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

----------x

In the Matter of: :

No. 2020-0034-C

JOHNSON & JOHNSON, :
JANSSEN PHARMACEUTICA, INC.,
JANSSEN PHARMACEUTICALS, INC., and :
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.,
:

Respondents.

----------x

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 25th day of January, 2021, 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 Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

20. Respondent Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceuticals is a wholly owned subsidiary of J&J.

21. Respondent Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with a principal place of business in Titusville, New Jersey.

22. Respondent Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

23. Respondents J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica are referred to herein collectively as "Janssen" or the "Janssen Respondents."

24. The Janssen Respondents manufactured and sold their own branded opioids and supplied the raw materials necessary to produce opioids to other manufacturers.

25. 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 Janssen Respondents manufactured approximately 0.6% of the opioids that flooded New York from 2006 to 2014. These opioids

accounted for approximately 1.7% of the total morphine milligram equivalents ("MME") introduced to New York via opioid products during this period.

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 Janssen 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 Janssen 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 Janssen 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 Janssen 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 Janssen Respondents

Duragesic

40. Janssen's first Schedule II opioid medication was Duragesic, a patch containing fentanyl, that the FDA first approved in 1990. A selling point for Duragesic was the claim that it delivered pain relief to the patient over the course of 72 hours, without the need to take a new dose every few hours, as was typical of other pain medications on the market.

41. Duragesic's label warned that the drug "contains a high concentration of a potent Schedule II opioid agonist, fentanyl," and that "Schedule II opioid substances . . . have the highest potential for abuse and associated risk of fatal overdose due to respiratory depression." The label goes on to warn that "the high content of fentanyl in the patches . . . may be a particular target for abuse and diversion."

42. Despite the risks specified on the drug's label, Janssen nonetheless marketed Duragesic as having less addiction potential by citing various studies and data. One primary data source Janssen used was from DAWN, or the Drug Abuse Warning Network. DAWN monitored emergency room visits for overdoses and collected data on which medications and drugs resulted in those overdoses. Janssen used the low incidence of Duragesic overdose rates to represent that the drug was less addictive than other drugs. Indeed, call notes from New York sales representatives document claims of less abuse potential from 1998 to as late as 2006.

43. A September 2004 FDA warning letter to Janssen ordered the company to stop making these claims, however, as DAWN data did not show that a drug is more or less addictive, but instead showed that it is abused more or less often than other drugs in a certain geographic

region. The letter noted that Duragesic had a relatively low market share that corresponded with the low rates of overdoses cited in the data, and that this was a more likely explanation for the data findings.

44. In addition to DAWN, Janssen also cited numerous studies that claimed to find low addiction potential and high efficacy for Duragesic. Many of these studies, however, have been found to be so flawed that their findings are useless, and internal emails show knowledge on the part of Janssen executives that such studies were not effective measures of the drug's safety or efficacy.

45. Indeed, as early as March 2000, Janssen received a notice of violation letter from the FDA for false claims in various Duragesic promotional materials such as:

- "Low abuse potential!"
- "Significantly LESS constipation!"
- "It's not just for end stage cancer anymore!"
- "…the #1 reason to convert your patients to the Duragesic patch: QUALITY of LIFE"

46. The FDA told Janssen that, not only did it lack substantial evidence to support any of the above claims, but also that Janssen had "not presented any risk information concerning the boxed warnings, contraindications, warnings, precautions, or side effects associated with Duragesic's use."

47. Despite these FDA actions, in or around 2002, Janssen published a brochure entitled "Life, Uninterrupted," whose title and overall message implied that the continuous use of Duragesic would result in an enhanced quality of life. In addition to heavy citations to the DAWN data to imply low addiction potential and flawed studies to claim a high degree of

efficacy, this brochure stated that while "DURAGESIC . . . has the potential for abuse," "[i]atrogenic addiction following opioid administration is relatively rare. Physicians should not let concerns of physical dependence deter them from using adequate amounts of opioids in the management of severe pain when such use is indicated."

48. Janssen also published a Duragesic promotional booklet that was targeted to patients entitled "Answers to Your Questions" and which contained numerous misleading statements. For example, the booklet stated that "addiction is relatively rare when patients take opioids appropriately" when in fact addiction can often occur when patients take opioids as directed by their doctors. It also downplayed the links between physical dependence and addiction, stating that "[p]hysical dependence is not the same as addiction. It is easily managed by gradually reducing the dose of the drug if the doctor decides it is appropriate to discontinue therapy." (Emphasis removed.)

