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

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In the Matter of:

TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
TEVA PHARMACEUTICALS USA, INC.,
CEPHALON, INC.,
WATSON LABORATORIES, INC.,
ACTAVIS PHARMA, INC.,
ACTAVIS LLC,
ACTAVIS ELIZABETH LLC,
ALLERGAN PLC, and
ALLERGAN FINANCE LLC,

Respondents.

No. 2020-0032-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 Teva Pharmaceutical Industries, Limited ("Teva Ltd.") is a global pharmaceutical company with its headquarters in Petah Tikva, Israel.

20. Respondent Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Ltd.

21. Respondent Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Ltd. acquired Cephalon, Inc. in 2011.

22. In or around August 2016, Teva purchased from Respondent Allergan plc certain Allergan companies that manufactured and sold both branded and generic pharmaceuticals including branded and generic opioid products. The purchase included Respondents Watson Laboratories, Inc., Actavis Pharma Inc., Actavis LLC, and Actavis Elizabeth LLC, (collectively referred to herein as "Actavis").

23. Respondent Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California.

24. Respondent Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is a Delaware corporation with its principal place of business in New Jersey.

25. Respondent Actavis LLC (f/k/a Actavis Inc.) is a Delaware limited liability company with its principal place of business in New Jersey.

26. Respondent Actavis Elizabeth LLC is a Delaware limited liability company with its principal place of business in New Jersey.

27. Upon information and belief, Watson Laboratories, Inc., Actavis LLC (f/k/a Actavis Inc.), Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.), and Actavis Elizabeth LLC, (collectively "Actavis"), are all subsidiaries of Teva Ltd.

28. Respondents Teva Ltd., Teva USA, Cephalon, and Actavis are referred to herein collectively as "Teva" or the "Teva Respondents."

29. Upon information and belief, Teva is solely liable for all claims relating to all generic opioids manufactured, sold, marketed, or distributed by Actavis.

30. The Teva Respondents manufacture and sell both branded and generic opioids nationally and within New York. Respondent Teva USA manufactures and sells generic opioids, including oxycodone and fentanyl. Respondent Cephalon manufactured and sold two branded fentanyl-based opioids under the names Actiq and Fentora. Respondent Actavis manufactures generic opioids.

31. Teva USA and Cephalon, Inc. work together to market, manufacture, distribute, and sell Cephalon products in the United States. Teva USA conducts Teva Ltd.'s sales and marketing activities for Cephalon in the United States and holds out Actiq and Fentora as Teva products to the public.

32. The Teva Respondents (Teva, Cephalon, and Actavis) 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 ("ARCOS"), a database maintained by the U.S. Drug Enforcement Administration ("DEA") that tracks the movement of controlled substances around the nation, the Teva Respondents manufactured approximately 20% of the

opioids that flooded New York from 2006 to 2014. These opioids accounted for approximately 10.5% of the total morphine milligram equivalents ("MME") introduced to New York via opioid products during this period.

33. In May 2013, Respondent Allergan plc was incorporated in Ireland as a private limited company and in September 2013 re-registered as a public limited company.

34. In March 2015, Actavis plc acquired Allergan plc, and, in June 2015, the combined company changed its name to Allergan plc.

35. Respondent Allergan Finance LLC, f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc. ("Allergan Finance"), is a Nevada limited liability company with its principal place of business in New Jersey. Allergan Finance is a wholly owned subsidiary of Allergan plc.

36. Allergan plc and Allergan Finance are hereafter referred to as "Allergan."

37. Allergan has manufactured and sold branded opioids nationally and in New York, including Kadian (morphine sulfate extended release) and Norco (hydrocodone bitartrate and acetaminophen), and others, and, prior to 2016, generic opioids including oxymorphone, extended-release morphine sulfate, fentanyl, and oxymorphone hydrochloride. Upon information and belief, Allergan owns the Kadian New Drug Application, though Teva currently manufactures Kadian.

38. Upon information and belief, Allergan is solely liable for all claims relating to Kadian, Norco, and other branded opioids it manufactured, sold, marketed, promoted, or distributed.

