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COMMONWEALTH OF KENTUCKY
FAYETTE COUNTY CIRCUIT COURT
DIVISION NO. 3
CIVIL ACTION NO. 18-CI-3767

OCT 26 2018

COMMONWEALTH OF KENTUCKY, *ex rel.*, ANDY BESHEAR, ATTORNEY GENERAL,

Plaintiff.

v.

TEVA PHARMACEUTICALS, USA, INC.; TEVA BRANDED PHARMACEUTICAL PRODUTS R&D, INC CEPHALON, INC.

Defendants.

COMPLAINT

JURY TRIAL DEMANDED

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I. PRELIMINARY STATEMENT

1. Plaintiff, the Commonwealth of Kentucky ("the Commonwealth" or "Kentucky"), is struggling with an opioid crisis. Unlike the crack cocaine and crystal methamphetamine epidemics that preceded it, this drug crisis arose because of corporate business plans. Teva Pharmaceuticals USA, Inc. and Cephalon, Inc. ("Teva" or "Defendants"), along with other opioid manufacturers, employed deceptive marketing practices that misrepresented the risks and overstated the benefits of opioids. These marketing practices encouraged doctors to prescribe opioids for the long-term treatment of common, chronic pain conditions like low back pain and headaches, while concealing or minimizing the risks of doing so.[1] As a direct consequence of Defendants' deceptive and misleading promotion of these highly addictive drugs, the opioid epidemic is ravaging Kentucky.

2. While the opioid epidemic is causing one of the deadliest drug crises in the history of the United States, the Commonwealth has been hit especially hard. It ranked sixth in the nation for opioid-related deaths in 2015. In 2015, 102 opioid prescriptions were written for every 100 Kentucky residents, which is 1.5 times the national average. The same year, there were 1,404 reported fatal drug overdoses in Kentucky—117 per month. In 2017, the number of reported fatal drug overdoses increased to 1,565, which is approximately 130 deaths per month. According to the National Institute on Drug Abuse, Kentucky has double the overdose rate of the national average.

3. The Commonwealth of Kentucky brings this action to redress Teva's campaign of unfairly, deceptively, fraudulently, and illegally marketing, promoting, and selling opioids.

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[1] Consistent with the commonly accepted medical usage, the term "chronic pain" as used herein refers to non-cancer pain lasting three months or longer.

4. Teva manufactures, markets, and sells branded prescription opioids, including Actiq and Fentora, and generic opioids. From 2006 to 2014, Teva's opioids accounted for the majority of opioids, in grams, sold in Kentucky, with almost 28% of total opioid grams sold.

5. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. While opioids can work to dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms that are often prolonged—including severe anxiety, nausea, headaches, tremors, delirium, and pain—if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e., the relief of pain), requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

6. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care. Consequently, the market for prescription opioids was sharply restricted.

7. In order to expand the market for opioids, Teva had to persuade doctors to prescribe opioids for the long term treatment of chronic pain conditions, even though its branded opioids, Actiq and Fentora, are only approved for the treatment of breakthrough cancer pain. Teva began to promote opioids generally, and its own opioids in particular, as safe, effective, and appropriate for long-term use for routine pain conditions by misrepresenting and downplaying the risks of such use and overstating the purported benefits. For example, Teva misrepresented the risk of addiction as modest, manageable, and outweighed by the benefits of opioid use. Teva's representations were

contrary to and undermined general concerns or warnings regarding addiction in drug labels and elsewhere, and were contrary to the indications approved by the U.S. Food and Drug Administration ("FDA") for Actiq and Fentora.

8. Teva's scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Teva's deceptive marketing scheme also increased the comfort level of doctors and patients in converting opioids prescribed for acute pain—surgery or injuries, for example—to long-term use by patients who experienced or reported ongoing pain.

9. As a direct and foreseeable result of Teva's conduct, states across the nation, including Kentucky, are now swept up in what the Centers for Disease Control ("CDC") has called a "public health epidemic." The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescriptions opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire or simply could not afford prescription opioids.

10. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2017 than 1999. Drug overdoses have become the leading cause of accidental death in the Commonwealth. As the then CDC director concluded in 2016, "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[2]

[2]Thomas R. Frieden et al., *Reducing the Risks of Relief - The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-04 (2016).

11. Thus, rather than compassionately helping patients, the explosion in opioid use, and in Teva's profits, has come at the expense of patients and has caused ongoing harm and damages to the Commonwealth.

12. In addition to opioid-related fatalities, the Commonwealth has seen a dramatic increase in opioid addiction, reflected, in part, in the increase in Medicaid spending for medications to treat such addiction, which doubled in just two years—from $56 million in 2014 to $117 million in 2016.

13. The widespread use of opioids and corresponding increases in addiction and abuse have also led to an increase in emergency room visits, emergency responses to overdoses, and emergency medical technicians' administration of naloxone—the antidote to opioid overdose. In Louisville, the police force administered 123 doses of naloxone in just the first six weeks of 2017, representing three overdoses each day. The explosion in opioid use also has resulted in the dramatic growth of drug-related crimes. In one Kentucky county, roughly 90% of prosecutions are related to prescription drug abuse or diversion. Across the Commonwealth, there have been increases in domestic violence, robberies, burglaries, and thefts, among other crimes.

14. In addition, in 2014, the Commonwealth had the third-highest rate of pregnant women with opioid use disorder in the country. Between August 1, 2014 and July 31, 2015, 1,234 infants in Kentucky were born addicted to opioids—more than 100 newborns per month. In 2017, the number of babies born with NAS (Neonatal Abstinence Syndrome) in the Commonwealth had increased by 375% since 2007. These infants spend weeks in neonatal intensive care units while they painfully withdraw from the drugs.

15. The burdens imposed on the Commonwealth are not the normal or typical burdens of government programs and services. Rather, they are extraordinary costs and losses that are

related directly to Defendants' illegal actions. Teva's conduct has created a public nuisance and a blight. Governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis.

16. Teva has not changed its ways or corrected its past misconduct but instead is continuing to fuel the opioid crisis.

17. Accordingly, the Attorney General brings this lawsuit in the public interest to bring the devastating march of this epidemic to a halt and to hold Teva accountable for its violations of the Consumer Protection Act ("KCPA"), KRS 367.110 *et seq.*; the Kentucky Medicaid Fraud Statute, KRS 205.8463; and the Kentucky Assistance Program Fraud Statute, KRS 194A.505. The Attorney General also seeks remedies for the creation and maintenance of a continuing public nuisance, fraud, unjust enrichment, and negligence. This action seeks repayment of the Commonwealth's Medicaid, workers' compensation, and other spending on opioids, disgorgement of Teva's unjust profits, civil penalties for its egregious violations of law, compensatory and punitive damages, and injunctive relief including abatement of the public nuisance Teva has helped create.

II. PARTIES

A. Plaintiff

18. The Plaintiff, Commonwealth of Kentucky, brings this action, by and through its Attorney General, Andy Beshear, in its sovereign capacity in order to protect the interests of the Commonwealth and its citizens. This suit concerns matters of state-wide interest. Andy Beshear is the duly elected Attorney General of Kentucky, an independent constitutional officer of the Commonwealth and its chief law enforcement officer, with full authority to initiate and prosecute cases, including this one, in which the Commonwealth has an interest. The Attorney General is vested with specific constitutional, statutory and common law authority to commence proceedings

to enforce KRS 194A.505, KRS 367.110 *et seq.*, and KRS 205.8451 through KRS 205.8483, to exercise all common law duties and authority pertaining to the office of the Attorney General under the common law pursuant to KRS 15.020, and pursuant to the Attorney General's authority to bring an action on behalf of the Commonwealth. The Attorney General has determined that these proceedings are in the public interest.

B. Defendants

19. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Cephalon, Inc. became a wholly owned subsidiary of Teva USA when Teva USA acquired Cephalon, Inc. in October of 2011. Teva is registered to do business in Kentucky under the name Teva Branded Pharmaceutical Products R&D, Inc.

20. Teva manufactures, promotes, sells, and distributes branded opioids Actiq, a fentanyl lollipop, and Fentora, a dissolving fentanyl pill, throughout the United States and in Kentucky. Actiq and Fentora have been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading off-label promotion of Actiq and two other drugs and agreed to pay $425 million.

21. Teva also sells generic opioids throughout the United States and Kentucky, including generic opioids previously sold by Allergan plc, whose generics business Teva Pharmaceutical Industries Ltd., Teva's parent company based in Israel, acquired in August 2016. Generic opioids sold by Teva include oxymorphone and hydrocodone.

III. JURISDICTION AND VENUE

22. This Court has subject matter jurisdiction over the Commonwealth's claims pursuant to KRS 23A.010, KRS 194A.505(8), KRS 205.8469, and KRS 367.190, as the claims enumerated herein arise exclusively under Kentucky statutory and common law and from the *parens patriae* authority of the Attorney General to protect the health and welfare of its citizens under the common law. The Commonwealth's claims are in excess of any minimum dollar amount necessary to establish the jurisdiction of this Court.

