

**COMMONWEALTH OF KENTUCKY
JESSAMINE CIRCUIT COURT, DIV. I
CIVIL ACTION NO. _____**

COMMONWEALTH OF KENTUCKY, *ex. rel.*
RUSSELL COLEMAN, ATTORNEY GENERAL,

Plaintiff,

v.

EXPRESS SCRIPTS, INC.; EXPRESS SCRIPTS
ADMINISTRATORS, LLC; MEDCO HEALTH
SOLUTIONS; ESI MAIL PHARMACY SERVICE,
INC.; EXPRESS SCRIPTS PHARMACY, INC.,

Defendants.

COMPLAINT

JURY TRIAL DEMANDED

45A37B09-7A79-4073-83EC-1FDFA B5A25A9 : 000001 of 000083

Presiding Judge: HON. HUNTER DAUGHERTY (613171)

COM : 000001 of 000077

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The Plaintiff, the Commonwealth of Kentucky (“Kentucky” or “the Commonwealth”), brings this action against Express Scripts, Inc., Express Scripts Administrators, LLC, Medco Health Solutions, ESI Mail Pharmacy Service, Inc., and Express Scripts Pharmacy, Inc. (referred to collectively herein as “Express Scripts” or “ESI” or “Express Scripts Defendants”) in order to abate the public nuisance caused in substantial part by these Defendants’ unreasonable acts and omissions fueling the opioid epidemic. Express Scripts collaborated with opioid manufacturers, partnering with them in the deceptive, dangerous marketing of these all too often lethal drugs and, in exchange for rebates and other payments from opioid manufacturers, offered standard, national formularies that gave opioids preferred status and with little to no limits on their approval for use. In addition, instead of reporting illegitimate prescribing and sales uniquely visible to them in the extensive data they collect, or using the data to reign in the deluge of opioid prescribing and limit abuse of these drugs, Defendants ignored evidence of misuse, addiction, and diversion and used their data to boost Express Scripts’ profits and manufacturers’ sales at the expense of public health and safety. In support of its claims, the Commonwealth states as follows:

INTRODUCTION

1. This case arises from the worst man-made epidemic in modern medical history—an epidemic of addiction, overdose and death caused by an oversupply of opioids flooding communities from powerful corporations who sought to profit at the expense of the public.

2. By now, most Americans have been affected, either directly or indirectly, by the opioid disaster. Due in substantial part to the wrongful conduct of the largest pharmacy benefit managers (PBMs) in the nation, described further below, the amount of prescription opioids sold annually in the U.S. quadrupled between 1999 and 2010. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for

a month. Since the push to expand prescription opioid use began in the late 1990s, the death toll has steadily climbed, with no sign of slowing. The CDC's National Center for Health Statistics provides provisional data on drug overdose deaths. According to the data, there were an estimated 107,622 drug overdose deaths in the United States during 2021. That is nearly a 15% increase from the estimated deaths in 2020.

3. From 1996 through 2019, nearly 500,000 people died from an overdose involving any opioids. The prescription opioids involved in these deaths include brand-name prescription medications like OxyContin, Opana ER, Vicodin, Subsys, Duragesic, and Ultram, as well as generics like oxycodone, hydrocodone, tramadol, and fentanyl.

4. Many of the overdoses from non-prescription opioids are also directly related to prescription pills. Many opioid users, having become addicted to but no longer able to obtain prescription opioids, have turned to heroin. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription painkillers—which, at the molecular level and in their effect, closely resemble heroin. In fact, people who are addicted to prescription painkillers are 40 times more likely to become addicted to heroin, and the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. Individuals who used prescription opioids who have turned to heroin are now frequently exposed to illicit fentanyl, with even more lethal effects.

5. As a result, in part, of the proliferation of opioid pharmaceuticals between the late 1990s and 2015, the life expectancy for Americans decreased repeatedly for the first time in decades.

6. According to the CDC, the number of drug overdose deaths increased by nearly 30% from 2019 to 2020 and has quintupled since 1999. Nearly 75% of the 91,799 drug overdose

deaths in 2020 involved an opioid. From 1999 to 2020, more than 263,000 people died in the United States from overdoses involving prescription opioids.

7. In 2020, Kentucky had the second-highest drug overdose death rate at 49.2 opioid-related deaths per 100,000 residents, behind only West Virginia. In 2021, Kentucky's drug overdose death rate increased to 55.6 opioid-related deaths per 100,000 residents, the fourth-highest death rate in the country. The Kentucky Office of Drug Control Policy reported 1,964 overdose deaths in 2020, a 49% increase from 2019. In 2021, there was a 14.5% increase in overdose deaths in Kentucky. That year Kentucky comprised 2,250 out of 107,000 national deaths, nearly twice its per capita share of the United States population. In 2022, for the first time in four years, Kentucky saw a slight decrease in drug overdose deaths with 2,135 deaths, and the number of overdose deaths decreased in 2023 to a still staggering 1,984 people.

8. The opioid crisis was fueled and sustained by those involved in the supply chain of opioids, with manufacturers, distributors, pharmacies, and Pharmacy Benefit Managers ("PBMs"), including Express Scripts, each playing a role. The role of Express Scripts in causing the opioid epidemic has been largely concealed from public view. But it has now become clear that, for no less than the last two decades, Express Scripts has had a key role in facilitating the oversupply of opioids through intentional conduct that disregarded needed safeguards in order to increase the prescribing, dispensing, and sales of prescription opioids. Express Scripts inserted itself into the chain of prescribing, dispensing, and sales of prescription opioids. As such, it assumed duties to act reasonably and to comport with state and federal controlled substances laws.

9. Express Scripts contracts with the manufacturers who make opioids, the pharmacies that dispense them, and the third-party payors who pay for them. They are at the center of the opioid dispensing chain. Express Scripts has operated behind the scenes to fuel the crisis in

multiple respects, while concealing its role and claiming concern for the public health. The conduct that fueled the increases in opioid prescribing and dispensing and led to oversupply included: (a) colluding with Purdue Pharma and other opioid manufacturers in the deceptive marketing of opioids in order to alter perceptions of opioids and increase their sales; (b) colluding with Purdue Pharma and other opioid manufacturers to increase opioid sales through preferred placement on national formularies in exchange for lucrative rebates and fees; (c) colluding with Purdue Pharma and other opioid manufacturers to restrict or eliminate utilization management tools on national formularies that would have limited opioid prescribing and/or dispensing; (d) deciding not to act on the vast amount of data and other information they had about the epidemic in order to limit the overflow of opioids into communities throughout the United States, including in Kentucky; and (e) dispensing prescription opioids through their mail order pharmacies without effective controls against diversion, in violation of Kentucky law and federal law.

10. Express Scripts' central role in the opioid crisis was facilitated by their unique combination of knowledge and power that provided them with the extraordinary ability to control the opioid supply throughout the United States. While the PBM industry began with limited fiscal and administrative functions, it has since evolved into far more. Now, "[a]lthough many people have never heard of [them], these powerful middlemen have enormous influence over the U.S. prescription drug system." PBMs such as Express Scripts, along with its affiliated companies, have more control over and insight into the flow of opioids into communities across the country than any other entities in the pharmaceutical distribution and payment chain.

11. Indeed, Express Scripts touts its substantial influence over nationwide drug utilization as one of its strongest selling points to its customers.

12. PBMs provide services to prescription benefit plans sponsored by health insurers, self-insured employees, and state and federal government agencies. PBMs have adopted business practices designed to increase the utilization of opioids and maximize their own profits. As a result, far greater quantities of prescription opioids entered the market than Express Scripts knew could be necessary for legitimate, safe, or appropriate medical uses.

13. PBMs' overall business practices have not gone unnoticed in Kentucky. Senate Bill 188, signed into law by the Governor on April 5, 2024, requires PBMs to pay minimum reimbursement rates to pharmacies, and prohibits PBM requirements or incentives to influence plan participants to use mail order pharmacies.

14. Nationally, a small number of PBMs dominate the market in their sphere. Express Scripts is one of the largest PBMs in the nation and in Kentucky and is the self-described manager of the pharmacy benefit for more than 100 million Americans, providing PBM services to its parent, Cigna, as well as to many other insurers and payors.

15. Express Scripts is also one of the largest pharmacies in the country and is owned by one of the largest insurance companies in the world, Cigna. In addition, Express Scripts is one of the largest healthcare data, consulting, and analytics companies in the United States.

16. Express Scripts controls pharmacy networks that include various retail pharmacies throughout the country, including pharmacies in Kentucky. Express Scripts' pharmacy network includes "nearly 64,000 pharmacies," which it contends provides an available in-network retail pharmacy within a 15-minute drive of "nearly every member's home."

17. Express Scripts also dispenses prescription opioids through its mail order pharmacies, serving patients nationally and throughout Kentucky.

18. Express Scripts receives, analyzes, and tracks detailed claims data for the millions of prescriptions it processes and dispenses each year, including prescriptions for opioids. Express Scripts has unique insight into prescribing habits at both the patient and prescriber levels, as well as data on prescribing and use of opioids in the aggregate. For each prescription, Express Scripts knows what doctor prescribed it, what pharmacy filled it, and where that pharmacy is located. Express Scripts knows if patients whose benefits they manage fill opioid prescriptions written by multiple prescribers and if they fill them at multiple pharmacies. Express Scripts knows if a patient who was prescribed opioids is later treated for overdose or substance use disorder. Express Scripts knows if a patient is filling prescriptions for opioids, benzodiazepines, and muscle relaxants at the same time. Express Scripts knows how many times an opioid prescription is refilled.

19. Express Scripts has especially broad and deep insight, because of the expansive reach of its business. It has access to and analyzes opioid utilization data for its approximately 100 million covered lives. Through that data, Express Scripts could effectively track the opioid epidemic, pill-by-pill, as it unfolded over decades and chronicle the opioid epidemic in real time.

20. Express Scripts has the power to drive prescribing, dispensing and sales of prescription drugs. It does this through the national formularies it offers to pharmacy benefit plans and through the standard “utilization management” (“UM”) rules it chooses to offer. Formularies, which are lists of drugs covered by a pharmacy benefit plan, control which drugs are available to the PBMs’ covered lives. Formularies contain tiers, where drugs listed on higher tiers require larger copays, or as exclusionary formularies, where preferred brand drugs are included and nonpreferred drugs are not included.

21. Standard UM programs include various tools for managing access and use of particular drugs. Examples of UM measures include step therapy, where a beneficiary is required

to try a different drug list, quantity limits, where the dosage or days' supply of a particular drug is limited, and prior authorization ("PA"), which requires confirmation from a physician that a particular drug is appropriate before the drug can be dispensed. Data, including in studies that Express Scripts itself conducted, shows that, when implemented, disfavored formulary placement and UM measures reduce inappropriate prescribing by making certain drugs more difficult or more expensive to obtain.

22. Express Scripts and opioid manufacturers knew that formulary offerings that provided preferred formulary placement without UM restrictions would result in prescriptions being written and dispensed with ease and frequency, to the detriment of public health and public safety. Opioids that are preferred on PBM formularies have significantly higher sales than drugs that are excluded or disadvantaged. As such, the PBMs act as the gatekeepers to the opioid market.

23. Given Express Scripts' dominant position in the market and its level of expertise, clients typically accept the offered standard, national formularies and UM programs without modifications. While clients elect to or not to use a particular plan, the Express Scripts' standard offerings, coupled with misinformation about opioids that Defendants delivered along with their manufacturer partners, minimized their clients' ability to make different choices regarding drug benefit programs. Customers hire PBMs for their specialized knowledge in constructing and managing prescription drug formularies and policing pharmacy networks. In addition, there are often significant financial penalties customers incur for deviating from standard formularies. Thus, PBM's formularies effectively control what opioids enter the marketplace and with what restrictions. As such, PBMs are uniquely situated to address the opioid crisis, influence Express Scripts has admitted in making belated, partial remedial efforts as it came under public scrutiny and pressure.

24. Instead of using its data and its power in the marketplace to ensure the appropriate use of prescription medication, improve safety and quality of care for patients, and make healthcare better - as they promised their clients and represented to the public that they would do – or to guard against diversion and public harm and report suspicious prescribers, as state and federal law required, Express Scripts used its data to further its own profits. This included offering services to Purdue and other opioid manufacturers to help them plan and carry out their marketing efforts and boost their sales. At the same time, Express Scripts colluded with manufacturers to further boost opioid sales, and its own profits, through formulary and UM offerings that encouraged opioid prescribing, paid for by manufacturers through rebates and fees. Express Scripts is not a bystander in the opioid crisis; it helped fuel the fire.

25. Express Scripts undertook and assumed a duty to create and offer standard, national formulary offerings and UM program offerings based on the health and safety of the public and of their clients' covered lives. Express Scripts represented to the public and its clients that its national formulary and UM offerings were based on the health and safety of the public and the lives its clients insured, when in fact it was doing the exact opposite and acting to maximize its own revenue via agreements with the opioid manufacturers. Express Scripts knew, at the time that they made these representations to the public and to their clients, that they would not base their national formulary and UM offerings on the health and safety of their clients' covered lives, nor of the public, but that they would make, and were already making, formulary and UM decisions, and taking formulary and UM actions, in order to increase profits to themselves.

26. As a result, the market for prescription opioids grew, prescribing, dispensing, and sales increased, and Express Scripts collected the profits from its agreements and relationships with opioid manufacturers. Express Scripts' profits increased from the rebates and fees it earned

from branded opioid manufacturers for making opioids easily available, and from pricing spreads and fees it received from the sale of generic and branded opioids. Express Scripts' profits also increased through the sale of the data they amassed about their covered lives, healthcare providers, and dispensing pharmacies, and from marketing and data analytics agreements that they entered into with opioid manufacturers.

27. In sum, the Express Scripts Defendants are legally responsible for their role in causing, contributing to, and maintaining the opioid epidemic because, among other things: (a) their conduct in colluding with the opioid manufacturers to increase the supply and utilization of opioids through false and misleading misrepresentations was intentional and/or negligent, and unreasonable and/or unlawful; (b) their knowing and/or negligent and unreasonable failure to offer formularies, UM protocols, and drug utilization review measures that would ensure safe and appropriate use of opioid medications was wrongful because they undertook to, and represented that they would, but instead, worked with the opioid manufacturers to increase the supply of opioids without regard to the safety or appropriateness of the drugs; (c) they intentionally and/or negligently and unreasonably decided, offered, and continued to offer only formularies, UM protocols, and drug utilization measures that placed no meaningful limitations on the prescribing and use of opioids, despite knowing, through their vast stores of data, that (i) unrestricted access to opioids was causing, and foreseeably would continue to cause, harm, including the foreseeable harm of diversion, to Kentucky communities, and (ii) those harms could be addressed through measures that the Defendants intentionally decided not to offer or otherwise make available; and (d) their conduct in dispensing opioids was unlawful and/or unreasonable, as well as intentional and/or negligent because they failed to comply with the Kentucky Controlled Substances Act and

federal law, both in their own mail-order pharmacy dispensing and in their other activities that increased the risks of diversion.

