IN THE COURT OF COMMON PLEAS
MADISON COUNTY, OHIO

STATE OF OHIO, **ex rel. Mike DeWine, in his capacity as Attorney General of the State of Ohio,** **PLAINTIFF,** **v.** **MCKESSON CORPORATION** **Agent: Corporation Service Company** **50 West Broad Street** **Suite 1330** **Columbus, OH 43215** **CARDINAL HEALTH, INC.** **Agent: CT Corporation System** **4400 Easton Commons Way** **Suite 125** **Columbus, OH 43219** **AMERISOURCEBERGEN DRUG CORPORATION** **Agent: CT Corporation System** **4400 Easton Commons Way** **Suite 125** **Columbus, OH 43219** **AND**	**Case No. _____** **(Judge _____)** **COMPLAINT** **JURY TRIAL DEMANDED AND ENDORSED HEREON**

MIAMI-LUKEN, INC.)
Agent: William Powers)
265 Pioneer Blvd.)
Springboro, OH 45066)
)
)
DEFENDANTS.)

TABLE OF CONTENTS

For its Complaint against Defendants McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen Drug Corporation, and Miami-Luken, Inc., Plaintiff, the State of Ohio ("The State"), by and through counsel, alleges as follows:

INTRODUCTION

1. Ohio is battling an opioid crisis. In Ohio, at least 14 people on average die each day due to drug overdoses. Ohioans became addicted when their communities were flooded with prescription opioids. These individuals continue to feed their addiction through the use of legally and illegally obtained prescription drugs, as well as through the use of illegal opioids such as heroin, fentanyl, and carfentanyl, further worsening the crisis. The problem extends to all four corners of Ohio and afflicts Ohioans from all walks of life. Opioids have created one of the worst public health crises in Ohio history and Ohio leads the country in drug overdose deaths per capita. The repercussions will be felt within Ohio for decades to come.[1]

2. Prescription opioids can cause dependence, addiction, overdose, and death, whether they are used legally for medical purposes or illegally for recreational or other non-medical purposes. Because of these significant dangers, the sale, distribution, prescription, and dispensing of opioids are heavily regulated by Federal and State authorities.[2] Since 1970, opioids have been regulated both nationwide under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, ("CSA") and in this State under the Ohio Controlled Substances Act , R.C. 3719.01 *et seq.*, ("OCSA"), and their implementing regulations. Collectively, these laws create a "closed system" that imposes obligations on everyone involved in the supply chain for controlled

[1] *See., e.g.,* OSU's Swank Program in Rural-Urban Policy, Taking Measure of Ohio's Opioid Crisis, http://osu.edu/betz.40/files/2017/10/SWANK-Taking-Measure-of-Ohios-Opioid-Crisis-1vtx548.pdf.

[2] State and Federal regulations imposes a variety of obligations on Defendants. This particular action does not seek to enforce, or make a claim under, any federal statutes or regulations. Rather, this action arises under the Ohio law of nuisance and negligence.

substances, including manufacturers and distributors, to prevent the release of prescription opioids into the marketplace for anything other than legitimate medical use.

3. This closed system is intended to prevent opioid diversion. Diversion occurs whenever the supply chain of prescription opioids is broken and drugs are transferred from a legitimate channel of distribution or use to an illicit one.

4. To prevent diversion, federal and state laws require wholesale distributors of prescription opioids to maintain effective controls over their prescription opioid supply chains and to maintain systems to monitor, identify, report, and suspend suspicious prescription opioid orders. Distributors also have common-law obligations in distributing these dangerous drugs, including a duty to exercise reasonable care in policing their supply and distribution chains, and a duty not to create a public nuisance by unreasonably interfering with the public health, safety, peace, comfort, or convenience as a result of these dangerous drugs making their way into the hands of drug dealers and addicts.

5. Defendants McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen Drug Corporation, and Miami-Luken, Inc. (collectively, "Defendants") are distributors and suppliers of prescription opioids - including hydrocodone, oxycodone, codeine, oxymorphone, morphine, and hydromorphone - within Ohio.

6. As established below, Defendants have consistently failed to comply with their federal, state, and common-law obligations, despite knowing that their failures have led to prescription opioids being diverted from the legitimate supply chain to illegitimate channels of distribution and illegal, non-medical use.

7. Specifically, Defendants have distributed enough opioids to fill an average of over 11.8 million prescriptions each year between 2011-16, and the total number of opioid doses

dispensed over the same timeframe averaged over 739 million each year.[3] Defendants distributed these opioids despite knowing that hundreds of thousands of these prescriptions and millions of the pills are diverted for illegal purposes and result in great harm to individuals in s.[4]

8. Defendants' conduct has harmed Ohio and its citizens. In particular, Defendants' conduct has led to millions of prescription opioid pills being diverted from the legitimate supply chain, which in turn has contributed to an epidemic of prescription opioid abuse in Ohio. This epidemic has resulted in thousands of prescription opioid-related overdoses and deaths each year in Ohio; use of opioids for non-medical purposes by tens of thousands of Ohio citizens; billions of dollars in damages to the State related to the excessive costs of healthcare, criminal justice, education, social services, lost productivity; and other economic losses as a direct result of the illicit use of these dangerous drugs caused by opioid diversion. For example, in Madison County, 126 drug overdoses were reported in the first nine months of 2017 and the number of unintentional drug overdose deaths more than doubled between 2015 and 2016.[5]

9. The State has sustained significant economic damages and a wide range of non-economic damages as a result of Defendants' conduct, and it will continue to sustain economic and non-economic damages in the future. As more fully set forth below, the State seeks injunctive relief and damages, including compensatory and punitive damages, and restitution.

10. Damages suffered by the State and its agencies include monies spent for the following:

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[3] State of Ohio Board of Pharmacy Annual Report, *available at* http://www.ohiopmp.gov/documents/Annual Report (2016).pdf.

[4] Prescribing data from the CDC indicates that 100 opioid prescriptions are dispensed each year for every 100 residents of Ohio. This rate of one prescription for every citizen is one of the highest in the nation. The dispensing rate indicates that over 11.6 million opioid prescriptions are filled each year in Ohio. CDC, Opioid Painkiller Prescribing (2014), https://www.cdc.gov/vitalsigns/opioid-prescribing/index.html.

[5] *See, e.g.*, Madison County Continues Opioid Addiction Fight (October 27, 2017), http://www.madison-press.com/news/270258/madison-county-continues-opioid-addition-fight; *see also* State of Ohio Board of Pharmacy Annual Report, *available at* http://www.ohiopmp.gov/documents/Annual Report (2016).pdf.

- medical care for patients suffering from opioid-related addiction or disease, including overdoses and deaths;
- treatment of infants born with opioid-related medical conditions;
- law enforcement and public safety measures necessitated by drug-related crime, overdoses, neglect and abuse of children, and other direct and immediate consequences of the opioid crisis;
- substance abuse prevention, counseling, and rehabilitation services;
- welfare and social services for children whose parents suffer from opioid-related disease or incapacitation; and
- expenditures by State agencies, State programs, and the State's employee health insurance plan related to prescription opioids used for non-medical purposes.

11. The State's ***annual*** damages resulting from prescription opioid abuse are estimated to be in excess of one billion dollars. Defendants' wrongful conduct, as alleged herein, is a proximate cause of these damages and they are jointly and severally liable.

12. Under Ohio law, the State seeks: (i) injunctive relief; (ii) an order to abate the public nuisance resulting from Defendants' conduct; (iii) compensatory damages for costs to Ohio's healthcare, criminal justice, social services, and education systems; (iv) punitive damages; (v) attorney's fees and costs; and (6) such further relief as justice and equity may require.

PARTIES

I. Plaintiff

13. Plaintiff, the State of Ohio, brings this action, by and through its Attorney General, Mike DeWine, in its sovereign capacity in order to protect the interests of the State and its citizens.

II. Defendants

14. Defendant McKesson Corporation ("McKesson") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at One Post Street, San Francisco, California 94104. McKesson is authorized to conduct business in Ohio, and its registered agent for service of process is Corporation Service Co., 50 West Broad Street, Suite 1330, Columbus, Ohio 43215. During all relevant times, McKesson has distributed substantial amounts of prescription opioids to providers and retailers in Ohio. McKesson has engaged in consensual commercial dealings with Ohio and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Ohio.

15. Defendant Cardinal Health, Inc. ("Cardinal") is a corporation organized and existing under the laws of the State of Ohio with its principal place of business located at 7000 Cardinal Place, Dublin, Ohio 43017. During all relevant times, Cardinal and its subsidiaries have distributed substantial amounts of prescription opioids to providers and retailers in Ohio. Cardinal has engaged in consensual commercial dealings with Ohio and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Ohio.

16. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 1300 Morris Drive, Chesterbrook, Pennsylvania 19087. AmerisourceBergen is authorized to conduct business in Ohio, and its registered agent for service of process is CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219. During all relevant times, AmerisourceBergen has distributed substantial amounts of prescription opioids to providers and retailers in Ohio. AmerisourceBergen has engaged in consensual commercial dealings with Ohio and its citizens,

and has purposefully availed itself of the advantages of conducting business with and within Ohio.

17. Defendant Miami-Luken, Inc. ("Miami-Luken") is a corporation organized and existing under the laws of the State of Ohio with its principal place of business located at 265 S. Pioneer Blvd., Springboro, Ohio 45066. During all relevant times, Miami-Luken has distributed substantial amounts of prescription opioids to providers and retailers in Ohio. Miami-Luken has engaged in consensual commercial dealings with Ohio and its citizens, and has purposefully availed itself of the advantages of conducting business with and within Ohio.

JURISDICTION AND VENUE

18. The jurisdiction of this Court is founded upon R.C. 2305.01, which gives the Court of Common Pleas general jurisdiction over civil actions. This Court has personal jurisdiction over Defendants because Defendants are Ohio entities, do business in Ohio, or have the requisite minimum contacts with Ohio necessary to permit the Court to exercise jurisdiction constitutionally, with such jurisdiction also being within the contemplation of the Ohio "long-arm" statute. R.C. 2307.382.

19. Defendants did, individually or in conjunction with others, supply, market, sell, and otherwise distribute prescription opioids in Ohio and specifically in Madison County.

20. Venue is appropriate in Madison County pursuant to Ohio Rule 3(B)(3).

FACTUAL BACKGROUND AND ALLEGATIONS

I. The Opioid Epidemic

A. Prescription Opioids Are Highly Dangerous, and Their Use Has Led to a National Opioid Crisis

21. Prescription opioids are powerful, analgesic medications. They include non-synthetic derivatives of the opium poppy (such as codeine and morphine, which are also called

"opiates"), partially-synthetic derivatives (such as hydrocodone and oxycodone), or fully-synthetic derivatives (such as fentanyl and methadone). Many opioids are classified as Schedule II controlled substances because of their "high potential for abuse which may lead to severe psychological or physical dependence." 21 U.S.C. § 812(b)(2).

22. Although prescription opioids have been approved by the United States Food and Drug Administration ("FDA") for use to treat certain medical conditions, they can pose serious risks to patients and the community at large. As noted on the FDA's website, "when misused or abused, they can cause serious harm, including addiction, overdose and death."[6]

23. The use of opioids has grown exponentially nationwide over the past two decades. Sales of these prescription drugs have quadrupled since 1999 and they are now the most prescribed drugs in the country. Overdose deaths from prescription opioids were five times higher in 2016 than 1999, and 40% of all U.S. opioid overdose deaths now involve a prescription opioid.[7]

24. In 2011, the United States Department of Health and Human Resources, Centers for Disease Control and Prevention (the "CDC"), declared overdoses from prescription opioids to have reached "epidemic levels."[8] That year, 16,917 people died from a prescription opioid-related overdose.[9] The CDC found that: (i) the death toll from overdoses of prescription painkillers had more than tripled in the past decade; (ii) more than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone; (iii) overdoses involving prescription painkillers are at

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[6] FDA, Opioid Medications, *available at* https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/uem337066.htm.
[7] CDC Prescription Opioid Overdose Data, https://www.cdc.gov/drugoverdose/data/overdose.html.
[8] CDC, *Prescription Painkiller Overdoses at Epidemic Levels* (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.
[9] CDC, Drug-poisoning Deaths Involving Opioid Analgesics: United States, 1999-2011 (Sept. 2014), *available at* https://www.cdc.gov/nchs/data/databriefs/db166.pdf.

epidemic levels and now kill more Americans than heroin and cocaine combined; (iv) almost 5,500 people start to misuse prescription painkillers every day; and (v) prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.[10] The CDC further determined that the large number of overdoses and deaths was due to the increased use of prescription painkillers for non-medical reasons, along with growing sales of opioids.[11] As outlined *herein*, the epidemic has worsened since 2011.

25. Since 2011, the death toll due to opioid use has only continued to rise. In 2015, 22,598 people died from an opioid-related overdose.[12] In 2016, that number increased again to 32,445.[13] Since 1999, the number of opioid overdoses in the country has increased five-fold.[14]

26. Ohio has been especially hard hit, with 2,875 prescription drug overdose deaths in 2016, a staggering 60% increase over 2015.[15]

27. On October 26, 2017, the President of the United States declared the opioid epidemic to be a "national health emergency." This declaration followed the recommendations in the interim report from the President's Commission on Combating Drug Addiction and the Opioid Crisis.[16]

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[10] CDC, *Prescription Painkiller Overdoses at Epidemic Levels* (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.
[11] *Id.*
[12] CDC, Wonder: Multiple Cause of Death Data, https://wonder.cdc.gov/mcd.html.
[13] *Id.*
[14] CDC Prescription Opioid Overdose Data, https://www.cdc.gov/drugoverdose/data/overdose.html.
[15] CDC, Wonder: Multiple Cause of Death Data, https://wonder.cdc.gov/mcd.html.
[16] *Trump declares opioid epidemic a national public health emergency*, CNN (Oct. 26, 2017), http://www.cnn.com/2017/10/26/politics/donald-trump-opioid-epidemic/index.html; President's Commission on Combating Drug Addiction and the Opioid Crisis, Interim Report, *available at* https://apps.npr.org/documents/document.html?id=3923064-President-Opioid-Commission-Interim-Report.