23. This Court has personal jurisdiction over Teva pursuant to KRS 454.210 because Teva has regularly transacted and/or solicited business in the Commonwealth and/or derived substantial revenue from goods used or consumed or services rendered in the Commonwealth and/or contracted to supply good or services in the Commonwealth and/or caused injury by an act or omission in the Commonwealth and/or caused injury in the Commonwealth by an act or omission outside the Commonwealth.

24. The Complaint herein sets forth exclusively state law claims against Teva. Nowhere does the Commonwealth plead, expressly or implicitly, any cause of action or request any remedy that arises under or is based on federal law. The Commonwealth expressly asserts that the only causes of action asserted and the only remedies sought herein are founded upon the statutory, regulatory, common, and decisional laws of the Commonwealth of Kentucky.

25. The claims asserted herein consist of common law and statutory claims on behalf of the Commonwealth of Kentucky for its own injuries, and common law claims brought pursuant to the Commonwealth's *parens patriae* authority to protect the health and welfare of its citizens. The Commonwealth does not assert any cause of action herein on behalf of any individual or any purported class of individuals.

26. Venue is proper in Fayette County pursuant to KRS 452.450 and 452.460 because injuries to the Commonwealth occurred in Fayette County and pursuant to KRS 367.190(1) because unlawful methods, acts and/or practices of Teva were committed in Fayette County.

IV. FACTUAL ALLEGATIONS

27. Teva relies on its sales representatives to convey its marketing messages and materials to prescribers in targeted, in-person settings. Publicly available data shows that Teva sales representatives visited Kentucky prescribers 79 times between the third quarter of 2013 and the end of 2016. However, these numbers understate the amount of "detailing" by each of Teva's sales representatives, as they reflect only payments over the reportable limit to prescribers.[3] Indeed, according to internal Teva documents, from 2012 until 2017, Fentora sales representatives visited and/or called Kentucky healthcare providers 3,031 times.

28. The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a Staff Report which noted the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices."[4] The Report quotes ProPublica findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."

29. To ensure that sales representatives delivered the desired messages to prescribers, Teva directed and monitored its sales representatives through detailed action plans, training, and review of representatives' "call notes" from each visit. It further ensured marketing consistency

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[3] Pharmaceutical detailing is a one-on-one marketing technique utilized by pharmaceutical companies to educate a physician about their products in hopes that the physician will prescribe the company's products more often.

[4] Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization.*

nationwide through sales representative training. Thus, upon information and belief, its sales forces in Kentucky carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country.

30. Teva also internally tracked its sales representatives to ensure that their messages were being absorbed by prescribers. According to an internal document, Teva tracked the impact of its sales representatives' key messages about Fentora. For example, from this tracking, Teva learned that Fentora sales representatives were more likely to be rated highly by doctors they visited if they reviewed a prescription savings program with the doctor, used the iPad, and discussed proper dosing. Additionally, some of the "success drivers" of the sales representatives' marketing of Fentora included messaging regarding the fast onset of its analgesic effect, improved patient physical and cognitive function with use, and its convenience and ease of use. Thus, Teva was aware of the strengths of its in-person marketing.

31. The effects of sales calls on prescribers' behavior is also well-documented in the literature. A study which involved research on different marketing practices, including visits by sales representatives, medical journal advertisements, and direct-to-consumer advertising, and found that visits by sales representatives have the strongest impact on driving drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the sales representatives' drugs to hospitals' formularies.

32. Teva also used "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs ("CMEs") that provided information through third party organizations about treating pain and the risks, benefits, and use of opioids. These KOLs

received substantial funding and research grants from Teva, and the CMEs were often sponsored by Teva—giving it considerable influence over the messenger, the message, and the distribution of the program. Upon information and belief, doctors supportive of the Defendants' messages regarding the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but helped doctors build their reputations and bodies of work. For example, one Teva KOL, Dr. Scott Fishman, is a prominent speaker on the under-treatment of pain, and has written a book about responsible opioid prescribing and claimed he received no royalties. However, he subsequently corrected himself and acknowledged that he received fees for teaching medical education courses, and some of which were funded by drug companies. Another leading KOL for Teva, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."

33. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Academy of Pain Medicine, that were influential because of their seeming independence. Teva exerted influence and control over such groups by providing funding directly to them. These "front groups" for the opioid industry created patient education materials and treatment guidelines that supported the use of opioids for chronic pain by overstating their benefits and understating their risks.[5]

[5] A recent investigation and report by the U.S. Senate notes, "many patient advocacy organizations and professional societies focusing on opioids policy have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers. Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies." Staff Report, *Fueling an Epidemic, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, at 3.

34. The FDA does not regulate unbranded advertising or marketing funneled through third-parties. Thus, neither these third-party unbranded materials, nor the marketing messages or scripts relied on by Teva's sales representatives, were reviewed or approved by the FDA.

35. Upon information and belief, all of the messages described below were disseminated to Kentucky prescribers and patients through sales representative visits, medical education programs, marketing materials, or other sources.

A. Teva Deceptively and Illegally Marketed Actiq and Fentora for Off-Label Use

36. Both Actiq and Fentora are extremely powerful fentanyl-based opioids. Actiq delivers fentanyl into the bloodstream via a lollipop lozenge that dissolves slowly in the mouth. As described by one patient, Actiq "tastes like the most delicious candy you ever ate."[6] Fentora is administered by placing the tablet in the mouth until it dissolves. Both are rapid-onset opioids that take effect within 10-15 minutes, but last only a short time. Neither is approved for, nor has either been shown to be safe or effective for, treating chronic pain. The drugs are approved solely for breakthrough cancer pain in patients who are tolerant to opioid therapy.

37. In fact, the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events"; and abuse which are greatest in non-cancer patients. In 2004, the FDA and Teva held a meeting regarding the FDA's concern over Teva's promotion of Actiq for off-label use. According to the meeting minutes, the FDA's specific concerns included Teva's prescriber targeting criteria and physician screening, as well as sales representative training practices that "inappropriately broaden the drug's

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[6] *See* John Carreyrou, *Narcotic 'Lollipop' Becomes Big Seller Despite FDA Curbs*, Wall St. J., Nov. 3, 2006.

labeled indication, the eliciting of and response to off-label inquiries regarding Actiq . . . and the promotional use of disease awareness materials that discuss conditions for which Actiq is not indicated to treat." Additionally, according to the minutes, the FDA told Teva that "off-label promotion is illegal, and especially with a drug with a risk profile like Actiq, raises significant public health concerns."

38. In 2008, the Department of Justice ("DOJ") accused Cephalon of promoting Actiq, along with two non-opioid drugs, for uses the FDA had not approved. Cephalon agreed to settle the charges for $425 million. The DOJ charged that Cephalon promoted Actiq to non-cancer patients for conditions such as "migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy."[7] The DOJ also accused Cephalon of promoting Actiq for patients who were not opioid-tolerant, "for whom it could have life threatening results." The DOJ outlined Cephalon's sales tactics as follows:

> Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners, and to promote the drug for many uses other than breakthrough cancer pain. . . . Cephalon also structured its sales quota and bonuses in such a way that sales representatives could reach their sales goals only if they promoted and sold the drugs for off-label uses. . . . Cephalon employed sales representatives and retained medical professionals to speak to doctors about off-label uses of Actiq. . . . The company funded continuing medical education programs, through millions of dollars in grants, to promote off-label uses of its drugs, in violation of the FDA's requirements.[8]

39. Acting U.S. Attorney Laurie Magid stated that Cephalon had violated the very process meant to protect the public from harm in order to boost its bottom line, and noted, "[p]eople have an absolute right to their doctors' best medical judgment. They need to know the

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[7] Press Release, Department of Justice, *Pharmaceutical Company Cephalon to Pay $425 Million for Off-Label Drug Marketing* (Sept. 29, 2008).

[8] *Id.* at 2.

recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved."[9]

40. Despite the multi-million dollar fine and admonitions from the DOJ and FDA, Teva conducted and continues to conduct a campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe, effective, and appropriate for treating non-cancer pain.

41. For example, Teva paid to have a CME it sponsored, "Opioid-Based Management of Persistent and Breakthrough Pain," published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.

42. In December 2011, Teva widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News*—three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain," and not just cancer pain."

43. Teva's sales representatives also set up speaker programs for doctors which promoted Actiq and Fentora for the treatment of non-cancer pain. According to a former Actiq and Fentora sales representative, the sales representatives were able to nominate speakers for

[9] *Id.*

Teva's speaker program. The expectation was that the speakers would increase their prescribing of Actiq and Fentora and identify patients in their practice who could receive free trials for the opioids.

44. Additionally, Teva targeted non-oncologists in order to boost its sales of Actiq and Fentora. Of the 3,031 visits and calls that Fentora sales representatives made to Kentucky healthcare providers between 2012 and 2017, only 5% of these visits were to hematologists and oncologists. Furthermore, according to an internal marketing plan, Teva developed a research and publication plan to target doctors outside of the cancer-treating population. This included focused promotional and educational efforts directed toward pain specialists in order to increase their prescribing of Actiq and Fentora. According to the document, "[e]ffective physician targeting continues to be critical to our success with Actiq."

