 408(a)(1)(A) of the New York Financial Services Law, the Superintendent has the authority to levy civil penalties upon any person who has committed any intentional fraud or intentional misrepresentation of a material fact with respect to a financial product or service or involving any person offering to provide or providing financial products or services, up to $5,000 per offense. "Financial product or service" includes, among other things, any financial product or service provided by person regulated by the

Superintendent under the New York Insurance Law. This includes commercial health insurance plans.

III.

RESPONDENTS

19. Respondent Endo International plc ("Endo plc") is an Irish public limited company, with its global headquarters in Dublin, Ireland, and its U.S. headquarters in Malvern, Pennsylvania. Endo International plc operates in the U.S. as Endo Pharmaceuticals.

20. Respondent Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. EHS is a wholly owned subsidiary of Endo plc.

21. Respondent Endo Pharmaceuticals, Inc. ("EPI") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. It is a wholly owned subsidiary of EHS.

22. Respondent Par Pharmaceutical Companies, Inc. ("PPCI") is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Respondent Par Pharmaceutical, Inc. ("PPI") is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. PPI is a wholly owned subsidiary of PPCI. PPCI and PPI were acquired by Endo International plc in September 2015. Respondents Endo plc, EHS, EPI, PPCI, and PPI are referred to herein collectively as "Endo" or the "Endo Respondents," or "Respondent."

23. The Endo Respondents have manufactured and sold a branded opioid that is three times more potent than morphine, extended release Opana ER, as well as generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

24. The Endo Respondents have been prolific manufacturers of opioids in the United States, including in New York. According to data from the Automation of Reports and Consolidated Orders Systems, a database maintained by the U.S. Drug Enforcement Administration that tracks the movement of controlled substances around the nation, the Endo Respondents manufactured approximately 18.4% of the opioids that flooded New York from 2006 to 2014. These opioids accounted for approximately 7.9% of the total morphine milligram equivalents ("MME") introduced to New York via opioid products during this period.

25. Opioids sales constituted a substantial portion of Endo's overall revenues. Opioids sales were responsible for roughly $403 million of Endo's overall revenues in 2012, $657 million in 2014, and $486 million of Endo's $4 billion in sales in 2016. Its branded opioid, Opana ER, yielded revenue of $1.15 billion from 2010 to 2013, and it alone accounted for 10% of Endo's total revenue in 2012.

IV.

FACTUAL ALLEGATIONS

A. Introduction

26. Opioids are a class of drugs that includes narcotic painkillers derived from opium or that mimic opium's effects. Older opium-derived drugs such as morphine, codeine, and heroin, are often referred to as "opiates"; newer, mostly synthetic drugs like oxycodone, hydrocodone, and fentanyl are distinguished from opiates and will be referred to herein as "opioids."

27. Like heroin and morphine, prescription opioids work by binding to receptors in the brain and on the spinal cord, thereby dampening the perception of pain. At sufficient doses, opioids slow the user's breathing and can cause respiratory depression and death.

28. Prior to the mid- to late-1990s, medical professionals generally viewed opioids as dangerous and therefore limited their use. As a result, opioids were primarily prescribed only to treat short-term pain in controlled settings (such as immediate post-surgical or trauma pain in hospitals), and for acute cancer pain and palliative (end of life) care.

29. There were no long-term studies demonstrating the safety and efficacy of opioids for long-term treatment of chronic pain. Indeed, no studies examined the use of opioids beyond 16 weeks, and there was no evidence that opioids improved patients' pain management or function in the long term. To the contrary, studies demonstrated that opioids were less effective than non-addictive analgesic alternatives and often resulted in the poor outcomes of opioid tolerance (*i.e.,* requiring ever-greater doses to get the same pain-relieving effect), diminished function, increased side effects, and addiction and abuse.

30. With the creation of powerful synthetic opioids in the mid-to late-1990s, however, opioid manufacturers and others embarked upon a deliberately false and misleading marketing and promotional campaign to change the perception of the danger and addictive quality of opioids. The goal of this campaign was to convince healthcare professionals to embrace opioids as safe and proper treatments for a much larger group of chronic pain sufferers, such as patients suffering from chronic back pain, arthritis, and migraine headaches, to name a few.