28. Data from the CDC suggest that over 2.6 million Americans are opioid-dependent.[17] Misuse and abuse of opioids can lead to addiction, overdose, and death. According to the CDC, opioids also have other significant negative health effects on individuals with serious health conditions.[18]

29. The CDC has also identified a "cycle of addiction" that starts with prescription opioids and all too often leads directly to heroin addiction. This cycle of addiction that starts with prescription opioid pills has resulted in a dramatic rise in heroin use in recent years. Studies report that roughly 75 to 80% of those who began their heroin abuse in recent years started with a prescription opioid,[19] and that prescription opioid use is the strongest risk factor for heroin use.[20] People who are addicted to opioids are forty times more likely to be addicted to heroin.[21] Overdose deaths involving heroin has continued to climb sharply in recent years, with heroin overdoses more than tripling between 2010 and 2014.[22] This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid misuse and dependence.

30. The National Institute on Drug Abuse has identified opioid misuse and addiction as "a serious national crisis that affects public health as well as social and economic welfare."[23] The economic burden of prescription opioid misuse alone has been estimated to be $78.5 billion

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[17] Lenny Bernstein, *Deaths from drug overdoses soared in the first nine months of 2016*, Washington Post (Aug. 8, 2017), https://www.washingtonpost.com/news/to-your-health/wp/2017/08/08/deaths-from-drug-overdoses-soared-in-the-first-nine-months-of-2016/?utm_term=.b050ce29a0f4.

[18] Susan Scutti, *Opioid Epidemic may be underestimated, CDC report says*, CNN (Apr. 25, 2017), http://www.cnn.com/2017/04/24/health/opioid-deaths-cdc-report/index.html.

[19] Theodore J. Cicero, et al., *The Changing Face of Heroin Use in the United States: A retrospective analysis of the past 50 years*, 71 JAMA Psychiatry 821 (July 2014), *available at* http://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575.

[20] CDC, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html.

[21] *Id.*

[22] CDC, Morbidity and Mortality Weekly Report, *Increases in Drug and Opioid Involved Overdose Deaths United States, 2010, 2015*, https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

[23] NIH, National Institute on Drug Abuse, Opioid Crisis, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis.

per year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[24]

B. The Opioid Epidemic in Ohio Has Been Catastrophic

31. The opioid epidemic in Ohio has been similarly disastrous. The CDC reports that, over the past six years, more than 7,272 Ohioans have died from overdoses of prescription opioids.[25] These statistics, however, may dramatically underestimate deaths from opioids because they ignore opioid-related complications to infectious diseases, such as pneumonia.[26]

32. Ohio's prescription opioid deaths are now the highest in the country. In 2016, Ohio had more prescription opioid deaths than any other state in the nation, with one of every 11 deaths from prescription opioids in the United States occurring in Ohio[27]

33. In 2016, prescription opioids caused the deaths of 2,875 Ohio residents, a 60% increase compared to 2015.[28] From 2004-16, 86.3% of all unintentional drug overdose deaths in Ohio involving specific drugs, including deaths from cocaine and many other drugs, involved opioids.[29] A recent poll found that 40% of adults in Ohio knew someone who had overdosed due to a prescription painkiller, and 56% knew someone who had overdosed from heroin.[30] Ohio leads the country in opioid overdose deaths per capita with estimated projected losses in the billions of dollars.[31]

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[24] *Id.*
[25] CDC, Wonder: Multiple Cause of Death Data, https://wonder.cdc.gov/mcd.html.
[26] Susan Scutti, *Opioid Epidemic may be underestimated, CDC report says*, CNN.com (Apr. 25, 2017), http://www.cnn.com/2017/04/24/health/opioid-deaths-cdc-report/index.html.
[27] CDC, Wonder: Multiple Cause of Death Data, https://wonder.cdc.gov/mcd.html.
[28] *Id.*
[29] *Id.*
[30] Interact for Health, 2016 Ohio Health Issues Poll, *available at* http://newsitetest.interactforhealth.org/upl/Heroin_use_prescription_drug_misuse_still_climbing_in_Ohio.pdf.
[31] *See, e.g.*, OSU's Swank Program in Rural-Urban Policy, *Taking Measure of Ohio's Opioid Crisis*, http://u.osu.edu/betz.40/files/2017/10/SWANK-Taking-Measure-of-Ohios-Opioid-Crisis-1vtx548.pdf.

34. Much of the data regarding opioid distribution, sales, and consumption is in the hands of Defendants or others. But even the publicly available data shows that Ohio as a whole and certain parts in particular consume an amount of opioids that can be explained only by the diversion of opioids for non-medical purposes.

35. In 2016 alone, 2.3 million Ohio patients - roughly 20% of the State's population - were prescribed an opioid drug.[32] According to public data from the DEA, over 18.8 billion milligrams - over 20 tons - of prescription opioids were distributed in Ohio from 2013-2016.[33] These conclusions about the extent of opioid diversion are further supported by data from the Ohio Automated RX Reporting System ("OARRS") showing that in 2016, the "average" county in Ohio received saw distributions of approximately 65 pills per person per year (including children) and several Ohio counties have seen annual distributions exceeding 100 opioid pills for every man, woman and child and 1,000 pills per user.[34]

C. **The Consequence of the Opioid Epidemic Are Far-Reaching**

36. Overdose deaths are only one consequence of the opioid epidemic. Opioid addiction and misuse has also resulted in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone - the antidote to opioid overdose. In Ohio, administrations of naloxone (or Narcan) by Ohio EMS personnel rose from 7,139 in 2006 to 40,837 in 2017 (through November 20, 2017).[35] This means that, on average, Ohio EMS personnel administered over 111 doses of naloxone every day in 2017 alone.

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[32] Ohio Automated RX Reporting System, 2016 Annual Report, *available at* https://www.ohiopmp.gov/documents/Annual%20Report%20(2016).pdf.

[33] DEA, ARCOS Retail Drug Summary Reports, https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/.

[34] Ohio Automated RX Reporting System, https://www.ohiopmp.gov/Default.aspx.

[35] Ohio Emergency Medical Services, Administration of Naloxone By Emergency Medical Services In Ohio – 2014, *available at* http://www.ems.ohio.gov/links/ems_NaloxoneFlyer.pdf; Ohio Department of Public Safety, Division of Emergency Medical Services, Naloxone Administration by Ohio EMS Providers, 2008-2017, *available at* http://www.ems.ohio.gov/links/emsNaloxone2008-2017.pdf.

37. Rising opioid use and abuse also have negative social and economic consequences far beyond overdoses. According to a 2016 study by a Princeton economist, unemployment is increasingly correlated with prescription painkiller use.[36] Nearly half of surveyed men not in the labor force said they took painkillers daily, and two-thirds of them were on prescription medications - compared to just 20% of employed men who reported taking painkillers.[37]

38. The abuse of opioids has caused additional medical conditions that have injured Ohio residents and required care often paid for by the State. For example, the number of cases of chronic Hepatitis C in Ohio nearly tripled from 2011-2015.[38] The increase is largely a result of intravenous drug use stemming from the opioid epidemic, including intravenous use of prescription OxyContin and other prescription painkillers.[39]

39. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS").[40] These infants painfully withdraw from the drug once they are born, cry and wail 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.[41] Research has indicated that these children are likely to suffer from continued, serious neurologic and cognitive

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[36] Alan B. Krueger, *Where Have All the Workers Gone? An inquiry into the decline of the U.S. labor force participation rate*, Brookings Papers on Economic Activity, Conference Draft (Aug. 26, 2017).
[37] *Id.*
[38] CDC, 2015 Ohio – State Health Profile, https://www.cdc.gov/nchhstp/stateprofiles/pdf/ohio_profile.pdf.
[39] Jon E. Zibbell, et al., *Increase in Hepatitis C Virus Infection Related to Injection Drug Use Among Persons Aged <30 Years – Kentucky, Tennessee, Virginia and West Virginia, 2006-2012*, 64 Morbidity and Mortality Weekly Report (2015), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6417a2.htm?s_cid=mm6417a2_w.
[40] Ohio Department of Health, Neonatal Abstinence Syndrome (NAS) in Ohio, 2006-2015 Report, *available at* https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/NAS-Summary-Report.pdf?la=en.
[41] *See* Intermountain Healthcare, Fact Sheet for Patients and Families, *available at* https://intermountainhealthcare.org/ext/Dcmnt?ncid=522597150.

impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life threatening. Babies with NAS typically require extensive hospital stays as they withdraw from opioids.

40. In Ohio, the incidence of NAS related to opioids and other illegal narcotics increased 816% between 2006 and 2015, with opioids and other illegal narcotics being the most commonly implicated drugs since 2009.[42]

41. In 2013, the average inpatient stay and bill for NAS infants in Ohio was four times longer and four times higher than for other infants.[43] Newborns with NAS spent approximately 26,000 days in Ohio hospitals in 2014, with health care costs totaling $105 million.[44] In 2014, 1,875 babies with NAS were admitted to inpatient settings in Ohio, an average of more than five per day. In April 2016, it was reported by the Ohio Perinatal Quality Collaborative that 4,000 babies had been treated for NAS at Ohio hospitals during the preceding 18-month period.[45] These figures continue to worsen with new data.[46]

42. Multiple State agencies and State programs have borne many of the costs associated with the medical treatment required by children suffering from NAS.

43. Children have also been injured by the dislocation caused by opioid abuse and addiction. In 2015, 28% of Ohio children taken into custody were removed from their homes

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[42] Ohio Department of Health, Neonatal Abstinence Syndrome (NAS) in Ohio, 2006-2015 Report, *available at* https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/NAS-Summary-Report.pdf?la=en.

[43] Ohio Department of Health, Neonatal Abstinence Syndrome and Drug Use Among Pregnant Women in Ohio 2004-2011, *available at* http://mha.ohio.gov/Portals/0/assets/Research/Reports/2013-no1-nas-2004-11-epidemiological-report.pdf.

[44] Ohio Maternal Opiate Medical Supports Project, 2016 Infant Mortality Summit, *available at* http://www.odh.ohio.gov/~/media/ODH/ASSETS/Files/cfhs/octpim/imsummit2016/MOMS---Maternal-Opiate-Medical-Support.pdf.

[45] Christopher Evans, *Addiction City: Ohio's Opiate Addicts Would Make the Fifth Largest City in the State* Cleveland.com (Apr. 23, 2016), http://www.cleveland.com/metro/index.ssf/2016/04/--_the_heroin_crisis_in_ohio.html.

[46] *See., e.g.,* Neontal Abstinence Sybdrome (NAS) in Ohio 2006-15 Report, *available at* https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/NAS-Summary-Report.pdf.

due to their parents' use of opioids.[47] Seventy percent of infants placed in Ohio's foster care system are children of parents with opioid addictions.[48] Between 2011 and 2015, Ohio's child protection agencies experienced a 9% increase in the number of children - nearly 1,100 - in foster care driven by parental drug addiction.[49] The State spends an estimated $45 million per year for placement costs of children in custody due to parental use of opioids or heroin.[50]

44. Opioid addiction is now the primary reason that Ohioans seek substance abuse treatment. In 2014, 37% of admissions for drug abuse were associated with a primary diagnosis of opioid abuse or dependence.[51]

45. Since 2014, the State has repeatedly increased spending on Medication Assisted Treatments ("MATs") to address opioid addiction. Expenditures on MATs have more than doubled, from $40 million in 2014 to over $110 million in 2016. This expense is in addition to treatment and counseling services which costs Ohio another $462 million between 2014 and 2016.[52] Courts, jails, and prisons received at least $16 million more in Ohio grants to cover the costs of MATs, treatment, and case management for the uninsured.[53]

46. Law enforcement agencies have increasingly associated opioid abuse with both violent crimes and property crimes. For example, the opioid epidemic has prompted a growing

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[47] Public Children Services Association of Ohio, Testimony of Angela Sausser (Executive Director) on Sub. H.B. 49 (May 17, 2017), *available at* http://advocatesforohio.org/perch/resources/PCSAO-Subcommittee-Testimony.pdf.
[48] Public Children Services Associate of Ohio, Child Welfare Opiate Engagement Project, *available at* http://www.pcsao.org/perch/resources/downloads/cw-opiate-white-paper-final-9-18-14.pdf.
[49] Public Children Services Association of Ohio, Ohio's Opiate Epidemic and Child Protection (2016), *available at* http://www.pcsao.org/pdf/advocacy/PCSAOOpiateEpidemicChildProtectionBrief2016.pdf.
[50] Public Children Services Association of Ohio, Opiate Epidemic, http://www.pcsao.org/programs/opiate-epidemic.
[51] Ohio Mental Health & Addiction Services, Unduplicated Admissions for Opiate Abuse and Dependence, *available at* http://mha.ohio.gov/Portals/0/assets/Research/Maps/Ohio_MACSIS_2014_v6.pdf.
[52] Rachel Dissell, *Ohio's spending on opioid addiction treatment drugs Vivitrol and Suboxone spikes, spurs debate on what treatments work*, Cleveland.com (Apr. 30, 2017), http://www.cleveland.com/metro/index.ssf/2017/04/ohios_spending_on_opioid_addiction_treatment_drugs_like_vivitrol_and_suboxone_spikes_spurs_debate_what_treatments_work.html.
[53] *Id.*

trend of crimes against pharmacies, including robbery and burglary. The number of criminal possession charges for opioids has also significantly increased since 2012.