45. Teva sales representatives who detailed prescribers in other states recalled primarily marketing to prescribers who were non-oncologists. According to former Actiq sales representatives, they knew that the only indication for Actiq was for cancer patients, but Teva's management dictated sales goals that required the representatives to detail prescribers other than oncologists or specialists treating cancer patients. Sales representatives recalled that if they had only marketed Actiq to doctors who treated the indicated patient population, they would not have been able to meet their sales goals.

46. An Actiq sales representative who worked for Defendants from 2001 until 2017 recalls targeting pain specialists, internal medicine physicians, and primary care doctors in order to promote Actiq between 2003 and 2005, specifically visiting doctors who would prescribe opioids to different types of patients, such as those with lower back pain and other conditions. Additionally, Teva provided the representative with data on the prescribing habits of doctors in his

territory, which showed him who the highest prescribers of short-acting opioids were in his area. The sales representative told prescribers that Actiq was for breakthrough cancer pain, but stated that this messaging was just a "formality"; he was responsible for selling the drug against the competition and was not concerned with why a prescriber prescribed many opioids per month, or what type of patients received the prescriptions.

47. Another Teva sales representative who marketed Fentora between 2012 and 2013 stated that Teva's management made the decision to target pain clinics, despite the fact that the doctors at the clinics did not treat cancer patients. The sales representative stated that 99% or more of the doctors who wrote prescriptions for Fentora in her territory were pain specialists who wrote the prescriptions for off-label use, and they told her that they did not treat cancer patients. The sales representative does not recall even one oncologist in her territory who wrote a prescription for Fentora. According to the sales representative, Teva targeted promotion of Fentora to pain specialists in order to increase prescriptions sales because oncologists were not prescribing the drug.

48. A third former Teva sales representative who marketed Actiq and, later, Fentora between 2005 and 2012, recalled visiting doctors of different specialties, including pain specialists, primary care physicians, and oncologists. However, the sales representative found that oncologists were not interested in prescribing Fentora or Actiq. He stated that his job was to keep doctors comfortable prescribing Actiq and Fentora for other conditions, and he provided prescribers with literature about back pain through medical inquiry requests. Approximately 95% of the Actiq and Fentora prescriptions in his territory were for conditions other than breakthrough cancer pain. He also stated that it was widely known that these opioids were rarely prescribed for cancer pain, despite the fact that they were only indicated for this use. He stated that Teva's sales goals and

culture created an astonishing amount of off-label use for both Fentora and Actiq, and if a sales representative did not keep up with his or her peers, the representative was at risk of losing his or her bonus or job.

49. On December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy ("REMS") for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl ("TIRF"). The TIRF REMS programs included mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not totally comprehensive and do not, for instance, disclose that addiction can develop when prescribed as directed, nor do they disclose that risks are greatest at higher doses—and patients must already be opioid-tolerant and taking high doses of opioids to be prescribed Actiq and Fentora. However, according to a former Fentora and Actiq sales representative, even after the TIRF REMS program was implemented, he continued to market to the same prescribers who prescribed Actiq and Fentora to non-cancer patients, and his promotional messages regarding Actiq and Fentora did not change.

50. The similarity of these reports from sales representatives from different states across the country demonstrates that the sales messages and practices were part of Teva's nationwide marketing strategy for Actiq and Fentora. Upon information and belief, these same messages and practices were similarly employed by Teva sales representatives in detailing prescribers in Kentucky. Teva's push to promote Actiq for off-label use demonstrates its efforts to boost its profits despite the limitations prescribed by the FDA.

B. Teva Falsely Trivialized, Mischaracterized, And Failed To Disclose The Known, Serious Risk Of Addiction

51. To convince prescribers and patients that opioids should be widely prescribed for the long-term treatment of chronic pain conditions, Teva deceptively represented that the risks of

abuse and addiction were modest, manageable, and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impression that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted; (2) patients with the greatest risk of addiction could be identified; and (3) all other patients could safely be prescribed opioids.

52. Teva sponsored American Pain Foundation's ("APF") guide *Treatment Options: A Guide for People Living with Pain* (2007), which teaches that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. Additionally, the guide advises against restricting access to opioids to prevent opioid abuse and states, "[r]estricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction." The guide also stigmatizes the term "narcotics" by associating the term with illegal drugs such as cocaine and heroin, while promoting opioids. The guide states that referring to opioids as narcotics "reinforces myths and misunderstandings as it places emphasis on their potential abuse rather than on the importance or their use as pain medicines."

53. In addition, a 2003 Teva-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

> [C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.[10]

[10] Michael J. Brennan et al., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape (Feb. 26, 2003).

54. Upon information and belief, Teva sales representatives regularly omitted any discussion of addiction caused by long-term opioid use from their sales conversations with Kentucky prescribers. According to a former Actiq sales representative in another state, he did not often discuss the risks associated with Actiq because he believed the doctors were aware that patients could die from an opioid overdose.

55. Teva also deceptively advised doctors to ignore signs of addiction as the product of an unfounded condition it called 'pseudoaddiction'. This concept was invented to foster the misconception that signs of addiction, such as drug-seeking behavior, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

56. Teva promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for Teva and other opioid manufacturers. Dr. Portenoy popularized the concept and falsely claimed that pseudoaddiction was substantiated by scientific evidence.

57. Teva, further promoted pseudoaddiction through its CME, Pharmacologic Management of Breakthrough or Incident Pain. According to the CME, pseudoaddiction is a term which refers to "drug-seeking behavior in patients who have severe unrelieved pain and who have not received effective pain therapy."[11] Additionally, it promotes the continued use of opioids by stating that "such behavior disappears when adequate analgesic treatment, including increased opioid dosing, is given."[12]

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[11] Michael J. Brennan et al., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape (Feb. 24, 2003).

[12] *Id.*

58. Teva's efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. In March 2016, the FDA emphasized the "serious risk[] of . . . addiction" of opioids."[13] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published the CDC Guideline for prescribing opioids for chronic pain. The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[14] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[15]

59. Nowhere in the CDC Guideline is it recommended that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the CDC Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[16] and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[17]

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[13] U.S. Food & Drug Admin., *FDA Announces Safety Labeling Changes and Postmarket Study Requirements fo rExtended-release and Long-acting Opioid Analgesics* (Sept. 10, 2013); *see also* U.S. Food & Drug Admin., *FDA Announces Enhanced Warnings for Immediate-release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death* (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[14] CDC Guideline at 2.

[15] *Id.* at 21.

[16] *Id.* at 13.

[17] *Id.* at 25.

C. Teva Overstated the Benefits of Chronic Opioid Therapy While Failing to Disclose the Lack of Evidence Supporting Long-Term Use

1. Mischaracterizing the benefits and evidence for long-term use

60. Teva sought to convince prescribers and patients that there were significant benefits in treating chronic pain with long-term opioid use. This is in sharp contrast with the findings of both the CDC and FDA. Assessing existing evidence, the CDC Guideline found that there is "*insufficient evidence* to determine the long-term benefits of opioid therapy for chronic pain."[18] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[19] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[20] The FDA also determined that opioid use disorder and overdose risk are present when opioids are taken as prescribed. As a result, the CDC recommends that opioids be used not in the first instance and only after prescribers have exhausted alternative treatments.

61. Teva touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence. The prominent professional medical organization, AAPM, received substantial funding from Teva—$119,788 from 2009 to 2012. Upon information and belief, Teva exercised considerable influence over AAPM's work on opioids. AAPM, along with the American Pain Society ("APS"), issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which

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[18] *Id.* at 10.

[19] *Id.* at 9.

[20] Letter from Janet Woodcock, M.D, Dir., Center for Drug Eval. & Research, to Andrew Kolodny, M.D. (Sept. 10, 2013).

endorsed opioids to treat chronic pain and claimed that patients' risk of becoming addicted to opioids was low. Teva KOL Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and was taken down only after a doctor complained.

62. AAPM, along with APS, continued to recommend the use of opioids to treat chronic pain by issuing treatment guidelines in 2009 ("AAPM/APS Guidelines"). Treatment guidelines such as these are particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors, who have no specific training in treating chronic pain. Seven of the twenty-one panel members who drafted the AAPM/APS Guidelines received income or research funding from Teva.

63. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Teva, made to the sponsoring organizations and committee members.

64. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and biased, including its high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

65. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence

on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature.

2. Overstating opioids' effect on patients' function and quality of life

66. Upon information and belief, Teva also claimed to Kentucky doctors, without evidence, that long-term opioid use would improve patients' quality of life.

67. A former Fentora sales representative who visited prescribers in another state has described being trained by Teva to tell prescribers that Fentora would improve patients' quality of life. The representative was instructed to use, and did use, messaging that focused on Fentora improving patients' function, allowing the patients to spend more time with their family members or return to a normal work pattern. Similarly, another former Teva sales representative promoted Actiq and Fentora by stating that they could "improve patients' quality of life, by letting them get back to their normal functions." Upon information and belief, the same messages regarding improvement of patient function were provided to prescribers in Kentucky by Teva sales representatives.

68. In addition, *Responsible Opioid Prescribing* (2007), a physician guide sponsored and distributed by Teva, taught that relief of pain by opioids, alone, improved patients' function. The book remains for sale online.