31. To accomplish this shift, opioid manufacturers, including the Endo Respondents, spent vast sums of money on a variety of false and misleading marketing and promotional activities. For example, among other things, the activities included developing and disseminating seemingly truthful scientific and educational and marketing materials that misrepresented the safety and efficacy of long-term use of opioids; paying sales representatives to deliver misleading messages about opioids to healthcare professionals; recruiting and funding healthcare

providers to draft misleading studies and present deceptive and misleading continuing medical education programs; and helping develop and fund seemingly independent, objective advocacy groups, herein called front groups, that themselves developed false and misleading educational materials and treatment guidelines that promoted long-term opioid use.

32. These efforts were designed to convince healthcare professionals and patients, falsely, that the benefits of using opioids to treat chronic pain outweighed the risks and that opioids could be safely used by most patients. Such efforts featured numerous material misrepresentations about opioids. Among other things, these efforts repeatedly overstated the benefits of long-term opioid treatment and failed to disclose the lack of evidence supporting such use; downplayed the risks of negative outcomes for patients, including the risk of addiction and abuse and the difficulty of withdrawal; falsely masked the signs of addiction by calling them "pseudoaddiction"; and overstated opioids' success versus other, less dangerous pain relief alternatives.

33. These false and misleading marketing efforts were both ubiquitous and highly successful. The deception tainted nearly every source that healthcare professionals could rely upon for information about the safety and efficacy of opioids for chronic pain relief, and the institutional and public perception of the standard of care for treating patients with chronic pain changed.

34. As a result, the prescription of opioid medications dramatically increased over time. Opioid prescriptions doubled between 1980 and 2000 and just kept rising thereafter. A study of 7.8 million doctor visits found that prescriptions for pain increased by 73% between 2000 and 2010, for example, even though the number of office visits in which patients complained of pain did not change and the prescribing of non-opioid pain medications actually

decreased during that period. Opioid prescriptions peaked in or around 2012, when more than 280 million prescriptions were issued (roughly a one-month supply for every American adult), and opioid prescription levels have remained far higher than historical norms through the present.

35. But for the misleading information disseminated by the opioid manufacturers, including the Endo Respondents, doctors would not have, in most instances, prescribed opioids as medically necessary or reasonably required to treat chronic pain.

36. It is well known that a strong correlation exists between opioid use and abuse, and the sharp increase in opioid use caused by the opioid manufacturers' actions, including those of the Endo Respondents, predictably led directly to a dramatic increase in opioid abuse, addiction, overdoses, and death. The CDC estimates that more than 400,000 deaths in the United States can be attributed to opioid-related drug abuse since 1997. Moreover, mortality statistics are just a small part of the picture: according to data from 2009, for every overdose death, there were nine abuse treatment admissions, 30 emergency room visits, and 118 people with addiction or abuse problems.

37. Moreover, opioid abuse can rapidly evolve from prescribed opioid pain management to street-level heroin and fentanyl abuse. For many, the cycle begins with a "legitimate" opioid prescription for chronic pain management. Some patients become addicted and request more opioids from their doctors, who eventually cut them off. Many addicts then doctor shop for additional prescriptions, and, when those sources run out, they turn to the streets for illicit opioids and other narcotics, including heroin and street-level fentanyl. It is estimated that a majority of heroin users began by using prescription opioids.

38. In sum, the causal chain is straightforward. The intentional falsehoods of the opioid manufacturers, including the Endo Respondents, about the safety and efficacy of opioids were successful in creating over-prescription of opioids on a massive scale. Then, that massive over-prescription resulted in an epidemic of abuse and addiction of opioids that itself has caused devastation in human and financial terms.