28. Although Express Scripts' role in creating and sustaining the opioid epidemic is largely hidden from public scrutiny, it nevertheless facilitated the reckless promotion of opioids by manufacturers, the oversupply of opioid shipments by distributors, and the irresponsible dispensing of prescription opioids by numerous pharmacies, including through direct support and sales from its own mail order pharmacies.

29. Express Scripts' conduct has had a severe and far-reaching public health consequence, the costs of which are borne by the Commonwealth and other state governmental entities.

30. Express Scripts' conduct has created a public nuisance and a blight. Kentucky's governmental entities, and the services they provide to the citizens of the Commonwealth, have been strained by this public health crisis.

31. The Commonwealth of Kentucky brings this suit to help address the devastating march of this epidemic and to hold Express Scripts responsible for the crisis it helped create.

JURISDICTION AND VENUE

32. This Court has personal jurisdiction over the Express Scripts Defendants, as they are registered with the Secretary of State to conduct business in Kentucky and have purposefully availed themselves of this forum by conducting business in the Commonwealth and by causing harm as a direct and proximate result of their actions. The Defendants 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 goods or services in the Commonwealth and/or caused tortious injury by an act or omission in the

Commonwealth and/or caused tortious injury in the Commonwealth by an act or omission outside the Commonwealth. Defendants have the requisite minimum contacts with Kentucky necessary to permit this Court to exercise jurisdiction.

33. Jessamine Circuit Court has subject matter jurisdiction over the claims submitted pursuant to KRS 23A.010, KRS 315.235, 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 act on behalf of the Commonwealth of Kentucky and its citizens. The Commonwealth's claims are in excess of any minimum dollar amount necessary to establish the jurisdiction of the Court.

34. Kentucky does not plead any cause of action or request any remedy arising under or founded in federal law. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332. The Commonwealth is not a citizen of any state.

35. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the Complaint, as it sets forth herein exclusively viable state law claims against Defendants. Nowhere herein does the Commonwealth plead, expressly or implicitly, any cause of action or request any remedy that arises under federal law. The issues presented in the allegations of this Complaint do not implicate any substantial federal issues and do not turn on the necessary interpretation of federal law. No federal issue is important to the federal system as a whole under the criteria set by the Supreme Court in *Gunn v. Minton*, 568 U.S. 251 (2013).

36. Specifically, the causes of action asserted, and the remedies sought herein, are founded upon the positive statutory, common, and decisional laws of Kentucky. Further, the assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. Accordingly, any exercise

of federal question jurisdiction is without basis in law or fact.

37. In this Complaint, Kentucky cites or alludes to federal statutes, regulations, or agency memoranda. It does so only to establish Defendants' knowledge, to state the duties owed under Kentucky law, or to explain the hybrid nature of industry oversight, not to allege an independent federal cause of action and not to allege any substantial federal question under *Gunn v. Minton*.

38. Federal officer jurisdiction is also not invoked by this Complaint. This lawsuit relates to the Defendants' conduct in the non-federal market which resulted in the increased use, abuse, and diversion of opioids. The allegations in this Complaint do not include and specifically exclude Defendants' provision of PBM or mail order pharmacy services pursuant to contracts with the Department of Defense, the Office of Personnel Management, or any other federal agency. The Complaint does not challenge the creation of custom formularies or administration or management of such formularies for or by a federal officer or federal agency, such as for any Federal Employees Health Benefits Act or TRICARE governed health benefits plan, or any other federal health benefit plan. The Complaint does not challenge the conduct of Defendants related to the provision of any services, including but not limited to formulary related services, rebate negotiation services, or pharmacy network negotiation services, pursuant to contracts with the Department of Defense, the Office of Personnel Management, or any other federal agency. The Complaint does not challenge Defendants' provision of mail order pharmacy services pursuant to contracts with the Department of Defense, the Office of Personnel Management, or any other federal agency, and does not challenge the Defendants' administration or operation of the TRICARE Home Delivery/Mail Order Pharmacy. The Commonwealth does not seek to recover moneys paid by the federal government pursuant to such plans, nor does it seek recovery of

federally mandated co-pays that were paid by such plans' patients. The Commonwealth does not seek declaratory relief, injunctive relief, abatement relief, any other relief, or civil penalties for the conduct of Defendants related to the provision of any services pursuant to contracts with the Department of Defense, the Office of Personnel Management, or any other federal agency.

39. Venue is appropriate in Jessamine Circuit Court under KRS 452.460, which allows venue in the county where the injury was suffered. Where the injury is suffered by the Commonwealth, its agents or employees, or the Commonwealth as a whole, venue is proper in Jessamine Circuit Court.

PARTIES

A. The Commonwealth of Kentucky

40. Plaintiff, the Commonwealth of Kentucky, brings this action, by and through its Attorney General, Russell Coleman, in its sovereign capacity to protect the interests of the Commonwealth and its citizens. The Attorney General is authorized to take action against Defendants for violation of state laws and regulations. Russell Coleman is the duly elected Attorney General of Kentucky, an independent constitutional officer of the Commonwealth and its chief law officer, with full authority to initiate and prosecute all cases 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 218A.240, KRS 315.235, KRS 367.110 *et seq.*, to initiate actions necessary 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 *parens patriae* authority, to bring an action on behalf of the Commonwealth and its citizens.

41. The Commonwealth is entitled to the protections of sovereign immunity. Pursuant to KRS 49.070(14), the filing of this action shall not be construed as a waiver of that immunity and no counterclaim, set-off, recoupment, cross-claim, or other form of avoidance may be asserted in this action against the Commonwealth. The Attorney General has determined that these proceedings are in the public interest.

B. Defendants

42. **Defendant Express Scripts, Inc.** is a Delaware corporation registered to do business in Kentucky with its principal place of business in St. Louis, Missouri.

43. Express Scripts, Inc. can be served through its registered agent: CT Corporation System, 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

44. During the relevant time, Express Scripts, Inc. was directly involved in the PBM and mail order services businesses in Kentucky, as well as Express Scripts' data and research services.

45. **Defendant Express Scripts Administrators, LLC** (f/k/a Medco Health, LLC) is a Delaware limited liability company. Express Scripts Administrators, LLC is registered to do business in Kentucky with its principal place of business in St. Louis, Missouri.

46. Express Scripts Administrators LLC may be served through its registered agent: CT Corporation System, 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

47. During the relevant time, Express Scripts Administrators, LLC provided PBM services in Kentucky, as alleged in this Complaint.

48. **Defendant Medco Health Solutions, Inc.** (f/k/a Merck-Medco Managed Care LLC) ("Medco") is a Delaware corporation registered to do business in Kentucky with its principal place of business located in St. Louis, Missouri.

49. Medco may be served through its registered agent: CT Corporation System, 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

50. Express Scripts acquired Medco in 2012 in a \$29.1 billion deal.

51. Prior to the merger, Express Scripts and Medco were two of the largest PBMs in the United States and in Kentucky. Medco provided PBM services to approximately 62 million members and provided mail order and data research services to customers nationwide.

52. Following the merger, the combined company continued under the name Express Scripts. All of Medco's PBM, mail order pharmacy, and data and research business was combined into Express Scripts, and all of Medco's customers became Express Scripts' customers. Express Scripts, Inc. became the largest PBM in the nation, filling a combined 1.4 billion prescriptions for employers and insurers.

53. As a result of the merger, Express Scripts Holding Company ("ESHC") was formed. In 2018, Cigna Corp. purchased Express Scripts Holding Company for \$54 billion, a merger publicized as having the potential to use aggregated data to improve products and services.

54. In October of 2020, Express Scripts Holding Company changed its name to Evernorth Health, Inc. ("Evernorth"). Evernorth, located at One Express Way, St. Louis, Missouri, is the indirect parent of Express Scripts, Inc., along with pharmacy and research subsidiaries that operate throughout Kentucky.

55. **Defendant ESI Mail Pharmacy Service, Inc.** is a Delaware corporation with its principal place of business located in St. Louis, Missouri.

56. ESI Mail Pharmacy Service, Inc. may be served through its registered agent: CT Corporation System, 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

57. ESI Mail Pharmacy Service, Inc. holds 6 active licenses with the Board of Pharmacy in Kentucky.

58. ESI Mail Pharmacy Service, Inc. dispenses opioids nationwide and dispensed opioids into Kentucky during the relevant time period as a mail order pharmacy.

59. **Defendant Express Scripts Pharmacy, Inc.** is a Delaware corporation and is registered to do business in Kentucky. Its principal place of business is in St. Louis, Missouri.

60. Express Scripts Pharmacy, Inc. may be served through its registered agent: CT Corporation System, 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

61. Express Scripts Pharmacy, Inc. holds 5 active licenses with the Board of Pharmacy in Kentucky.

62. Express Scripts Pharmacy, Inc. dispensed opioids into Kentucky during the relevant time period as a mail order pharmacy.

63. As a unit, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Medco Health Solutions was the third largest dispensing pharmacy in the United States for the 2006 – 2014 time period.

64. Collectively, Defendants Express Scripts, Inc., Express Scripts Administrators LLC, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., and Express Scripts Pharmacy, Inc., including all predecessor and successor entities, are referred to herein as “Express Scripts,” “ESI,” or “Express Scripts Defendants.”

65. In 2022, Evernorth, in large part through Express Scripts’ PBM and mail order pharmacy business, generated revenue of \$140.34 billion, contributing more than 75% of Cigna’s revenue in 2022.

66. Express Scripts is named as a defendant for its conduct as:

- i. a PBM;
- ii. a data, analytics, and research provider; and
- iii. a mail order pharmacy (i.e. a dispenser).

At all relevant times, Express Scripts performed these services in Kentucky.

FACTUAL ALLEGATIONS

I. A Few Large PBMs Exert Substantial Influence in a Way That is Often Not Transparent, Even to Their Customers.

A. What are PBMs?

67. “According to the Pharmaceutical Care Management Association (PCMA), the PBM trade group, PBMs process prescriptions for the vast majority of Americans.” Although there exist dozens of PBMs nationwide, a select few, including Express Scripts, dominate the market, as described above.

68. PBMs review and pay claims. PBMs also review and decide “which medications are most effective for each therapeutic use.”

69. PBMs offer national, standard formularies which set the criteria and terms under which pharmaceutical drugs are reimbursed. PBMs decide what, if any, UM measures will be included in the national plans they offer. PBMs commit to monitor their customers’ drug plans and monitor their customers’ utilization, including through concurrent drug utilization review (“Concurrent DUR” or “cDUR”).

70. Concurrent drug utilization review involves the PBMs real-time evaluation of drug therapy for potential problems, including over-utilization and clinical abuse/misuse of prescribed drugs. Express Scripts’ cDUR terms in its standard client contract offerings required it to conduct concurrent DUR at the point of sale on all prescriptions.

71. Express Scripts' standard, national formulary and plan offerings control:

- i. Which opioids will be available (or not available) to patients;
- ii. In what quantities the opioids will be dispensed;
- iii. At what co-pay the opioids will be dispensed;
- iv. What level of authorization will be required for the dispensing of opioids to a consumer patient; and
- v. What less addictive pain treatments, beneficial drugs or other treatments will not be available.

72. ESI made these formulary offerings in Kentucky and served as a PBM for Kentucky residents who received insurance from their employers or other payors that utilized ESI as a PBM.

73. Express Scripts represents to its clients, patients, and the public that it designs its formularies and drug programs in a manner that promotes safe use and appropriate prescribing of opioids. For example, Express Scripts claims that its Pharmacy and Therapeutics Committee (the “P&T Committee”) considers drug safety and efficacy and “fully compl[ies] with the P&T Committee’s clinical recommendations regarding drugs that must be included or excluded from the formulary based on their assessment of safety and efficacy.”

74. Express Scripts also claims that it uses drug utilization review to “review prescriptions for safety and effectiveness, in real-time, electronically and systematically, when presented to . . . pharmacies” and that it will “alert the dispensing pharmacy to detected issues.” Additional examples of such statements are throughout ESI’s or its predecessor companies’, SEC filings or other statements:

- i. For years between 2000 and 2010, Express Scripts represented in its SEC filings that it “works with clients, manufacturers, pharmacists and physicians to . . . improve members’ health outcomes and satisfaction.”
- ii. ESI stated that it “is a company dedicated to making the use of prescription drugs safer . . . for plan sponsors and over 50 million members and their families.”

- iii. Medco represented in its filings that it “capitalize[s] on our clinical expertise and advanced information technology infrastructure . . . to improve safety and the quality of care for patients . . . by developing action-oriented clinical programs and services based on clinical rationale.”
- iv. In its 2008 annual report, Medco represented that “[a]t Medco innovation, precision, and advocacy are in our DNA. We strive to make all of medicine smarter and as a result make healthcare better.”
- v. In a 2013 interview, Express Scripts CIO Gary Wimberly represented that “by filling 1.4 billion prescriptions per year, we have over 10 petabytes of useful data from which we can gain insights and for which we can develop solutions . . . [to] improve the health of patients.” In addition, Mr. Wimberly stated, “[Express Scripts] has researchers and scientists whose sole job is to interpret and analyze the data to identify opportunities to improve health outcomes.”

75. Similarly, in a September 2013 letter to the Pennsylvania House of Representatives Committee on Health, Express Scripts stated that “[o]ur company’s mission is to make prescription drugs safer . . .”

76. In a 2013 interview, Express Scripts CIO Gary Wimberly summed it up: “Everything we do every day focuses on health outcomes.”

77. Express Scripts’ acknowledgement that it is supposed to construct formulary and UM offerings that promote safe and affordable drugs for their members, it has not actually done so. To the contrary, Express Scripts has used its power to negotiate rebates and other fees, to control the offered formulary structures, to refrain from implementing or offering UM measures, and to refrain from using its drug utilization review process to identify and control opioid misuse, all in an effort to allow the opioid manufacturers unfettered access to their formularies so that the number of opioids prescribed and sold could continue to grow and generate more profits for it and the opioid manufacturers, fueling the opioid crisis as a result.

78. Furthermore, while Express Scripts’ national formularies made it easier for patients to receive opioids, they made it harder for patients to receive addiction treatment. A

ProPublica/New York Times study found that insurers erected more hurdles to addiction treatment than they have for the addictive substances themselves. Only after public pressure did some make it easier for patients to receive addiction treatment drugs.

B. Express Scripts' Financial Incentives

79. Opioid manufacturers cannot effectively influence drug prescribing and opioid utilization alone. Other participants in the drug distribution and reimbursement system play key roles in the availability of their opioids.

80. Using their market power, PBMs, including ESI, require and receive incentives from manufacturers to keep certain drugs on and off formularies.

81. Drug manufacturers compete for PBM formulary placement and pay PBMs incentives to avoid pre-authorization and other utilization management tools that would slow down flow, such as quantity limits, refill limits, and step edits. PBMs' ability to negotiate these incentives from drug manufacturers derives from their control of the factors driving utilization, including formulary development and plan design.