49. The booklet, billed as "[a] guide to controlling your pain and controlling your life," heavily promoted the use of Duragesic for chronic long-term use. Its pages depicted images of seemingly happy individuals engaged in activities like fishing. The cover included the aforementioned tagline "Life, Uninterrupted," implying that the continued use of the opioid would result in an improved quality of life. "Life, Uninterrupted" also instructed patients to continue wearing the patch until their doctors told them to stop, and told them that "if you feel better, it's probably because DURAGESIC is working . . . ."

50. Duragesic's patent expired in 2005. Around that time, Janssen began to wind down marketing of the drug, eventually stopping all Duragesic-specific marketing in or around 2008.

Nucynta

51. Janssen's second Schedule II opioid was Nucynta, which it had begun developing in 2001. Nucynta is a tablet medication containing the synthetic opioid analgesic tapentadol, which contains both an opioid and another drug, a norepinephrine uptake inhibitor. The FDA approved Tapentadol in 2008, and Janssen released it that same year. The FDA approved an extended release formulation of tapentadol tablets, Nucynta ER, in 2011 and Janssen released it that year.

52. Janssen told New York sales representatives that "Nucynta is extremely promotion sensitive" and to "sell hard on every call." In particular, Janssen wanted its sales representatives to sell hard to seniors in nursing homes, military families (to whom Janssen offered discounts), and individuals with lower back pain. Later, in 2013, to sell Nucynta ER, Janssen used a "Pain Force" of sales representatives to specifically target New York among three other states characterized by Janssen employees as "launch-friendly."

53. Janssen claimed that Nucynta's innovation was the drug's so-called "dual mechanism" described above, which was thought to act as a means of delivering the pain relief of an opioid without the usually associated euphoria, or high. Nevertheless, Nucynta's original 2008 label states that it is "an opioid analgesic indicated for the relief of moderate to severe acute pain" and that "abuse potential may occur." Nucynta ER's original 2011 label warns that the drug is "a mu-opioid agonist and Schedule II controlled substance, with risk of misuse, abuse, and diversion similar to other analgesics."

54. Despite these labels, however, Janssen touted the possibility of Nucynta containing "non-opioid" qualities, thereby creating a misconception that the drug was somehow less severe than other Schedule II opioids. Not only was this claim not definitively proven, but it

was based only on preclinical trial data that the FDA has warned is "not a substitute for studies of ways the drug will interact with the human body."

55. In 2010, Janssen further attempted to claim that Nucynta had a tamper-resistant formula. The FDA, however, rejected Janssen's application for a labelling change to that effect, finding that Janssen had not provided sufficient studies or data to back up such a claim.

56. With Nucynta, Janssen also continued the misleading practice of understating risks of addiction. In its Risk Evaluation and Mitigation Strategies ("REMS") submission for Tapentadol (Nucynta) ER, Janssen repeated its assertions that addiction was easily distinguishable from dependence and tolerance. The publication stated that "[m]ost patients who receive prolonged opioid therapy will develop physical dependence, and some will develop tolerance. However, the majority of these patients do not develop addictive disorders. The key distinction is that addiction refers to a maladaptive pattern of behavior, while physical dependence and tolerance are biologic changes." It went on to advocate the use of the "Opioid Risk Tool," a five question self-reported survey that purportedly measured a patient's risk of addiction that had been developed by a prominent "key opinion leader."

57. Upon information and belief, Janssen sold Nucynta to Depomed in 2015.

58. Despite its relatively small market share, like other opioid manufacturers Janssen poured substantial sums of money into various front groups to promote the use of opioids generally. These included organizations like the American Pain Foundation ("APF"), the American Pain Society ("APS"), the American Geriatrics Society ("AGS"), the American Academy of Pain Medicine ("AAPM"), the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), and the American Academy of Pain Management, later known as the Academy of Integrative Pain Management ("AIPM"). Janssen and these groups used several

tactics to disseminate their misleading information, including books, direct marketing, patient education materials, and websites targeting both patients and prescribers.

59. From 1997-2017, Janssen spent over $4,500,000 on front groups, with nearly $2 million alone going to APS. AAPM, JCAHO, APF, and AGS each netted over $500,000 each during that time period.

60. APS and AAPM were instrumental organizations in the early promulgation of opioids for widespread treatment of chronic pain. In 1996, they adopted a "consensus statement" entitled "The Use of Opioids for the Treatment of Chronic Pain," in which opioids were recommended for the treatment of chronic pain and their addiction potential was minimized. The primary authors were prominent key opinion leaders, one of whom would receive substantial funding from Janssen as early as 1998.