39. This chain of events caused tremendous financial harm to New York's commercial health insurance companies and the consumers who pay their premiums. New York commercial health plans have paid millions of claims for opioid prescriptions that were not medically necessary, legitimate, and/or appropriate, and to cover treatment for opioid-related abuse such as overdose, addiction counseling, emergency room visits, and anti-overdose medication that resulted from the opioid epidemic. In the past 10 years, New York consumers of commercial health insurance have overpaid an estimated $1.8 billion in premiums as a result of the opioid epidemic.

B. Specific Allegations Concerning Endo Respondents

Endo's False and Misleading Marketing to Prescribers and Patients

40. Like other opioid manufacturers, Endo falsely and misleadingly promoted its opioid products, and opioids generally, in New York and elsewhere by understating their risks and overstating their safety and efficacy. Endo did this through a multitude of marketing channels, including direct sales calls to healthcare providers by sales representatives trained in a culture of misrepresentations, the use of front groups, and unbranded promotional materials — all to influence prescriber, patient, and health insurance payer decisions.

41. Between 2009 and 2013, Endo paid its pain-specific sales force to deliver misleading messages about opioids to healthcare professionals. Respondent targeted 27,000 healthcare providers in the United States; sending its sales representatives to New York

providers on over 164,000 occasions. To overcome physicians' long-held resistance to prescribing opioids, Respondent trained these sales representatives to make statements and sales pitches that diminished and distorted the risk of addiction and other side effects associated with opioids generally and Opana ER in particular.

42. Notes by sales representatives detailing their interactions with physicians show how Endo trained them to minimize the perception that opioids were harmful and to make statements downplaying the addictive nature of opioids and the connection between addiction and physical dependence and tolerance to therapy.

43. From 2004-2014, Respondent produced a wide variety of seemingly truthful, unbiased, and educational and marketing materials related to the safety and efficacy of opioids when used to treat chronic pain. These materials were deceptively misleading and false and/or without basis. For example, Respondent's website for Opana, www.Opana.com, contained a page called "About Opioids" that told consumers that "[m]ost doctors who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." The website provides no scientific support for this unsubstantiated claim.

44. The same misleading message was contained in a guide Respondent developed for caregivers called "*Living with Someone with Chronic Pain*." This caregiver's guide stated that "[m]ost healthcare providers who treat people with pain agree that most people do not develop an addiction problem" when taking opioids. The guide was available, including to New York consumers, on the Opana.com website as well as in brochure format.

45. Another tactic Endo used was to fund seemingly independent advocacy groups, or front groups, that would develop and disseminate unsubstantiated and misleading educational materials and treatment guidelines that promoted long-term opioid use. Respondent funded, and

exercised editorial control over, deceptive and misleading messages that front group American Pain Foundation ("APF") conveyed through its National Initiative on Pain Control ("NIPC") and its website www.PainKnowledge.com. Respondent provided substantial financial support to NIPC and selected APF to manage NIPC, even as Respondent obscured its own involvement. Indeed, upon information and belief, Respondent was one of the biggest financial supporters of APF, giving APF nearly $6 million between 1999 and 2012.

46. NIPC was a key piece of Respondent's marketing strategy, and Respondent used its financial support of NIPC and its website www.PainKnowledge.com to disseminate deceptive and misleading messages. NIPC through PainKnowledge.com claimed, for example, that "[p]eople who take opioids as prescribed usually do not become addicted." Claims such as this misled physicians into believing that the risks attendant to opioid treatment were minimal.

47. A brochure available on PainKnowledge.com entitled "*Pain: Opioid Facts*" stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." This message is yet another example of the manner in which Respondent misled physicians by fostering the idea that the risk of opioid addiction is minimal.

48. PainKnowledge.com also made several unsubstantiated sweeping claims that with opioids "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." In addition to "improved function," the website touted improved quality of life as a benefit of opioid therapy without scientific data to back the claim.

49. Another NIPC initiative that Endo sponsored was a series of continuing medical education courses entitled "Persistent Pain in the Older Patient," which misleadingly and without

scientific support claimed that chronic opioid therapy has been shown to "improve depressive symptoms and cognitive functioning." The CME was available via webcast to New York physicians.