82. Generally, prescription drug manufacturers pay higher rebates for preferred formulary placement on lower tiers (i.e., tier 2 status instead of tier 3 status). This is because prescribers are more likely to write prescriptions and consumers to fill prescriptions for drugs with lower cost-share amounts.

83. Higher priced drugs will typically generate higher rebates. This creates an incentive to have standard formulary offerings that provide favorable formulary placement to brand-name, higher priced drugs such as OxyContin, a frequently diverted opioid.

84. Under a traditional PBM pricing model, PBMs have passed through only a portion of these rebates to their clients and retained the rest as profit.

85. Rebates are paid to the PBMs on every eligible drug dispensed; thus, the more the PBMs drive utilization, the more rebates are paid by opioid manufacturers to the PBMs.

86. Since 2014, payments to PBMs by manufacturers as rebates or fees to ensure the formulary placement of their drugs have risen by 16% per annum, and now constitute 40% or more of branded prescription drug costs.

87. The rebates PBMs negotiate are highly confidential and, for the most part, the exact terms of the agreements between PBMs and prescription drug manufacturers are unknown to others in the supply chain and their customers – creating a pricing black box.

88. Rebate payments are only part of the payments Express Scripts receives from opioid manufacturers. In addition to rebates, drug manufacturers, including opioid manufacturers, have paid Express Scripts substantial amounts of various “administrative fees,” “service fees” or other fees in exchange for, among other things, ensuring a given drug’s formulary placement and providing various services to the drug makers—the same services they are already being paid to provide to their clients.

89. Historically, administrative fees have not been passed on to clients, which has prompted disputes and concerns over whether rebate payments are being disguised as other revenue, such as administrative fees.

90. Express Scripts also obtains revenue through fees from maintaining pharmacy networks, profiting from the “spread” between what clients pay them for generic prescription drugs and the amounts the PBMs reimburse to pharmacies. Retail pharmacies pay Express Scripts fees for every opioid sold, and Express Scripts reimburses the pharmacies based on the lowest available published prices while paying its own mail order pharmacies based on higher published prices for

the same drugs. In other words, the more filled prescriptions a PBM processes, the higher profit it earns.

91. Express Scripts further increased its profits from generic opioids by failing to put into place utilization management tools that would have reduced illegitimate use and dissemination of these drugs. As the market shifted from branded opioids to generics in the mid-2000s, ESI continued to provide generic opioids unrestricted and preferred placement on their standard formularies because of the profits generic drugs generated for the Defendants through spread pricing and other means.

92. In sum, although PBMs contract with third-party payors to provide pharmacy benefit management services, they also contract with drug manufacturers and with pharmacies. They are paid by their clients to make safe and effective drug therapies available to their covered lives. But, as further described below, they are also paid by drug manufacturers to provide the greatest access to their products, so as to increase sales, with little to no regard for safety or efficacy. And they are paid by the pharmacies where the plan beneficiaries' prescriptions are filled, to verify coverage but also to assist the pharmacy in ensuring that a prescription is appropriate. Thus, in any given transaction, a PBM may be receiving money from both the payor and the pharmacy to exercise independent judgment about whether to authorize payment for a prescription, while also receiving money from the manufacturer to ensure that the sale is made.

93. The business model that PBMs, including Express Scripts, use is thus rife with conflicts of interest and self-dealing through which they have enriched themselves at the expense of their clients and the public. Inherent in the services offered by Express Scripts in its agreements with the opioid manufacturers (and with pharmacies) are the same services for which it is already

ostensibly receiving payment from their clients, albeit with the incentives often running in the opposite direction.

94. Because Express Scripts is paid based on the volume of prescriptions, including for opioids, that flow through its formularies, restricting this flow would cause Express Scripts to lose substantial revenue.

95. Express Scripts resisted efforts to limit access to prescription opioids due to the revenue generated from the dispensing of opioids and concerns about the impact on the rebates it received from opioid manufacturers. It was only well after the opioid epidemic had reached its peak and public pressure had mounted that Express Scripts began to utilize its unique access to data to offer utilization measures to address the unfettered access to prescription opioids which it helped create.

96. Express Scripts links opioid manufacturers to prescribing physicians, pharmacists, clients, and consumers with the objective of influencing drug utilization. Internal documents revealed that the services and products offered by PBMs “help drive [consumer] behaviors” by engaging in each link of the prescription drug distribution chain.

97. As part of its business model, Express Scripts offers services to assist manufacturers in the marketing of drugs in other ways as well, providing manufacturers with detailed prescribing data that furthered their marketing efforts, as described further below.

98. On information and belief, and as described below, Express Scripts engaged in all these practices in Kentucky.

II. ESI Had Access to Data Indicating Diversion, Misuse, and Abuse of Opioids But Failed to Use it to Make Meaningful Efforts to Prevent Diversion.

99. Armed with a wealth of information and data, ESI knew or should have known of the dangerous prescribing patterns that demonstrated issues like diversion, misuse, abuse, doctor

shopping, overdose, and outsized use in the Commonwealth. Yet, upon information and belief, ESI took no meaningful steps to report or address outlier prescribers or pharmacies or to otherwise rein in the facially suspicious volume of opioids being dispensed in the Commonwealth or throughout the country.

100. Instead, as described further below, ESI provided manufacturers with preferred formulary status without restrictions and aided their marketing efforts even though they knew that dangerous numbers of opioids were being utilized in Kentucky and throughout the nation and were causing an unprecedented crisis of addiction, overdose, and death.

101. At all times since the 1990s, Express Scripts and PBMs like it have had as much—if not more—detailed claims data on opioid utilization and prescribing than any other entity in the pharmaceutical industry.

102. ESI has publicly acknowledged its unique ability to collect data. An ESI representative has stated, “Because Express Scripts interacts with patients, pharmacies, prescribers, payors, our company is uniquely situated to collect data when patients receive and fill a prescription for an opioid under pharmacy benefit.”

103. ESI also recognized the value of its data. ESI has a “research arm” which has performed health economics and outcomes research and/or drug utilization review using its “own database[,]” including on behalf of Purdue.

104. Apart from its research arm, ESI can monitor its clients’ opioid utilization and the overall utilization of particular opioids. Its data shows: the volume, nature, dosage, and conditions for which health care providers are prescribing opioids to individual patients and on an aggregate basis; the volume of opioids obtained by individual patients and by geography; the pharmacies at

which opioids were dispensed and the volume of opioids dispensed by geographic area, among other data. ESI also tracks the number of opioids that move through its own mail order pharmacies.

105. At the individual level, ESI could monitor its data to identify conduct commonly associated with opioid misuse, addiction, and diversion, such as early refills of opioid prescriptions, multiple prescriptions for one individual or for dangerously high volumes or dosages of opioids or “doctor shopping,” the practice by which individuals receive multiple opioid prescriptions from unknowing prescribers. On the prescriber level, it could identify problematic prescribers who were prescribing unreasonably high volumes of opioids to unreasonably high numbers of patients, co-prescribing opioids with drugs commonly abused with them, such as benzodiazepines or the “Holy Trinity,” prescribing opioids outside the regular scope of their practice, or who wrote prescriptions for the same dose and duration to all of their patients – all classic signs of “pill mills.”

106. Thus, ESI like other PBMs, can see detailed information on individual prescribers, prescriptions, and pharmacies, but can also aggregate that data across manufacturers, patients, pharmacies, and payors. ESI’s insight is both uniquely granular and comprehensive.

107. ESI tracked pill-by-pill data by employing advanced data analytics collected from hundreds of millions of pharmacy claims. The data showed nearly every aspect of the pills’ movement through the prescription drug distribution and payment systems.

108. Express Scripts had access to all of this data well before Kentucky and other states established their Prescription Drug Monitoring Programs in order to perform these analyses and stem the tide of the opioid crisis.

109. Furthermore, by 2011 at the latest, Defendants had been put on notice by the Centers for Medicare and Medicaid Services (CMS) that all actors involved in the delivery of

healthcare in the United States needed to take steps to address the overutilization of prescription opioids, which was contributing significantly to the growing opioid crisis. CMS advised that Medicare data showed overutilization of opioids that was “highly indicative of drug seeking behavior due to drug abuse or diversion.”

110. Express Scripts represented to the public and its clients that it would identify potential fraud and abuse, giving rise to an expectation that it was identifying and addressing instances of over-prescribing and diversion. Instead, it was making business decisions to increase its bottom line while eliminating patient safeguards in exchange for more lucrative contracts with manufacturers.

111. Although ESI was acutely aware of the opioid epidemic, it failed to use its extensive data to combat it, and instead helped to maintain the flow of opioids. By at least 2002, ESI was fielding questions from its customers who were concerned about abuse and diversion of OxyContin. A March 2002 Purdue email discusses the fact that Medco requested an “overview of the abuse and diversion issue surrounding OxyContin” because it would help them “respond to their customers [sic] questions/concerns.”

112. In 2003, Medco’s largest client, UHC, expressed concerns that “there were patients taking 960-1000 tabs of OxyContin per month” and stated that it wanted to take action “to reduce the abuse and diversion issues.” Following this, Medco and Purdue worked together to compile research and data to provide to this client to alleviate these concerns.

113. In 2003, an ESI employee giving a presentation at a conference stated when discussing OxyContin, “This is a narcotic. All narcotics are addictive. In addition, this is a controlled release narcotic so when someone would crush it up and either ingest it or inject it there

[is] . . . a potential for serious injury or even death.” ESI’s own data demonstrated these problems as well.

114. ESI was directly involved in the administration of Purdue’s Indigent Patient Assistance Program (“IPAP”), which provided it with an additional source for prescribing and dispensing data regarding Purdue opioids, including the total number of prescriptions filled and tablets dispensed each month, and with additional information about abuse and diversion of opioids.

115. Purdue created the Indigent Patient Assistance Program to assure “that all patients for whom our oxycodone or morphine products are being prescribed not be denied the benefit of these products because of financial limitations,” while reaping the “ancillary benefit” of “the goodwill of important physicians.” Although the data could have been readily used to detect potential addiction and misuse, the Purdue-ESI partnership was focused more on ensuring the continued availability of Purdue’s opioid products.

116. In November 1994, ESI assumed operating responsibilities for the processing of Purdue prescriptions (OxyContin and MS Contin) through the IPAP program. As of at least January 2001, Express Scripts’ mail order pharmacy was acting as the “fulfillment pharmacy” for the IPAP opioids.

117. Through the IPAP program in particular, ESI had a ringside seat to, and an active role in, the earliest rounds of the opioid epidemic. As early as 2000, Purdue’s Vice President of Medical Affairs noted that, through the IPAP program, the ESI pharmacy was supplying large volumes of opioids, “supporting polypharmacy,” and filling prescriptions for dosing more frequent than the 12-hour dosing Purdue marketed as a key selling point for OxyContin (including a prescriber writing for as many as 5 doses of OxyContin per day).

118. For example, a pain doctor in Virginia was prescribing 900 tablets a month to a patient in the IPAP program. An ESI representative allegedly commented to the doctor that IPAP patients were “all on zillions of tablets.” There is no reason to believe that the excess, including from the prescribers whose goodwill Purdue sought to earn, was confined to the IPAP program. Quite the opposite, the prescribers writing these “zillions of tablets” for IPAP patients were doing the same for others. Purdue noted that the “more active” prescribers in the IPAP were “also generally higher prescribers for the strong narcotic classes and usually for MS Contin/OxyContin in particular” and were a geographically diverse group that “share[d] the characteristic of generally being in the highest decile class of prescribing activity.”

119. By 2001, ESI was responsible for maintaining Purdue’s prescription database. In a 2001 letter to the FDA, Purdue described its IPAP program and Express Script’s role in its operation, stating, “the patient is responsible for obtaining subsequent prescriptions from the practitioner and sending them to Express Scripts. The medications are shipped directly to the patient’s home. The prescription information is maintained in a database managed by Express Scripts.”

120. Both Purdue and ESI knew, based on the prescription data, that issues had emerged regarding the overprescribing of opioids. In February 2001, the companies met to discuss the implementation of “additional controls” around the IPAP. The issues included “excessive dosing and quantities, off label prescriptions, shipping large quantities, lost shipments, education, grandfathered patients, Adverse Event Reporting, and the timeline of new policies.”

121. ESI had access to patient information as well. In 2002, it began administering the enrollment and eligibility functions of the IPAP.

122. However, ESI's overall lack of diligence was such that it failed to meet even Purdue's standards. In 2008, Purdue Corporate Security conducted an audit of the IPAP and "discovered a series of discrepancies in ESI's due diligence on patients accepted into IPAP. The audit found numerous applications had been accepted from persons who submitted fraudulent information. As a result, new controls were placed on the program." Purdue concluded that as a result of Express Scripts' lack of due diligence, during a 4-month period Express Scripts shipped 18,000 Oxy tablets to 39 people who falsified their applications.

123. Outside of the IPAP program, ESI's own data capacities allowed the company to identify inappropriate use and prescribing of opioids, as seen in drug trends reports, research posters, and the 2014 ESI report *A Nation in Pain*. The report discussed the results of Express Scripts' review of 36 million opioid pharmacy claims, and detailed the indicia of the opioid epidemic that was apparent in the data. *A Nation in Pain* notes that the study found that 60% of patients using opioids were taking a dangerous combination of drugs that are potentially fatal, such as benzodiazepines with an opioid. The study also noted that a separate Express Scripts study that analyzed ESI's data found that 40% of opioid prescriptions filled by members with employer sponsored drug coverage between 2011 and 2012 were written by only 5% of prescribers.

124. This unique access alerting ESI to the problems with opioids, should have triggered a robust data review to identify signs of misuse, abuse and diversion. This is particularly true, given ESI's knowledge of Purdue's improper marketing tactics. ESI knew, at least as of 2003, that part of the "high growth rate of OxyContin" appeared to be due to "improper detailing" by Purdue, which ESI claimed to be "looking at." At its 2003 annual conference, an ESI representative acknowledged as much in a presentation regarding an OxyContin study it was conducting for Georgia Medicaid. As part of its study, ESI looked "across the book of business at Express

Scripts,” not only at Georgia Medicaid, and found “similar patterns,” including a shift to higher doses. Yet, ESI continued its efforts to work with Purdue to reduce barriers to OxyContin use, and promote higher volumes of opioid prescribing.

125. While ESI started utilizing its data as part of a Fraud, Waste, and Abuse program in the late 2000s, the program was only used for certain clients, and it was not widely known within the company. In 2015, a director in the Fraud, Waste, and Abuse department at ESI sent an email to Andrew Behm, Express Scripts Vice President, stating “[w]e have been seeing way to [sic] many egregious drug seeking activity over the years . . . it is hard to defend how our system would allow 68 control scripts by 47 physicians, and 28 pharmacies in a year for one patient. This is one of many...examples...” Mr. Behm responded, “I think we’d all be supportive of shutting this down. We don’t really understand the FWA offering. If you could provide some color there, it might help...to understand the existing gaps.”