39. Upon information and belief, Kadian had been on the market since 1996. In 2008, Actavis Inc. purchased Kadian from King Pharmaceuticals. In October 2012, Watson

Pharmaceuticals acquired Actavis, Inc. and, in January 2013, the combined company changed its name to Actavis, Inc.

40. As stated above, in or about August 2016, Respondent Actavis LLC (f/k/a Actavis Inc.) was sold to Teva. Actavis LLC is a Delaware limited liability company with its principal place of business in New Jersey. Prior to its sale to Teva, Actavis LLC was a subsidiary of Watson Laboratories, Inc., and one of its subsidiaries was Actavis Elizabeth, LLC.

41. ARCOS data shows that Allergan manufactured approximately 420,000 pills that were sold in New York State from 2006 to 2014. Upon information and belief, between 2009 and April 2018, Kadian was prescribed at least 109,235 times in New York, and between 1997 and April 2018, Norco was prescribed at least 300,407 times.

IV.

FACTUAL ALLEGATIONS

A. Introduction

42. 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."

43. 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.

44. 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.

45. 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.

46. 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.

47. To accomplish this shift, opioid manufacturers, including the Teva and Allergan 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.

48. 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.

49. 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.

50. 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.

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

52. 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 Teva and Allergan 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.

53. 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.

54. In sum, the causal chain is straightforward. The intentional falsehoods of the opioid manufacturers, including the Teva and Allergan 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.

55. 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 Teva and Allergan Respondents

Teva's False and Misleading Marketing to Prescribers and Patients

56. Cephalon has a long history of fraudulent conduct related to the marketing of its opioid products which continued despite criminal, civil, and regulatory sanctions.

57. Cephalon's branded opioid Actiq (fentanyl citrate) is an opioid lozenge, similar to a lollipop, that was first approved in 1998. According to one patient, Actiq "tastes like the most delicious candy you ever ate."

58. Fentanyl is a powerful opioid approximately 100 times stronger than morphine. By way of example, oxycodone, the main ingredient in OxyContin, is 1.5 times as strong as morphine.

59. In November 1998, the FDA approved Actiq "ONLY for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." Because of Actiq's dangers, the FDA prescribing guidelines directed that wider, off-label uses were not permitted:

> This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Actiq is contraindicated in the management of acute or postoperative pain.

60. The FDA prescribing guidelines further stated that Actiq is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

61. A drug may not be marketed or promoted for "off-label" uses — meaning any use not specified in an application and approved by FDA.

62. Cephalon acquired Actiq in 2000. In the fall of 2000, Cephalon initiated the Actiq Master Plan, a deliberate and systematic scheme to market Actiq for off-label uses.

63. The Actiq Master Plan acknowledged that the market for on-label uses was small and that "feedback from the field indicates that oncologists simply aren't treating that many people for breakthrough cancer pain or, aren't using strong opioids to treat breakthrough pain."

64. Cephalon's research found "the pain management specialist is likely to be a more aggressive writer and a rapid adopter of Actiq." Furthermore, according to the Master Plan:

> from a business perspective, these physicians tend to have patients who are more likely to be truly chronic, with many years of potential usage of the product, either for breakthrough pain or more generally for other chronic pain conditions.

65. The Master Plan proposed that the "strategy for expansion to non-cancer breakthrough pain focus on regulatory strategy and negotiation rather than the accrual of clinical data."

66. Cephalon continued this off-label strategy for years. In the 2002 Actiq Marketing plan, Cephalon outlined its public relations plan: "The primary goals of the 2002 ACTIQ PR

plan are to increase awareness of BTP [breakthrough pain] and ACTIQ among targeted physician and patient populations. The targeted patient populations will be both cancer patients and chronic non-malignant pain patients, as well as patients suffering from episodic pain such as migraine headaches and sickle cell disease."

67. According to an August 2002 internal Cephalon email, a New Jersey-based Cephalon sales representative asked a pharmacy to stock $30,000 of Actiq for "significant off-label usage." The pharmacy was located in a southern New Jersey area where a suspicious pain clinic was operating (and under investigation by the DEA). Prior to the representative's request, the pharmacy stocked very little Actiq and was concerned about possible collusion with the pain clinic. The pharmacy informed the State Board of Pharmacy which in turn notified Cephalon executives at a National Association of Chain Drug Stores meeting.