61. In 2009 AAPM and APS teamed together again to issue a set of guidelines entitled "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain." The 2009 Guidelines were compiled by a panel of 21 doctors, 14 of whom received funding from Janssen and other opioid manufacturers.

62. Janssen also helped to support two separate editions of AGS guidelines supporting the use of opioids for chronic pain in older patients: one published in 2002 entitled "The Management of Persistent Pain in Older Persons," and a second published in 2009 entitled "Pharmacological Management of Persistent Pain in Older Persons." The 2009 AGS Guidelines described the risk of addiction as "exceedingly low in older patients with no current or past history of substance abuse." It recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy." This broad claim made no room for the fact that elderly patients are particularly vulnerable to the effects of opioids, as they are at greater risk of

side effects like increased falls and fractures, as well as neuropsychiatric symptoms. In 2010, Janssen paid AGS at least $158,209 for "educational grants."

63. Upon information and belief, Janssen helped fund the distribution of APF's 2009 book, *Exit Wounds*, which marketed opioids to veterans. *Exit Wounds* was presented as a narrative by a returning soldier, Derek McGinnis (at that time, an employee of APF), dealing with chronic pain, but it was in fact written by a medical writer for the pharmaceutical industry. The book lauded opioids as the "gold standard of pain medications," but complained they were "often underused," because prescribers were "afraid to prescribe them" due to unreasonable fears of addiction. The book described physical tolerance as "simply a psychological process that doesn't occur for all people or with all medications" and minimized the risks of addiction. According to *Exit Wounds*, "[d]enying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids."

64. *Exit Wounds* also negatively compared Nonsteroidal Anti-inflammatory Drug ("NSAID") alternatives to opioids, claiming that NSAIDs presented severe risks like "kidney failure," "gastrointestinal (GI) bleeding," and a "possible higher risk of stroke or heart attack." Acetaminophen, meanwhile, "could cause liver damage." By contrast, the book assured readers, "with the exception of constipation, most [opioid] side effects disappear after a few days." Notably, it misleadingly failed to warn readers of the risks of fatal interactions between opioids and anti-anxiety medicines known as benzodiazepines, which are commonly prescribed to veterans with post-traumatic stress disorder. In fact, a VA Office of Inspector General Report has stated that 96.4% of veterans that are prescribed opioid drugs on a long-term basis were also

prescribed benzodiazepines, even though there is an increased danger of respiratory depression when both opioids and benzodiazepines are taken concurrently.

65. Janssen also sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which targeted elderly patients. AAPM and AGS were listed as "partners." The guide described as "myth" the claim that opioids are addictive and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." Featuring a man playing golf on the cover, it listed examples of expected functional improvement from opioids, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide told patients that "opioids may make it easier for people to live normally," without addressing the life-altering effects of addiction and the material risks of abuse and addiction when discussing side effects of opioids. It also mischaracterized dose limitations as "disadvantages" of alternative pain management medications, without discussing the risks associated with increasing opioid dosages. The guide was written by the same person who served as the medical writer of *Exit Wounds*.

66. The website entitled "Let's Talk Pain," which started in 2009 at the time of Nucynta's launch, was ostensibly created by the "Let's Talk Pain Coalition," consisting of Janssen along with the front groups APF, AIPM, and the American Society for Pain Management Nursing ("ASPMN"). It purported to be an advocacy site for patients with untreated chronic pain, though, upon information and belief, Janssen exercised significant control over its content. The website promoted the concept of "pseudoaddiction," which it described as "patient behaviors that may occur when pain is under-treated" but differs "from true addiction because such behaviors can be resolved with effective pain management." The website also misinformed consumers that "the stigma of drug addiction and abuse" associated with the

use of opioids stemmed from a simple "lack of understanding about addiction." "Let's Talk Pain" misleadingly stated that the use of opioids for the treatment of chronic pain would lead to patients regaining functionality and featured a video interview claiming that opioids were what allowed a patient to "continue to function."

67. In partnership with AIPM, Janssen also set up a website aimed at healthcare providers entitled "Prescribe Responsibly," retaining sole control over the site's content. "Prescribe Responsibly" claimed to be a resource for healthcare providers to determine when and how to prescribe opioids to their patients but was, in fact, yet another marketing tool filled with misrepresentations about the efficacy and addiction potential of opioids.

68. "Prescribe Responsibly" emphasized the alleged difference between "physical dependence," "pseudoaddiction," and actual addiction. Physical dependence, for example, "should be expected," according to "Prescribe Responsibly," and was characterized as "a state of physiological adaption manifested by a withdrawal syndrome produced by abrupt discontinuation of a medication," though it was "important to note that physical dependence is not the same as addiction."