47. A study by the Ohio Substance Abuse Monitoring Network reported on the connection between oxycodone use and heroin addiction, finding that "young new heroin abusers seeking treatment reported OxyContin abuse prior to becoming addicted to heroin," often after OxyContin became too expensive or difficult to obtain.[54] In 2014 and 2015, Ohio recorded the largest number of heroin-related fatal overdoses of any state, with one in every nine deaths in the United States occurring in Ohio.[55] In 2015, heroin was involved in 46.7% of all overdose deaths in Ohio.[56]

II. The Distribution of Opioids Is Highly Regulated

48. Given the extreme risks posed by prescription opioids, these drugs are heavily regulated under both federal and state law. Under the federal Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, many opioids are classified as Schedule II controlled substances. This is due to their "high potential for abuse which may lead to severe psychological or physical dependence."[57] Opioids are likewise a controlled substance under Ohio law and are categorized as "dangerous drugs." R.C. 4729.01(F).

49. To prevent the diversion of pharmaceutical drugs (including opioids) for illicit use, federal and state laws create a closed system of distribution for all controlled substances. This closed system imposes very specific duties upon anyone involved in the supply

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[54] Ohio Substance Abuse Monitoring Network, OSAM Rapid Response Investigation Reveals Connection Between OxyContin Abuse and Heroin Addiction in Some Individuals, *available at* http://mha.ohio.gov/Portals/0/assets/Learning/OSAM/Jan02ConnxtsOxy.pdf.

[55] The Henry J. Kaiser Family Foundation, Opioid Overdose Deaths (2014 and 2015), https://www.kff.org/other/state-indicator/opioid-overdose-deaths-by-type-of-opioid/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

[56] Ohio Department of Health, 2015 Ohio Drug Overdose Data General Findings, *available at* https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2015-Overdose-Data/2015-Ohio-Drug-Overdose-Data-Report-FINAL.pdf.

[57] DEA, Controlled Substance Schedules, https://www.deadiversion.usdoj.gov/schedules/.

chain for controlled substances, including pharmaceutical manufacturers, distributors, and retailers. Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance is required to register with the DEA. 21 C.F.R. § 1301.11. This includes wholesale distributors such as Defendants. Ohio law likewise requires wholesale drug distributors to obtain a license as a wholesaler of controlled substances from the Ohio Board of Pharmacy. R.C. 4729.52(B)(1)(a)(i).

50. As a registrant with the DEA, each Defendant has a duty to comply with all of the requirements imposed by the CSA regulatory scheme and Ohio's own laws and regulations regarding the distribution of opioids. These requirements of the CSA have been adopted and incorporated into Ohio law. *See, e.g.*, Ohio Admin. Code § 4729-9-16(L).

51. The closed system governing controlled substances is specifically designed to ensure that controlled substances are not "diverted" to an illegal channel of distribution for illicit purposes.

52. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distributors, like Defendants. Distributors then supply opioids to retail pharmacies, hospitals, nursing homes, and other healthcare providers, which then dispense the drugs to pharmacy customers.

53. At the distributor level, diversion may occur whenever opioid distributors fill suspicious orders from retailers. Suspicious orders include orders of an unusually large size, orders of a size that are disproportionately large in comparison to the population of a community served by a pharmacy, orders of unusual frequency, and orders that deviate from a normal pattern. Diversion also occurs when distributors allow opioids to be lost or stolen in transit.

54. As detailed below, Defendants have specific obligations with respect to controlled substances, under the CSA and its implementing regulations and under Ohio laws and

regulations, to prevent diversion. Each Defendant has a duty to exercise reasonable care under the circumstances that includes an obligation not to create a foreseeable risk of harm to others. Additionally, a Defendant that engages in conduct that it realizes or should realize creates an unreasonable risk of harm to another has a duty to exercise reasonable care to prevent the foreseeable harm.

A. Distributors Have A Duty Under Federal and State Law to Guard Against and Report Unlawful Diversion

55. The CSA and Ohio laws and regulations impose both a broad duty to "provide effective controls and procedures to guard against theft and diversion of controlled substances," 21 C.F.R. § 1301.71(a), and specific obligations on opioid distributors, including Defendants. Ohio regularly looks to the interpretation and enforcement of the CSA by the DEA for guidance concerning its own laws and regulations of controlled substances. While these federal statutes and regulations set a standard of care for distributor conduct to which Defendants must adhere under State law, this lawsuit does not seek to enforce, or make a claim under any federal statute or regulation.

56. Federal law requires that opioid distributors maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). Ohio law incorporates these requirements through Ohio's Pharmacy Board Regulations, which provide that "wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations." Ohio Admin. Code § 4729-9-16(L).

57. Federal law further requires wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). "Suspicious orders" include those "of unusual size, orders deviating substantially

from a normal pattern, and orders of unusual frequency." *Id.* A distributor that "discover[s]" a "suspicious order" must inform the DEA. *Id.*

58. Ohio law imposes similar requirements. Wholesale drug distributors are required to "design[] and operate[]" a "system . . . to disclose orders for controlled substances and other dangerous drugs subject to abuse." Ohio Admin. Code § 4729-9-16(H)(1)(e). This includes an obligation to detect and report "suspicious orders," which "are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns." Ohio Admin. Code § 4729-9-16(H)(1)(e)(i). A wholesale distributor must report all suspicious orders to the Ohio Board of Pharmacy. *Id.*

59. In addition to reporting all suspicious orders, wholesale distributors must also stop shipment of any order flagged as "suspicious." *See* 21 U.S.C. § 823(b) (requiring distributors to "maint[ain] effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels").[58] The distributor may only ship the order after due diligence has allowed it to determine that the order is not likely to be diverted. Even then, the distributor must still report all suspicious orders to the DEA and/or Ohio Board of Pharmacy. 21 C.F.R. § 1301.74(b); Ohio Admin. Code § 4729-9-16(H)(1)(e).

60. The CSA also creates a distribution-monitoring system for controlled substances. At the heart of this system are registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA's Automation of Reports and Consolidated Orders System ("ARCOS") is an automated drug reporting system that monitors the distribution, shipment by shipment, of the controlled substances at issue here.

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[58] *See also* Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 20120), Dkt. #14-51. A copy of the September 27, 2006 Rannazzisi Letter is attached hereto as **Exhibit A.**

61. Defendants and all others who are registered to distribute controlled substances must report acquisition and distribution transactions to the DEA through ARCOS. Acquisition and distribution transaction reports must provide data on each addition to inventory and each reduction from inventory. 21 U.S.C. § 827(d)(1); 21 C.F.R. §§ 1304.33(d), (e). Inventory that has been lost or stolen must also be reported to the DEA.

62. In addition, each distributor must maintain a complete and accurate record of each substance manufactured, sold, delivered, or otherwise disposed of. 21 U.S.C. § 827(a)(3); 21 U.S.C. §§ 1304.21(a), 1304.22(b).

63. Ohio laws and regulations similarly require each distributor to maintain a complete and accurate record of each substance manufactured, sold, delivered, or otherwise disposed of. R.C. 3719.07(B)(2); Ohio Admin. Code § 4729-9-16(H).

B. The DEA Has Provided Wholesale Distributors, Including Defendants, With Specific Guidance Regarding Their Duties

64. In addition to the Federal and State laws and regulations regarding controlled substances, Defendants have received detailed, specific instructions from the DEA for identifying and minimizing the risk of opioid diversion in their supply chains by identifying any suspicious orders.

65. For example, since 2007, the DEA has hosted at least five conferences to provide registrants with updated information about diversion trends and regulatory changes that affect the drug supply chain and suspicious order reporting.[59] All of the major distributors, including Defendants, attended at least one of these conferences.

[59] Distributor Conferences, https://www.deadiversion.usdoj.gov/mtgs/distributor/index.html; Manufacturer Conferences, https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/index.html; National Conference on Pharmaceutical and Chemical Diversion, https://deadiversion.usdoj.gov/mtgs/drug_chemical/index.html; Diversion Awareness Conferences, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html.

66. On September 27, 2006, the DEA Office of Diversion Control sent letters to all registered distributors - including Defendants - providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion (the "September 27, 2006 DEA Letter").[60] (A copy of the September 27, 2006 DEA Letter is attached hereto as **Exhibit A.**)

67. The September 27, 2006 DEA Letter reiterated that wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[61]

68. The September 27, 2006 DEA Letter also reminded wholesale distributors that they have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[62] It explained that each distributor is required to exercise due care in confirming the legitimacy of all orders.[63] The DEA also warned that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[64]

69. Also in its September 27, 2006 DEA Letter, the DEA described specific circumstances that could indicate diversion, including orders containing

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[60] Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 20120), Dkt. #14-51, attached hereto as **Exhibit A**.

[61] *Id.*

[62] *Id.*

[63] *Id.*

[64] *Id.*

- excessive quantities of a limited variety of controlled substances while ordering few if any other drugs;
- a disproportionate ratio of controlled substances to non-controlled prescription drugs;
- excessive quantities of a limited variety of controlled substances in combination with certain other drugs; and
- the same controlled substance being ordered from multiple distributors.[65]

70. On December 27, 2007, the DEA sent a second letter to all wholesale distributors - including Defendants - reminding them of their statutory and regulatory duties to "maintain effective controls against diversion" by "design[ing] and operat[ing] a system to disclose to the registrant suspicious orders of controlled substances" (the "December 27, 2007 DEA Letter").[66] (A copy of the December 27, 2007 DEA Letter is attached hereto as **Exhibit B.**)

71. The December 27, 2007 DEA Letter further reiterated that wholesalers must report suspicious orders when discovered and that monthly transaction reports of excessive purchases do not meet the regulatory criteria for suspicious order reporting.[67] The letter also advised registrants that they must perform an *independent* analysis of a suspicious order prior to completing the sale to determine if the controlled substances would likely be diverted, and that filling a suspicious order and then completing the sale absent this independent analysis violates their legal responsibility.[68]

72. The December 27, 2007 DEA Letter also provided additional details and examples regarding when orders should be considered "suspicious." The DEA stated that suspicious orders include those "orders of unusual size, orders deviating substantially from a

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[65] *Id.*
[66] Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 20120), Dkt. #14-8, attached hereto as **Exhibit B.**
[67] *Id.*
[68] *Id.*

normal pattern, and orders of an unusual frequency."[69] It made clear that "[t]hese criteria are disjunctive and are not all inclusive."[70] Thus, "if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious."[71] Moreover,

> a registrant need not wait for a 'normal pattern' to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the particular patterns throughout the segment of the regulated industry.[72]

73. The December 27, 2007 DEA Letter also warned that wholesale distributors which "rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders."[73] The DEA explained that

> a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.[74]

74. In addition, Defendants were also on notice that their own industry group, the Healthcare Distribution Management Association ("HDMA"), published Industry Compliance Guidelines entitled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" that stressed the critical role of each member of the supply chain in distributing

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[69] *Id.*
[70] *Id.*
[71] *Id.*
[72] *Id.*
[73] *Id.*
[74] *Id.*

controlled substances.[75] (A copy of these guidelines is attached hereto as **Exhibit C**.) These industry guidelines explained that, by being "[a]t the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."[76] The guidelines further set forth recommended steps in the "due diligence" process of identifying potentially suspicious orders.[77]

III. Defendants Breached Their Duties to Prevent Opioid Diversion

75. Despite their obligation to prevent opioid diversion and their knowledge of the risks diversion poses, Defendants have intentionally, unlawfully, recklessly, and/or negligently allowed it to occur. As a result of their misconduct, a number of the Defendants have had action taken against them by the DEA and other Federal and State agencies.

A. McKesson

76. To date, McKesson has agreed to pay over $163 million to resolve government charges regarding diversion.

77. In May 2008, McKesson entered into a settlement agreement with the DEA to settle claims that McKesson had failed to maintain effective controls against diversion of controlled substances in Florida, Maryland, Colorado, Texas, Utah, and California (the "2008 McKesson Settlement Agreement").[78]

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[75] Healthcare Distribution Management Association (HDMA), *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, attached hereto as **Exhibit C**.
[76] *Id.*
[77] *Id.*
[78] U.S. Dep't of Justice, *McKesson Corporation Agrees to Pay More than $13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications*, https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html.

78. In the 2008 McKesson Settlement Agreement, McKesson agreed to pay a $13.25 million civil fine for its failure to report suspicious orders from rogue Internet pharmacies around the country that resulted in millions of doses of controlled substances being diverted.[79]

79. In the 2008 McKesson Settlement Agreement, McKesson specifically "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA."[80] Specifically, McKesson agreed to "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders . . . and follow the procedures established by its Controlled Substance Monitoring Program."[81] But McKesson failed to do so. It was later revealed that McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that, in a five-year period, it filled more than 1.6 million orders, but reported just 16 orders as suspicious - all from only a single consumer.[82]

80. In January 2017, McKesson further admitted to its ongoing breach of its duties to monitor, report, and prevent suspicious orders of oxycodone and hydrocodone by entering into a Settlement Agreement and Release With the DEA and the United States Department of Justice (the "2017 Settlement Agreement").[83] (A copy of the 2017 McKesson Settlement Agreement is attached hereto as **Exhibit D**.)

