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."