69. Teva's claims that the use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of opioid use beyond 12 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety,

post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

70. One pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[21] Studies of patients who suffer from pain have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

71. The FDA and other federal agencies have made these risks clear for years.[22] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[23] The CDC Guideline concluded that "[w]hile benefits for pain relief,

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[21] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?

[22] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[23] CDC Guideline at 2.

function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[24] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[25]

D. Teva Told Doctors that Opioids Could Be Taken in Ever Higher Doses Without Disclosing Their Greater Risks

72. Teva falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. Upon information and belief, Teva needed to generate a comfort level among doctors to prescribe higher doses, rather than prescribing opioids for more frequent dosing.

73. Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs (nonsteroidal anti-inflammatory drugs) in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200, far fewer than from opioids).[26] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication omitted known risks of opioid therapy while emphasizing and exaggerating the risks of competing products so that prescribers and

[24] *Id* at 18.

[25] *See id.* at 18.

[26] The higher figure reflects deaths from all causes.

patients would be more likely to choose opioids over other therapies such as over-the-counter acetaminophen or NSAIDs.

74. Teva also reinforced its message of the lack of a ceiling dose for opioids through its sales representatives. According to a former Actiq and Fentora representative, he told doctors that there was no ceiling dose for either opioid.

75. Teva's misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 19.3% to 29.1% of visits while NSAID and acetaminophen prescriptions fell from 36.9% to 29.1%.

76. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[27] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[28]

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[27] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[28] CDC Guideline at 16.

E. Teva Failed to Report Suspicious Prescribing

77. Despite having knowledge of suspicious prescribing, Teva failed to implement policies and procedures that would enable sales representatives to report suspicious prescribing. One sales representative recalled visiting a family practitioner in his area who was a high prescriber of Actiq and other Teva drugs. During his visits, he recalled seeing one patient with two Actiq lollypops in his mouth at the same time—one in each cheek. According to the sales representative, he knew that seeing this patient meant that the doctor was writing several prescriptions for Actiq, which would increase the sales representative's sales numbers. This doctor eventually lost his medical license due to his prescribing practices. The sales representative visited another doctor in his area and classified the practice as a "pill mill." When he visited the office on occasional Saturdays, the waiting room smelled of cigarettes, and the majority of the patients saw the doctor because they "wanted drugs." This doctor was eventually arrested when his office was raided by regulatory authorities.

78. The sales representative was not aware of any process at Teva to report such doctors. Additionally, he stated that he and other sales representatives did not want to report these doctors because they were "the money makers—you don't want to shoot the golden goose." Additionally, according to the sales representative, Teva's management "had to have known" that these two doctors and others like them were high prescribers of Actiq and were not prescribing the opioids for breakthrough cancer pain, but they "looked the other way."

79. Another sales representative recalled visiting doctors who appeared to engage in overprescribing. The representative remembered that at one clinic, a receptionist was behind thick bullet proof glass, and at other clinics, large numbers of patients lined up to see doctors who were known to provide Fentora and other opioids. However, the sales representative reported never receiving any training on the signs of suspicious prescribing while working at Teva, and continued

to call on these clinics in order to reach Teva's sales goals. The sales representative was unaware if Teva reviewed prescribing habits of doctors in order to identify suspicious prescribers, and did not know of any instances in which Teva reported such prescribing.

80. A third sales representative also did not recall receiving any training on signs of suspicious prescribing and was never told to stop visiting or calling a doctor due to his or her prescribing habits. The similarity of the reports of these sales representatives from different states across the country demonstrate that the sales messages and practices, including lack of reporting, were part of Teva's nationwide marketing strategy for Actiq and Fentora. Upon information and belief, Teva sales representatives also failed to report suspicious prescribers in detailing prescribers in the Commonwealth.

F. By Increasing Opioid Prescriptions and Use, Defendants Collectively Fueled The Opioid Epidemic And Significantly Harmed Kentucky and its Residents

81. The vast market for opioids was created and sustained in significant part by opioid manufacturers', including Teva's, deceptive and illegal marketing, which established opioids as a first-line treatment for chronic pain. Teva's marketing was intended to, and did, increase prescribing not only of its own branded opioids, but also of opioids in general, including its generic opioids. Teva's deceptive marketing caused health care providers to make and refill opioid prescriptions that maintained patients' dependence and addiction, caused patients to believe they would not become addicted, and caused addicted patients to seek out more drugs.

82. Overall sales of prescription opioids in Kentucky have skyrocketed. From 2006 to 2015, the Commonwealth had more opioid prescriptions than people. In 2015, Kentucky ranked sixth in the nation in opioid-related deaths. In 2016, 97.2 opioid prescriptions were written for every 100 Kentucky residents. Teva is directly responsible for the opioid epidemic in Kentucky.

From 2006 to 2014, Teva's opioids accounted for the majority of opioids, in grams, sold in Kentucky, with almost 28% of total opioid grams sold.

83. Nationwide, approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are now the most common treatment for chronic pain, and approximately 20% of office visits now include the prescription of an opioid.

84. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."

85. In August 2016, U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis facing America" and linking that crisis to deceptive marketing.[29] He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors. Many of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[30]

86. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic

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[29] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm; Vivek H. Murthy, M.D., M.B.A., *Letter from the U.S. Surgeon General*, Aug. 2016, available at https://www.aafp.org/patient-care/public-health/pain-opioids/turn_the_tide.html.

[30] *Id.*

exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[31] In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Prescription opioids and heroin account for the majority of overdoses. For these reasons, the CDC concluded that efforts to improve the safer prescribing of opioids must be intensified "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

87. Most opioid addiction begins with legitimately prescribed opioids. An estimated 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. A study of 254 accidental opioid overdose deaths in Utah found that 92% of the decedents had been receiving prescriptions from health care providers for chronic pain. Sales to patients who doctor-shop (or visit multiple doctors to hide illicit or over-use) constitute approximately only 1% to 2% of opioid volume. This study is consistent with the observations of a Kentucky law enforcement officer, who perceived prescription opioids and heroin as among the most abused drugs in his region of Kentucky. In his experience, which was confirmed by addiction treatment providers in Kentucky, prescription opioid abuse stems from overprescribing opioids, and almost all heroin abuse begins with prescription opioid abuse.

88. Upon information and belief, the escalating number of opioid prescriptions written by doctors who were deceived by Teva's deceptive marketing schemes, caused a correspondingly dramatic increase in opioid addiction, overdose, and death throughout Kentucky.

89. Addiction has consumed the lives of countless Kentuckians exposed to opioids prescribed by doctors either directly, from their own prescriptions, or indirectly, from prescription

[31] Theodore J Cicero et al., *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16.8 Pharmacoepidemiology & Drug Safety, 827-40 (2007).

drugs obtained by others and found in family medicine cabinets. It is difficult to describe the lifelong struggle individuals addicted to opioids will face. The desire to get drugs becomes so consuming that addicts can no longer work or care for their children, and will resort to desperate means to persuade doctors to provide their next prescription—even pulling their own teeth. Opioids have had devastating effect on Kentucky's work force. According to one study, in 2015, nearly one-million eligible Kentucky employees were absent from the work force due to opioids.

90. Opioids have contributed to a significant labor shortage in Eastern Kentucky, as employment in the region dropped by 21% from 2006 to 2016 due, in part, to the high rate of opioid use in the region. 'Recent research has demonstrated that the Commonwealth's high rate of opioid usage has reduced the work force, created high turnover, increased employers' costs to train new employees, and caused an increase in employee thefts.

91. Additionally, according to a study conducted by the Appalachian Regional Commission, small businesses and large manufacturing firms are having difficulties hiring employees who are able to pass drug screening tests. Convenience stores that are open 24 hours per day are having difficulties operating with fewer employees. The shortage in work force impacts customer service, and requires managers to work extra shifts, which increases overtime costs. According to a Commonwealth resident who owns convenience stores in London and Manchester, Kentucky, "[t]his is the hardest I've ever seen getting workers and keeping workers."[32]

92. The Commonwealth has incurred considerable costs in treating opioid addiction. At the beginning of 2014, the Medicaid program spent roughly $56 million on behavioral health

[32] Bill Estep, *'Nobody to pick from.' How Opioids Are Devastating the Workforce in Eastern Kentucky,* Lexington Herald Leader, June 27, 2018, https://www.kentucky.com/news/state/article213189309.html.

and substance abuse treatment. By the end of 2016, Kentucky was spending about $117 million in Medicaid money on those treatments.

93. In 2016, there were 1,404 reported fatal drug overdoses in Kentucky—117 per month. This was a 12.4% increase from 2015, a year which, in turn, had seen in a 23.6% increase in fatalities from drug overdoses as compared to 2013. Altogether, between 2012 and 2016, drug overdoses claimed a total of 5,822 Kentuckians. In 2017, there were 1,565 fatal drug overdoses in Kentucky, which is an increase to approximately 130 deaths per month.

94. In the first month of 2017 alone, Louisville saw 695 overdoses (a figure which includes prescription drugs, illicit drugs, and alcohol). Louisville Metro Emergency Medical Services received 151 of these overdose calls within just four days.