81. The 2017 McKesson Settlement Agreement required McKesson to pay a record $150 million civil penalty for violations of the CSA for its operations in California, Colorado,

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[79] *Id.*
[80] *Id.*
[81] *Id.*
[82] Press Release, U.S. Dep't of Justice, *McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs* (Jan. 17, 2017), https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.
[83] Settlement Agreement and Release, attached as **Exhibit D**.

Florida, Illinois, Massachusetts, Michigan, Missouri, Kentucky, Nebraska, New Jersey, Ohio, Washington, West Virginia, and Wisconsin.[84]

82. In the 2017 McKesson Settlement Agreement, McKesson admitted that, between January 1, 2009 and January 17, 2017, it "did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[85] Despite its obligations contained in the 2008 Settlement Agreement, McKesson "failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b)."[86]

83. In the 2017 McKesson Settlement Agreement, McKesson further admitted that it had "distributed controlled substances to pharmacies even though those [McKesson] Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04(a)."[87] McKesson admitted that it had "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations."[88]

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[84] *Id.*
[85] *Id.* at 5.
[86] *Id.* at 3.
[87] *Id.* at 4.
[88] *Id.* at 3.

84. As part of the 2017 McKesson Settlement Agreement, McKesson admitted that these violations had included its distribution center located in Washington Courthouse, Ohio.[89] Due to these violations, McKesson agreed that its authority to distribute controlled substances from the Washington Courthouse, Ohio facility - in addition to 11 other distribution centers - would be partially suspended for several years.[90] The overall sanctions included in the 2017 Settlement Agreement were the most severe ever imposed on a DEA-registered distributor.

B. Cardinal

85. To date, Cardinal has paid a total of $98 million in fines and other amounts involving multiple DEA and various state actions relating to its improper management and distribution of opioids to pharmacies across the United States.

86. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven warehouses around the United States (the "2008 Cardinal Settlement Agreement").[91] (A copy of the 2008 Cardinal Settlement Agreement is attached hereto as **Exhibit E.**) These allegations included failing to report to the DEA thousands of suspicious orders of hydrocodone that Cardinal then distributed to pharmacies that filled illegitimate prescriptions originating from rogue Internet pharmacy websites.[92]

87. In connection with the 2008 Cardinal Settlement Agreement, the DEA stated that "[d]espite [its] repeated attempts to educate Cardinal Health on diversion awareness and prevention, Cardinal engaged in a pattern of failing to report blatantly suspicious orders for

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[89] *Id.* at 3.
[90] *Id.*
[91] Settlement and Release Agreement and Administrative Memorandum of Agreement (Sept. 30, 2008), attached hereto as **Exhibit E**; Press Release, U.S. Attorney's Office Dist. Of Colo., *Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims that it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances* (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.
[92] *Id.*

controlled substances filled by its distribution facilities located throughout the United States."[93] The DEA concluded that "Cardinal's conduct allowed the 'diversion' of millions of dosage units of hydrocodone from legitimate to non-legitimate channels."[94]

88. In 2012, Cardinal reached another settlement with the DEA relating to systemic opioid diversion in its Florida distribution center (the "2012 Cardinal Settlement Agreement").[95] (A copy of the 2012 Cardinal Settlement Agreement is attached hereto as **Exhibit F**.) Cardinal's Florida center received a two-year license suspension for supplying more than 12 million dosage units to only four area pharmacies, nearly fifty times as much oxycodone as it shipped to the rest of Florida and an increase of 241% in only two years.[96] The DEA found that Cardinal's own investigator warned Cardinal against selling opioids to these pharmacies, but that Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacies.[97] Instead, Cardinal's opioid shipments to the pharmacies increased.[98]

89. In the 2012 Cardinal Settlement Agreement, Cardinal agreed that it had (i) failed to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted; (ii) failed to detect and report suspicious orders of controlled substances as required by the CSA, on or before May 14, 2012; and (iii) failed to adhere to the provisions of the 2008 Cardinal Settlement Agreement.[99]

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[93] *Cardinal Health Inc. Agrees to Pay $34 Million to Settle Claims that It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances*, United States Attorney's Office (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

[94] *Id.*

[95] Administrative Memorandum of Agreement (May 14, 2012), attached hereto as **Exhibit F**; Press Release, Drug Enf't Admin., *DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility* (May 15, 2012), https://www.dea.gov/pubs/pressrel/pr051512.html.

[96] *Id.*

[97] *Id.*

[98] *Id.*

[99] Ex. F.

90. In December 2016, Cardinal again settled charges that it had violated the CSA by failing to prevent diversion of oxycodone for illegal purposes, this time for $44 million (the "2016 Cardinal Settlement Agreement").[100] The settlement covered DEA allegations that Cardinal had failed to report suspicious orders across Washington, Maryland, New York, and Florida.[101] The same Florida distribution center at the heart of the 2012 settlement was *again* implicated in this case.[102] The settlement also covered a Cardinal subsidiary, Kinray, LLC, which failed to report a single suspicious order despite shipping oxycodone and hydrocodone to more than 20 New York-area pharmacy locations that placed unusually high orders of controlled substances at an unusually frequent rate.[103]

91. In January 2017, Cardinal paid $20 million to settle a lawsuit by West Virginia that Cardinal had shipped increasing amounts of opioids to numerous counties without utilizing proper controls, in essence benefitting from West Virginia's problem with prescription drug abuse.[104]

C. AmerisourceBergen

92. AmerisourceBergen has paid $16 million in settlements and had certain licenses revoked as a result of allegations related to the diversion of prescription opioids.

93. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids

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[100] *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act*, United States Attorney's Office (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

[101] *Id.*

[102] *Id.*

[103] *Id.*

[104] *Cardinal Health to pay West Virginia $20M to settle opiates lawsuit*, Columbus Business First (Jan. 9, 2017), https://www.bizjournals.com/columbus/news/2017/01/09/cardinal-health-to-pay-west-virginia-20m-to-settle.html.

to Internet pharmacies.[105] Over the course of one year, AmerisourceBergen had distributed 3.8 million dosage units of hydrocodone to "rogue pharmacies."[106] The DEA suspended AmerisourceBergen's registration after determining that "the continued registration of this company constitutes an imminent danger to public health and safety."[107]

94. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of particular controlled substances into non-medically necessary channels.[108]

95. In January 2017, AmerisourceBergen paid West Virginia $16 million to settle allegations that it knowingly shipped increasing amounts of opioids without sufficient monitoring or control, facilitating six-fold increases in opioid consumption in some counties. In addition to the monetary settlement, AmerisourceBergen agreed to adhere to stricter reporting guidelines within the state.[109]

D. Miami-Luken

96. On November 23, 2015, the DEA issued an Order to Show Cause to begin the process of revoking Miami-Luken's Certificate of DEA Registration.[110]

97. In its revocation proceeding, the DEA has alleged that Miami-Luken failed to maintain effective controls against diversion of controlled substances and that the company failed to operate a system to disclose suspicious orders of controlled substances when it shipped

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[105] DEA, *DEA Suspends Orlando Branch of Drug Company from Distributing Controlled Substances* (Apr. 24, 2007), https://www.dea.gov/pubs/states/newsrel/mia042407.html.
[106] *Id.*
[107] *Id.*
[108] Jeff Overley, *AmerisourceBergen Subpoenaed by DEA Over Drug Diversion*, Law360.com (Aug. 9, 2012), https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed -by-dea-over-drug-diversion.
[109] *Id.*
[110] Miami-Luken is seeking information from the DEA to challenge this action. *See Miami-Luken, Inc. v. Drug Enforcement Agency*, No. 1:2016mc00012 (S.D. Ohio 2016).

controlled substances, particularly oxycodone and hydrocodone, to customers in southern Ohio, eastern Kentucky, and southern West Virginia.[111]

98. In early 2016, Miami-Luken agreed to pay the state of West Virginia $2.5 million to resolve allegations that the company knowingly shipped opioids to West Virginia pharmacies without exercising sufficient monitoring or control.[112]

E. Despite Prior Regulatory Actions, Defendants Violated Their Duties in Ohio

99. Despite being penalized by the DEA, Defendants have not changed their conduct. Rather, they have treated fines as a cost of doing business in an industry that generates billions of dollars in revenue.

100. In fact, Defendants have supplied and continue to supply quantities of prescription opioids in and around Ohio without taking proper measures based on their actual or constructive knowledge that individuals were consuming opioids for non-medical purposes. Defendants should have stopped or investigated any shipment orders of unusual size, orders deviating substantially from a normal pattern, or orders of an unusual frequency, but they have intentionally, unlawfully, recklessly, and/or negligently failed to do so.

101. Each Defendant knew or should have known that the amount of opioids that it allowed to flow into Ohio far exceeded what could be consumed for medically necessary purposes in the relevant communities, especially given that each Defendant knew it was not the only opioid distributor servicing those communities.

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[111] *See* September 25, 2017, Letter from the U.S. House of Representatives Committee on Energy and Commerce, *available at* https://energycommerce.house.gov/wp-content/uploads/2017/09/2010925Miami_Luken.pdf.

[112] West Virginia Department of Military Affairs and Public Safety, *W.Va. public safety, public health departments welcome $2.5 million drug settlement news* (Feb. 3, 2016), http://dmaps.wv.gov/News-Announcements/Pages/W.Va.-public-safety,-public-health-departments-welcome-$2.5-million-drug-settlement-news.aspx.

102. Defendants intentionally, unlawfully, recklessly, and/or negligently failed to control their supply lines to prevent diversion. A reasonably-prudent distributor of controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example,

- taking greater care in hiring, training, and supervising employees;
- providing greater oversight, security, and control of supply channels;
- looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly abused opioids in amounts much greater than justified by the size of the local populations;
- investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around Ohio; and
- informing pharmacies and retailers about opioid diversion.

103. On information and belief, Defendants made little to no effort to visit Ohio pharmacies to perform sufficient due diligence inspections to ensure that the controlled substances Defendants had furnished were not being diverted to illegal uses.

104. On information and belief, the compensation Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing Ohio, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

105. Defendants failed to report "suspicious orders" originating in Ohio to either the DEA or the Ohio Board of Pharmacy and/or filled such orders without taking appropriate steps to investigate, address, or prevent the suspected diversion.

106. Defendants intentionally, unlawfully, recklessly, and/or negligently filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, or orders of unusual frequency that originated in Ohio.

107. Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," as required by 21 C.F.R. § 1301.74(b), as well as their duty to report suspicious orders originating from Ohio to either the DEA or the Ohio Board of Pharmacy.

108. Defendants breached their duties to monitor, detect, investigate, halt, and report suspicious orders of opioids originating from Ohio.

109. Defendants breached their duty to exercise due diligence to avoid filling suspicious orders in Ohio that might be diverted into channels other than legitimate medical, scientific, and/or industrial channels.

110. Defendants' breach of these duties contributed to an illegal opioid market in Ohio.

IV. Defendants' Misconduct Has Injured and Continues to Injure the State and Its Citizens

111. Despite Defendants' duties regarding opioid diversion, which presents a known or foreseeable danger of serious injury, Defendants intentionally, unlawfully, recklessly, and/or negligently failed to prevent opioid diversion - fueling an illegal opioid market in the Ohio - causing substantial injury to the State and its citizens.

112. Defendants' misconduct has contributed to a range of social problems, including violence and delinquency. Adverse social outcomes include deaths, personal injuries, child neglect, family dysfunction, babies born addicted to opioids, criminal behavior, poverty, property damage, unemployment, and social despair. As a result, more and more of the State's public resources are devoted to addiction-related problems. Meanwhile, the prescription opioid crisis diminishes Ohio's available workforce, decreases productivity, increases poverty, and consequently requires greater State expenditures.

113. Costs to the State are a direct and proximate result of Defendants' having intentionally, unlawfully, recklessly, and/or negligently turned a blind eye to opioid diversion, thus contributing to an illegitimate market for opioids.

114. It was reasonably foreseeable to Defendants that their conduct in violating their duties under Federal and State laws and regulations and flooding the market in and around Ohio with highly addictive opioids would allow opioids to be diverted into illegitimate channels for non-medical uses.

115. It was reasonably foreseeable to Defendants that, when unintended users gained access to opioids, tragic, preventable injuries would result, including addiction, overdoses, and death. It was also reasonably foreseeable that many of these injuries would be suffered by Ohio's citizens, and that the costs of these injuries would be shouldered by the State.

116. Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to Ohio's opioid epidemic, and would create access to opioids by unauthorized users, which, in turn, would perpetuate the cycle of addiction, demand, and illegal transactions.

117. Defendants knew or should have known that a substantial amount of the opioids dispensed in and around Ohio were being dispensed based on invalid or suspicious prescriptions. It was reasonably foreseeable that filling suspicious orders for opioids would cause harm to the State and its citizens.

118. Defendants were aware of widespread prescription opioid abuse in and around Ohio, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas - and in such quantities, and with such frequency - that Defendants knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

119. If Defendants had adhered to effective controls to guard against diversion, the State and its citizens would have avoided significant injury and loss.