50. Respondent's repeated minimization of the risk of addiction was intentionally misleading to make providers more comfortable with prescribing opioids and patients more comfortable with taking them.

51. On its website, and in "Dear Healthcare Professional" marketing pamphlets distributed to prescribers, Endo relied extensively on the Hale 12-week Low Back Pain Study but intentionally omitted adverse events described in that study. Specifically, the Hale Study showed that 5.7% of patients who took the drug in the "treatment" phase of the study experienced pain *exacerbation*, and 6.9% of patients who were given the drug experienced opioid withdrawal symptoms after discontinuing. Respondent entirely omitted these adverse events from "Dear Healthcare Professional" pamphlets it distributed to prescribers in New York.

52. Another tactic Respondent employed was to promote the unsubstantiated concept of "pseudoaddiction." Respondent instructed its sales representatives to deliver to doctors misleading messages about the pseudoscientific concept of "pseudoaddiction." For example, a 2006 sales force training manual defined "pseudoaddiction" as "a term used to describe iatrogenic phenomenon in which a patient with undertreated pain is perceived by healthcare professionals to exhibit behaviors similar to those seen in addiction but is not truly addicted." The sales training document advised sales representatives that the "physician can differentiate addiction from pseudoaddiction by speaking to the patient about his/her pain and increasing the patient's opioid dose to increase pain relief. Pseudoaddiction behaviors such as clock watching (counting down the time until the next dose) will resolve when the pain is properly treated."

53. Respondent spent hundreds of thousands of dollars buying copies of a book written by a physician, "Responsible Opioid Prescribing" (2007), which was distributed by Respondent's sales force. Respondent and others recruited and funded the physician to draft this book which asserted that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction." The book went on to claim that though sometimes people behave as though they are addicted, what they are really in need of is more medication, and the indicated treatment is a higher dose of medicine.

54. Similarly, Respondent distributed another book entitled *Avoiding Opioid Abuse While Managing Pain,* which told healthcare providers that, in the face of drug-seeking behavior, increasing the patient's opioid dosage "in most cases . . . should be the clinician's first response."

55. *A Clinical Guide to Opioid Analgesia* authored by other physicians who were Endo "Key Opinion Leaders" (KOLs) stated: "Pseudoaddiction refers to the development of abuse like behaviors that are driven by desperation surrounding unrelieved pain and are eliminated by measures that relieve the pain, such as increase in medication dose."

56. A 2013 sales force training guide reiterated this approach by dismissing legitimate addiction concerns as pseudoaddiction. The document taught Respondent's sales representatives that "[p]seudoaddiction is a pattern of drug-seeking behavior among pain patients with unrelieved pain. Differentiating between addiction and pseudoaddiction can be challenging and may often take multiple patients encounters. One key difference from addiction is that in pseudoaddiction, the patient's drug seeking behavior stops once his or her pain has been effectively treated."

57. Respondent also promoted the idea, including through its speakers program, that there is no maximum or ceiling dose for its opioid products, other than that imposed by the patient's ability to tolerate side effects, again without disclosing the increased risks of taking higher doses of opioids. Respondent's marketing for Opana ER emphasized the availability of seven different dosage strengths and advised doctors to increase the dosage until adequate pain relief was achieved without disclosing the increased risks of taking higher doses of opioids.

58. Some of the Key Opinion Leaders supported by Respondent have since recanted their pro-opioid marketing messages and acknowledged that the pro-opioid marketing went too far. One prominent KOL has admitted, for example, that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to the KOL, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. He also conceded that "[d]ata about the effectiveness of opioids does not exist." The KOL candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."