95. The increase in opioid-related deaths has created a shortage of forensic pathologists within the Commonwealth qualified to perform autopsies and post mortem toxicology tests. As of May 2018, the Commonwealth's medical examiner office only had nine doctors, and the demand for coroners has only increased due to growth in opioid-related deaths. The Kentucky Justice Cabinet recently announced a collaboration with the University of Kentucky to contract for forensic pathology services, which will increase training for medical students and strengthen salaries for doctors. The University of Kentucky will provide up to four pathologists and the University of Louisville will provide up to six in the Commonwealth's medical examiner office in order to keep up with the surge in opioid-related deaths.

96. Because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin when they can no longer get access to or afford the pills. Teva also could have, and did, foresee that users who become addicted to a particular prescription opioid, such as Fentora and Actiq, would migrate to another drug (including heroin) if those drugs become less

expensive or more readily available. According to a former Fentora and Actiq sales representative, a doctor told him that Fentora was too expensive, so his patient purchased heroin instead.

97. Nationally, roughly 80% of heroin users previously used prescription opioids. In Kentucky, toxicology reports showed that 34% of fatal overdoses in Kentucky in 2016 involved the use of heroin. Synthetic fentanyl has made its way into Kentucky communities. In 2017, fentanyl was involved in 763 overdose deaths in Kentucky, which accounted for 52% of all drug-related deaths. This was an increase from 2016, where fentanyl-related deaths accounted for 47% of all fatal drug overdoses in the Commonwealth. One Kentucky treatment provider confirmed that, in his experience, most heroin users started with prescription opioids.

98. The loss of each of these individuals cannot be adequately conveyed by statistics, nor can the depth and breadth of the impact on those who survive. Because the addictive pull of opioids is so strong, relapse is more common than with other drugs. Opioid addiction and misuse result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone—the antidote to opioid overdose. For example, Louisville Metro Police Major, Eric Johnson, said that the police force administered 123 doses of naloxone in one six-week period between January 1st and February 15th, 2017. One opioid addiction treatment center in Paducah doubled in size to meet the growing needs of the community. The center reports seeing as many as 300 patients, of all ages and from all backgrounds, for addiction to prescription opioids, heroin, and fentanyl. A law enforcement officer in Kentucky similarly observed opioid addiction and abuse affecting people across varying ages and demographics.

99. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. Prescription drug abuse causes an increase in crimes such as domestic violence, burglaries, and thefts. An estimated 90% of defendants in Floyd County are prosecuted for crimes

related to prescription drug abuse or diversion. A report from a 2012 Prescription Drug Abuse Summit in Kentucky noted that the "pill explosion" had increased armed robberies to six per month in areas of Kentucky when there were previously two to three per year in the same area. Domestic violence, burglaries, thefts, and driving under the influence are also now commonly linked to opioid use. One corrections officer estimated that nearly all of the inmates in a Woodford County jail were struggling with addiction, that almost all of the inmates with drug problems started with abusing opioids, and that 90% of the crimes for which they were convicted were drug related.

100. The abuse of opioids, including opioids manufactured by Teva, and the resulting increase in heroin use and addiction have caused outbreaks of HIV, chronic Hepatitis C, and TTP. In 2016 the CDC published a report which listed the top counties in the nation that are at risk of spreading HIV and Hepatitis C due to injecting drugs. Of the top 220 counties, 54 were located in Kentucky, including Wolfe County, which had the greatest risk in the United States. One researcher who has tracked 503 drug users since 2008 found that 70% of them have contracted Hepatitis C. Kentucky had the highest rate of new Hepatitis C infections in the nation—more than six times the national average—from 2008 through 2015. St. Elizabeth Healthcare in Edgewood reports that it sees up to ten new cases of Hepatitis C daily.

101. Additionally, according to an infectious-disease physician at the University of Kentucky College of Medicine, the opioid epidemic is quickly spreading infectious diseases in the Commonwealth. The doctor stated that "[o]ne IV drug user who might be infected with Hepatitis C is likely to infect up to another 20 people."[33] The doctor also noted that the individual using the drugs is not the only one affected by infectious diseases. The doctor also said "[t]hat

[33] Mary Kuhlman, *Experts Take a Deeper Dive Into the KY Opioid Epidemic*, Public News Service, Sept. 24, 2018, https://www.publicnewsservice.org/2018-09-20/health-issues/experts-take-a-deeper-dive-into-ky-opioid-epidemic/a64024-1.

individual who may acquire HIV disease from injecting drugs has the potential for passing it on to someone else—a spouse, a partner—or a women who becomes pregnant passing it on to her unborn child."[34]

102. In 2016, the Commonwealth spent $69.7 million on pharmacy claims to provide Hepatitis C drugs to 833 patients (which does not include the costs of testing for the infection or other treatment-related costs). The list price for a course of treatment ranges from $84,000 to close to $100,000. The total number of state Medicaid enrollees with a diagnosis of Hepatitis C increased from 8,000 in 2013 to 16,000 in 2014, though the CDC estimates that 90% of infections are unreported because the patients are still not symptomatic. If untreated, Hepatitis C continues to be transmitted, including in childbirth. The CDC reports that nationwide from 2009 to 2014, Hepatitis C present at the time of delivering a baby increased 89 percent, to 3.4 per 1,000 live births, according to the CDC, but in Kentucky, the rate was much higher at 15.1%.

103. Children have not been spared by the opioid crisis. As of June 2017, there were over 8,000 children in foster care in Kentucky, compared to 6,000 in 2012, most commonly because of parent's abuse of drugs or alcohol. According to one foster parent recruiter, the increasing number of children in foster care in Ashland, Kentucky has reached a "crisis point" as a result of the opioid epidemic.[35]

104. According to a 2017 CDC study, one in seven high school students in the U.S. has misused opioids. In 2016, 90 Kentucky residents ages 15-24 years-old died of fatal drug overdoses. In 2017, 2 children ages 5-14 died in the Commonwealth due to fatal drug overdoses.

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[34] *Id.*

[35] Marie Simoneaux, *States Hit Hard by Opioid Crisis See Increase in Foster Care Kids*, Daily Indep., Jan. 19, 2017.

School districts also have seen a dramatic increase in suspensions of high school students found possessing, distributing, or under the influence of prescription drugs.

105. Drug use is also having an effect on local schools and playgrounds. In one school year, elementary schools in Boyd County found a total of 18 syringe needles on their playgrounds. To fight the epidemic, students from Ashland Middle school created a prototype to safely pick up and dispose of syringes and created a database enabling residents to see where the needles were found.

106. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from Neonatal Abstinence Syndrome ("NAS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening.

107. NAS has become a great source of concern within the Commonwealth. In 2014, the Commonwealth had the third-highest rate of pregnant women with opioid use disorder in the United States. From August 1, 2014 until July 31, 2015, there were 1,234 cases of NAS reported to the Kentucky Department of Public Health. This translates to about 100 newborns per month. In 2017, the number of babies born with NAS in the Commonwealth had increased by 375% from 2007. As recently as March 2018, Madison County officials, including healthcare providers and

social workers held a conference in order to solve the increasing problem of pregnant women being addicted to opioids. The goal of the conference was to create a plan that would provide support to mothers and families after giving birth, and the plan is currently in process.

108. Andy Beshear, the Attorney General of the Commonwealth, has taken initiatives to combat the opioid epidemic in Kentucky. As recently as August 2018, Attorney General Beshear provided Muhlenberg County with pouches that allow for the proper disposal of unwanted or outdated prescription medications, including opioids. According to Attorney General Beshear, a Kentucky resident is able to dispose of up to 45 prescription opioids in one pouch. The pouches were created in order to prevent the diversion of opioids within the Commonwealth. Attorney General Beshear plans to distribute 50,000 pouches throughout the Commonwealth, which will allow for up to 2.2 million pills to be properly disposed of.

109. While the use of opioids has taken an enormous toll on the Commonwealth and its residents, Teva has realized millions of dollars in revenue from use of its opioids for chronic pain as a result of its deceptive, unfair, and unlawful conduct.

G. Teva Fraudulently Concealed Its Misconduct

110. Teva made, promoted, and profited from its misrepresentations about the risks and benefits of opioids for chronic pain even though it knew that its marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. Teva had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based

on existing medical evidence that conclusively exposes the known falsity of these misrepresentations.

111. Notwithstanding this knowledge, at all times relevant to this Complaint, Teva took steps to avoid detection of and to fraudulently conceal its deceptive marketing and unlawful and fraudulent conduct. Teva disguised its role in the deceptive marketing of chronic opioid therapy by funding and working through unbranded marketing, third party advocates, and professional associations.

112. In addition, Teva has affirmatively assured the public that it is working to curb opioid use and abuse.

113. Teva thus successfully concealed from the medical community, patients, and the Commonwealth of Kentucky facts sufficient to arouse suspicion of the claims that the Commonwealth now asserts. The Commonwealth did not know of the existence or scope of Teva's fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

V. CAUSES OF ACTION

COUNT I
Deceptive Acts and Practices in Violation of Kentucky Consumer Protection Act (KRS 367.110 et seq.)

114. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

115. Kentucky's Consumer Protection Act ("KCPA"), KRS 367.110 *et seq.* prohibits "unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce." KRS 367.170.

116. Under KRS 367.190, "[w]henever the Attorney General has reason to believe that any person is using, has used, or is about to use any method, act or practice declared by KRS 367.170 to be unlawful, and that proceedings would be in the public interest," he may seek injunctive relief.