120. Defendants made substantial profits based on their failure to prevent illegal diversion of opioids into illegitimate channels in Ohio. Defendants' wrongdoing has foreseeably caused injuries to Ohio's citizens and financial damages to the State. Defendants knew full well that the State would be unjustly forced to bear the costs of these injuries and damages.

121. At all relevant times, Defendants engaged in wrongful conduct, and continue to do so, knowing that the State, in its role of providing protection and care for its citizens, would have to provide or pay for additional costs to the healthcare, criminal justice, social services, and education systems, and would also have to bear the loss of substantial economic productivity and tax revenue.

122. Defendants' distribution of excessive amounts of prescription opioids resulted in opioid diversion and contributed to an illegal opioid market in Ohio, while showing a reckless disregard for the safety of the State and its citizens. Defendants' conduct poses a continuing threat to the health, safety, and welfare of the State and its citizens.

123. It was reasonably foreseeable to Defendants that the State would be forced to bear substantial expenses as a result of Defendants' acts in failing to prevent opioid diversion and contributing to an illegal opioid market and improper opioid use in Ohio.

CAUSES OF ACTION UNDER OHIO LAW

COUNT I

ABSOLUTE PUBLIC NUISANCE

124. Paragraphs 1 through 123 of the Complaint are hereby repeated and re-alleged as if fully set forth herein.

125. The Attorney General is authorized to bring suit on behalf of the State and its citizens to address an absolute public nuisance.

126. Defendants, through the actions described in the Complaint, have created - or were a substantial factor in creating - an absolute public nuisance by unreasonably and intentionally or unlawfully interfering with a right common to the general public.

127. Defendants have caused an absolute public nuisance, in that they have committed offenses against the public order and economy of the State by unlawfully and/or intentionally

a. facilitating the distribution and sale of prescription opioids from premises in and around Ohio to Ohio citizens who should not be receiving them - including children, people at risk of overdose or suicide, and criminals;

b. failing to implement effective controls and procedures in their supply chains to guard against the diversion of controlled substances; and

c. failing to design and operate an adequate system to detect, halt, and report suspicious orders of controlled substances.

128. The State and its citizens have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience that has resulted from Defendants' illegal conduct related to the diversion of opioids.

129. Defendants' misconduct has unreasonably interfered with the common rights of the public, including, but not limited to, the right to be free from the nuisance alleged herein.

130. Defendants' interference with these public rights is unreasonable because it

a. has harmed and will continue to harm the public health and public peace of Ohio;

b. has harmed and will continue to harm Ohio neighborhoods and communities by increasing the levels of vagrancy and property crime, and thereby interfering with the rights of the community at large;

c. violates Federal and State statutes and regulations;

d. is of a continuing nature, and has produced long-lasting effects; and

e. is, or should be, known to Defendants that their conduct has a significant effect upon the public rights of Ohio citizens and the State.

131. The nuisance undermines Ohio citizens' public health, quality of life, and safety. It has resulted in increased crime and property damage and in higher rates of addiction, overdoses, and dysfunction within Ohio's families and communities.

132. Public resources are being consumed in efforts to address the opioid epidemic, thereby reducing available resources that could be used to benefit the Ohio public at large.

133. At all times, all Defendants had the obligation and ability to control the nuisance-causing distribution of opioids in Ohio.

134. As a direct and proximate result of the nuisance, Ohio citizens have suffered in their ability to enjoy rights of the public.

135. As a direct and proximate result of the nuisance, the State has sustained significant economic harm by spending substantial sums trying to fix the societal harms caused by Defendants' nuisance-causing activity, including costs to the State's healthcare, criminal, justice, social services, and education systems. The State has also incurred costs relating to lost productivity and lower tax revenue.

136. The State has also suffered unique harms of a kind that are different from Ohio citizens at large, namely, that the State has been harmed in its proprietary interests.

137. The State asserts this cause of action as a common law tort claim for absolute public nuisance and not as a "product liability claim" as defined in R.C. 2307.71. The State seeks recovery of its economic damages and not any compensatory damages for death, physical injury to person, emotional distress, or physical damage to property.

138. Pursuant to Ohio Rule 8(A), the State avers that it seeks damages in excess of twenty-five thousand dollars.

139. The State respectfully requests that this Court enter judgment in its favor jointly and severally against Defendants and seeks:

a. an order to abate the nuisance and prevent the further occurrence of such harm and inconvenience by enjoining Defendants from failing to fulfill their obligations to prevent opioid diversion, including, but not limited to,

i) requiring each Defendant to provide quarterly shipment data in ARCOS format to the Attorney General for three (3) years with substantial penalties for failure to do so;

ii) requiring each Defendant to provide copies of all suspicious order reports filed with the DEA to the Ohio Board of Pharmacy and to the Attorney General simultaneously when filed with the DEA with substantial penalties for failure to do so; and

iii) requiring each Defendant to provide a written explanation and report as to how any suspicions of diversion were resolved to both the Ohio Board of Pharmacy and the Attorney General prior to filling any order reported to the DEA as "suspicious";

b. compensatory damages for increased costs and expenses for the State, including, but not limited to, damages relating to Ohio's healthcare, criminal, justice, social services, and education systems;

c. punitive damages;

d. attorney's fees and costs; and

e. such further relief as justice and equity may require.

COUNT II

QUALIFIED PUBLIC NUISANCE

140. Paragraphs 1 through 139 of the Complaint are hereby repeated and re-alleged as if fully set forth herein.

141. The Attorney General is authorized to bring suit on behalf of the State and its citizens to address a qualified public nuisance.

142. Defendants, through the actions described in the Complaint, have created - or were a substantial factor in creating - a qualified public nuisance by unreasonably, negligently, and/or carelessly interfering with a right common to the general public.

143. Defendants have caused a qualified public nuisance, in that they have committed offenses against the public order and economy of the State, by, among other things, unlawfully and/or negligently

a. facilitating the distribution and sale of prescription opioids from premises in and around Ohio to Ohio citizens who should not be receiving them - including children, people at risk of overdose or suicide, and criminals;

b. failing to implement effective controls and procedures in their supply chains to guard against theft, diversion, and misuse of controlled substances; and

c. failing to design and operate an adequate system to detect, halt, and report suspicious orders of controlled substances.

144. The State and its citizens have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience that has resulted from Defendants' illegal conduct related to the diversion of opioids.

145. Defendants' activities unreasonably interfere with the common rights of the public, including, but not limited to, the right to be free from the nuisance alleged herein.

146. Defendants' interference with these public rights is unreasonable because it

a. has harmed and will continue to harm the public health and public peace of Ohio;

b. has harmed and will continue to harm Ohio neighborhoods and communities by increasing the levels of vagrancy and property crime, and thereby interfering with the rights of the community at large;

c. violates Federal and State statutes and regulations;

d. is of a continuing nature, and has produced long-lasting effects; and

e. is, or should be, known to Defendants that their conduct has a significant effect upon the public rights of Ohio citizens and the State.

147. Defendants' actions are in violation of the standard of care set by Ohio and Federal law and regulations.

148. The nuisance undermines Ohio citizens' public health, quality of life, and safety. It has resulted in increased crime and property damage and in higher rates of addiction, overdoses, and dysfunction within Ohio's families and communities.

149. Public resources are being consumed in efforts to address the opioid epidemic, thereby reducing available resources that could be used to benefit the Ohio public at large.

150. At all times, all Defendants have had the obligation and ability to control the nuisance-causing distribution of opioids in Ohio.

151. As a direct and proximate result of the nuisance, Ohio citizens have suffered in their ability to enjoy rights of the public.

152. As a direct and proximate result of the nuisance, the State has sustained significant economic harm by spending substantial sums trying to fix the societal harms caused by Defendants' nuisance-causing activity, including costs to the State's healthcare, criminal, justice, social services, and education systems.

153. The State has also suffered unique harms of a kind that are different from Ohio citizens at large, namely, that the State has been harmed in its proprietary interests.

154. The State asserts this cause of action as a common law tort claim for qualified public nuisance and not as a "product liability claim" as defined in R.C. 2307.71. The State seeks recovery of its economic damages and not any compensatory damages for death, physical injury to person, emotional distress, or physical damage to property.

155. Pursuant to Ohio Rule 8(A), the State avers that it seeks damages in excess of twenty-five thousand dollars.

156. The State respectfully requests that this Court enter judgment in its favor jointly and severally against Defendants and seeks:

a. an order to abate the nuisance and prevent the further occurrence of such harm and inconvenience by enjoining Defendants from failing to fulfill their obligations to prevent opioid diversion, including, but not limited to,

i) requiring each Defendant to provide quarterly shipment data in ARCOS format to the Attorney General for three (3) years with substantial penalties for failure to do so;

ii) requiring each Defendant to provide copies of all suspicious order reports filed with the DEA to the Ohio Board of Pharmacy and to the Attorney General simultaneously when filed with the DEA with substantial penalties for failure to do so; and

iii) requiring each Defendant to provide a written explanation and report as to how any suspicions of diversion were resolved to both the Ohio Board of Pharmacy and the Attorney General prior to filling any order reported to the DEA as "suspicious";

b. compensatory damages for increased costs and expenses for the State, including, but not limited to, damages relating to Ohio's healthcare, criminal, justice, social services, and education systems;

c. punitive damages;

d. attorney's fees and costs; and

e. such further relief as justice and equity may require.

COUNT III

NEGLIGENCE

157. Paragraphs 1 through 156 of the Complaint are hereby repeated and re-alleged as if fully set forth herein.

158. Defendants owed a duty of reasonable care under the circumstances to the State and its citizens.

159. Defendants' conduct fell below this standard of reasonable care. Defendants' negligent acts include, but are not limited to,

a. oversupplying the market in and around Ohio with highly addictive prescription opioids;

b. using unsafe distribution practices;

c. enhancing the risk of harm from prescription opioids by failing to act as a line of defense against diversion;

d. inviting criminal activity into Ohio by disregarding precautionary measures built into the CSA and the laws and regulations of Ohio;

e. failing to adhere to all applicable laws and regulations pertaining to the distribution of prescription opioids;

f. failing to train or investigate their employees properly;

g. failing to provide effective controls and procedures to guard against theft and diversion of controlled substances; and

h. failing to police adequately the integrity of their supply chains.

160. Defendants' actions are in violation of the established standard of care.

161. Each Defendant had an ability to control the transfer of prescription opioids at a time when it knew or should have known it was passing control of the opioids to an actor further down in the supply chain that was acting illegally or unreasonably.

162. Each Defendant sold prescription opioids in the supply chain when it knew or should have known that: (i) there was a substantial likelihood that many of the sales were for non-medical purposes; and (ii) opioids are an inherently dangerous product.

163. Defendants were negligent or reckless in not acquiring or not using special knowledge and special skills that relate to the dangerous activity of distributing and selling opioids in order to prevent or ameliorate such distinctive and significant dangers.

164. Defendants were also negligent or reckless in failing to guard against foreseeable third-party negligence or misconduct.

165. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

166. Defendants are in a limited class of registrants authorized to distribute controlled substances in Ohio. This places Defendants in a position of great trust and responsibility vis-à-vis Ohio. Defendants owe a special duty to Ohio; the duty owed cannot be delegated to another party.

167. Defendants' conduct was a cause-in-fact and proximate cause of injuries and damages to the State and its citizens, including but not limited to the following: increased costs for Ohio's healthcare, criminal, justice, social services, and education systems, as well as costs associated with lost productivity and lower tax revenues.

168. The injuries to the State would not have happened in the ordinary course of events if Defendants had used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

169. The reckless, wanton, and reprehensible nature of Defendants' conduct entitles the State to an award of punitive damages and attorney's fees and costs.

170. Pursuant to Ohio Rule 8(A), the State avers that it seeks damages in excess of twenty-five thousand dollars.

171. The State respectfully requests that this Court enter judgment in its favor jointly and severally against Defendants and seeks the following relief:

a. compensatory damages for increased costs and expenses for the State, including, but not limited to, damages relating to Ohio's healthcare, criminal, justice, social services, and education systems;

b. punitive damages;

c. attorney's fees and costs; and

d. such further relief as justice and equity may require.

REQUEST FOR JURY TRIAL

The State respectfully requests that all issues presented in this Complaint be tried by a jury, with the exception of those issues that, by law, must be tried before the Court.

Date: February 26, 2018

Respectfully submitted,

STATE OF OHIO
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EXHIBIT A

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

CARDINAL HEALTH
2045 INTERSTATE DRIVE
LAKELAND, FL 33805-0000

September 27, 2006

In reference to registration
RC0182080

Dear Sir or Madam:

This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Administration (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.

Background

As each of you is undoubtedly aware, the abuse (nonmedical use) of controlled prescription drugs is a serious and growing health problem in this country.[1] DEA has an obligation to combat this problem as one of the agency's core functions is to prevent the diversion of controlled substances into illicit channels. Congress assigned DEA to carry out this function through enforcement of the Controlled Substances Act (CSA) and DEA regulations that implement the Act.

The CSA was designed by Congress to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion. Distributors are, of course, one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.[2]

The Statutory Scheme and Legal Duties of Distributors as DEA Registrants

Although most distributors are already well aware of the following legal principles, they are reiterated here as additional background for this discussion.

The CSA uses the concept of registration as the primary means by which manufacturers, distributors, and practitioners are given legal authority to handle controlled substances. Registration also serves as the primary incentive for compliance with the regulatory requirements of the CSA and DEA regulations, as Congress gave DEA authority under the Act to revoke and suspend registrations for failure to comply with these requirements. (Depending on the circumstances, failure to comply with the regulatory requirements might also provide the basis for criminal or civil action under the CSA.)