126. ESI knew or should have known from its own data that opioid abuse, overdose, and diversion were rising with the increasing amount of opioids that were being dispensed in the Commonwealth—and yet it failed to take any of a number of steps it could have taken to stop it. Instead, ESI continued to prioritize its profits and decline to do anything meaningful about the opioid crisis.

127. ESI was aware of and acknowledged its failures to utilize its data to reduce opioid misuse and diversion. In a 2014 email chain, ESI employees discussed ESI’s poor score in a survey regarding, among other things, managing opioid misuse. The employees also noted that ESI did have some monitoring programs in place for Medicare clients, but they did not have them for the commercial side of the business. One employee stated, “That’s unfortunate that what is

available in Medicare is not fully available in Commercial, and we continue to just be okay with lacking in these areas.”

III. Express Scripts Worked Directly With Manufacturers to Boost Opioid Sales and Aid Deceptive Marketing.

A. Background on Opioid Manufacturers’ Deceptive Marketing of Opioids

128. As Purdue developed OxyContin in the mid-1990s, it knew that to expand its market and profits, it needed to change the perception of opioids from medications that were appropriate only for short-term acute pain or for palliative (end-of-life) care to medications that could be used long-term for widespread chronic conditions, like back pain, migraines, and arthritis. Purdue, together with other opioid manufacturers, such as Teva, Janssen, and Endo, cultivated a narrative that pain was undertreated and pain treatment should be a higher priority for health care providers, and that opioids were safe, effective, and appropriate for long-term use for chronic, routine pain conditions. There were no studies that supported the claim that opioids were appropriate for chronic pain, and the manufacturers failed to disclose the lack of evidence that opioids were safe or effective long-term or the other risks from long-term use of opioids. Purdue and other manufacturers misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

129. Purdue and other manufacturers spent hundreds of millions of dollars on promotional activities and materials that continued to falsely deny or trivialize the risk of addiction and overstate the benefits of opioids. They deceptively marketed opioids to prescribers through advertising, websites, and in-person sales calls. They also relied upon paid physician speaker programs, continuing medical education (“CME”) seminars, non-credit education programs, treatment guidelines, mass mailings to physicians and patients, and other publications and programs they developed with patient advocacy groups, professional associations, paid physicians,

and other third parties, including Defendants.

130. The misrepresentations included claims that:

- i. patients receiving opioid prescriptions for pain generally would not become addicted, and that doctors could use screening tools to exclude patients who might;
- ii. patients who did appear addicted were not; they were instead “pseudoaddicted” and needed more opioids;
- iii. opioids relieved pain when used long-term and were appropriate for use for chronic pain conditions;
- iv. opioids could be taken in higher and higher doses (without disclosing the increased risk to patients);
- v. OxyContin provided 12 hours of relief (when Purdue knew that, for many patients, it did not);
- vi. opioids would improve patients’ function and quality of life (while trivializing or omitting the many adverse effects of opioids that diminish patients’ function and quality of life).

131. Between the 1990s and 2011, prescriptions of oxycodone, an active ingredient in OxyContin and other opioid drugs, more than doubled in the United States. During the same time period, opioid prescriptions increased some 31% from approximately 1.6 million to approximately 2.2 million. According to a U.S. Department of Health and Human Services Fact Sheet, “[i]n 2014, more than 240 million prescriptions were written for prescription opioids, which is more than enough to give every American adult their own bottle of pills.”

132. The opioid manufacturers have faced substantial civil and criminal liability for their roles in creating the opioid public health crisis, and have agreed to pay billions of dollars to address the devastation caused by their misleading marketing and other misdeeds. For example:

- i. In 2007, Purdue agreed to pay approximately \$600 million in fines and other payments to resolve criminal and civil charges related to the company’s misrepresentations regarding OxyContin’s addiction and abuse risks, admitting that it had falsely “marketed and promoted OxyContin as less addictive, less

subject to abuse and diversion and less likely to cause tolerance and withdrawal than other pain medications;

- ii. In October 2020, the Department of Justice announced that Purdue entered into a federal settlement of more than \$8 billion to resolve pending criminal and civil allegations related to its marketing of OxyContin;
- iii. In February 2022, the largest U.S. drug distributors and opioid manufacturer Janssen agreed to finalize a proposed \$26 billion settlement resolving claims by states and local governments that they helped fuel the opioid epidemic;
- iv. In July 2022, Teva announced it would pay up to \$4.25 billion as part of a nationwide settlement to end litigation regarding its role in the opioid crisis; and
- v. In August 2022, Endo agreed to pay \$450 million to states to resolve opioid lawsuits across the country.

B. Express Scripts Worked Directly with Manufacturers to Increase Opioid Sales

133. Express Scripts worked directly with Purdue and other manufacturers to create, provide support for, and disseminate opioid manufacturers' marketing messages in a number of ways. They made data and data portals available to manufacturers that would help them target their messages and develop marketing strategies for their sales forces. They partnered with manufacturers to conduct studies and develop data that would reinforce Purdue's and other manufacturers' deceptive messaging. In addition, they helped Purdue and other manufacturers draft and disseminate their messages to prescribers through "educational" materials.

134. ESI touted its "Pharma Portal" as providing "pharmaceutical manufacturers concrete data on 40 million buyers spending \$3 billion a year on prescription drugs." "Armed with this intelligence" manufacturers could use ESI's "advanced tools" to, among other things, "[d]evelop marketing and sales strategies" and "monitor and evaluate their success." To make sure manufacturers could take full advantage of these tools, ESI's website "also provides customer service and FAQs."

135. The portal, among other things, allowed marketers to use this aggregate data to “compare results with [their] competitors and calculate market share” by “matching details about therapy classes, manufacturers, physicians and Express Scripts’ clients” and to “produce countless graphs and online reports” to help them “expect success” in their efforts.

136. ESI also offered “Encore” “Contract Pulse” and “Invoice Direct” “database products” for the benefit of Purdue and, upon information and belief, other manufacturers. Encore (Contract Pulse) served, among other things, to “[a]llow the manufacturer to . . . evaluate . . . promotional programs and “develop sales force strategies.” Together, ESI estimated that its Pharma Portal and Encore had enough worth to manufacturers to provide a “fair market value” of “around \$125,000 per quarter.” This meant that as of late 2002, the “current customers” were “big pharma only.”

137. Other manufacturers were able to receive market share data and other information from ESI and could send teams to training sessions on ESI’s databases.

138. ESI cooperated with Purdue and other manufacturers to pursue profits by directly collaborating in concerning marketing efforts in other respects as well. As early as 2000, ESI and Purdue conferenced to discuss a range of “initiatives,” including “internet opportunities” such as placing a coupon on the web, a pharmacy preceptorship program that would “educate” clinical program managers regarding opioids, and “physician connectivity technology,” as “Express Scripts demonstrated that technology can change prescribing behavior.” Purdue also contemplated that Express Scripts might send out a piece related to “[o]pioid guidelines, NEJM quotes, and addiction terms” that its own legal department had said sales representatives could not use. The goal of a such a mailing “would be to educate the physician on the beneficial uses of OxyContin and the preferred formulary status.”

139. Express Scripts' affiliate research entity, Practice Patterns Sciences, Inc. ("PPS"), and Medco's Institute for Effectiveness Research provided research and studies for Purdue in order to aid its efforts to expand the opioid market. In one example from 2001, Express Scripts/PPS developed a study for Purdue on "The Value of OxyContin Therapy in Patients with Moderate to Severe Pain due to Osteoarthritis."

140. Several of these joint programs between Express Scripts and Purdue were driven by Express Scripts' desire to work with Purdue to address negative attention that OxyContin was receiving related to abuse and diversion in the early 2000s. A March 14, 2001 letter from Express Scripts to Purdue explained "[c]learly with the market turbulence surrounding OxyContin you and your organization have significant demands on your time . . . there are several strategic initiatives where Express Scripts can support Purdue Pharma in your efforts to educate the market on the prescribing, administration and consumption of OxyContin."

141. An April 2001 Purdue memo similarly explained the reasons Express Scripts was interested in sending a mailing to physicians at that time: "ESI has told use that this mailing is necessary so that they may squelch the anti-OxyContin pushback from their clients' (Managed Care Organizations and Employer Groups) due in large part to the national media attention OxyContin is receiving."

142. ESI developed a study for Purdue entitled, "Quantifying Patterns of Analgesic Use in Conditions with Non-Malignant Pain," which utilized ESI's data and, according to the study's summary, could "support [Purdue's] ongoing strategy to promote the effective use of OxyContin over other drugs and drug classes in the treatment of severe pain."

143. As another example, a 2001 letter from ESI to a Purdue Brand Manager offered to assist with "strategic initiatives where Express Scripts can support Purdue Pharma in your efforts

to educate the market on the prescribing, administration and consumption of Oxycontin” and proposed “three communication efforts that can be rapidly deployed to select audiences.” Express Scripts also provided a “more detailed description of the suggested programs,” which include targeting physicians, pharmacies, and patients with Purdue Pharma produced materials such as “Dispelling the Myths about Opioids.” Among other misrepresentations, “Dispelling the Myths about Opioids” labeled the true statement that “opioid addiction ... is an important clinical problem in patients with moderate to severe pain treated with opioids as a “myth” and further stated that “addiction risk appears to be low.”

144. In addition, Express Scripts offered Purdue the opportunity to give a presentation as an “expert[] in pain management” at a June 2001 advisory board that Express Scripts was hosting and which would consist of “leading workers’ compensation carriers from across the country.”

145. Express Scripts also coordinated with Purdue on a mailing planned for 1,900 physicians in relation to OxyContin in April 2001, with Purdue suggesting changes to the language about abuse and diversion, along with the addition of language on 12-hour dosing—a focal point of deceptive marketing claims by Purdue.

146. A 2011 email chain shows Express Scripts allowed Purdue to edit its clinical guidance on the use of opioids that was required by an ESI worker’s compensation client, in which ESI removed a sentence that stated (appropriately): “Opioids appear to be no more effective than safer analgesics.” By removing this warning, ESI created the false impression that opioids are more effective than safer analgesics even though ESI knew it was false. This conduct, and the other conduct described herein, aided the overall effort by Purdue to deceptively inflate the benefits of

opioids while downplaying their dangers, and is demonstrative of Express Scripts' collusion with Purdue in these efforts.

147. In addition, to assist in the marketing efforts of opioid manufacturers, Express Scripts has for years provided opioid manufacturers with lists of their clients and the names of physicians participating in their provider networks. The manufacturers used this information to target high opioid prescribers with pull-through marketing.

148. For example, Endo sales representatives were instructed to “[m]aximize pull-through with key managed care plans,” “[d]rive brand awareness across top [Opana ER] prescribers,” and promote favorable Opana ER formulary positioning. Sales representatives were instructed to direct their attention on providers “that have the most potential” and not “waste time” on other physicians, and promoted Opana ER’s formulary status to prescribers.

149. Beginning in 2006, Express Scripts and Purdue entered into an ongoing “Participating Manufacturer Agreement” where Express Scripts, in exchange for “administrative fees,” would provide numerous deliverables to Purdue which would enable Purdue to more effectively pull through its drugs’ formulary status to physicians. The “administrative fees” were tied to the number of opioids sold—*i.e.*, the more opioids sold, the more Express Scripts made. This agreement was strictly confidential, was renewed on at least three occasions, and it was in place until at least the end of 2010.

IV. Express Scripts Facilitated and Encouraged the Use of Opioids and Flooded the Market through Self-Serving Formulary and Utilization Management Offerings.

150. ESI exerts significant control over the prescribing, use, and distribution of opioids throughout the nation, including in Kentucky. As described above, ESI determines what drugs are included on the national formularies it offers and, as such, what drugs will be reimbursed. In doing so, ESI largely controls what drugs are prescribed by doctors, dispensed by pharmacies, and used

by patients. Manufacturers tout formulary status of their drugs when marketing the drugs to prescribers, a fact that ESI was well aware of but was not known to the Commonwealth.

151. Express Scripts is contractually obligated to negotiate formulary placement and rebates on behalf of its clients, for its clients' benefit, and its rebate negotiations and formulary offerings are supposed to be consistent and in accordance with its clients' larger, overall interests of providing safe and affordable drugs to their members. However, Express Scripts' negotiations with manufacturers are not client specific; its negotiations determine the placement of opioids on its national formularies and implementation of UM measures on its standard, national plans that Express Scripts offers to its clients. Nevertheless, Express Scripts knows that its clients rely on it to perform these functions in the clients' and patients' best interests and that its clients generally accept the standard formularies and plans that it offers. In pursuit of profits, Express Scripts intentionally disregarded these obligations, to the detriment of communities around the country, including in Kentucky.

152. Express Scripts did not always prioritize its profits over patient safety. Express Scripts' predecessor, Medco, initially put a strict quantity limit of 80mg/day on OxyContin when it was introduced in 1996, and it sent letters to prescribers informing them that it would not pay for OxyContin prescriptions for non-cancer pain treatment.

153. During this time, opioids were prescribed infrequently and generally only for acute pain on a short-term basis, for palliative care in end-of-life cancer patients. PBMs recognized the dangers of opioids and installed various routine controls on quantity and access.

154. Purdue knew that this was a substantial threat to OxyContin's success and worked to change the PBMs' policies about OxyContin and opioids generally. It did this not (primarily) by convincing the PBMs that OxyContin was safe and effective for the treatment of chronic, non-

cancer pain, but by convincing them that they could make significant amounts of money by allowing unrestricted access to opioids.

155. In January of 1997, Purdue sales and marketing executive Michael Friedman sent an email to Purdue's President, Dr. Richard Sackler, stating, "If we do not . . . [demonstrate the value of OxyContin], I can promise you that we will eventually be shut out . . . This is a serious matter that we cannot ignore and that we must discuss . . . We cannot go on ignoring the reality of [the PBMs'] economic proof requirements . . . If we are to stay in business we need this proof of economic performance." Purdue recognized that it needed to demonstrate to Medco and other PBMs the economic value of OxyContin use for chronic non-cancer pain.

156. In 1997 Medco was Purdue's largest customer. Had Medco decided to exclude OxyContin from its national formularies or put in place UM measures to continue to restrict the use of OxyContin for non-cancer pain treatment, it would have had a substantial impact on the widespread use of OxyContin, possibly even driving it off the market. Other companies, such as Cigna and Prescription Solutions, had excluded OxyContin from their formularies.

157. However, Medco did not take action to continue to restrict the sales of OxyContin for non-cancer pain, or to exclude it from its standard formulary offerings. By May of 1997, Medco had reversed course and had "become very interested in 'partnering with Purdue'" on numerous projects.