Respondent's False and Misleading Marketing of An Abuse-Deterrent Formulation

59. During 2011, with opioid overdoses in New York nearing a record high, Respondent claimed to offer a solution to the problem of opioid misuse and abuse. In fact, Opana ER was nearing the expiration of its patent, and Respondent needed to change its product sufficiently to warrant further patent protection. This prompted Respondent to promote the idea that, to curb abuse and improve safety, Endo would develop an abuse-deterrent formulation of Opana ER. Respondent argued that the addition of crush-resistance technology amounted to a new form of medication. Indeed, Endo went so far as to petition the Food and Drug

Administration ("FDA") to declare the original formulation of Opana as unsafe so as to prevent other manufacturers from making generic versions of oxymorphone, the active ingredient in Opana. Respondent released Reformulated Opana ER with INTAC, which purportedly contained abuse-deterrent properties, in February 2012. In May 2012, Respondent notified the FDA it had discontinued original Opana for safety reasons.

60. The FDA, however, denied Endo approval to use abuse-deterrent labeling due to a lack of substantial evidence. In December 2011, the FDA determined that "the data did not show that the reformulation could be expected to meaningfully reduce abuse" and that "[t]he product label should not include language asserting that [Reformulated Opana] provides resistance to crushing because it may provide a false sense of security since the product may be chewed and ground for subsequent abuse."

61. Incredibly, Endo nonetheless marketed Reformulated Opana ER as safer than the original version and safer than generic oxymorphone. Respondent trained its sales representatives to promote Reformulated Opana ER as "designed to be crush resistant" even though the clinical significance of INTAC Technology or its impact on abuse had not been established.

62. Market research commissioned by Respondent showed that Respondent's marketing *did* influence healthcare prescribers; many believed that Reformulated Opana was safer and less likely to be abused than generic oxymorphone without crush resistance.

63. While promoting Reformulated Opana as crush-resistant, Respondent's own studies showed that the alleged abuse-deterrent properties of the reformulation were either nonexistent or overstated: the pills could be easily cut (which would result in dose-dumping if ingested), were as prone to or more prone to intravenous abuse than the original formulation, and

had minimal improvement concerning crushing over the old formulation. Respondent also had evidence that the rate of intravenous abuse of the reformulated Opana ER exceeded the rate of snorting of the original formulation.

64. Notwithstanding the FDA labelling decision and its own internal studies, Endo continued in its efforts to thwart its competitors by claiming that the earlier formulation of Opana (which it was marketing and selling just a year or so before) was unsafe. Endo submitted a Citizen's Petition to the FDA to block previously approved generics from competing for Opana's market share. The Petition alleged that the original formulation was withdrawn for safety reasons and replaced by the supposedly safer, crush-resistant Reformulated Opana. The 2012 Petition requested the FDA make such determination and thereby suspend and withdraw the approval of any drug applications using original Opana as their reference listed drug.

65. The FDA responded to the Petition on May 10, 2013, concluding that original Opana had not been withdrawn from the market for safety reasons. Significantly, the FDA could not find that Reformulated Opana carried safety advantages over original Opana.

66. Pursuant to a 2016 settlement with the New York Office of the Attorney General, Endo agreed to stop marketing reformulated Opana ER as being crush resistant.

67. In 2017, a joint meeting of the FDA Risk Management Advisory Committee and the Anesthetic and Analgesia Drug Products Advisory Committee found that the benefits of Reformulated Opana ER did not outweigh its risks. The FDA based its decision on a review of all available post-marketing 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 had been associated with a serious outbreak of HIV and hepatitis C, as well as cases of a serious blood disorder (thrombotic microangiopathy).

68. Based on the conclusions of the advisory committee, the FDA requested that Endo remove Reformulated Opana ER from the market in June 2017 due to its high risk of abuse. Respondent voluntarily withdrew Reformulated Opana ER from the market in July 2017.

Respondent Made False and Misleading Representations Directly to Insurers

69. In addition to targeting patients and prescribers with false and materially misleading marketing, Endo also directed its aim at commercial insurers. During its 2012 campaign to promote Reformulated Opana, Respondent engaged in direct and concerted efforts to woo insurance companies to favor Reformulated Opana over other opioids — directly misleading insurers about Opana's crush-resistance properties and falsely presenting Reformulated Opana ER as a panacea to the opioid crisis. As part of this effort, Endo's Health Outcomes and Pharmacoeconomics team gave a presentation to numerous insurers entitled "*Prescription Opioid Abuse: Impact and Interventions for Health Plans and Systems*." In setting up presentation appointments, Respondent admitted that there was an opioid epidemic in America yet misleadingly tried to leverage the opioid crisis into a selling point for Reformulated Opana by explaining that: "As we all know, opioid prescription abuse has become somewhat of an epidemic within the United States. At Endo, we are doing our part to try to limit abuse of our long acting opioid where possible. In 2012, we launched Opana ER with INTAC technology which is designed to be crush resistant."