117. The Commonwealth is included among the persons in interest to whom the Court may order restoration of money or property under KRS 367.200.

118. At all times relevant to this Complaint, Teva, directly, through its control of third parties, and/or by aiding and abetting third parties, violated the KCPA by making or causing to be made, and by disseminating unfair, false, deceptive, and misleading statements and statements that were false and misleading by virtue of material omissions, to Kentucky prescribers and consumers to promote the sale and use of opioids to treat chronic pain. These unfair, false, deceptive, and misleading statements included, but were not limited to:

a. Mischaracterizing the risk of opioid addiction and abuse;

b. Promoting the misleading concept of pseudoaddiction, thus concealing the true risk of addiction;

c. Claiming or implying that opioids have no ceiling dose;

d. Promoting Actiq and Fentora for uses that were not approved by the FDA nor shown to be appropriate, safe, or effective;

e. Claiming or implying that opioids would improve patients' function and quality of life, despite the lack of evidence supporting this claim.

119. Teva knew at the time of making or disseminating these misstatements and material omissions, or causing these misstatements and material omissions to be made or disseminated, that they were unfair, false, deceptive, and misleading and therefore likely to deceive the public. In addition, Teva knew or should have known that its marketing and promotional efforts created an

unfair, false, deceptive, and misleading impression of the risks, benefits, and superiority of opioids generally and its opioids in particular.

120. At all times relevant to this Complaint, Teva directly, as well as through its control of third parties, and/or by aiding and abetting third parties, violated the KCPA by engaging in unfair acts or practices to promote the sale and use of opioids to treat chronic pain. These acts or practices are unfair in that they are unconscionable, offend public policy, and are immoral, unethical, oppressive, or unscrupulous.

121. Teva's unfair acts or practices include, but are not limited to:

a. Engaging in untrue, false, unsubstantiated, and misleading marketing;

b. Promoting Actiq and Fentora for uses for which it was not approved and which are not appropriate, safe, or effective;

c. Deliberately using unbranded marketing to evade FDA oversight and rules prohibiting deceptive marketing; and

d. Failing to report suspicious prescribers.

122. For each of Teva's willful violations of KRS 367.170, the Commonwealth is entitled to recover a civil penalty of not more than two thousand dollars ($2,000) per violation and ten thousand dollars ($10,000) for each violation targeted at consumers over the age of 60.

COUNT II
Restoration of Property due to Violations of Kentucky Consumer Protection Act (KRS 367.110 et seq.)

123. Teva's conduct also was deceptive to both patients and prescribers. Patients are laypersons and lack the medical expertise to independently assess pharmaceutical marketing. Physicians, in turn, are inclined to trust the advice of front groups, and other seemingly independent sources of objective medical information. By engaging in the conduct described above, Teva co-opted the sources reasonable physicians relied upon to convince those physicians that the risks related to opioids were minimal, that the benefits were substantial, and—as a result—

that opioids were medically necessary to treat their patients' chronic pain. Furthermore, Teva's misleading and deceptive marketing increased the demand for opioids, creating an environment ripe for diversion and abuse of opioids.

124. Teva's conduct has caused substantial, indeed grievous, injury to Kentucky persons. The staggering rates of opioid use, abuse, and addiction resulting from Teva's marketing efforts and reporting failures have caused substantial injury to the Commonwealth, its residents, and to businesses including, but not limited to:

a. Nationally, upwards of 30% of all adults over 45 have used opioids, with the vast majority of the use stemming from prescribing for chronic pain conditions.

b. A substantial number of Kentucky residents prescribed opioids long-term for chronic pain have experienced the life-upending effects of addiction, abuse, misuse, overdose and death. For those who can stop taking narcotic opioids, there are years of struggling with the pull of the drugs and the fear of relapse (and often relapse itself), counseling sessions, or lining up each morning for daily maintenance drugs. And those who cannot overcome the need for opioids must deal with the compulsive use of and need for opioids, the haziness when they are on the drugs, and the nearly constant struggle to maintain their supplies of the drugs, whatever the cost. Both groups face a dramatically heightened risk of serious injury or death and sometimes an unrecoverable toll on their health, work, and family.

c. Elderly Kentuckians are particularly vulnerable to serious adverse outcomes, including overdose, injury, and death.

d. Kentuckians, including thousands of infants and children, who have never taken opioids also have also been and continue to be injured. Infants have suffered NAS and painful withdrawal, children have lost parents [and even grandparents] and/or have been displaced from homes, and adults have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids.

e. Kentuckians have incurred health care costs due to the prescription of opioids for chronic pain and the treatment of opioids' adverse effects, including addiction and overdose.

f. The increased demand for prescription opioids has created additional illicit markets in other opiates, particularly heroin. Patients addicted to opioids frequently migrate to lower-cost heroin, with the serious personal costs that accompany their use of unlawful drugs.

g. All of this has caused substantial injuries to the Commonwealth and its residents—in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken lives, families, and homes.

125. These profound injuries are not outweighed by any countervailing benefits to consumers or competition since there is no benefit from the deceptive marketing of these narcotic drugs. Further, no public policy justifies Teva's conduct in overstating the benefits and denying or downplaying the risks of opioids, or in marketing Actiq and Fentora for uses that were not approved by the FDA nor shown to be safe and effective, both of which deprived patients and doctors of the honest and complete information they need to make informed choices about their treatment. In light of Teva's campaign of misinformation (and especially given the addictive nature of these drugs), the injuries caused by Teva's misconduct could not reasonably have been avoided by those Teva harmed.

126. Teva's acts and practices as alleged herein substantially impacted the community of patients, health care providers, law enforcement, and other Kentucky government functions, and caused significant actual harm.

127. The Commonwealth is entitled, pursuant to KRS 367.200, to restoration of moneys paid out when the Commonwealth paid for prescription opioids as a direct result of Teva's violations of the KCPA and the ongoing expenditures for additional medical care and provision of other services that the Commonwealth has been required to make as a direct result of the violations alleged herein.

COUNT III
Violations of Kentucky Medicaid Fraud Statute
(KRS 205.8463; KRS 446.070; KRS 205.8469(1))

128. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

129. KRS 205.8463 is violated when any person "intentionally, knowingly, or wantonly make[s], present[s], or cause[s] to be made or presented to an employee or officer of the Cabinet for Health and Family Services any false, fictitious, or fraudulent statement, representation, or entry in any application, claim, report, or document used in determining rights to any benefit or payment." KRS 205.8463(2).

130. It is likewise a violation of KRS 205.8463 for any person to "in any matter within the jurisdiction of the Cabinet for Health and Family Services under this chapter, knowingly falsify, conceal, or cover up by any trick, scheme, or device a material fact, or make any false, fictitious, or fraudulent statement or representation, or make or use any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry." KRS 205.8463(4).

131. Under KRS 205.8469(1), "[t]he Attorney General, on behalf of the Commonwealth, may commence proceedings to enforce KRS 205.8451 to 205.8483."

132. Additionally, KRS 446.070 provides that "[a] person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation."

133. Teva's practices, as described in the Complaint, violated KRS 205.8463(2) & (4). Teva, through its misleading marketing of opioids for chronic pain and deceptive promotion of Actiq and Fentora for uses that were not approved by the FDA or shown to be safe and effective.

Through these acts Teva either presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used a false statement, or statement which concealed or covered up a material fact, to get a false or fraudulent claim paid or approved by a program within the jurisdiction of the Cabinet for Health and Family Services.

134. Medicaid was created in 1965 and operates under Title XIX of the Social Security Act. Medicaid is a cooperative venture between the Federal and State governments to assist States in the provision of medical care to their poorest and most vulnerable citizens, including the poor, the disabled, the elderly, the blind, pregnant women, infants and dependent children. Medicaid is the largest program providing medical and health-related services to America's poorest people.

135. Within broad federal statutory and regulatory guidelines a State: (a) establishes its own eligibility standards; (b) determines the type, amount, duration, and scope of services; (c) sets the rate of payment for services; and (d) administers its own program. These statutes and regulations are set forth generally in the Grants to States for Medical Assistance Programs sections of the United States Code (42 U.S.C. § 1396 *et seq.*) and the Code of Federal Regulations (42 C.F.R. § 430 *et seq.*). The Medicaid program is administered at the federal level by the United States Department for Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").

136. The Medicaid program in Kentucky ("Kentucky Medicaid") is administered at the State level by the Kentucky Department for Medicaid Services ("DMS"). DMS is a body politic created by the Kentucky Constitution and laws of the Commonwealth of Kentucky and, as such, is not a citizen of any State. DMS is a governmental agency in the Executive Branch of the Commonwealth of Kentucky. Finally, DMS is the single state agency charged with administration of the Kentucky Medicaid program pursuant to Title XIX of the Federal Social Security Act, 42

U.S.C. § 1396a(a)(5), 42 C.F.R. § 431.10, 42 C.F.R. § 100, KRS 12.020(II)(8)(k), KRS 194A.030(2), KRS Chapter 205, KAR Title 907, and other applicable law.