158. The opioid manufacturers recognized early on that Express Scripts would provide unrestricted formulary status on their standard formulary offerings in exchange for rebates and other fees. For example, in a February 15, 2000 email exchange, Purdue Managed Care Account Executive David Wallen explained that he could get Express Scripts "to steer [OxyContin] prescriptions" to retail pharmacies because of the rebates it received. Wallen stated, "Express

Scripts makes their money from the rebate, so they cannot make any money on this account if they do not get rebates.” In a later February 25, 2000 email, Wallen explained that Express Scripts pressured its clients to agree to formularies that include OxyContin without restrictions, stating “[Express Scripts] can put pressure on [their client] . . . because they make their money from rebates, and they do not get rebates if OxyContin is [subject to UM restrictions that reduce prescriptions].”

159. Motivated by its own profits, Medco/ESI gave OxyContin preferred formulary status on its national formulary offerings and acceded to Purdue’s request not to impose prior authorization or other limits on the use of OxyContin. Medco/ESI’s early preferential treatment of OxyContin facilitated the widespread use and over-use of the drug nationally and in Kentucky, paving the way for the opioid epidemic.

160. A 1996 memo describes Purdue offering a 10% rebate at OxyContin’s launch for placement of the drug on Merck Medco’s standard formulary offerings. From at least 1997, Purdue and Medco and Purdue and Express Scripts had agreements for Purdue to pay rebates to Medco and Express Scripts for opioids dispensed by pharmacies to individuals covered by Medco’s and Express Scripts’ prescription plans.

161. According to a 2000 spreadsheet of invoices of \$25,000 and over, Purdue paid over \$3.7 million to Merck Medco in accrued HMO Rebates, and nearly \$500,000 to Express Scripts for these rebates for a single month. These early payments helped gain acceptance and use of OxyContin in the key early years after its launch and laid the foundation for the over-use, misuse, diversion and other harms that followed.

162. ESI gave OxyContin “Preferred Status” on its standard formulary offerings, sparking Purdue to conduct targeted marketing to “managed care organizations that utilize Express Scripts as their PBMs.”

163. Purdue’s 2003 Business Plan for Medco acknowledges that Purdue provided “financial incentives” to increase utilization of OxyContin and indicates that in 2001, Purdue paid Medco over \$36 million in rebates and generated \$250 million in sales through Medco. Likewise, Medco requested rebates of 17% to 20.25% on OxyContin in return for placing OxyContin on its preferred drug list (or “PDL”) for the 11 million lives it covered.

164. According to a 2005 OxyContin Marketing Plan document, Purdue rebates paid to MCO (“Managed Care Organizations”) and PBMs in 2003 were \$193 million or an average of 17% of sales, demonstrating Purdue’s recognition of the importance of these payments to the commercial success of OxyContin.

165. A Purdue spreadsheet from 2011 shows that ESI was Purdue’s largest vendor. Purdue paid ESI more than \$56.5 million in rebates in 2011 alone.

166. Purdue knew that ESI’s placement of OxyContin on its standard, national formulary offerings as a preferred drug was essential to its success, noting that Medco – Commercial was “20-25% of our total OxyContin gross business” and that “*the spillover effect of a negative move by ESI on OxyContin . . . cannot be underestimated.*” (emphasis added)

167. Express Scripts knew that its placement of OxyContin on its standard formulary offerings as a preferred drug was a problem. In 2012, an Express Scripts executive acknowledged that “OxyContin use at [Medco] is out of control compared with our peers . . . patients are selecting [Medco] because [it has] OxyContin in a preferred position.” In 2013, another Express Scripts’ executive commented that the company was “out of alignment with the rest of the PBM/Health

Plans in actually putting [OxyContin] on a preferred tier . . . other organizations have leaned more towards taking a harder stance on this highly abused medication.” Nevertheless, ESI continued its collusion with Purdue and its preferred placement of OxyContin.

168. While ESI represents publicly that it approves drugs for its formulary through exhaustive clinical review based on their efficacy and appropriateness, as well as cost, it was actually ESI’s rebates that drove its decisions. For instance, as late as 2014, ESI notified Purdue that it was reviewing its standard commercial formulary offering for opioids and “would require deeper discounts to retain OxyContin Preferred status.” The Purdue email summarizing negotiations with ESI noted the “importance and impact of this customer on OxyContin sales” and continued, “ESI made it clear that they would prefer not to make changes to OxyContin formulary status. However, they did state that their decision will be contingent on the level of rebate offered, and overall financial value in our bid in making their decision for 2015.”

169. ESI also made agreements with Purdue that undermined the policy for prior authorizations, as the enticing rebate agreements between Purdue and ESI were conditioned on the elimination or easing of requirements for prior authorization or other restrictions on OxyContin, while also easing availability of OxyContin by lowering copays. Thus, in sum and substance, Purdue paid ESI in order to make OxyContin more available to patients – and ESI complied. As concerns arose regarding quantities prescribed, ESI again prioritized profits from and its partnership with Purdue over health and safety.

170. In its rebate relationships with PBMs, Purdue prioritized preventing the imposition of prior authorization and other requirements that would limit access to opioids. A former Purdue official responsible for ensuring favorable treatment for OxyContin explained, “We would negotiate a certain rebate percentage for keeping it on a certain tier related to copay or whether it

has prior authorization. We like to keep prior authorization off of any drug.” The former Purdue official’s relationship with Medco was especially important, so much so that, upon information and belief, Purdue moved her geographically to be closer to Medco’s New Jersey headquarters.

171. Medco bowed to Purdue’s wishes. For example, as described by a media outlet which obtained unsealed court records from litigation in West Virginia, state officials planned to require prior authorization for OxyContin after noticing a surge in deaths attributable to oxycodone, the branded drug’s active ingredient, in 2001. Specifically, 2004 deposition testimony revealed that state officials contacted Medco, with whom it contracted to manage the state’s employee health plan, and asked the PBM to put in place a plan to limit OxyContin prescribing, but “basically they were refused.” Another state official described similar resistance, testifying that the PBM “felt strongly, and [it was] very, very reluctant or resistant.”

172. ESI even used its large-scale data in an effort to avoid implementing such restrictions, suggesting that in areas other than West Virginia “there were not that many prescriptions for OxyContin, it was not that much of problem.”

173. Internal Purdue emails show how the data that Medco provided helped eliminate potential UM restrictions and further strengthen the partnership between Medco and Purdue. In 2003, Purdue’s Medco Account Representative, Bernadette Katsur, stated:

I do see tremendous value in the data that [Medco] is willing to provide. As he explained to me the large MCO’s could be identified by number, and then he would be willing to discuss opportunities or concerns on a plan sponsor by plan sponsor basis. He would then be willing to work with me to develop individualized strategy for that account. That would mean pulling in Medco Client Manager as well as the local account executive. This type of working relationship has proven to be extremely successful with AdvancePCS. We have eliminated many attempts to [prior authorization] and place [quantity limits] on product through this type of process. We have not had that degree of intimacy with Medco, and I think that Ed

[Adamcik] would be willing to take that leap with the understanding that the extra percentage is being paid for that purpose.

174. In a March 2017 internal ESI email, employees expressed regret that ESI did not target OxyContin with prior authorization on certain formularies, stating “I would feel better if [this decision was] escalated ... up to ensure the rebate gain outweighs the likely erosion of our reputation.” Another employee responded by stating, “This is really sad, really disheartening” and made “[n]o clinical sense to say the least.”

175. Lucrative rebates drove not only decisions regarding formulary placement offerings and prior authorization requirements, but also quantity limits. PBMs determine criteria such as the number of pills per prescription. Instead of imposing appropriate limits, however, Express Scripts, through its Medco predecessor, became a “behind the scenes” partner working alongside Purdue to persuade plans to accept its standard offerings that did not impose tighter limits.

176. As discussed above, Medco initially implemented an 80 mg/day quantity limit at the release of OxyContin. Within five months of the drug’s release and following further discussions with Purdue, Medco had doubled the quantity limit to 160 mg/day by May of 1996. By 2001, Medco had again doubled the quantity limit and the “most restrictive [quantity limit] that Medco would recommend [was] for 320 mg/day as per [Purdue’s] platform.” Medco’s 320 mg/day allowance is equivalent to 480 MME/day – over four times the limit that Medco originally placed on OxyContin upon its release, as well as over five times the limit that Express Scripts now imposes on the drug as part of its Advance Opioid Program.

177. Express Scripts and Purdue worked together to prevent Express Scripts’ clients from implementing strict quantity limits. An August 2002 internal Purdue e-mail chain notes that Purdue reached out to ESI with a suggested talking point in connection with an effort to convince a particular ESI client to loosen quantity limits on OxyContin, by reminding the client that it would

lose rebates if it did not do so. The ESI representative later advised Purdue that ESI's client was going to "change their initial thought regarding the quantity limits."

178. Similarly, a 2003 Purdue email chain noted that a payor agreed to adopt a 124 pill per prescription limit, rather than 68, after ESI was "able to demonstrate the potential loss of rebates and plan impact," and noting that without ESI's "detailed analysis" in this regard, the insurer had been prepared to move forward with a different choice. The same email also notes a different "success" in which "Medco also got the PA [prior authorization] lifted" at a different health plan covering "192,000 lives" in Pennsylvania.

179. ESI recognizes that quantity matters when it comes to the abuse and diversion of opioids, and has acknowledged the problem of excess supply, stating that six in ten patients had or expected to have leftover opioids. Express Scripts has also acknowledged that, "[w]ith a 10-day supply of opioids, 1 in 5 become long-term users." It further cited information from the CDC showing that 25% of long-term opioid users struggle with addiction, while one in thirty-two people with dosages above 200 MME per day die.

180. ESI also acknowledged in 2017 that "rebate contract restrictions had previously prevented clients from obtaining any rebates if certain UM [utilization management] strategies were in place" and that these UM strategies, such as prior authorization, have a "significant impact on the opioid market."

181. But ESI had long been aware of the effectiveness of UM tools. In 2003, ESI studied the effect of UM tools on opioid utilization in Medicaid patients in Georgia. One ESI employee noted that the deployment of a prior authorization process that included quantity limits significantly curtailed OxyContin use in that state. ESI found that "OxyContin went from ranked number seven to number 14 in drugs spent [*sic*] after the PA implementation." Most significantly,

ESI found that “patients who did not receive OxyContin did not have a greater use of medical services[,] so there was not an unintended medical consequence from this program.” In other words, the study showed that the UM measures worked, and there was no medical reason to prevent the implementation of appropriate steps to curtail the excessive use of opioids. A 2006 Express Scripts’ study similarly found that prior authorization and quantity limits were effective at reducing Oxycontin utilization, without negative effect. Yet, Express Scripts admitted in 2013, “we don’t really have a standard OxyContin PA program.”

182. Furthermore, throughout its confidential negotiations with the opioid manufacturers, in exchange for rebates and other fees, Express Scripts agreed that it would not “disadvantage” their opioid drugs, nor would it place UM restrictions on their use within their standard offerings. Effectively, this has meant that Express Scripts bartered away application of UM measures, which opened the floodgates to these dangerous drugs. Thus, the parties agreed that none of the opioid drugs would be disadvantaged and that they all would have the same UM restrictions as other drugs that did not have the propensity for abuse inherent in opioid drugs. These parity and “no disadvantage” contract terms had the effect of Express Scripts and the opioid manufacturers sharing a common purpose of ensuring the unfettered access to opioids across the entire class of opioid drugs.

183. Express Scripts’ standard rebate agreements defined the term “disadvantage” as any time when the opioid manufacturer’s product is “subject to prior authorization, NDC blocks, counter-detailing, co-pay differentials, or a step edit that negatively affects the reimbursement and/or Formulary status of the Product as compared to other products in its designated [competitive product category]”

184. Express Scripts and Purdue's 2002 contract included language stating Purdue would not pay rebates if its opioids were restricted. Likewise in 2009, Purdue would only pay rebates if its opioids were "unrestricted on the preferred brand tier." Again in 2014, Purdue would only pay rebates on OxyContin if it was on "lowest preferred brand tier, without restrictions, including no prior authorization or step therapy." Even as late as 2016, Express Scripts acknowledged that if it tried to put any restrictions on OxyContin (such as restricting opioid use to acute pain, blocking opioids unless the use was for cancer or other approved uses, or requiring prior authorization) that it would violate its rebate agreements with Purdue and would result in a loss of rebates.

185. Another example occurred in 2010. During negotiations between Janssen and Medco (Express Scripts' predecessor) regarding the formulary placement of the fentanyl drug Nucynta, the parties agreed Janssen would only pay rebates so long there were no step edit restrictions and agreed that Nucynta would be protected from "being disadvantaged vs. any branded agent in our defined market basket" of short-acting opioid ("SAOs").

186. Likewise, in 2012 negotiations between Express Scripts and Endo the parties agreed that "Endo Products are 'not disadvantaged to any other brand name pharmaceutical product in the same [competitive product category]'" and that this disadvantaged language meant any UM restrictions must apply to all products in the competitive class.

187. Despite its knowledge of the nationwide opioid health crisis, and despite its knowledge of the impact that formulary placement offerings with preferred formulary placement and a lack of UM restrictions had on increasing opioid sales, Express Scripts failed to create or to offer a standard prior authorization or other UM protocol on opioids to its clients until 2017. While Express Scripts claimed to have put in place a step therapy policy on long-acting opioids (LAO)

in order to combat opioid abuse in 2010, the policy was, in actuality, a cost containment measure. Express Scripts Clinical Director Amy Gross stated, “The [long acting opioid step therapy policy] has nothing to do with pain treatment guidelines. It is just generic before brand.” Of course, requiring a patient to start with a generic version of a long-acting opioid before a brand version did not combat opioid abuse, as generic opioids are just as addictive as the brand versions.

188. The same year that Express Scripts implemented its LAO step policy, Express Scripts Vice President of Clinical Evaluation & Policy, Andrew Behm acknowledged that “overutilization of opiates continue to be significant problem” and recognized that “non-opiate pharmacotherapies” should be promoted. Yet, Express Scripts opted instead to create a policy that substituted an opioid for another opioid.

V. Express Scripts Chose Not to Use Its “Drug Utilization Review” Tools to Address Overprescribing, Abuse, and Diversion.

189. In addition to failing to make national formulary and UM offerings that would have controlled the flow of opioids, ESI did not use its DUR program to restrict access to opioids. Rebates from opioid manufacturers directly impacted how ESI managed its obligations to monitor opioid dispensing on a real-time basis through concurrent drug utilization review.

190. Concurrent DUR (“cDUR”) includes screening at the point of sale for potential drug therapy problems due to therapeutic duplication, age/gender related contraindications, over-utilization and under-utilization, drug-drug interactions, incorrect drug dosage or duration of drug therapy, drug-allergy contraindications, and clinical abuse/misuse.

191. Express Scripts refused to use cDUR to control opioid misuse because doing so would have impacted their receipt of rebates, the income generated from opioid dispensing, and other fees. Express Scripts failed to deploy cDUR initiatives to ensure that only appropriate opioid prescriptions were being dispensed in pharmacies across the country, including in their own mail

order pharmacies. This refusal permitted the dramatic increase in medically inappropriate prescribing and dispensing of prescription opioids that fueled the opioid epidemic.