68. In January 2003 email, a Midwest sales representative resigned after repeated alleged harassment and abuse. In the email, she stated that she had "been forced to sell of[f] label by this company for along time [sic]." She further alleged that she had "been harassed and retaliated against" and that "Human Resources did nothing."

69. In December 2003, Cephalon's Pacific Northwest Area Manager reported that a colleague stated that "Cephalon has been crossing the line for years in their physician targeting strategy" and that the colleague said he "had never been in an office with a representative who was seeing a physician specifically to use our products in-label . . . all physicians targeted are targeted for off-label utilization."

70. According to a 2007 internal marketing presentation, in a sample of patients prescribed Actiq in 2006, 80% suffered from a non-cancer related pain (back pain, neuropathic, headache, and arthritis). Only 8% had cancer.

71. The off-label strategy was enormously successful. In 1999, Actiq sales were $2 million, and in 2000, when Cephalon acquired the drug, sales reached $16 million. But by 2006, sales exceeded $590 million.

72. In September 2008, Cephalon pleaded guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay a $50 million fine.

73. In September 2008, Cephalon also settled four *qui tam* actions. Cephalon agreed to pay $375 million to resolve False Claims Act allegations arising from claims to Medicaid, Medicare, and other federal programs. At the same time, Cephalon entered into a five-year Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The agreement required that Cephalon (a) inform doctors of the settlement terms and give them a means to report questionable conduct of its sales representatives; (b) disclose payments to doctors on its website; and (c) regularly certify that the company has an effective compliance program.

74. Even as Cephalon was facing enforcement inquiries regarding Actiq, however, it began aggressively marketing its other branded opioid, Fentora. Fentora (fentanyl citrate) is a buccal tablet that was first approved in 2006 and indicated for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."

75. According to a 2007 Fentora Marketing Plan, a key strategy was to "expand [the] FENTORA prescribing audience with Actiq users and beyond."

76. Teva knew that its scheme to induce doctors to write prescriptions for off-label use of Fentora might meet resistance from commercial insurance companies. To overcome

denials of coverage, Teva supplied its sales representatives with form letters that doctors could send to insurance companies when coverage for off-label prescriptions were denied. The doctor only had to supply information about the patient and the rest of the letter was already written. The form letter stated that the off-label prescription was "medically necessary" and provided a long list of medical studies and reports to support this. However, many of the cited reports and studies were produced by health care providers and front groups funded by Teva and other opioid manufacturers.

77. In September 2007, Cephalon sent letters to doctors warning of deaths and other "serious adverse events" connected with the use of Fentora, indicating that "[t]hese deaths occurred as a result of improper patient selection (*e.g.*, use in opioid non-tolerant patients), improper dosing, and/or improper product substitution."

78. Also in September 2007, the FDA issued its own Public Health Advisory regarding Fentora. The FDA emphasized, once again, that Fentora should be prescribed only for approved conditions and that dosing guidelines should be carefully followed. The FDA Advisory made clear that several Fentora-related deaths had occurred in patients who were prescribed the drug for off-label uses. The FDA Advisory warned that Fentora should not be used for any off-label conditions, including migraines, postoperative pain, or pain due to injury, and that it should be given only to patients who have developed opioid tolerance. The Advisory reiterated that, because Fentora contains a much greater amount of fentanyl than other opiate painkillers, it is not a suitable substitute for other painkillers.

79. In December 2007, the FDA issued a Labeling Supplement for Fentora stating that "physicians and other healthcare providers must become familiar with the important

warnings in this label." The Labeling Supplement reiterated all the warnings in the Public Health Advisory.

80. Despite these actions, Cephalon's aggressive and fraudulent marketing did not cease.

81. A January 2008 internal audit of Cephalon's Sales & Marketing Compliance Programs concluded that the Fentora tactical plans reference "targeting 'high opioid' prescribers without qualifying comments regarding break through cancer pain (BTCP) usage" which "may give regulators the incorrect appearance that off-label promotion is occurring and being planned." Furthermore, the same report acknowledged that Cephalon lacked a process to confirm that speakers' program participants were following Cephalon's written, formal policies, and noted that "noncompliant [Cephalon Speaker Programs] may be taking place."