[1] See National Institute on Drug Abuse Research Report: Prescription Drug Abuse and Addiction (revised August 2005), available at www.drugabuse.gov/PDF/RRPrescription.pdf

ATTACHMENT 1

[2] 21 U.S.C. 801(2)

Before taking an action to revoke a registration, DEA must serve the registrant an order to show cause, which advises the registrant of its right to an administrative hearing before the agency (21 U.S.C 824(c)). The CSA also gives DEA discretionary authority to suspend any registration simultaneously with the initiation of revocation proceedings in cases where the agency finds there is an imminent danger to the public health and safety (21 U.S.C. 824(d)).

DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion. Moreover, all registrants - manufacturers, distributors, pharmacies, and practitioners - share responsibility for maintaining appropriate safeguards against diversion. Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm. Accordingly, DEA will use its authority to revoke and suspend registrations in appropriate cases.

The statutory factors DEA must consider in deciding whether to revoke a distributor's registration are set forth in 21 U.S.C. 823(e). Listed first among these factors is the duty of distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. In addition, distributors must comply with applicable state and local law. Congress also gave DEA authority under this provision to revoke a registration based on the distributor's past experience in the distribution of controlled substances and based on "such other factors as may be relevant to and consistent with the public health and safety."

The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

It bears emphasis that the foregoing reporting requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.

Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.

In a similar vein, given the requirement under section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

In addition, distributors are required to file reports of distributions of certain controlled substances to the DEA ARCOS Unit, in the time and manner specified in the regulations (21 C.F.R. 1304.33). The failure to file ARCOS reports in a complete and timely manner is a potential statutory basis for revocation under section 823(e). Depending on the circumstances, the failure to keep or furnish required records might also be the basis for civil fines or criminal penalties under the CSA, as provided in 21 U.S.C. 842.

Circumstances That Might Be Indicative of Diversion

DEA investigations have revealed that certain pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose often display one or more of the following characteristics in their pattern of ordering controlled substances:

1. Ordering excessive quantities of a limited variety of controlled substances (e.g. , ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any, other drugs

2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered

3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs

4. Ordering the same controlled substance from multiple distributors

A distributor seeking to determine whether a suspicious order is indicative of diversion of controlled substances to other than legitimate medical channels may wish to inquire with the ordering pharmacy about the following:

1. What percentage of the pharmacy's business does dispensing controlled substances constitute?

2. Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?

3. Is the pharmacy soliciting buyers of controlled substances via the Internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?

4. Does the pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?

5. Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?

6. Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?

7. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?

8. Does the pharmacy offer to sell controlled substances without a prescription?

9. Does the pharmacy charge reasonable prices for controlled substances?

10. Does the pharmacy accept insurance payment for purchases of controlled substances made via the Internet?

These questions are not all-inclusive; nor will the answer to any of these questions necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).

We look forward to continuing to work in cooperation with distributors toward our mutual goal of preventing the diversion of pharmaceutical controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

EXHIBIT B

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

CARDINAL HEALTH
2045 INTERSTATE DRIVE
LAKELAND FL, 33805-0000

December 27, 2007

In reference to registration
RC0182080

Dear Registrant:

This letter is being sent to every entity in the United States registered with the Drug Enforcement Administration (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).

In addition to, and not in lieu of, the general requirement under 21 USC 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Title 21 CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

ATTACHMENT 2

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

For additional information regarding your obligation to report suspicious orders pursuant to 21 CFR 1301.74(b), I refer you to the recent final order issued by the Deputy Administrator, DEA, in the matter of Southwood Pharmaceuticals Inc., 72 FR 36487 (2007). In addition to discussing the obligation to report suspicious orders when discovered by the registrant, and some criteria to use when determining whether an order is suspicious, the final order also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

EXHIBIT C

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA) INDUSTRY COMPLIANCE GUIDELINES: REPORTING SUSPICIOUS ORDERS AND PREVENTING DIVERSION OF CONTROLLED SUBSTANCES

Introduction

The U.S. healthcare supply chain is one of the most sophisticated in the world, providing a strong system for the safe and efficient delivery of medicines. Manufacturers, distributors, pharmacies and healthcare practitioners share a mission and responsibility to continuously monitor, protect and enhance the safety and security of this system to combat increasingly sophisticated criminals who attempt to breach the security of the legitimate supply chain.

The *HDMA Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,* have been developed as part of HDMA member distributors' ongoing commitment to the safe and efficient distribution of all prescription medicines including controlled substances. These Industry Compliance Guidelines are consistent with, and further extend, the distributors' track record of supporting and implementing initiatives designed to improve the safety, security and integrity of the medicine supply. They have been prepared in recognition of a growing problem of misuse and diversion of Controlled Substances (CS) and the critical role of each member of the supply chain in helping to enhance security.

At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers. Due diligence can provide a greater level of assurance that those who purchase CS from distributors intend to dispense them for legally acceptable purposes. Such due diligence can reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach.

These Industry Compliance Guidelines can help identify facts and information about controlled substance product orders, and the customers placing the orders.

History

In 1970, Congress enacted into law the Controlled Substances Act (CSA) as part of Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The CSA provides the Drug Enforcement Administration (DEA) within the Department of Justice (DOJ) with the authority to regulate the manufacture, importation, possession and distribution of certain drugs. An additional federal agency, the Food and Drug Administration (FDA), and individual states, regulate many other aspects of drug supply chain safety and security. The CSA also created a closed system of distribution for those authorized to handle CS. Since its enactment in 1970, the CSA has been amended several times, including by the following statutes:

- The Psychotropic Substances Act of 1978;
- The Controlled Substances Penalties Amendments Act of 1984;
- The Chemical Diversion and Trafficking Act of 1988;
- The Domestic Chemical Diversion and Control Act of 1993;
- The Federal Analog Act; and
- The Methamphetamine Precursor Control Act which was superseded by the Combat Methamphetamine Epidemic Act of 2005.

The regulations in Title 21, Code of Federal Regulations (C.F.R.) part 1300 to 1316 apply to all individuals and firms desiring to conduct business in CS. All such individuals and firms must be registered with DEA, and are required to maintain complete and accurate inventories and records of all transactions involving CS, as well as security for the storage of controlled substances. Additionally, Sections 823(b) and (d) of the CSA call for the maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels.

In addition, distributors are required by 21 C.F.R. § 1301.74(b) to report suspicious orders of CS:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. [Emphasis added.]

Distribution Industry Commitment to Prevent Diversion of CS

Although distributors have been required to identify and report "suspicious orders" of CS and listed chemicals, increasing concerns about the potential misuse of prescription CS have elevated awareness within the supply chain and have led to increased expectations by DEA. Therefore, HDMA developed these Industry Compliance Guidelines to further scrutinize purchase orders for these products. For example, in public statements to Congressional Committees, DEA has noted

the growing problem of diversion and abuse of controlled pharmaceuticals, and has indicated the agency is taking stronger measures to address this matter.[1]

With the strong endorsement and expertise of our members, the Healthcare Distribution Management Association (HDMA) has developed the following Industry Compliance Guidelines for preventing diversion and reporting suspicious orders. We believe that implementation of these guidelines will help ensure that CS are appropriately distributed to supply chain customers involved in the legitimate dispensing of these important pharmaceutical products to patients, and will help distributors identify possible diversion activities.

OUTLINE

The *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, contains the following elements:

I. Know Your Customer Due Diligence
II. Monitoring for Suspicious Orders
III. Suspend/Stop an Order of Interest Shipment
IV. Investigation of Orders of Interest
V. File Suspicious Order Reports With DEA
VI. Employees, Training and Standard Operating Procedures (SOPs)
VII. Additional Recommendations
Glossary of Abbreviations

[1] See testimony provided by Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration; December 13, 2005, July 26, 2006, September 18, 2007, and June 24, 2008; and by Michele M. Leonhart, Acting Administrator, Drug Enforcement Administration, United States Department of Justice, March 12, 2008.

I. KNOW YOUR CUSTOMER DUE DILIGENCE

a. Introduction

Before opening an account for a new customer, the distributor should (i) obtain background information on the customer and the customer's business; (ii) review that information carefully, and, where appropriate, verify the information; and (iii) independently investigate the potential customer. To help ensure that the Industry Compliance Guidelines remain robust and adaptable, the "Know Your Customer Due Diligence" phase also describes "Additional Recommendations and Documentation" containing further suggestions for managing the distributor's procedures.

A distributor may tailor this part of its customer evaluation procedure to the type of customer under review. If a distributor does so, it is recommended that the distributor categorize each potential customer according to the customer's DEA "Business Activity" type as indicated on the customer's DEA registration certificate; for example, Retail Pharmacy, Hospital/Clinic, Practitioner or Distributor.

The following steps are recommended.

b. Information Gathering

All information requested by a distributor should be provided by the owner of the potential customer, the pharmacist in charge; or, in the case of a non-pharmacy customer, an equivalent designee. Each completed application, questionnaire or other document providing information requested by the distributor from the potential customer should be signed by the potential customer's owner, pharmacist in charge or equivalent designee. The signature should be notarized or should be accompanied by the statement: "*I declare under penalty of perjury that the foregoing is true and correct. Executed on [date].*"

The information gathering step would include:

- Provide potential customer with a credit application;
- Provide potential customer with a background questionnaire requesting the following information:
  - Business background,
  - Customer base,
  - Average number of prescriptions filled each day,
  - Average number of CS item prescriptions filled each day,
  - Percentage of CS purchases compared to overall purchases,
  - Verification of physical security controls for CS storage,
  - Questions based on DEA guidance and communications,
  - Copies of all their state and federal licenses and registrations,
  - If the potential customer is not currently conducting Internet prescription fulfillment, certification that they are not doing so, and will notify the distributor before conducting Internet prescription fulfillment;

- If the potential customer is conducting Internet prescription fulfillment, obtain the following information from any potential customer utilizing the Internet to receive and fill prescriptions:
  - The date the potential customer began conducting Internet prescription fulfillment,
  - Products the potential customer expects to purchase,
  - The quantity of each product the potential customer expects to purchase,
  - Practitioners who will be writing prescriptions that will be filled by the potential customer, including each practitioner's DEA and state registration and license numbers, address, telephone number(s), and other relevant contact information, and
  - National Association of Boards of Pharmacy (NABP) Verified Internet Pharmacy Practice Sites (NABP VIPPS) check.
- Names of individuals authorized to sign DEA Form 222[2],
- A description of how the pharmacy/dispenser fulfills its corresponding responsibility to ensure that the prescriptions they receive are issued for a legitimate medical purpose (as required in 21 C.F.R. § 1306.04),
- Inspections:
  - Indicate whether DEA has audited/inspected the pharmacy/dispenser over a period of at least the last two (2) years and if so, explain why,
  - Indicate whether the pharmacy/dispenser has been inspected by the state regulatory/inspection authority such as the State Board of Pharmacy, and
- Identification of physicians and other treatment centers that are the potential customer's most frequent prescribers or highest purchasing doctors.

c. Information Review

After the information is received from the potential customer, it should be reviewed thoroughly. The review should include the following steps:

- Verify that the credit application is complete, and carefully review the information submitted;
- Verify that the customer background information supplied is complete, and carefully review the information submitted;
- Verify that the answers to the questions based on DEA guidance and communications are complete, and carefully review the information contained; and
- Verify the potential customer's state and federal licenses, registrations and CS schedule authorizations.

[2] See: 21 C.F.R. § 1301 regarding *"Orders for Schedule I and II Controlled Substances"* for DEA's regulations for ordering these products by means of either DEA Form 222 or electronically, including signature requirements.

d. Independent Investigation

The distributor should independently investigate the potential customer as follows:

- Check with the distributor's local DEA office for any information regarding the potential customer, such as DEA actions against the potential customer[3];
- Check with state oversight authorities, including the state Board of Pharmacy (for a potential pharmacy customer) and Board of Medicine (for a potential physician customer) to request further background information, such as state actions against the potential customer (some states may provide readily accessible information through the state's Web site);
- Check the DEA Web site and the Federal Register for any actions against the potential customer; and
- Conduct an Internet search to determine whether any potential Internet business can be identified as relating to the potential customer and whether there is any other relevant information that could affect the decision to do business with the potential customer.

e. Additional Recommendations and Documentation

It is recommended that:

- Individuals selected to develop questionnaires for part (a) and to conduct reviews and investigations under parts (b) and (c) above should receive appropriate training.
- The distributor should update the questionnaire(s) periodically, particularly if a concern arises during an investigation.
- The performance and results of all steps in the customer review process should be fully documented as to each potential customer, and such documentation should be retained in an appropriate file.
- After completing the steps outlined above, the reviewer of the potential customer should sign and date the information (in a designated location of the file) to indicate that the reviewer has conducted a thorough/complete review, and that the information contained in the file is accurate and complete to the best of his/her knowledge.
- A distributor may seek further information about a potential customer, including when the distributor determines that obtaining further background information, confirmation, or verification is warranted.
- The distributor may include provisions for notification of state and federal authorities of an unlawful activity identified under the "Know Your Customer Due Diligence" as required by local, state or federal law.

[3] Depending on the direction received from the local DEA office, the distributor may consider contacting the potential customer's local DEA office for further information regarding the potential customer.