70. In the presentation to insurers, Respondent presented slides depicting in granular detail the gravity of the opioid crisis in America. In slide 11 of the presentation, Respondent presented a graph showing the sharply rising trend of "opioid analgesics contributing to drug poisoning" between the years 1999-2008. In slide 15, Respondent calculated the "Annual societal costs of opioid abuse, dependence, and misuse in the United States" at $55.7 billion.

Respondent concluded the presentation by touting the benefits of abuse-deterrent and abuse-resistant opioid formulation directly to insurers. Respondent's insurer-directed marketing falsely and misleadingly touted the benefits of crush-resistant opioids that were not in fact crush-resistant.

Respondent Failed to Detect Unusual Prescribing Patterns

71. Endo failed to use readily available information to detect unusual prescribing patterns that could indicate abuse or diversion of the drug.

72. Respondent received reports of healthcare provider prescribing levels for Opana ER. Respondent's Vice President of Sales confirmed in testimony that "at any given period for a given product," information regarding which prescribers were prescribing the most product was available to him. Upon information and belief, there is no indication, however, that Endo used this information to identify unusual prescribing patterns that could indicate abuse or diversion of the drug.

73. For example, a Buffalo, New York, neurologist pled guilty in the U.S. District Court for Western New York to prescribing opioids unlawfully from 2006 to 2016. This included prescribing without a legitimate medical purpose and prescribing to patients he knew were addicted and had previously overdosed. During 2010, that doctor was Endo's top New York prescriber of Opana ER.

SPECIFICATION OF VIOLATIONS

COUNT ONE
New York Insurance Law § 403
(Against Each Respondent)

74. The Department realleges and incorporates by reference the assertions contained in paragraphs 1-73 above as if set forth fully herein.

75. Pursuant to Section 403 of the New York Insurance Law, the Superintendent has the authority to levy civil penalties upon any person who has committed a fraudulent insurance act, as defined in Section 176.05 of the New York Penal Law.

76. Under New York Penal Law Section 176.05, a fraudulent insurance act is an act "committed by any person who, knowingly and with intent to defraud presents [or] causes to be presented . . . to . . . an insurer . . . or any agent thereof: . . . a claim for payment, services or other benefit pursuant to [a health insurance] policy, contract or plan that he or she knows to: (a) contain materially false information concerning any material fact thereto; or (b) conceal, for the purpose of misleading, information concerning any fact material thereto . . . ."

77. At least since the mid-2000s, Respondents have knowingly and with intent to defraud caused to be presented to an insurer or any agent thereof written statements or other physical evidence as part of or in support of claims for payment, services or other benefit pursuant to a health insurance policy or private or public health plan that they knew to (a) contain materially false information concerning any material fact thereto; or (b) conceal, for the purpose of misleading, information concerning any factor material thereto.

78. Specifically, Respondents knowingly and with intent to defraud made numerous misrepresentations, directly or through third parties, concerning the safety and efficacy of opioids.

79. Those misrepresentations caused healthcare providers to present false claims for payment to insurers regulated by DFS on multiple and continuous occasions over the past decades in the form of written prescriptions for opioid medications and related documentation.

80. Such prescriptions carried with them express and/or implied representations that the opioid drugs being prescribed were medically necessary, legitimate and/or appropriate.

Respondents were aware that such representations were, for the majority of the opioid prescriptions written during the relevant time period, false. The falsity of these representations was material to the successful claims for payment.