82. In March 2009, the FDA issued a Warning Letter to Cephalon, stating the promotional materials for Fentora amounted to deceptive, off-label promotion of the drug. The FDA also warned Cephalon that, based on a review of Cephalon-sponsored links for Fentora on internet search engines, the company's advertisements were "misleading because they make representations and/or suggestions about the efficacy of Fentora, but fail to communicate any risk information associated with the use" of the drug.

83. Teva and Cephalon also used front groups and continuing medical education courses to change the perception of the safety and efficacy of opioids generally. For example, Cephalon sponsored a book published by the front group American Pain Foundation ("APF") titled *Treatment Options: A Guide for People Living with Pain* (2007). That book stated that opioids, when used properly, "give [pain patients] a quality of life we deserve." Despite warning

that non-steroidal anti-inflammatory drugs have greater risks with prolonged duration of use, *Treatment Options* gave no similar warning for opioids.

84. *Treatment Options* also stated the following:

> You and your healthcare provider may worry about tolerance, physical dependence and addiction. It's sometimes easy to confuse the meaning of these words. Tolerance refers to the situation in which a drug becomes less effective over time. However, many persons with persistent pain don't develop tolerance and stay on the same dose of opioid for a long time. Many times when a person needs a larger dose of a drug, it's because their pain is worse or the problem causing their pain has changed.

85. *Treatment Options* is still available online.

86. Direct outreach to doctors was also as critical part of the fraudulent marketing plan. In 2002, 45% of the Actiq marketing budget went to "CME programs and peer-to-peer medical education programs," according to the Actiq 2002 Marketing Plan.

87. Cephalon created a "tri-annual" newsletter, "Emerging Solutions in Pain" that by 2004 had a circulation of approximately 11,000 healthcare providers (including 8,000 physicians and 2,000 nurses), according to the 2004 Actiq Marketing Plan. The newsletter had an accompanying website that served as a repository of all CME programs created.

88. Teva also made payments to New York doctors. According to a June 2018 NYS Department of Health report titled *Follow the Money: Pharmaceutical Manufacturer Payments and Opioid Prescribing Patterns in New York State*, between 2013 and 2015 Teva contributed $336,863 to 438 physicians in New York. The money was broken up into 2,671 payments and were all related to Fentora.

89. Teva also had issues with diversion. In November 2012, certain Teva operations employees were trying to investigate and resolve DEA holds on Teva products with an opioids distributor that included four Fentora shipments. According to a Teva customer operations

manager: “We generally don’t look into who we’re selling to.” A Teva Diversion Investigator replied privately (italics in original):

> As we discussed privately, knew this was the culture here but to see someone put it in an email is a bit shocking. To state that “*Our business reason for these two orders is we need to supply our customer with product because they won’t be able to fulfill their customers demand without it*” is not a reason to release a DEA order in my book. On top of that he is basically saying he does not care where the product goes just that it says in the contract that we need to continue to ship it when their inventory gets below a certain point so that what we should be doing. Can’t wait to see what happens when we really have an issue . . .

90. Cephalon also had lax compliance regarding a program that provided vouchers directly to patients. In 2008, a sales representative was called directly by a patient requesting Fentora vouchers. The sales representative told Cephalon that she had already been contacted directly by the patient’s doctor asking for vouchers for the patient. The sales representative provided the doctor with vouchers and information on how to get reimbursement, but after te sales representative ran out of her allotted vouchers, the patient called Cephalon. Upon contacting Cephalon, the patient apparently not only was told that sales representatives held a limitless supply of vouchers but also was given the sales representative’s contact information. The patient sent emails to the representative and finally an angry voicemail accusing the representative of withholding the vouchers from him. Only at this point was the representative told to cease contact with the patient.