II. MONITORING FOR SUSPICIOUS ORDERS

a. System Design

It is recommended that a distributor develop an electronic system, with accompanying written Standard Operating Procedures (SOPs), to meet the DEA's requirement in section 1301.74(b) that a distributor "design and operate a system to disclose to the registrant suspicious orders of controlled substances" (emphasis added). Distributors should assign responsibilities for identifying and investigating potentially suspicious orders, and for reporting suspicious orders. Specific elements of the monitoring system are further described below.

b. Identify Product and Customer Characteristics

Separate/classify/group customers into appropriate/different classes of trade. For example, retail pharmacies, hospitals, doctors, or dentists.

Separate the CS the distributor sells into groups or "families" of drugs (e.g., all CS items containing codeine). The following information may be useful for identifying the "families" of drugs:

- A distributor may use the DEA Web site to obtain DEA's designation of a drug's "controlled substance code number" to aid in developing a drug "family" for purposes of defining a threshold.[4]
  - (See: http://www.deadiversion.usdoj.gov/schedules/schedules.htm or http://www.usdoj.gov/dea/pubs/scheduling.html)
- Distributors may also use the National Technical Information Service (NTIS) system, which (i) identifies each individual CS Stock Keeping Unit (SKU) by National Drug Code (NDC) number, (ii) lists the active ingredient and (iii) lists the corresponding DEA controlled substance code number. The DEA controlled substance code number is set up by NDC number. An electronic copy of this information may be used to help identify the drug "families."
- Alternatively, a distributor may choose to identify "families" of drugs and track the dosage unit (e.g., tablet) order levels for each SKU.[5]
- A distributor should maintain contact with DEA through the local field office or the Office of Diversion Control's Web site, www.deadiversion.usdoj.gov, to ascertain changes in diversion patterns or new "Drugs of Concern" as the information is developed by the agency. Such new information should be made part of the identification of particular CS drugs or "families" to be monitored, as appropriate.

[4] For further information on the controlled substance code numbers, see 21 C.F.R. § 1308.03.
[5] This method may present implementation challenges due to of the different strengths of the drugs.

c. Develop "Thresholds" to Identify Orders of Interest

"Thresholds" for identifying orders of interest, *i.e.*, orders that warrant follow-up inquiry to determine whether they are suspicious, may be made by using averages shipped to a particular customer facility that are consistent with the class of customers to which the particular customer belongs. It is recommended that distributors develop such thresholds by calculating the average single order and the average monthly order per "family," per customer, and class of trade.

When evaluating thresholds, orders of "unusual size" and "unusual frequency" can be used to signal that an order may need further review. Distributors are also encouraged to structure their thresholds to support evaluation of whether the order deviates substantially from a normal pattern and/or is of unusual frequency. The following examples may aid in developing the thresholds:

- Patterns of ordering such as comparing the present order to:
  - past orders from the same customer (including the frequency of orders),
  - orders for extraordinary quantities outside of normal purchasing patterns typically followed by the customer or by other customers within the same class of trade, and
  - geographical area(s) of the country they service (e.g., orders from other establishments of the same type in the locale or region),
- Orders of more than one controlled substance that are known to be taken together (combinations) outside of normal prescribing and patient treatment practices, and
- DEA/State input.

Distributors are also encouraged to consider the following when developing "thresholds":

- Quantities of products the dispenser initially indicated during the "Know Your Customer Due Diligence" phase that it expected to purchase;
- A minimum of six months sales history and a maximum of 24 months sales history are recommended; Maintain contact with DEA through the local field office or the Office of Diversion Control's Web site, www.deadiversion.usdoj.gov, to ascertain changes in diversion patterns or emerging local or regional concerns; such new information may be used to adjust thresholds as appropriate; and
- Thresholds for all new customer accounts should be established at the lowest level indicated by information obtained during the "Know Your Customer Due Diligence" review.

d. Cumulative Reviews/Thresholds

A very important component of the system will be to include a mechanism for periodic review of cumulative orders from the same customer over time, to evaluate trends in purchasing patterns. This would include, for example,

- A mechanism to compare percentages of orders for CS (individual products and/or "families") to orders of non-CS prescription drugs so as to identify a shift in a customer's business focus that may warrant further review.

- Determining if the purchaser's ordering pattern, for a period of several months, shifts in a manner inconsistent with their previous ordering patterns or inconsistent with the class of trade for that customer (e.g., a pharmacy that orders relatively few controlled substances over several months suddenly places a large order or several large orders in a concentrated period of time.)

e. Supplemental Mechanisms for Determining Orders of Interest

Distributors are encouraged to recognize that their methods for identifying an "Order of Interest" do not need to be limited to an electronic "threshold" system. Based on the distributors' knowledge of his/her customers, overall drug purchasing trends, information available from DEA and elsewhere, distributors are encouraged to allow for alternative criteria, in addition to those incorporated into the electronic system, to serve as indicators of an order of interest.

III. SUSPEND/STOP AN ORDER OF INTEREST SHIPMENT

If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.

Ideally, the electronic system would contain a process to automatically "block" the order or otherwise stop the ordered product from being shipped. The distributor may, however, ship any non-CS included in the order and any other CS products as to which the order did not exceed a threshold or otherwise become characterized as an order of interest. A distributor may choose to report an order of interest to DEA immediately as a suspicious order or may first investigate the order as described in Section IV below and report it at the conclusion of the investigation if, but only if, it is determined to be a suspicious order.

IV. INVESTIGATION OF ORDERS OF INTEREST

a. Preliminary Steps

If a product order meets or exceeds a threshold, and is thereby identified as an order of interest (or on other grounds is characterized as an order of interest), it is recommended that the distributor examine the order further. The examination is intended to aid the distributor in reaching a decision to either ship product to fill the order or to continue to hold the order. Further examination will also aid in determining whether and when to report the order to DEA under 21 C.F.R. § 1301.74(b).

The drug or drugs that cause an order to become an order of interest should not be shipped to the customer placing the order while the order is an order of interest.

It is recommended that the distributor designate a person with suitable training and experience to investigate orders of interest.

b. Initial Review

When initially reviewing an order of interest, a distributor should first examine the specific drug code product order to determine whether the reasons the order met or exceeded the thresholds, or on other grounds was characterized as an order of interest, are not "suspicious" or whether the order warrants still further examination. The examination may include obtaining additional verification from the customer that placed the order. For example, the customer may be able to identify whether the order contained an error, or whether there has been a change in the customer's business circumstances that warrants a shift in its purchasing practices that can be readily identified.

c. Investigating the Order

If, after initial review, it is determined that the order should be examined further, it is recommended that the distributor conduct an additional review as quickly as possible. The following elements are recommended as part of the additional review:

Review prior orders
The distributor should review the customer's past purchasing history for trends/discrepancies to determine whether:

- The distributor had to investigate a prior order and the circumstance and results of any prior investigation, including whether a prior order exceeded the same or a different threshold, and how the present order compares to the past order(s) of interest;
- There has been an increase (or decrease) in orders for this "group" or "family" of CS products;
- There has been other unusual activity, such as "spikes" in prior orders (e.g., a pattern of ordering over several months where the customer has placed no orders, followed by a month with a large order);
- There has been a decrease in orders for other products, (potentially indicating a shift in focus or customer base);
- There has been a change in the customer's operating environment (e.g., a new medical establishment recently opened in the customer's neighborhood);
- There has been a change in availability of drugs (such as a new drug dosage form that has recently been approved by FDA) identified as a Drug of Concern by DEA's Office of Diversion Control; and
- There are end-of-year C-II quota issues.

Interview customer
Ask: Why is there an "unusual" order? What will you do with it? Who is prescribing it? (Who, what, when, where, why, how?)

Verify customer input – (where appropriate)
How and what information provided by the customer needs to be verified will be determined on a case-by-case basis, but examples of information that could be verified include:

- If a customer says there is a new medical establishment located nearby, verify the establishment's existence, name, address, practitioner(s) names and DEA registration numbers.
- If the customer says it called DEA, verify that it actually did so.
- If the customer states that a natural disaster destroyed its pharmacy and that it must restock, verify the disaster.
- If the customer claims it "lost" a shipment, verify the loss[6].

Additional Information
The distributor may seek additional information about the order and/or the customer who placed the order if, during the examination, it is determined that further confirmations or background information is warranted.

d. Documentation

All investigations should be fully documented, and all records of the investigation should be retained in an appropriate location within the firm (such as with other records relating to the particular customer).

At a minimum, documentation should include the name(s), titles(s) and other relevant identification of the representative of the customer contacted (e.g., "pharmacist in charge"), dates of contact, and a full description of questions asked and requests for information made by the distributor and of information provided by the customer. The documentation should include a clear statement of the final conclusion of the investigation, including why the order investigated was (or was not) determined to be "suspicious." That statement should be signed and dated by the reviewer. Copies of any written information provided by the customer should also be retained as part of the documentation of the investigation.

e. Shipment and Reporting Decisions (under 21 C.F.R. § 1301.74(b)); SOPs

At an appropriate point in the examination process, the distributor will decide how to resolve the order, specifically, whether the order is "suspicious," and should be reported. Employees should be selected and authorized to make shipment and reporting decisions based on their knowledge of DEA requirements, the distributor's business, customers and other relevant factors. (Further recommendations as to reporting to DEA can be found in Section V below.)

Orders that are determined to be "suspicious" should be reported to DEA under § 1301.74(b) immediately upon being so determined. It is assumed that the order will continue to be placed on

[6] Distributors should also determine whether there is an obligation to report the loss under 21 C.F.R. § 1301.76(b).

hold and/or cancelled, once it has been identified as "suspicious." An exception can be made if the distributor subsequently obtains additional or alternative information that leads to the conclusion that the order was misidentified as "suspicious," and/or is consistent with the pharmacy/dispenser's practice. In such instances, the order may be shipped. Full documentation of the reasons for the conclusion is recommended.

Each distributor is encouraged to develop SOPs that:

- Describe how an initial review and investigation will be conducted;
- Reflect the distributor's and its customers' business conditions;
- Are sufficiently flexible to adjust the review/investigation to address the individual product/order/customer circumstances that are likely to occur;
- Include a process and/or guidance/criteria for making the final determination that an order is, or is not, "suspicious";
- Define a process for reporting to DEA under 21 C.F.R. § 1301.74(b); and
- Define a process for allowing release of a shipment, or cancellation of an order, as appropriate.

f. Future Customer Orders

In instances where a distributor concludes that an order is (or remains) "suspicious" after conducting an investigation, in addition to notifying DEA, it is recommended that the distributor evaluate its business relationship with the customer that placed the order. The distributor may consider whether to subject future orders from the same customer for the same drug code product (or all CS) to more rigorous scrutiny than was applied before the determination that the order is suspicious. A distributor may also consider whether to cease filling all future orders of the drug code product (or all CS) placed by that customer.

V. FILE SUSPCIOUS ORDER REPORTS WITH DEA

a. Immediate DEA Notification

Under 21 C.F.R. § 1301.74(b), orders designated as "suspicious" must be reported to DEA "when discovered." Once the distributor has made the determination that an order is suspicious, a phone call to report the order to the local DEA office is recommended to meet this requirement (unless DEA provides other direction). The distributor should provide additional documentation to DEA upon request.

Additional considerations:

- Even if there is some ambiguity regarding a customer or an order's status, occasions may arise when the intended use of an order is questionable. For example, the distributor may identify information that leads them to believe that a potential customer, prior to entering a formal business arrangement with that customer, may

intend to order CS products with a frequency, volume or other indicator that could be considered "suspicious." In such instances, the distributor should provide DEA with a report of this information under 21 C.F.R. § 1301.74(b).

- Distributors are strongly encouraged to regard timeliness of reporting to DEA as a critical component in meeting the requirement to report "when discovered."

b. Correspondence for Reporting

It is recommended that all correspondence to DEA (containing reports of suspicious orders) should be sent registered mail with a return receipt requested, by electronic mail or by another system that creates for the distributor a permanent record that DEA has received the notification. Although correspondence to the local DEA office is encouraged as a follow-up to a telephonic notification, distributors are encouraged to discuss with the local DEA office whether that office prefers to receive a follow-up written notice and the form for such notice.

The cover letter for reports of suspicious orders may read: "This report is submitted to you in accordance with the requirements of 21 C.F.R. § 1301.74(b) and is for (company name)." When the return receipt is received, it should be stapled to the cover letter as proof of submittal. (It is suggested that the distributor title the report "21 C.F.R. § 1301.74(b)" report.)

In some states, additional reporting requirements may apply. Each distributor should determine whether a state report is required, and should comply accordingly.

It is recommended that the same person conduct the investigation, decide (perhaps in consultation with one or more superiors) whether or not to cancel the order, and also provide the report to DEA.

c. Documentation

All additional contact with DEA, either by telephone or in person, should be documented; and a record of the contact should be maintained.

VI. EMPLOYEES, TRAINING AND STANDARD OPERATING PROCEDURES

a. Employees/Training

Individuals working in CS areas should be screened and selected for their attention to detail, ability to recognize the importance of accuracy, length of tenure with the company and work ethic.

It is recommended that employee training:

- Include a review of DEA rules and regulations;
- Fully cover the firm's procedures for compliance;

- Include backup training to cover instances when the employee primarily responsible for monitoring for suspicious orders will not be available (e.g., due to vacation leave or sick leave); and
- Provide for periodic retraining.

It is recommended that training be conducted for all personnel involved in:

- Receiving, shipping, handling and record-keeping with respect to CS items;
- Sales, or in establishing new accounts and persons who interact with customers; and
- Reviewing, investigating and/or deciding whether to fill orders.