137. Spending on Kentucky Medicaid has grown exponentially. During FY 2016, Kentucky's state share of Medicaid was $1,611,591,800, which is roughly 30.9% of the Kentucky State budget. Spending on Kentucky's Medicaid increased by about 69.5 percent between fiscal years 2012 and 2016 and continues to increase. For FY 2019, the Kentucky General Assembly appropriated $1,881,992,500 for the operation of Kentucky Medicaid and $2,043,016,800 for FY 2020.

138. Enrollment in Kentucky Medicaid continues to expand as well. As of April 2018, Kentucky Medicaid covered over 1,278,799 men, women and children, or approximately 28.6% of Kentucky's total population of 4,472,265.

139. Teva engaged in a deceptive and misleading marketing scheme that was designed to, and successfully did, change the perception of opioids and cause their prescribing and sales to skyrocket in Kentucky. Teva disseminated false and misleading information about the risks and benefits of opioids, which minimized the risks of addiction and overdose and exaggerated the purported benefits, and promoted its branded opioids for uses that were not approved, appropriate, or safe.

140. Teva knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and were made, in part, for the purpose of getting the Kentucky Medicaid program to pay for opioids for long-term treatment of chronic pain. In addition, Teva knew or should have known that its marketing and promotional efforts created an

untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

141. Teva's misrepresentations and/or omissions were likely to deceive and confuse, and did actually deceive and confuse, Kentucky health-care providers into prescribing opioids that they would not otherwise have prescribed.

142. Teva's scheme caused doctors to write prescriptions for opioids to treat chronic pain that were presented to the Commonwealth's Medicaid program for payment.

143. The Commonwealth's Medicaid program only covers the costs of care that "meets professionally recognized standards," are not obtained through fraud, material misrepresentation, or material omission, or do not constitute "provider abuse." *See* 907 KAR 1:671(40) (defining "unacceptable practice[s]" prohibited by Kentucky's Medicaid regulations). Kentucky's Medicaid regulations expressly provide that it is an "unacceptable practice" to "[k]nowingly submit[], or caus[e] the submission of false claims." 907 KAR 1:671(40)(a). "[I]nducing, or seeking to induce, a person to submit false claims" is also an "unacceptable practice," as are "[k]nowingly making, or causing to be made, or inducing, or seeking to induce, a false, fictitious or fraudulent statement or misrepresentation of material fact in claiming a Medicaid payment, or for use in determining the right to payment" and "[h]aving knowledge of an event that affects the right of a provider to receive payment and concealing or failing to disclose the event or other material omission with the intention that a payment be made or the payment is made in a greater amount than otherwise owed." 907 KAR 1:671(40)(a)-(c). Further, Teva's deceptive marketing with and through front groups constitutes conspiracy and complicity, in violation of 907 KAR 1:671(40)(j).

144. Doctors, pharmacists, other health care providers, and/or other agents of the Medicaid program expressly or impliedly certified to the Commonwealth that opioids were

medically necessary and reasonably required to treat chronic pain because they were influenced by the false and misleading statements Teva disseminated about the risks, benefits, and superiority of opioids for chronic pain, and about the approved and appropriate uses for their branded opioids, Actiq and Fentora. Doctors, pharmacists, other health care providers, and/or other agents of the Medicaid program expressly or impliedly certified to the Commonwealth that it was not paying for "unacceptable practices."

145. As a direct and proximate result of Teva's misrepresentations and/or omissions, Kentucky health-care providers and Kentucky patients were deceived or mislead or were not provided with accurate information about the risks and benefits of using opioids to treat chronic pain.

146. Teva knew or should have known that, as a natural consequence of their actions, governments such as the Commonwealth would necessarily be paying for long-term prescriptions of opioids to treat chronic pain, which were dispensed, diverted and abused as a consequence of Teva's fraud.

147. Teva's misrepresentations were material because if the Commonwealth had known of the false statements disseminated by Teva and its third-party allies and that doctors, pharmacists, and other health care providers, based upon those untrue, false, or misleading information, were certifying and/or determining that opioids were medically necessary, the Commonwealth would have refused to authorize payment for, or otherwise severely restricted, the use of opioid prescriptions to treat chronic pain.

148. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic pain were paid by the Commonwealth.

149. By virtue of the above-described acts, Teva knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Commonwealth to approve and pay such false and fraudulent claims.

150. To the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by Teva's deceptive marketing.

151. The Commonwealth, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Teva, paid the claims that would not have been paid but for Teva's illegal business practices.

152. By reason of Teva's unlawful acts, the Commonwealth has been damaged, in a substantial amount to be determined at trial. Medicaid spending accounts for nearly 30% of all funds appropriated under the 2016-2018 biennium budget. Historically, costs of prescription drugs have represented the largest component of Kentucky's Medicaid budget. These costs have increased over time. Costs of prescriptions written due to Teva's deceptive marketing scheme, and costs of addressing the public health crisis caused or substantially contributed to by that scheme, are direct and proximate results of Teva's violations as alleged herein and a significant financial burden on the Commonwealth. From 2010 to 2015, Kentucky's Medicaid spent $123,452 on Teva opioids. In 2016, Kentucky's Medicaid spending for medications to treat opioid addiction was $117 million, double the amount from only two years prior, which totaled $56 million in 2014.

153. As a direct and proximate result of Teva's misrepresentations and/or omissions, the rising number of persons addicted to prescription opioids have led to a dramatic increase in social problems, including drug abuse and criminal acts to obtain opioid drugs, including prescription

opioids, heroin, and fentanyl. These social problems significantly and negatively impact the public health and the resources provided for Medicaid, emergency, and other services.

154. Because Teva's unbranded marketing caused the doctors to prescribe and the Commonwealth to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Teva caused and is responsible for those costs and claims, as well.

COUNT IV
Violations of Kentucky Assistance Program Fraud Statute
(KRS § 194A.505(6); KRS § 194A.990)

155. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

156. KRS 194A.505(6) provides that "[n]o person shall, with intent to defraud or deceive, devise a scheme or plan a scheme or artifice to obtain benefits from any assistance program by means of false or fraudulent representations or intentionally engage in conduct that advances the scheme or artifice."

157. Teva, by reason of the acts and/or omissions set forth herein, with the intent to defraud or deceive, devised a scheme or artifice to obtain benefits from the Kentucky Medicaid program that it was not entitled to receive, in violation of KRS 194A.505(6).

158. KRS 194A.505(8) provides that "[t]he Attorney General on behalf of the Commonwealth of Kentucky may commence proceedings to enforce this section, and the Attorney General shall in undertaking these proceedings exercise all powers and perform all duties that a prosecuting attorney would otherwise perform or exercise."

159. Additionally, KRS 446.070 provides that "[a] person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation."

160. KRS 194A.990(5) provides that "[a]ny person who violates KRS 194A.505(1) to (6) shall, in addition to any other penalties provided by law, forfeit and pay a civil penalty of payment to the cabinet in the amount of all benefits and payments to which the person was not entitled."

161. By engaging in the conduct set forth above, Teva violated KRS 194A.505(6), and the Kentucky Medicaid program, as a direct and proximate result, paid for opioid prescriptions that were not medically necessary and will be required to make payments for ongoing medical treatment and care on behalf of Kentucky Medicaid patients in the future.

162. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover damages from Teva in an amount to be proved at trial.

163. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from Teva additional civil damages in accordance with the provisions of KRS 446.070.

164. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from Teva, in addition to any other penalties provided by law, forfeit and pay a civil penalty in the amount of all benefits and payments to which Teva was not entitled in accordance with the provisions of KRS 194A.990(5).

165. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from Teva civil penalties in an amount equal to three (3) times the amount of the benefits and payments to which Teva was not entitled in accordance with the provisions of KRS 194A.990(6)(a).

166. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from Teva all reasonable expenses that the court determines have been

necessarily incurred by the Commonwealth in the prosecution of this action in accordance with the provisions of KRS 194A.990(6).

COUNT V
Continuing Public Nuisance

167. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

168. A public nuisance is an unreasonable interference with a right common to the general public.

169. Circumstances that may sustain a holding that an interference with a public right is unreasonable include conduct that involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience.

170. A common or public nuisance also has been described as a condition of things which is prejudicial to the health, comfort, safety, property, sense of decency, or morals of the citizens at large, which may result either from an act not warranted by law, or from neglect of a duty imposed by law.

171. Through its deceptive marketing, Teva has created or assisted in the creation of a condition that significantly interferes with the public health, the public safety, the public peace, the public comfort or the public convenience and is prejudicial to the health, comfort, safety, property, sense of decency, or morals of the citizens at large.

172. The public nuisance was foreseeable to Teva, which knew or should have known of the harm it would cause.

173. The public nuisance is substantial and unreasonable. Teva's actions were not only unreasonable, but unlawful and grievously harmful to the health and safety of Kentucky residents, and the harm from Teva's intentional misconduct outweighs any offsetting benefit.

174. This injury to the public includes, but is not limited to (a) a distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (b) high rates of opioid abuse and addiction, overdoses, and outbreaks of other serious diseases (like Hepatitis C), and fatalities; (c) children removed from their homes and newborns born addicted to opioids; (d) lost employee productivity due to opioid-related addiction and disability; (e) the creation and maintenance of a secondary, criminal market for opioids; (f) greater demand for emergency services, law enforcement, addiction treatment, and social services; and (g) increased health care costs for individuals, families, and the Commonwealth.