192. In 2013, when the FDA removed the indication for use of long-acting narcotics to treat moderate pain, Express Scripts still did not change its cDUR program or other UM measures, stating that its OxyContin UM strategy was “more focused on driving preferred products and managing quantities.” One Express Scripts employee at the time described the FDA change as “kind of a non-event.”

193. Even when some clients attempted to place cDUR dosage limits on excessive use of opioids, Express Scripts colluded with the opioid manufacturers to push back.

194. For example, in 2016, when ESI tried to implement cDUR limits on Purdue’s drugs, Purdue pushed back by reminding ESI that the cDUR limits, which would have restricted opioid use to acute pain, blocked opioids unless the use was for cancer or other approved uses, or required prior authorization for all opioids, would be in violation of its rebate agreement.

VI. Express Scripts’ Publicity of Belated Efforts Effectively Admits It Could Have Acted Sooner.

195. It was not until far too late, in 2017 at the 21st Annual Express Scripts Outcomes Symposium, that ESI announced a “solution” to lower the risks of opioids at each touchpoint of the care continuum “from safe disposal, to tools for physicians at the point of care and safety checks for dispensing pharmacies.” By then, it was much too late for the thousands of Kentucky residents who were suffering from opioid addiction.

196. The belated steps that Express Scripts took demonstrate its ability to reduce the supply of opioids through formulary offerings that included appropriate formulary management steps that could, and should, have been taken far earlier.

197. For example, Express Scripts communicated in its 2017 Drug Trend Report that it made several efforts around the opioid epidemic including:

- i. [E]xtraordinary progress in reducing the amount of unnecessary and dangerous dispensing of opioids to our members through the launch of Advanced Opioid Management (Launched in 9/17).
- ii. Average days' supply declined nearly 60% in just 90 days for patients in [the] program receiving a first-time opioid prescription.
- iii. Plans participating in their solution observed a 60% reduction in the average days' supply per initial fill, from 18.6 days to just 7.5 days.
- iv. Among commercial plans, the days' supply of opioids dispensed per person per year decreased 10.3%, while utilization of drugs to treat opioid dependence rose 8.5%.

198. It was not until 2018 when Express Scripts released its Advanced Opioid Management (AOM) program, that ESI put covered patients in greater compliance with the CDC Guidelines. The Express Scripts program includes:

- a. First time prescription opioid users are limited to a seven-day supply of short-acting prescription opioids.
- b. Prior authorization is required for the first fill of a long-acting prescription opioid.
- c. Pharmacy intervention is triggered when patient dosage across all prescription opioids reaches a certain level based on MME per day.
- d. Through Express Scripts' proprietary clinical rules engine, the PBM identifies and sends daily alerts to prescription opioid prescribing physicians via their EHR/EMR to make them aware of duplicative therapy, misuse and abuse, medication interactions, use of multiple prescribers or pharmacies, or when their patient is approaching the MME thresholds.

199. The Advanced Opioid Management programs utilize ESI's ongoing review of claims data that ESI has always had the ability to conduct. There is no legitimate reason why this program, or similar programs, could not have been implemented long before 2018, especially

given ESI's early knowledge of the abuse and diversion of opioids. A 2017 ESI Power Point presentation demonstrates the significance of ESI's delay. The presentation, entitled "Comprehensive Opioid Solution: What is Express Scripts Doing to Combat this Epidemic?", included a slide detailing how many of its covered lives would die in the future if ESI did nothing to combat the epidemic. The slide stated that 11,760 ESI beneficiaries had the potential to die if the company did nothing. ESI's ability to calculate with precision the number of lives that would be lost going forward if it failed to act demonstrates the significance of its failure to take action to combat the epidemic in the past and the likely extent of lives lost due to that failure.

200. While ESI publicly asserts that efforts to curb opioid abuse and misuse remain its highest priorities, its 2018 standard formulary offering still afforded OxyContin, one of the most frequently diverted opioids, preferred alternative status over other long-acting opioids.

201. In 2019, ESI internal emails acknowledged the power that ESI always had to prevent the opioid crisis, using the opioid litigation as a tactic to sell their AOM program. ESI's 2019 proposed AOM program sales document described a Johns Hopkins study regarding utilization management, in which ESI asked questions like, "What devastation will it do to your plan when you're hit with a lawsuit claiming your plan contributed to the flow of opioids into the community causing overdoses, death and other severe consequences?" and "What if there was a way to truly stop the opioid crisis in its tracks and get in front of any potential litigation before you are at risk? [...] Only Express Scripts' multi-faceted advanced opioid management program can solve this issue."

202. Express Scripts had the capability to implement such a program long before 2017, but it did not have the corporate will to do so. Instead, for years, it chose to continue in profitable agreements with Purdue and other opioid manufacturers to give opioids preferred status on its

formulary offerings without implementing restrictions for their use, inevitably resulting in increased opioid utilization, increased opioid addiction, and increased overdose and death. It also chose to continue partnerships with Purdue and other manufacturers to develop research and provide analyses to assist in manufacturers' deceptive opioid marketing efforts. By 2018 when the company decided to take action and develop the AOM, more than half a million people, including thousands of Kentuckians, had already died from opioid overdose.

VII. Express Scripts Disregarded Its Obligations Under Both Kentucky and Federal Controlled Substances Acts in Dispensing Opioids from Its Own Pharmacies.

203. ESI operates one of the largest mail order pharmacies in the United States, dispensing opioids to patients in Kentucky as well as throughout the United States. As such, ESI is part of the closed system and is required to comply with the provisions of the Kentucky Controlled Substances Act ("KY CSA") and the Federal Controlled Substances Act ("CSA") and their implementing regulations.

204. Kentucky law mandates that all pharmacies apply for and receive a license from the Kentucky Board of Pharmacy. *See* KRS 315.035; KRS 315.0351. Express Scripts' mail order pharmacies must certify compliance with all applicable state and federal laws to maintain their licenses to dispense prescription opioids in Kentucky.

205. Express Scripts' mail order pharmacy's obligation included the responsibility to prevent the diversion of opioids. This includes an obligation to use the information available to it, such as the vast amounts of prescription and prescriber data they maintained or could access, to prevent the diversion of opioids. Upon information and belief, ESI failed to utilize this data to detect or guard against diversion, and otherwise failed to meet its KY CSA and CSA obligations.

206. As a dispenser of opioids, ESI was required to ensure that adequate safeguards were in place to dispense opioids in a safe and effective manner, provide effective controls and

procedures to deter and detect theft and diversion, and comply with Kentucky and federal controlled substances laws, such as the requirement to maintain effective controls against diversion. *See, e.g.* 201 KAR 2:205, KRS 315.121, 21 U.S.C. 801, *et seq.*

207. Under Kentucky law and the federal Controlled Substances Act, a prescription is legally valid only if it is issued for “a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” KRS 218A.180(3)(a), 21 C.F.R. § 1306.04(a).

208. A pharmacist may not fill a controlled substance prescription unless it has been issued for a legitimate medical purpose. Consequently, a pharmacist is required to refuse to fill a prescription if he or she knows or has reason to know that the prescription was not written for a legitimate medical purpose. *Id.* The pharmacist has a legal duty to recognize “red flags” or warning signs that raise (or should raise) a reasonable suspicion that a prescription for a controlled substance is not legitimate. These “red flags” include, but are not limited to, those listed by the Kentucky Board of Pharmacy, such as:¹

- a. Does the pharmacist have a relationship with the prescriber?
- b. What is the distance a patient is driving to see the prescriber?
- c. What is the home address of the patient?
- d. In what community is the prescriber practicing?
- e. When prescriptions are filled for one patient, do many, many more start coming to the pharmacy?
- f. Is every patient receiving the exact same prescriptions?
- g. Does the prescriber take cash only?

209. The existence of such indicia obligates the pharmacist to conduct a sufficient investigation to determine that the prescription is actually legitimate before dispensing. ESI failed to meet these obligations in its mail order pharmacy operations.

¹ Kentucky Board of Pharmacy, Controlled Substances Questions, <https://pharmacy.ky.gov/Pages/Controlled-Substances-Questions.aspx> (last accessed September 6, 2024).

210. Instead, during the period for which ARCOS data is available, ESI shipped over 1 billion dosage units of opioids to individuals across the nation.

211. Further, as described above, ESI shipped opioids to patients of high-volume prescribers being targeted with Purdue's deceptive marketing campaign.

212. Express Scripts did little to fulfil its duties to ensure that prescriptions it was filling were issued to legitimate patients for legitimate medical purposes by practitioners acting in the usual course of professional practice, as is evident by the large amounts of opioids being dispensed by its mail order pharmacy throughout the United States.

213. The volume of opioids dispensed by Express Scripts is not surprising, given how its mail order pharmacies operated to push as many prescriptions as possible out the door, with little or no attempts to identify or resolve red flags.

214. For example, employees at Express Scripts complained of being under significant pressure to fill as many prescriptions as possible in as short amount of time as possible. Express Scripts instituted a point system that governed the prescription-filling process in its mail order facilities. Under this system, employees were awarded points for each prescription processed, and were given daily, weekly, or monthly point targets to reach. Employees would be able to leave early if a daily point threshold was reached and were penalized if specific point targets were not reached. A pattern of point shortfalls would result in employees being placed on a termination plan or other reprimands.

215. This point system acts as an incentive for Express Scripts pharmacists and technicians to fill as many opioid prescriptions as possible in as little time as possible, despite the legal requirements to properly and adequately identify and resolve red flags.

216. Express Scripts' mail order pharmacies provided a vehicle for diversion to continue despite efforts to contain it. Purdue's sales representatives noted, for example, that "mail order pharmacies [we]re filling in" what would otherwise have been "gaps in access to OxyContin and other meds" due to "monitoring or quota issues."

217. In 2012, Express Scripts, Inc. and Express Scripts Pharmacy Services, Inc. agreed to pay the U.S. Government \$2.75 million to settle a case against the companies. A DEA inspection revealed that from 2002 through 2006, prescription-controlled substances were diverted into illicit channels at several ESI mail order facilities located in Pennsylvania. The diversion included thefts by employees, inventory discrepancies, and failures to report to the DEA losses that occurred during the mail order delivery process. Perhaps most disturbing, the DEA also found that ESI employees generated invalid DEA registration numbers when ESI lacked registration numbers from pharmacists, which should have been not only a red flag, but an absolute barrier to dispensing these drugs.

218. As part of the settlement, Express Scripts was required to develop a comprehensive Controlled Substances Security Compliance Plan that included diversion protection measures far beyond those required by law, including improved physical security, enhanced inventories, reconciliations and audits, employee background checks, and mandatory training for employees who have contact with controlled substances. Express Scripts executives, including the General Manager of Pharmacy Operations and the Chief Compliance Officer, were required to certify compliance with the terms of the Plan. In addition to the measures to protect against diversion of controlled substances, Express Scripts was also required to cease use of phony DEA numbers and agreed to set up an automated system to check the validity of prescribers' DEA and NPI (National Physician Identifier) numbers against a national registry.

219. ESI failed to comply with its obligations under Kentucky and federal controlled substances laws and failed to use reasonable care in the operation of its mail order pharmacies, permitting an untold number of opioid prescriptions to be filled and the opioids mailed, even though the pills were likely to be diverted.

VIII. Express Scripts Created a Public Health Crisis in Kentucky by Dramatically Increasing the Availability of Opioids.

220. By its conduct in improperly increasing opioid prescriptions, failing to address evidence of overuse, abuse, and addiction, and failing to report suspicious prescribers or to adequately monitor for, identify and not fill suspicious prescriptions, Express Scripts, which portrays itself as a champion of public health but had financial incentives to sell higher volumes of opioids, prioritized pursuit of profits over the well-being of the community and even its own clients. This oversupply allowed non-patients to become exposed to opioids and facilitated access to opioids for both patients who could no longer afford or otherwise access prescription opioids and individuals struggling with addiction and relapse. Individuals addicted to prescription opioids often transition to heroin due to its lower cost, ready availability, and similar high, and often become exposed to the even more potent illicit opioid fentanyl.

221. The opioid epidemic in America is unparalleled. According to the Centers for Disease Control (“CDC”), 292 Americans die every day from a drug overdose. Between 1999 and 2021, more than one million people in this country died due to drug overdoses. In 2021, opioids were involved in 75.4% of drug overdose deaths.

222. According to the DEA, for every one unintentional opioid overdose death in 2010, there were another 108 persons with abuse or dependency issues, and 733 nonmedical opioid users.

223. Opioids are the prime contributor to the addiction and overdose crisis. In 2015, nearly two-thirds of drug overdoses were linked to opioids like Percocet, OxyContin, heroin, and

fentanyl. Americans consume more opioids than any other country in the world, over 47 doses per 1,000 persons per day from 2013 to 2015, and over 34 doses from 2019-2021. In 2015, the amount of opioids prescribed in the United States was enough for every American to be medicated around the clock for three weeks.

224. The troubling reality for states like Kentucky is sadly much worse. From February 1, 2016, to January 31, 2017, pharmacies in the Commonwealth filled prescriptions for 307,234,816 doses of Schedule II prescription drugs, which breaks down to 69 doses of Schedule II narcotics for every man, woman, and child in the Commonwealth. Kentucky's overdose fatalities, which were already high, increased dramatically in that same time frame and beyond. Overdose deaths of Kentucky residents, regardless of where the death occurred, and non-residents who died in Kentucky, numbered 1,249 in 2015, topping the already unacceptable 1,088 overdose deaths in 2014. Those numbers skyrocketed to 1,964 overdose deaths in 2020 and 2,250 overdose deaths in 2021. Research indicates that an opioid was involved in 90% of all overdose deaths in Kentucky.

225. In 2015, drug overdoses accounted for 59.17% of Kentucky's statewide accidental deaths. The CDC identified Kentucky as having a statistically significant drug overdose death rate increase from 2019 to 2020, noting a nearly 51.4% increase from Kentucky's already elevated death rates. According to the CDC, in 2020 Kentucky had the second highest overdose rate in the country. Data from 2013 onward shows that Kentucky has the third highest drug overdose mortality rate in the country. In a 12-month period ending in May 2020, Kentucky saw a 22% increase in drug overdose deaths. That is greater than the overdose deaths increase nationwide. For every 100,000 Kentuckians, 37 of them fatally overdosed.

226. The number of lives lost statewide to drug overdoses in 2020 was more than two-

and-a-half times that of car accidents. In Northern Kentucky, the opioid-overdose reversal drug naloxone was administered in 30% of Emergency Medical Services runs in 2018-2019; and on average, 23 response calls per day were to drug-related incidents.

227. Opioid addiction and misuse also resulted 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 1 and February 15, 2017. One opioid addiction treatment center in Paducah, Kentucky 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. Law enforcement officers in Kentucky similarly observed opioid addiction and abuse affecting people across varying ages and demographics.