91. Actavis also marketed its generic drugs. In the summer of 2011, Actavis implemented a new marketing program for the recently launched generic oxymorphone ER (Opana ER) tablets. This marketing campaign included a direct-mail campaign to the top 10,000 prescribers; advertising in journals that covered both prescribers and pharmacists; and utilizing its branded sales team to deliver materials directly to physicians. The marketing campaign also

focused on pharmacists and targeted specific pharmacy chains and stores. For example, a large national chain was offered a "store level incentive to top volume stores." Actavis also partnered with a national distributor and to use a "telemarketer to call 500 independent pharmacies with [the] highest script history and provide incentives" to sell the new generic drug.

Allergan's False and Misleading Marketing to Prescribers and Patients

92. When Kadian was introduced into the market in 1996, the original indication was for "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time." In 2014, the FDA changed the indication to limit usage only to "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

93. In a 2010 warning letter, the FDA determined that representations made in certain promotional materials that Kadian improved functioning were false and misleading:

> [W]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect the drug has in alleviating pain, taken together with any drug-related side effects patients may experience (such as the common adverse events of drowsiness, dizziness, constipation and nausea), results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life. In addition, we are not aware of any studies demonstrating that the level of pain reduction experienced by patients on Kadian therapy corresponds with a positive impact on the outcomes claimed.

94. The warning letter also found that the promotional materials made misleading and unsubstantiated superiority claims that compared Kadian to MS-Contin and OxyContin. The promotional materials failed to "include the complete approved indication for Kadian, and present broad claims about the drug's use in treating pain, therefore implying that Kadian is appropriate for use in a broader range of patients than it is approved to treat."

95. Through its "Learn More about customized pain control with Kadian" patient material, Allergan claimed that while it is possible to become addicted to drugs like Kadian, it is "less likely" to happen in those who "have never had an addiction problem," suggesting the addiction risk was *de minimis*. It also stated that a need for a "dose adjustment" is the result of tolerance, and "not addiction."

96. In 2007 Allergan produced a guide for prescribers titled "Kadian and Abuse Potential" in which it falsely touted Kadian as having both lower abuse and lower addiction potential, stating that the "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users." The guide also highlighted Kadian as having a "slow onset of action," "lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "long duration of action," and "minimal fluctuations in peak to trough plasma levels of morphine at steady state" — statements that improperly suggest a lower state of euphoria caused by the drug and thus a lower abuse potential.

97. Allergan also conducted unbranded marketing through funding of front groups and websites. Allergan was a member of several industry front groups including the American Academy of Pain Medicine, American Pain Society, American Geriatrics Society, Pain Care Forum, and the New York State Pain Society.

98. In 2012, for example, Allergan was a supporter and exhibitor for the New York Pain Society's Annual Meeting, held in White Plains, New York. At this meeting, a prominent Key Opinion Leader in the opioid industry gave a presentation titled "Striving Towards Effective Opioid Use in Chronic Pain Management," during which he promoted the concept of

pseudoaddiction. CME credit was available for doctors who attended the meeting. Allergan was also a sponsor and exhibitor at the Society's 2013 annual meeting.

99. In 2011, Allergan sponsored a website called painedu.com that that offered CMEs and other medical educational materials relating to pain management. The CME page offered "[i]nteractive case-based learning modules address a range of topics in pain assessment and pain management," as well as "[a]rticles and treatment recommendations explore a balanced approach to care with the patients who are prescribed opioids."

100. An internal Allergan training document titled the "Kadian Learning System" trained Kadian sales representatives to disseminate the idea of pseudoaddiction, which was defined as "a set of behaviors that are exhibited by patients with inadequately treated pain, including cancer pain. Pseudoaddictive behaviors are not signs of substance abuse, but rather should be considered symptoms of inadequately treated pain."

SPECIFICATION OF VIOLATIONS

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

101. The Department realleges and incorporates by reference the assertions contained in paragraphs 1-100 above as if set forth fully herein.

102. 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.

103. 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 . . . ."

104. 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.

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

106. 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.

107. 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.

108. 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.

109. 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)

110. Petitioner realleges and incorporates by reference the assertions contained in paragraphs 1-109 above as if set forth fully herein.

111. 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.

112. 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.

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

114. 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.

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

116. 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
August 17, 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

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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.