175. Teva's actions were, at the very least, a substantial factor in opioids becoming widely available and widely used, in deceiving prescribers and patients about the risks and benefits of opioids for the treatment of chronic pain, and in the public health crisis. Without Teva's actions, opioid use would not have become so widespread, and the opioid epidemic that now exists in Kentucky would be much less severe.

176. The public nuisance—i.e., the opioid epidemic—created and maintained by Teva can be abated.

177. The health and safety of Kentucky's citizens is a matter of great public importance and of legitimate concern to the Commonwealth and its residents.

178. The Commonwealth has been, and continues to be, injured by Teva's actions in creating a public nuisance. As a direct result of Teva's acts in creating the public nuisance, the

Commonwealth has suffered economic harm, including substantial and ongoing expenditures to prevent further harm and to provide services to Kentuckians impacted by the opioid epidemic.

COUNT VI
Fraud

179. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

180. Teva, itself and acting through third-party agents, fraudulently, intentionally, willfully, or recklessly made misrepresentations and omissions of facts material to the Commonwealth and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

181. These misrepresentations and omissions include, but are not limited to:

a. Mischaracterizing the risk of opioid addiction and abuse;

b. Promoting the misleading concept of pseudoaddiction, thus concealing the true risk of addiction;

c. Claiming or implying that opioids have no ceiling dose;

d. Promoting Actiq and Fentora for uses that were not approved by the FDA nor shown to be appropriate, safe, or effective; and

e. Claiming or implying that opioids would improve patients' function and quality of life, despite the lack of evidence supporting this claim.

182. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, and in promoting Actiq and Fentora for uses that are not approved by the FDA, appropriate, or safe, Teva has engaged in misrepresentations and knowing omissions of material fact.

183. Teva's statements about opioids generally and its opioids in particular were false.

184. Further, Teva's omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and likely to mislead when taken in the context of the surrounding circumstances.

185. Teva fraudulently, intentionally, willfully, or recklessly made these misrepresentations and omissions, which were reasonably calculated to deceive and in fact did deceive the Commonwealth and its residents.

186. Teva intended that the Commonwealth and its residents would rely on its misrepresentations and omissions.

187. The Commonwealth and its residents reasonably relied upon Teva's misrepresentations and omissions.

188. As a direct and proximate result of Teva's misrepresentations and omissions of material fact, the Commonwealth suffered actual pecuniary damage.

COUNT VII
Unjust Enrichment

189. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

190. Many Kentucky citizens who could not otherwise afford medical care rely on the Commonwealth to provide medical care through programs such as Medicaid, and the Commonwealth also pays for opioids through, for instance, its workers compensation program.

191. By illegally and deceptively promoting opioids to treat chronic pain, Teva has unjustly enriched itself at the Commonwealth's expense. The Commonwealth has made payments for opioid prescriptions, and Teva benefited from those payments. Teva received, or will receive, income, profits, and other benefits, which it would not have received if it had not engaged in the

deceptive and illegal conduct described in this Complaint. This enrichment was without justification.

192. Teva has unjustly retained a benefit to the Commonwealth's detriment, and its retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

193. While the Commonwealth and its institutions are struggling to pay for the services needed to combat the opioid crisis, and have expended funds in paying for prescription opioids that could otherwise have been used to serve Kentucky's residents, Teva has reaped millions of dollars in profits from its deceptive marketing campaign.

194. In equity and fairness, it is Teva, not the Commonwealth and its taxpayers, who should bear the costs occasioned by Teva's deceptive marketing campaign.

195. Accordingly, under principles of equity, Teva should be disgorged of money retained by reason of its deceptive and illegal acts that in equity and good conscience belong to the Commonwealth and its citizens.

COUNT VIII
Negligence

196. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

197. Teva owed the Commonwealth a duty to not expose the citizens of the Commonwealth to an unreasonable risk of harm.

198. Teva had a legal duty under Kentucky common law to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in manufacturing, marketing, and selling opioids.

199. Teva has a duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others. In addition, Teva, having engaged in conduct that created an unreasonable risk of harm to others, had, and still has, a duty to exercise reasonable care to prevent the threatened harm.

200. Teva breached its duty to exercise the degree of care commensurate with the dangers involved in selling dangerous controlled substances.

201. Teva breached its duty to the Commonwealth by aggressively marketing opioids in a way that minimized the risks of abuse, addiction, and overdose and exaggerated the purported benefits of long-term use of opioids for the treatment of chronic pain.

202. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

203. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the Commonwealth's communities.

204. Reasonably prudent manufacturers of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs that would be imposed upon the governmental entities associated with those communities.

205. Reasonably prudent manufacturers of opioids would know that aggressively marketing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids and to turn to the illegal drug market as a result of a drug addiction that was foreseeable to Teva.

206. Teva had control over its conduct in the Commonwealth. Teva controlled its deceptive advertising and efforts to mislead the public, including its acts and omissions in detailing

by its sales representatives, online communications, publications, and other means described in this Complaint.

207. Upon information and belief, Teva's actions were a substantial factor in opioid use becoming so widespread, and the consequential enormous public health crisis of prescription opioid and heroin overuse, abuse, and addiction that now exists.

208. Upon information and belief, Teva acted with actual malice and a wanton and reckless disregard for the lives and safety of others, and said actions have a great probability of causing substantial harm.

209. The Commonwealth seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of Teva. It does not seek damages that may have been suffered by individual residents of the Commonwealth for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions Teva.

210. The Commonwealth is not asserting a cause of action under any federal controlled-substances laws. Rather, it seeks to remedy harms caused to it by the breach of duty created by the statutory and common law of the Commonwealth of Kentucky.

211. Teva's misconduct alleged in this case is ongoing and persistent.

212. As a direct and proximate result of Teva's negligence, the Commonwealth has suffered actual pecuniary damage including substantial and ongoing expenditures to prevent further harm and to provide services to Kentuckians impacted by the opioid epidemic.

COUNT IX
Negligence per se

213. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

214. Violation of a statute gives rise to a private right of action where the injured is within the class of persons the statute intended to be protected. This is true even where the statute is penal in nature and provides no civil remedy.

215. Teva's conduct was negligence *per se* in that it violated the Kentucky laws discussed herein, including, but not limited to, KRS 367.170, KRS 194A.505, KRS 205.8463.

216. The Commonwealth was a party intended to be protected by such laws and whose injuries said laws were designed to prevent. Teva's violations of said laws proximately caused injury to the Commonwealth.

217. Teva violated these laws, by, *inter alia*:

a. Disseminating unfair, false, deceptive, and misleading statements and statements that were false and misleading by virtue of material omissions in its promotion of opioids;

b. Presenting or causing to be presented false or fraudulent claims to the Commonwealth through its deceptive marketing of opioids;

218. As a direct and proximate result of Teva's negligence *per se*, the Commonwealth has suffered actual pecuniary damage including substantial and ongoing expenditures to prevent further harm and to provide services to Kentuckians impacted by the opioid epidemic.

COUNT X
Punitive Damages
(KRS 411.186)

219. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

220. By engaging in the conduct set forth above, Teva acted toward the Commonwealth with oppression, fraud, malice, gross negligence, and/or reckless disregard for the lives and safety

of others to a degree sufficient to warrant the imposition of punitive damages pursuant to KRS 411.186 to deter such further conduct on behalf of Teva and similarly situated parties.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the Commonwealth of Kentucky, *ex rel.* Attorney General Andy Beshear, respectfully requests the following:

a. Entry of judgment against Teva, finding that it committed repeated violations of KRS 367.170;

b. For an injunction, pursuant to KRS 367.190, prohibiting Teva from further marketing, sales, or distribution practices violating KRS 367.170;

c. An award of civil penalties in the amount of two thousand dollars ($2,000) for each violation of KRS 367.170, and ten thousand dollars ($10,000) for each violation targeted to consumers over the age of 65, pursuant to KRS 367.990;

d. Restoration to the Commonwealth of all moneys or property which it has paid out as a result of Teva's violations of the KCPA alleged in this Complaint, pursuant to KRS 367.200;

e. An order directing Teva to abate and pay damages for the public nuisance;

f. An order declaring pursuant to KRS 446.070 that Teva committed repeated violations of KRS 205.8463 and KRS 194A.505;

g. Civil penalties in the amount of all benefits and payments to which Teva was not entitled in accordance with the provisions of KRS 194A.990(5);

h. Civil penalties in the amount of all benefits and payments to which Teva was not entitled in accordance with the provisions of KRS 194A.990(5);

i. Civil damages not addressed by KRS 194A.990(5) in accordance with the provisions of KRS 446.070;

j. Pecuniary damages for past and future losses and expenditures;

k. Punitive damages against Teva pursuant to KRS 411.186;

l. Restitution or disgorgement of Teva unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;

m. An award of reasonable attorney's fees, interest, and costs to Plaintiff for pre-judgement and post-judgement conduct;

n. A trial by jury;

And any and all such other relief as this Honorable Court deems just and proper.

Respectfully submitted,

ANDY BESHEAR
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