81. In the alternative, to the extent that third parties engaged in conduct that violated New York Penal Law §176.05, including without limitation prescribing doctors who wrote fraudulent prescriptions and patients who sought and obtained such fraudulent prescriptions, Respondents are liable for such conduct because they, knowingly and with an intent to defraud, solicited, requested, commanded, importuned and/or intentionally aided such third parties in such conduct.

82. Accordingly, Respondents have committed a fraudulent insurance act as that term is defined in New York Insurance Law §403. As a result, the Department is entitled to levy a civil penalty not to exceed five thousand dollars ($5,000) plus the amount of each claim paid, for each violation. In this case, each fraudulent prescription constitutes an independent violation.

COUNT TWO
New York Financial Services Law § 408
(Against Each Respondent)

83. Petitioner realleges and incorporates by reference the assertions contained in paragraphs 1-82 above as if set forth fully herein.

84. Pursuant to Section 408(a)(1)(A) of the New York Financial Services Law, the Superintendent has the authority to levy civil penalties upon any person who has committed any intentional fraud or intentional misrepresentation of a material fact with respect to a financial product or service or involving any person offering to provide or providing financial products or services. “Financial product or service” includes, among other things, any financial product or

service provided by person regulated by the Superintendent under the New York Insurance Law. This includes commercial health insurance plans.

85. Respondents, through their marketing, promotion, manufacture and supply of opioids drugs to patients for whom such drugs were not medically necessary, legitimate, and appropriate, committed acts of intentional fraud or intentional misrepresentation of material facts with respect to claims for insurance products or services or involving any person offering to provide or providing financial products or services.

86. Respondents, with the intent to defraud, made knowingly false representations about the safety and efficacy of opioid drugs.

87. These misrepresentations were made with the intent of increasing the demand for opioids into areas of treatment that were not medically necessary, legitimate, and appropriate.

88. Respondents were aware that the increase in demand would cause fraudulent claims to be made to insurance companies.

89. Accordingly, Respondents committed intentional fraud and/or made intentional misrepresentations of material facts with respect to a financial product or service and are thus liable to pay a civil penalty of up to five thousand dollars ($5,000) per offense. In this case, each fraudulent prescription constitutes an independent offense.

PLEASE TAKE NOTICE THAT, as a result of these charged violations, the Department is seeking the following relief:

a) The imposition of civil monetary penalties against Respondents;

b) An order directing Respondents to cease and desist all activity that constitutes the violations of law enumerated herein; and

c) Such other relief as is deemed just and appropriate.

PLEASE TAKE FURTHER NOTICE THAT:

(A) This Notice of Hearing and Statement of Charges is issued to Respondents pursuant to § 403 of the Insurance Law and §§ 305 and 306 of the Financial Services Law, and notice of the hearing is given to Respondents in accordance with § 304 of the Financial Services Law.

(B) Your attention is directed to a statement in plain language, attached hereto as Appendix A, summarizing the provisions of 23 NYCRR Part 2. **This statement contains important information concerning your rights and the Department's hearing procedures and should be read carefully.** A copy of 23 NYCRR Part 2 will be furnished upon request.

(C) Interpreter services shall be made available to deaf persons, at no charge.

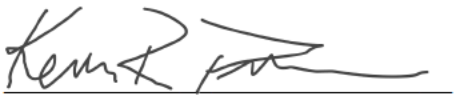
(D) Should you fail to appear at the time and place set forth above, or at any subsequent date fixed for the hearing, the hearing will proceed as scheduled and may result in the following:

i. The issuance of a report by the Superintendent finding violations of Section 403 of the Insurance Law and Section 408 of the Financial Services Law and the issuance of an order upon the Respondent requiring it to cease and desist from engaging in such violations; and

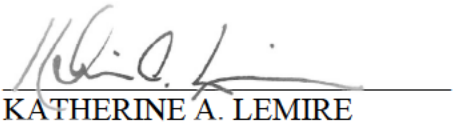
ii. The assessment of monetary fines against the Respondents pursuant to Insurance Law § 403(c) and Financial Services Law § 408.