228. Rising opioid use and abuse have other negative social and economic consequences as well. According to a 2016 study by a Princeton economist, the increase in opioid prescriptions from 1999 to 2015 could account for roughly 20% of the decline in labor force participation for men and 25% for women. Two-thirds of the surveyed men, not in the labor force and taking pain medication daily, said they took *prescription* painkillers — compared to just 20% of employed men.

229. Prescription drug abuse causes an increase in crimes such as domestic violence, burglaries, and thefts. 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. 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.

230. Children have not been spared by the opioid epidemic. As of September 2022, there were over 8,500 children in foster care in Kentucky, compared to 6,000 in 2012, most commonly because of their parents' abuse of drugs or alcohol. According to one foster parent recruiter, the increasing number of children in foster care in Ashland, Kentucky reached a "crisis point" as a result of the opioid epidemic.

231. School districts have also seen a dramatic increase in suspensions of high school students, relating to possession of, distributing, or being under the influence of prescription drugs.

232. 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 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.

233. NAS has become a great source of concern within the Commonwealth. In 2020, there were 993 NAS births in Kentucky, accounting for 19.4 births for every 1,000 live births among Kentucky residents, more than double the national average. The rate skyrockets in Appalachian areas of Kentucky. In 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.

234. Most of the overdoses from non-prescription opioids are also directly related to prescription pills. Numerous studies show that prescribed opioid use causally increases the risk of heroin use, and the risk of unregulated synthetic opioid use and exposure, especially in recent years.

235. Faced with increased tolerance, addicted people are compelled to seek out higher and stronger doses. Many opioid users, having become addicted to but no longer able to obtain prescription opioids or trapped in a cycle of addiction that causes those who suffer from the disease to need stronger and more potent drugs, have turned to heroin, fentanyl, and other illicit drugs. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription painkillers—which, at the molecular level, closely resemble heroin.

236. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain. As such, heroin produces a very similar high to prescription opioids for a much lower cost. Indeed, opioids are akin to medical-grade heroin. As a result, addicted opioid users soon find themselves turning to street drugs to satisfy the cravings and withdrawal of addiction.

237. Even among those who use opioids medically, there is a higher risk of transition to heroin use than among those who never use prescription opioids. Heroin and synthetic opioid use began increasing exponentially after 2010, and overdose rates due to heroin and synthetic opioids continued to climb. The increases in heroin use largely occurred among individuals who were

prescription opioid users. Among individuals who use prescription opioids, heroin use increased by 138% from 2002-2004 to 2011-2013, and the connection is particularly strong among young adults. The vast majority of individuals who use heroin began with prescription opioid use, and even small increases in progression to heroin use creates a significant public health burden. The rise in prescription opioid use and abuse triggered a resurgence in heroin abuse, imposing additional burdens on states and local governments, including in the Commonwealth of Kentucky.

238. The Substance Abuse and Mental Health Services Administration Center for Behavioral Health and Statistics Quality reports that four out of every five new heroin users begin with use of prescription opioids. Opioid addiction feeds heroin addiction, as heroin produces similar highs and costs substantially less to the user. In fact, people who are addicted to prescription painkillers are 40 times more likely to become addicted to heroin, and the CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. According to the CDC, the percentage of heroin users who also use opioid pain relievers rose from 20.7% between 2002 and 2004 to 45.2% between 2011 and 2013. More current studies cement the connection between heroin and prescription opioids.

239. Dr. Robert DuPont, former director of the National Institute on Drug Abuse and former White House drug czar, opined that opioids are more destructive than crack cocaine:

“[Opioid abuse] is building more slowly, but it’s much larger. And the potential[] for death, in particular, [is] way beyond anything we saw then. . . . [F]or pain medicine, a one-day dose can be sold on the black market for \$100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem.”

240. Northern Kentucky, in particular, has witnessed the effects of the opioid epidemic and resulting upswing in heroin use. In Northern Kentucky, one person died from a drug overdose

every 40 hours in 2015. The Northern Kentucky Health Department logged 37 cases of HIV-positive patients in 2017, with 18 of those cases reporting injection drug use among their risk factors for contracting the disease. This is a significant increase compared to the 5 HIV cases with injection drug use as a risk factor reported in 2016. The substantial increase in HIV cases is another tragic result of the opioid epidemic. Throughout the Commonwealth, there were 368 new infections of HIV in 2018.

241. Beyond the dangers associated with heroin, a new drug has emerged with far more serious risks: synthetic fentanyl and its analogs like carfentanil. Fentanyl is a powerful opioid prescribed for cancer pain or in hospital settings, that, in synthetic form, has made its way into Kentucky communities. Carfentanil, a powerful synthetic derivative of fentanyl, has increasingly been found in heroin and fentanyl sold illicitly. Carfentanil is approximately 10,000 times more potent than morphine and 100 times more potent than fentanyl. In fact, Carfentanil is so strong that it is typically used in veterinary medicine to sedate large wild animals such as elephants and has been researched as a chemical weapon. A dose the size of a grain of salt can rapidly lead to deadly overdose in humans. The proliferation of carfentanil was associated with a significant spike in opioid overdose deaths in 2016-2017, before its presence in the illicit drug market began decreasing. However, several data sources indicate that in 2022 and 2023, carfentanil began resurging, including in Kentucky.

242. Available evidence indicates that fentanyl and other high-potency opioids have been adulterating the supply of both heroin and illicitly manufactured prescription opioids. Given the evidence that prescription opioid use is causally related to heroin use, prescription opioid use is also responsible for the increase in fentanyl and other synthetic opioid harms. Indeed, individuals who use prescription opioids who both obtain illicitly manufactured prescription

opioids, as well as heroin, will be potentially exposed to fentanyl, increasing the risk of overdose and death. Available evidence from San Francisco County, for example, indicates that between 2018 and 2020, people who use heroin transitioned to using fentanyl, indicating that the pathway between heroin and fentanyl, and thus prescription opioids and fentanyl, has the same causal components. Because the heroin supply has been contaminated with high-potency synthetic opioids (e.g., fentanyl) since approximately 2013, prescription opioid use is also causally related to the increase in synthetic opioid morbidity and mortality. Approximately 70-80% of fentanyl-involved opioid deaths are attributable to prescription opioid use, whether fentanyl is unintentionally used when mixed in heroin, or intentionally used, given that the pathway to use from prescription opioids to fentanyl is the same as with heroin.

243. In 2021, the Kentucky Office of Drug Control Policy reported that fentanyl was detected in more than 70% of all overdose deaths. The increases in opioid related overdose deaths coincides with increases in heroin and fentanyl use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use, specifically among persons who report past-year dependence or abuse.

244. Defendants' actions have caused and will continue to cause the Commonwealth to expend substantial sums from the Commonwealth's Treasury to deal with the effects of the opioid epidemic that was substantially fueled by Defendants' unlawful and unreasonable actions as described herein. The conduct alleged herein has proximately caused a multigenerational health epidemic of addiction and resulting disease and deaths in Kentucky.

245. The Attorney General, in fulfilling his duties and exercising his authority under Kentucky law, brings this action to stop the harmful conduct, reverse the effects of the opioid

epidemic, and hold Defendants accountable for their wrongful conduct.

IX. Express Scripts Concealed Its Unlawful Conduct

246. Express Scripts' conduct described herein – colluding with manufacturers deceptively marketing opioids to alter perceptions of opioids and increase their sales, ignoring evidence of misuse, addiction, and diversion visible in their data and instead leveraging the data in further support of manufacturers' opioid marketing, placing opioids on its national formularies with preferred status and without restrictions in exchange for lucrative rebates and fees from manufacturers, failing to maintain effective controls against diversion in its mail order pharmacy operations, and failing to report suspicious prescribers – was concealed from the Commonwealth and the public at large.

247. Express Scripts intentionally undertook efforts to conceal its conduct by misrepresenting its role in the pharmaceutical marketplace as promoting safe and effective use of and appropriate dispensing of opioids, and by failing to make public information in its possession and control that would have revealed the truth regarding its relationships with manufacturers and its financial interest in the increased utilization of opioid medications.

248. Express Scripts fraudulently hid the details of its relationships with opioid manufacturers.

249. The Commonwealth did not and could not have known that Express Scripts developed its national formularies based on profit and rebates, not based on the safety and efficacy of the medications as they claim.

250. Kentucky did not learn that it had been injured by Express Scripts' actions, the source of those injuries, or that those injuries were part of a pattern of conduct until only recently, when documents revealing those facts were produced in discovery by various entities in In re:

National Prescription Opiate Litigation, Case No. 1:17-md-2804-DAP (N.D. Ohio) and other opioid litigation.

251. Express Scripts undertook efforts, to purposefully conceal its wrongful conduct by: (1) manipulating and distorting public information, knowledge, and facts; (2) assuring the public and governmental authorities that it was complying with its obligations and acting to prevent diversion and drug abuse; (3) misrepresenting its role in the pharmaceutical market as promoting safe use and appropriate opioid dispensing; (4) concealing the true nature of its relationships with opioid manufacturers; (5) failing to make public information, over which Express Scripts had exclusive possession, dominion, and control, that would have revealed the truth; (6) entering into overly-broad confidentiality agreements with manufacturers, pharmacies, and other entities with whom it contracted; and (8) deliberately and fraudulently concealing the truth.

252. Express Scripts intended its false statements and omissions to be relied upon.

253. Express Scripts knew of its wrongful acts and had material information pertinent to their discovery, but concealed the information from the public, including from the Commonwealth.

254. Express Scripts knew of its widespread misinformation campaign and of its repeated, intentional failures to prevent opioid overutilization and diversion and concealed this information from the public, including from the Commonwealth.

255. Due in large part to its deceptive, intentional, and fraudulent conduct, the full scope of Express Scripts' wrongful conduct and its central role in the opioid epidemic has not yet come to light.

CAUSES OF ACTION

FIRST CLAIM FOR RELIEF (Violations of the Kentucky Consumer Protection Act)

256. Express Scripts engaged in trade or commerce in the Commonwealth of Kentucky.

257. Kentucky’s Consumer Protection Act (“KCPA”), KRS 367.110 *et seq.*, prohibits “[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce.” KRS 367.170.

258. Under KRS 367.190, “[w]henver 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.

259. The unfair, false, misleading, and/or deceptive acts committed by Defendants constitute a breach of the duties enumerated under Kentucky law, including but not limited to the KCPA.

260. Express Scripts’ acts and practices were unfair under KRS 367.170. These unfair acts or practices include, but are not limited to, ignoring evidence of addiction, abuse, and illegitimate prescribing in their data and failing to implement adequate utilization management measures on opioid prescriptions in exchange for payments from opioid manufacturers, failing to create and offer national formularies where opioid placement was based on the safety and efficacy of the drugs instead of the rebates and fees Express Scripts would receive from opioid manufacturers, colluding with manufacturers in their deceptive marketing schemes that were designed to and did increase utilization of opioids, failing to maintain effective controls against diversion of opioids through their mail order pharmacies in violation of the KY CSA.

261. In addition, Defendants concealed vital knowledge and information from the Commonwealth of Kentucky, its agents and employees, resulting in significant harm to the public and the public coffers.

262. Defendants had access to information and data pointing to diversion that is

unavailable to government entities and did not share that information and data.

263. Express Scripts' acts and practices as alleged herein substantially impacted the community of patients, health care providers, law enforcement, and other state government functions, and caused significant actual harm.

264. As a result of Express Scripts' conduct as alleged herein, Kentucky consumers, including the Commonwealth and its agencies, suffered and continue to suffer injury.

265. Express Scripts' conduct has caused substantial injury to the Commonwealth—in lives lost to drug overdoses, addictions endured, emergency room visits, the creation of an illicit drug market and all its concomitant crime and costs, and broken lives, families, and homes.

266. Express Scripts' acts and practices as alleged herein were motivated by a desire to retain and increase its profits.

267. For each of Defendants' 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.

SECOND CLAIM FOR RELIEF
(Continuing Public Nuisance)

268. The Attorney General represents the citizens of this Commonwealth and can “institute equitable proceedings for the abatement of public nuisances which affected or endangered the public safety of convenience.” *Hancock v. Terry Elkhorn Mining Co., Inc.*, 503 S.W.2d 710, 715 (Ky. 1973). To this end, the Attorney General may bring suit regarding a public nuisance in Kentucky to protect the Commonwealth's citizens to abate public safety concerns.

269. A public nuisance “includes maintaining a condition of things which is prejudicial to the health, safety, comfort, property, sense of decency, or morals of the citizens at large.” *Maum v. Commonwealth*, 490 S.W.2d 748, 749 (Ky. 1973). Certainly, the flooding of the Commonwealth with an exorbitant number of opioids qualifies as a public safety concern. Opioids

are a highly addictive drug that contribute to high addiction and overdose rates in the Commonwealth.

270. Interference with the public's quality of life and common right to health and safety is the violation of a public right. Prior cases, which surround similar fact patterns, have found that the influx of large quantities of opioids have caused adverse consequences and violated public rights. *See Commonwealth v. CVS Health Corp.*, No. 21-CI-00445, slip op. (Ky. Franklin Cir. Ct. Jan. 19, 2022); *Commonwealth v. McKesson Corp.*, No. 18-CI-00056, slip op. (Ky. Franklin Cir. Ct. May 21, 2019); *Commonwealth v. Endo Health Sols., Inc.*, No. 17-CI-01147, slip op. (Ky. Franklin Cir. Ct. July 10, 2018); *Commonwealth v. Walgreens Boots All., Inc.*, No. 18-CI-00846, slip op. (Ky. Boone Cir. Ct. July 22, 2019). Facilitating and encouraging the prescribing and use of opioids and the resulting influx of large amounts of opioids into the Commonwealth is detrimental to public health and safety, which is a public right for all citizens. Defendants' actions substantially contributed to the creation and continuation of a public nuisance, which is still continuing today.

271. Defendants' conduct created a public nuisance that, if unabated, will continue to threaten the health, safety, and welfare of Kentucky's citizens.

272. Express Scripts' conduct is proscribed by statutes and regulations, including the Kentucky Consumer Protection Act, the KY CSA, and the CSA and regulations incorporated therein, in addition to violating the common law of Kentucky.

273. Express Scripts, by colluding with manufacturers to make opioids more available and ignoring evidence of addiction and misuse found in its own claims data and/or other actions and inactions described herein, created and maintained the opioid epidemic in the Commonwealth, which is harmful and disruptive to and unreasonably annoys, injures, endangers, and interferes

with the public health, public safety, public peace, public comfort, and/or public convenience. The public nuisance caused by Express Scripts has significantly harmed the Commonwealth and a considerable number of Kentucky residents.