69. On the site, Janssen also promoted so-called risk mitigation strategies, or tools that would ostensibly allow prescribers to limit the risk of a patient becoming addicted to their opioid medication. It advertised, for example, the "CAGE Questionnaire," a screening tool that consists of four questions to be answered by the patient themselves. Another was an "agreement" to be made between doctor and patient that the latter would follow the treatment plan as instructed. Indeed, even if a patient were to become addicted, doctors were told that "a concurrent addictive disorder" did not obviate the need to medicate the patient for their pain.

70. In addition to the above activities, Janssen funded numerous continuing medical education programs ("CMEs") on opioid use that further lent false legitimacy to their misrepresentations. For example, a CME given in 2002 titled "Appropriate Opioid Pharmacotherapy for Chronic Pain Management" told doctors that "the probability of addiction overall is presumably small" and promoted the idea of pseudoaddiction. Another, released in 2009 in partnership with AIPM titled "Opioid Prescribing: Clinical Tools and Risk Management Strategies" promoted the aforementioned Opioid Risk Tool as an effective deterrent to addiction and reassured prescribers that "[i]solated instances of aberrant behavior can often be attributed to unrelieved pain and managed."

Raw Materials Supplier

71. The success of Janssen's fraudulent and misleading marketing scheme to promote opioid use generally helped to create demand for the raw materials for opioids, which in turn benefited the Janssen Respondents as they controlled a large proportion of the raw material supply chain.

72. In the 1980s, to secure raw materials and supply for its Tylenol with Codeine pain medications, J&J acquired businesses and formed two subsidiaries: (a) Tasmanian Alkaloids, which grew and processed alkaloid-rich poppy plants, from which they extracted the chemical thebaine; and (b) Noramco, which imported the thebaine from Tasmanian Alkaloids into the United States; converted it into the Active Pharmaceutical Ingredients ("API") that are in turn used to make oxycodone, oxymorphone, hydrocodone, hydromorphone, morphine, and codeine, among other opioids; and then sold the APIs to other drug manufacturers.

73. In or around 1994, scientists at Tasmanian Alkaloids developed a high thebaine poppy variety, called the "Norman Poppy." J&J internally described it as "a transformational technology that enabled the growth of oxycodone."

74. The Janssen Respondents and their related entities thus controlled the largest thebaine producer and the largest oxycodone API manufacturer. Over time, Noramco grew to become the top API supplier for oxycodone, hydrocodone, codeine, and morphine production in the U.S.

75. Through long-term supply agreements, which typically mandated that the supplier constitute about 80% of the customer's volume, Noramco supplied API, including oxycodone, to approximately 240 opioid manufacturers, including all 7 of the top U.S. generic companies. For example, a 2006 presentation from Rhodes Pharmaceuticals (a sister company to Purdue Pharma) stated that "Purdue/Rhodes must purchase 100% of thebaine requirements from Noramco up to 20 MT's." In total, these agreements constituted over 80% of Noramco's opioid sales. Indeed, by February 2011, J&J stated that its high-thebaine poppy had "up to 80% of the worldwide market for Oxycodone raw materials."

76. In 2016, J&J sold both Tasmanian Alkaloids and Noramco to the firm SK Capital in a deal reportedly worth as much as $800 million.

SPECIFICATION OF VIOLATIONS

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

77. The Department realleges and incorporates by reference the assertions contained in paragraphs 1-76 above as if set forth fully herein.

78. 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.

79. 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 . . . ."

80. 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.

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

82. 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.

83. 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.

84. 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.

85. 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)

86. Petitioner realleges and incorporates by reference the assertions contained in paragraphs 1-85 above as if set forth fully herein.

87. 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.

88. 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.

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

90. 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.

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

92. 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.

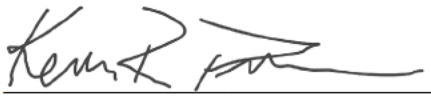
(D) Should you fail to appear at the time and place set forth above, or at any subsequent date fixed for the hearing, the hearing will proceed as scheduled and may result in the following:

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

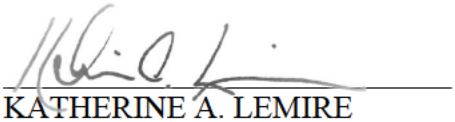
ii. The assessment of monetary fines against the Respondents pursuant to Insurance Law § 403(c) and Financial Services Law § 408.

Dated: New York, New York
September 8, 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

LILLIAN GRINNELL
NICOLAS KELLER
LINDA DONAHUE
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.