Dated: New York, New York
June 08, 2020

NEW YORK STATE
DEPARTMENT OF FINANCIAL SERVICES

By: 

KEVIN R. PUVALOWSKI
Senior Deputy Superintendent
Consumer Protection and Financial Enforcement



KATHERINE A. LEMIRE
Executive Deputy Superintendent
Consumer Protection and Financial Enforcement

JANET LIPINSKI
LINDA DONAHUE
ELIZABETH FARID
NICOLAS KELLER
MICKELLE DAMASSIA
AVERY HEISLER
Of Counsel

One State Street
New York, New York 10004
(212) 709-5578

APPENDIX A

NEW YORK STATE
DEPARTMENT OF FINANCIAL SERVICES
ONE STATE STREET
NEW YORK, NEW YORK 10004

SUMMARY OF HEARING PROCEDURES

Summary of Hearing Procedures for Adjudicatory Proceedings as Set Forth in 23 NYCRR 2, as Required by section 301.3 of the State Administrative Procedure Act.

1. The Hearing will be conducted and administered in compliance with the State Administrative Procedure Act and the Financial Services Law and regulations promulgated thereunder and will be held before an impartial hearing officer who will make a Report of findings and recommendations to the Superintendent.

2. You must be ready and prepared with your evidence to present your case on the hearing date.

3. You may be represented by an attorney at the hearing. In the event you do not have an attorney, you may appear on your own behalf, a member of the partnership may appear on behalf of the partnership, or an authorized officer of an entity may represent that entity.

4. You may file a written answer to notice of action or proposed action. If you do so, it should be delivered at least two (2) days before the hearing date to the New York State Department of Financial Services ("Department") official who signed the notice of action or proposed action.

5. You may present evidence and have witnesses testify at the hearing. If you believe a witness will not appear voluntarily and you do not have an attorney representing you, you may request the Superintendent, a Deputy Superintendent, the hearing officer assigned to hear the matter, or any employee of the department authorized by the Superintendent to furnish you with a subpoena to compel the witness' attendance. If the subpoena is issued to you, the service of the subpoena upon the witness and payment of all required fees is your responsibility.

6. All parties are entitled to discovery of the evidence intended to be introduced at the hearing.

7. All witness will be sworn or give an affirmation.

8. The rules of evidence are not the same as those in a court of law. Evidentiary and burden of proof issues are governed by Financial Services Law section 305(e) and State Administrative Procedure Act section 306.

9. The burden of proof is substantial evidence.

10. Prior to the commencement, a hearing may be postponed upon your written request if there is a good reason why the hearing should not begin on the scheduled date. To request a postponement you should contact the Department official who signed the notice of action or proposed action.

11. A hearing in progress may be adjourned by the hearing officer at your request if you can give a good reason and support your request with written evidence as the hearing officer deems appropriate.

12. If you do not appear or are not represented at the hearing, the hearing will take place as scheduled and a decision on the charges will be made. The decision may result in the revocation or suspension of your license(s) and the denial of any pending applications, and such other action as may be permitted by law, including the imposition of monetary fines.

13. If you do not appear at a hearing and a decision against you is issued, the hearing may be reopened upon a written application, if you satisfy the hearing officer that there are valid reasons for your failure to appear or your failure to request an adjournment or postponement and you have a meritorious case. If you do appear at the hearing and the decision is made against you, the hearing may be reopened on written request to the hearing officer if you can show newly discovered evidence or a compelling reason for such reopening. The application to reopen must be made within one-hundred and twenty (120) days from the date of the Superintendent's decision.

14. You may request a copy of the hearing officer's report and an opportunity to comment on it in writing before the Superintendent acts on the report. The request must be made to the hearing officer on the record prior to the close of the hearing.

15. Once a decision is made against you, you may, if you wish, take an appeal to the courts. This appeal must be made within one-hundred and twenty (120) from the date the decision was effective. It should be emphasized that your right to take an appeal is not connected in any way with your right to reopen the hearing as described in section 13, and an application to reopen does not extend your time to take an appeal to the courts.