274. Express Scripts has created and maintained a public nuisance through its ongoing conduct of facilitating and encouraging the use of dangerously addictive opioids by colluding with manufacturers to place opioid drugs on formularies with preferred status, declining to impose limits on their approval for use in exchange for payments and fees from manufacturers, assisting in promoting but failing to disclose the real risks and appropriate limits on the use of opioids, and failing to use the wealth of data available to it to identify and address signs of over-prescribing, illegitimate and dangerous use of opioids, misuse, abuse, and diversion. This conduct caused utilization of opioids to skyrocket, and Express Scripts failed to take measures to restrict opioid utilization even as evidence of the epidemic mounted, including in the Commonwealth, flooding Kentucky with opioids and facilitating and encouraging the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to Kentucky and its residents.

275. Express Scripts knew, or should have known, that its intentional, unreasonable, and/or unlawful conduct would and did cause opioids to be used and possessed illegally and that its conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental effect upon the public health, welfare, safety, peace, comfort, and convenience of the Commonwealth and its residents.

276. The interference is unreasonable because Express Scripts' nuisance-creating conduct:

- i. Involves a significant interference with the public health, the public safety, the public peace, the public comfort, and/or the public convenience;

- ii. At all relevant times was and is proscribed by state and federal laws and regulations; and/or
- iii. Is of a continuing nature and, as Express Scripts knows, has had and is continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.

277. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes but is not limited to:

- i. The creation and fostering of an illegal, secondary market for prescription opioids;
- ii. Easy access to prescription opioids by children and teenagers;
- iii. A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths;
- iv. Infants being born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;
- v. Employers losing the value of productive and healthy employees; and
- vi. Increased costs and expenses for Kentucky relating to healthcare services, law enforcement, the criminal justice system, social services, and education systems.

278. Express Scripts knowingly, intentionally, recklessly, and/or unlawfully allowed as many opioids onto the market as possible, fueling addiction to and diversion of these powerful narcotics, resulting in increased addiction and abuse, an elevated level of crime, death and injuries to the residents of Kentucky, a higher level of fear, discomfort and inconvenience to the residents of Kentucky, and direct costs to Kentucky and its residents.

279. Express Scripts' intentional and unreasonable nuisance-creating conduct, for which the gravity of the harm outweighs the utility of the conduct, is described throughout this Complaint and includes:

- i. Facilitating the increased use of opioids by giving opioids unwarranted preferred formulary status in exchange for profiting from payments from opioid manufacturers;

- ii. Failing to impose prior authorization requirements or limits on the availability of opioids in exchange for payments from opioid manufacturers;
- iii. Colluding with opioid manufacturers in deceptive marketing schemes that were designed to, and successfully did, change the perception of opioids and cause their prescribing and sales to skyrocket;
- iv. Ignoring evidence of addiction, abuse, and illegitimate prescribing found in their own extensive data instead of using it to report suspicious prescribers and pharmacies or to enact policies to help address these issues;
- v. Failing to maintain adequate safeguards to dispense opioids in a safe and effective manner and to maintain effective controls against diversion of opioids dispensed through their mail order pharmacies; and
- vi. Failing to report suspicious prescribers and pharmacies.

280. At all times relevant to this Complaint, Express Scripts knew that increasing the availability of opioids would increase the number of opioids that would be abused, misused, and diverted into the illegal, secondary market and would be obtained by persons with criminal purposes. Express Scripts also knew, or should have known from its own data, that the marketing by manufacturers with which it colluded was deceptive and that its conduct served to increase opioid sales.

281. At all times relevant to this Complaint, Express Scripts knew that opioids were dangerous because these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

282. It was foreseeable to Express Scripts that its conduct would unreasonably interfere with the public health, public safety, public peace, public comfort, and/or public convenience.

283. Express Scripts' conduct is widespread and persistent and creates substantial and ongoing harm. Express Scripts' conduct has caused deaths, serious injuries, and a severe

disruption of public peace, health, order and safety. Express Scripts' ongoing and persistent misconduct is producing permanent and long-lasting damage.

284. Express Scripts' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used in Kentucky. Because of Express Scripts' actions in using its unique position to increase the availability of opioids in the marketplace and inflate opioid sales, because of its collusion with manufacturers in the deceptive marketing of opioids, and because of Express Scripts' unique position within the system of opioid dispensing, without Express Scripts' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

285. Express Scripts had control over its conduct in and affecting Kentucky as is described in this Complaint, and that conduct has had an adverse effect on the public. Express Scripts had sufficient control over, and responsibility for, the public nuisance it created. Express Scripts was in control of the "instrumentality" of the nuisance, namely the dissemination of prescription opioids, its collusion with manufacturers in promoting opioids, and benefit plan design, formulary placement, and drug utilization management that increased utilization of opioids as described herein.

286. The Commonwealth has suffered and continues to suffer special injuries distinguishable from those suffered by the general public. As discussed herein, it has incurred and continue to incur substantial harms.

287. Express Scripts' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a state would reasonably expect to occur and is not part of the normal and expected costs of a state government's existence. Kentucky has incurred and will incur

expenditures for special programs to abate the nuisance that are over and above the Commonwealth's ordinary public services.

288. The public nuisance – i.e., the opioid epidemic – created, perpetuated, and maintained by Express Scripts can be abated and further recurrence of such harm and inconvenience can be abated.

289. Kentucky is asserting its own rights and interests and its claims are not based upon or derivative of the rights of others.

290. Kentucky has suffered an indivisible injury as a result of the tortious conduct of Express Scripts.

291. Express Scripts acted with actual malice because it acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

292. The Commonwealth seeks all legal and equitable relief as allowed by law for public nuisance, including inter alia injunctive relief, abatement, attorneys' fees and costs, pre- and post-judgment interest, and such other relief as this Court deems appropriate.

PRAYER FOR RELIEF

WHEREFORE, Kentucky prays that the Court grant the following relief:

- A. Declaring that Defendants committed willful violations of KRS 367.170;
- B. Permanently enjoining Defendants, and their employees, officers, directors, agents, successors, assigns, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries, and any and all persons acting in concert or participation with Defendants, from future false, misleading, deceptive, and/or unfair acts or practices as described herein, pursuant to KRS 367.190;
- C. Permanently enjoining Defendants and their employees, officers, directors, agents, successors, assigns, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries, and any and all persons acting in concert or

participation with Defendants, from continuing their unlawful conduct, acts and practices, as described herein;

- D. Ordering Defendants to abate the public nuisance caused in whole or in part by Defendants;
- E. Awarding civil penalties of \$2,000 for each willful violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990(2);
- F. Awarding the Commonwealth of Kentucky its costs and attorneys' fees;
- G. Awarding the Commonwealth of Kentucky prejudgment interest as permitted by law;
- H. Awarding any other relief to which the Commonwealth is entitled, or the Court deems appropriate and just;
- I. For a trial by jury on all issues so triable;

Dated: September 25, 2024

Respectfully submitted,

RUSSELL COLEMAN
ATTORNEY GENERAL

By: /s/ Shea W. Conley
Shea W. Conley (KY Bar No. 87472)
MORGAN & MORGAN
333 West Vine Street, Suite 1200
Lexington, KY 40507
sconley@forthepeople.com
Tel: (859) 286-8364

Justin Clark (KY Bar No. 89313)
J. Christian Lewis (KY Bar No. 87109)
Stephen B. Humphress (KY Bar No. 84880)
J. Christopher Bowlin (KY Bar No. 90479)
Office of the Kentucky Attorney General
700 Capital Avenue, Suite 118
Frankfort, Kentucky 40601
justind.clark@ky.gov
christian.lewis@ky.gov
steve.humphress@ky.gov
christopher.bowlin@ky.gov
Tel: (502) 696-5300
Fax: (502) 573-8317

Linda Singer*
Mimi Liu*
Elizabeth Smith*
David I. Ackerman*
Brendan Austin*
MOTLEY RICE LLC
401 9th Street NW, Suite 630
Washington, DC 20004
lsinger@motleyrice.com
mliu@motleyrice.com
esmith@motleyrice.com
dackerman@motleyrice.com
baustin@motleyrice.com
Tel: (202) 232-5504
Fax: (202) 386-9622

James D. Young*
jyoung@forthepeople.com
MORGAN & MORGAN
COMPLEX LITIGATION GROUP
501 Riverside Ave., Suite 1200
Jacksonville, FL 32202
Tel: (904) 361-0012
Fax: (904) 366-7677

Juan Martinez*
juanmartinez@forthepeople.com
MORGAN & MORGAN
COMPLEX LITIGATION GROUP
201 North Franklin Street, 7th Floor
Tampa, FL 33602
Tel: (813) 393-5463

**Pro Hac Vice To Be Submitted*

*Attorneys for Plaintiff the Commonwealth of
Kentucky*



CIVIL SUMMONS

Plaintiff, **COMMW. OF KY, EX. REL. RUSSELL COLEMAN VS. EXPRESS SCRIPTS,,** *Defendant*

**TO: CT CORPORATION SYSTEM
306 W. MAIN STREET, SUITE 512
FRANKFORT, KY 40601**

Memo: Related party is EXPRESS SCRIPTS, INC.

The Commonwealth of Kentucky to Defendant:
EXPRESS SCRIPTS, INC.

You are hereby notified that a **legal action has been filed against you** in this Court demanding relief as shown on the document delivered to you with this Summons. **Unless a written defense is made by you or by an attorney on your behalf within twenty (20) days** following the day this paper is delivered to you, judgment by default may be taken against you for the relief demanded in the attached complaint.

The name(s) and address(es) of the party or parties demanding relief against you or his/her (their) attorney(s) are shown on the document delivered to you with this Summons.

Jessamine Circuit Clerk
Date: **9/25/2024**

Proof of Service

This Summons was:

Served by delivering a true copy and the Complaint (or other initiating document)

To: _____

Not Served because: _____

Date: _____, 20____

_____ Served By

_____ Title



45A37B09-7A79-4073-83EC-1FDFA B5A25A9 : 000078 of 000083

Presiding Judge: HON. HUNTER DAUGHERTY (613171)

CI : 000001 of 000001



CIVIL SUMMONS

Plaintiff, **COMMW. OF KY, EX. REL. RUSSELL COLEMAN VS. EXPRESS SCRIPTS,,** *Defendant*

**TO: CT CORPORATION SYSTEM
306 W. MAIN STREET, SUITE 512
FRANKFORT, KY 40601**

Memo: Related party is EXPRESS SCRIPTS ADMINISTRATORS, LLC

The Commonwealth of Kentucky to Defendant:
EXPRESS SCRIPTS ADMINISTRATORS, LLC

You are hereby notified that a **legal action has been filed against you** in this Court demanding relief as shown on the document delivered to you with this Summons. **Unless a written defense is made by you or by an attorney on your behalf within twenty (20) days** following the day this paper is delivered to you, judgment by default may be taken against you for the relief demanded in the attached complaint.

The name(s) and address(es) of the party or parties demanding relief against you or his/her (their) attorney(s) are shown on the document delivered to you with this Summons.

Jessamine Circuit Clerk
Date: **9/25/2024**

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CIVIL SUMMONS

Plaintiff, **COMMW. OF KY, EX. REL. RUSSELL COLEMAN VS. EXPRESS SCRIPTS,,** *Defendant*

**TO: CT CORPORATION SYSTEM
306 W. MAIN STREET, SUITE 512
FRANKFORT, KY 40601**

Memo: Related party is MEDCO HEALTH SOLUTIONS, INC.

The Commonwealth of Kentucky to Defendant:
MEDCO HEALTH SOLUTIONS, INC.

You are hereby notified that a **legal action has been filed against you** in this Court demanding relief as shown on the document delivered to you with this Summons. **Unless a written defense is made by you or by an attorney on your behalf within twenty (20) days** following the day this paper is delivered to you, judgment by default may be taken against you for the relief demanded in the attached complaint.

The name(s) and address(es) of the party or parties demanding relief against you or his/her (their) attorney(s) are shown on the document delivered to you with this Summons.

Jessamine Circuit Clerk
Date: **9/25/2024**

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This Summons was:

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To: _____

Not Served because: _____

Date: _____, 20____

Served By

Title





CIVIL SUMMONS

Plaintiff, **COMMW. OF KY, EX. REL. RUSSELL COLEMAN VS. EXPRESS SCRIPTS,,** *Defendant*

**TO: CT CORPORATION SYSTEM
306 W. MAIN STREET, SUITE 512
FRANKFORT, KY 40601**

Memo: Related party is EXPRESS SCRIPTS PHARMACY, INC.

The Commonwealth of Kentucky to Defendant:
EXPRESS SCRIPTS PHARMACY, INC.

You are hereby notified that a **legal action has been filed against you** in this Court demanding relief as shown on the document delivered to you with this Summons. **Unless a written defense is made by you or by an attorney on your behalf within twenty (20) days** following the day this paper is delivered to you, judgment by default may be taken against you for the relief demanded in the attached complaint.

The name(s) and address(es) of the party or parties demanding relief against you or his/her (their) attorney(s) are shown on the document delivered to you with this Summons.

Jessamine Circuit Clerk
Date: **9/25/2024**

Proof of Service

This Summons was:

Served by delivering a true copy and the Complaint (or other initiating document)

To: _____

Not Served because: _____

Date: _____, 20____

Served By

Title





CIVIL SUMMONS

Plaintiff, **COMMW. OF KY, EX. REL. RUSSELL COLEMAN VS. EXPRESS SCRIPTS,,** *Defendant*

**TO: CT CORPORATION SYSTEM
306 W. MAIN STREET, SUITE 512
FRANKFORT, KY 40601**

Memo: Related party is ESI MAIL PHARMACY SERVICES, INC.

The Commonwealth of Kentucky to Defendant:
ESI MAIL PHARMACY SERVICES, INC.

You are hereby notified that a **legal action has been filed against you** in this Court demanding relief as shown on the document delivered to you with this Summons. **Unless a written defense is made by you or by an attorney on your behalf within twenty (20) days** following the day this paper is delivered to you, judgment by default may be taken against you for the relief demanded in the attached complaint.

The name(s) and address(es) of the party or parties demanding relief against you or his/her (their) attorney(s) are shown on the document delivered to you with this Summons.

Jessamine Circuit Clerk
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Title





Commonwealth of Kentucky
Doug Fain, Jessamine Circuit Clerk

Case #: 24-CI-00594

Envelope #: 8902403

Received From: SHEA CONLEY

Account Of: SHEA CONLEY

Case Title: COMMW. OF KY, EX. REL. RUSSELL COLEMAI **Confirmation Number:** 188791387

VS. EXPRESS SCRIPTS
 Filed On 9/25/2024 2:21:36PM

#	<u>Item Description</u>	<u>Amount</u>
1	Court Facilities Fee	\$25.00
2	Access To Justice Fee	\$20.00
3	Money Collected For Others(Court Tech. Fee)	\$20.00
4	Money Collected For Others(Postage)	\$133.50
5	Money Collected For Others(Attorney Tax Fee)	\$5.00
6	Library Fee	\$1.00
7	Civil Filing Fee	\$150.00
8	Charges For Services(Copy - Photocopy)	\$39.50
9	Charges For Services(Jury Demand / 12)	\$70.00
TOTAL:		\$464.00

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