All such training should be documented, and the documentation should be maintained.

b. SOPs

It is recommended that, to implement these Industry Compliance Guidelines, specific written company SOPs be developed and maintained.

VII. ADDITIONAL RECOMMENDATIONS

It is recommended that a distributor include in its "system" provisions for:

- Periodic internal audits of suspicious orders, compliance procedures and results;
- Periodic reviews and revisions of internal SOPs for compliance with §§ 1301.71(a) and 1301.74(b) and new DEA guidance, as well as employee training requirements/procedures;
- Periodic review of the distributor's system for monitoring for suspicious orders, including the system design and the thresholds, to determine whether revisions should be developed. For example, if the FDA approves a new controlled substance, or a new indication for use of an existing controlled substance, or if DEA makes new information available regarding a Drug of Concern, revisions to the thresholds may be needed; and
- If appropriate, update customer and/or order records on the basis of information obtained while investigating an order under Section IV above.

Glossary of Abbreviations

	Abbreviation	Explanation of Term
	ARCOS	Automation of Reports and Consolidated Orders System
	C.F.R.	Code of Federal Regulations
	C-I, C-II, C-III, C-IV, C-V	References the DEA's designation of individual controlled substances into one of the five levels under 21 C.F.R. §1308
	CS	Controlled Substances has the meaning given in section 802(6) of Title 21, United States Code (U.S.C.)
	CSA	Controlled Substances Act
	DEA	Drug Enforcement Administration
	DOJ	Department of Justice
	FDA	Food and Drug Administration
	HDMA	Healthcare Distribution Management Association
	NABP	National Association of Boards of Pharmacy
	NDC	National Drug Code
	NTIS	National Technical Information System
	SKU	Stock Keeping Unit
	VIPPS	Verified Internet Pharmacy Practice Sites

EXHIBIT D

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement and Release ("Settlement Agreement" or "Agreement") is entered into between the United States of America, acting through the United States Department of Justice ("DOJ"),[1] and on behalf of the Drug Enforcement Administration ("DEA") (collectively referred to herein as the "United States"), and McKesson Corporation ("McKesson").

II. RECITALS

A. McKesson is a corporation organized and existing under the laws of the State of Delaware. McKesson's corporate headquarters and principal place of business is located at One Post Street, San Francisco, California.

B. McKesson is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. McKesson distributes pharmaceuticals through a network of distribution centers located throughout the United States, including distribution centers located in the following areas: Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; La Crosse, Wisconsin; Lakeland, Florida; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California. McKesson formerly distributed pharmaceuticals through a distribution center located in Landover, Maryland, which closed in January 2012 (the "Landover Distribution Center"), and in La Vista, Nebraska, which closed in October 2016. A list of all McKesson U.S. Pharmaceutical distribution

[1] The Department of Justice is represented by the following 12 U.S. Attorney's Offices: Central District of California; Eastern District of California; District of Colorado; Middle District of Florida; Eastern District of Kentucky; Northern District of Illinois; District of Massachusetts; Eastern District of Michigan; District of Nebraska; District of New Jersey; Northern District of West Virginia; and Western District of Wisconsin.

centers that hold a DEA Certificate of Registration as of the Effective Date of this Agreement is attached hereto as Appendix A. Collectively, the distribution centers listed in Appendix A and the Landover Distribution Center are referred to herein as the "McKesson Distribution Centers."

C. At times relevant to this Agreement, the McKesson Distribution Centers were required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 *et seq.* (the "CSA" or the "Act"), and the regulations promulgated thereunder, 21 C.F.R. Part 1300 *et seq.*

D. The DEA is the DOJ component agency primarily responsible for administering the CSA and the regulations promulgated thereunder, and is vested with the responsibility of investigating CSA violations.

E. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA and the regulations promulgated thereunder. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

F. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. § 1301.74(b).

G. The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. § 1301.74(b). *See* 21 U.S.C. §§ 842(a)(5) and (c)(1)(B).

III. COVERED CONDUCT

The United States contends that it has certain civil claims against McKesson under 21 U.S.C. §§ 821, 823, 827, and 842(a)(5) for engaging in the following conduct (the "Covered Conduct") from January 1, 2009, through the Effective Date as that term is defined in Section

VI(F) (the "Covered Time Period"):

A. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations at McKesson Distribution Centers, including the following specific centers:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
La Crosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;
Washington Courthouse, Ohio; and
West Sacramento, California.

B. In 2008, McKesson entered into a settlement agreement with the DOJ and a Memorandum of Agreement with the DEA (collectively referred to herein as the "2008 Agreements") arising out of, among other things, McKesson's failure to report suspicious orders of controlled substances to the DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP") in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to the DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to the DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b).

C. McKesson failed to follow the procedures and policies set forth in the McKesson

CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP.

D. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of suspicious orders of controlled substances made by its customers during the Covered Time Period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. §1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements.

E. McKesson failed to report suspicious orders for controlled substances in accordance with the standards identified and outlined by the DEA in three letters from the DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including McKesson, on September 27, 2006, February 7, 2007, and December 27, 2007.

F. Certain McKesson Distribution Centers distributed controlled substances to pharmacies even though those Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

IV. ACCEPTANCE OF RESPONSIBILITY

A. On or about September 27, 2006, February 7, 2007, and December 27, 2007, DEA's

Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum. The Compliance Addendum is an attachment to the Administrative Memorandum of Agreement (the "2017 MOA") entered into by McKesson and DEA contemporaneously with this Agreement. The Compliance Addendum and the 2017 MOA are attached hereto as Appendix B.

B. On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided, among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its CSMP. McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to

prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

V. TERMS AND CONDITIONS

In consideration of the mutual promises, covenants, and obligations set forth in this Settlement Agreement, the United States and McKesson agree as follows:

A. McKesson shall pay the United States the sum of One Hundred Fifty Million Dollars ($150,000,000.00) (the "Settlement Amount") within five (5) business days of the Effective Date of this Settlement Agreement, by electronic funds transfer ("EFT") pursuant to written instructions to be provided by the United States.

B. In consideration of the fulfillment of the payment of the Settlement Amount, the United States agrees to:

1. Fully and finally release McKesson and all McKesson facilities, including McKesson subsidiary entities, affiliates, and registrants, (collectively, the "Released Parties") from any and all civil penalty claims under 21 U.S.C. § 842 that the United States could have asserted, or may assert in the future, against McKesson related to the Covered Conduct; and

2. Refrain from filing any action for civil penalty claims under 21 U.S.C. § 842 by any U.S. Attorney's Office and/or DOJ based on the Covered Conduct.

C. Nothing in this Settlement Agreement shall prohibit or limit any other agency within DOJ or any other law enforcement, administrative, or regulatory agency of the United States from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that has initiated or initiates an investigation, action, or proceeding involving the Covered Conduct, but will not otherwise initiate or refer any civil action to any U.S. Attorney's Office or to any

component of DOJ, based on the Covered Conduct.

D. McKesson fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the investigation and prosecution thereof by the United States.

E. Notwithstanding any term of this Settlement Agreement, specifically reserved and excluded from the scope and terms of this Settlement Agreement, and the releases set forth herein, as to any entity or person (including McKesson) are the following:

1. Any potential criminal liability;

2. Any civil, criminal, or administrative liability arising under Title 26, United States Code (the Internal Revenue Code);

3. Any civil or administrative liability to the United States for any conduct other than the Covered Conduct, as described in paragraph III(A)-(F); and

4. Any liability based upon any obligation created by or arising under this Settlement Agreement.

F. Contemporaneously with the execution of this Settlement Agreement, McKesson will enter into the 2017 MOA, which will resolve administrative claims that DEA has or may have against McKesson related to the Covered Conduct. *See* Appendix B. McKesson acknowledges that it is required to comply with the controlled substance record keeping and reporting requirements of the CSA. McKesson represents that it has taken, is taking, and will be taking further good faith actions to detect and prevent diversion. *See* Compliance Addendum attached hereto in Appendix B.

G. Nothing in this Settlement Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against McKesson for violations of the CSA, and regulations promulgated thereunder, unrelated to the Covered Conduct as described in Section III of this Settlement Agreement or which occur after the Effective Date of this Settlement Agreement.

H. McKesson agrees that any and all costs it has, will, or may incur in connection with this matter – including payment of the Settlement Amount under this Settlement Agreement, attorney's fees, costs of investigation, negotiation, future compliance efforts, and remedial action - shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

I. McKesson warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(l), and will remain solvent following its payment to the United States of the Settlement Amount. Furthermore, the Parties warrant that, in evaluating whether to execute this Settlement Agreement, they (a) intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to McKesson, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded that the mutual promises, covenants, and obligations set forth herein do, in fact, constitute such a contemporaneous exchange. In addition, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value which is not meant to hinder or delay payment to, or to

defraud any entity to which McKesson was or became indebted on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

J. If, within 91 days of the Effective Date of this Settlement Agreement or of any payment made hereunder, McKesson commences, or a third-party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (i) seeking to have any order for relief of McKesson's debts, or seeking to adjudicate McKesson as bankrupt or insolvent; or (ii) seeking appointment of a receiver, trustee, custodian, or other similar official for McKesson or for all or any substantial part of McKesson's assets, McKesson agrees as follows:

> 1. McKesson's obligations under this Settlement Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and McKesson will not argue or otherwise take the position in any such case, proceeding, or action that: (i) McKesson's obligations under this Settlement Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) McKesson was insolvent at the time this Settlement Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Settlement Agreement do not constitute a contemporaneous exchange for new value given to McKesson;
>
> 2. If McKesson's obligations under this Settlement Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Settlement Agreement, and bring any civil claims that would otherwise be covered by the release provided in Paragraph 2, above. McKesson agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that McKesson will not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) that McKesson will not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought

by the United States within 90 calendar days of written notification to McKesson that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of the Settlement Agreement; and (iii) the United States may pursue any and all claims it had as of July 1, 2014, in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding; and

3. McKesson acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided by and through this Settlement Agreement.

K. Each Party to this Settlement Agreement will bear its own legal expenses and other costs incurred in connection with this matter, including those for the preparation and performance of this Settlement Agreement.

L. This Settlement Agreement is intended to be for the benefit of the Parties only.

M. McKesson represents that this Settlement Agreement is freely and voluntarily entered into, without any degree of duress or compulsion whatsoever. McKesson also acknowledges that it was represented by legal counsel of its choosing throughout the negotiation and execution of this Settlement Agreement.

N. McKesson consents to the disclosure of this Settlement Agreement, information about this Settlement Agreement, and the settlement memorialized herein by the United States to the public.

O. Nothing in this Settlement Agreement constitutes an agreement by the United States concerning characterization of the Settlement Amount for purposes of Title 26 of the United States Code (Internal Revenue Code).

VI. GENERAL PROVISIONS

A. Governing Law: This Settlement Agreement is governed by the laws of the United States of America. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties regarding this Settlement Agreement and its terms shall be the United States District Court for the Northern District of West Virginia.

B. Headings: The section and paragraph headings in this Settlement Agreement are inserted solely for the convenience of the Parties and shall not be construed to be part of or in any way affect the substantive provisions of this Settlement Agreement.

C. Merger Clause: This Settlement Agreement, including Attachments, constitutes the complete agreement and understanding by and between the United States and McKesson with respect to the settlement of claims against McKesson arising out of the Covered Conduct and no promises, agreements, or understandings, written or oral, not contained herein shall be of any force or effect. This Settlement Agreement may be amended at any time by mutual consent of the parties hereto, with any such amendment to be invalid, unless in writing, signed by an authorized agent of McKesson and an authorized representative of the United States.

D. Counterparts: This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

E. Binding: This Settlement Agreement is binding on McKesson and its successors, transferees, and assigns.

F. Effective Date: This Settlement Agreement shall be effective when the last signatory to this Settlement Agreement executes the Agreement.

G. Drafting: For purposes of construing this Settlement Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

H. Authority to Sign: Each person who signs this Settlement Agreement in a representative capacity warrants that he or she is fully authorized to do so. The government signatories represent that they are signing this Settlement Agreement in their official capacities.

IN WITNESS WHEREOF, the United States and McKesson have duly executed this Settlement Agreement with the intent to be bound by the terms, conditions, and representations herein.

THE UNITED STATES OF AMERICA

Dated: 12/30/2016

William J. Ihlenfeld, II
U.S. Attorney
Northern District of West Virginia

Dated: 1/17/17

Robert C. Troyer
Acting U.S. Attorney
District of Colorado

THE UNITED STATES OF AMERICA

Dated: 01/05/17

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: _____

_____
Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: 1/5/2017

_____
John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

_____
Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

_____
Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

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Dated: 01-05-17

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Eastern District of Michigan

Dated: _____

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U.S. Attorney
Eastern District of Kentucky

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U.S. Attorney
Northern District of Illinois

Dated: _____

_____
John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

_____
Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: 1-6-17

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: 1/4/17

Deborah R. Gilg
U.S. Attorney
District of Nebraska

Dated: _____

Phillip A. Talbert
U.S. Attorney
Eastern District of California

Dated: _____

Carmen M. Ortiz
U.S. Attorney
District of Massachusetts

Dated: _____

Paul J. Fishman
U.S. Attorney
District of New Jersey

THE UNITED STATES OF AMERICA

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District of Nebraska

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THE UNITED STATES OF AMERICA

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Eastern District of California

Dated: _____

Carmen M. Ortiz
U.S. Attorney
District of Massachusetts

Dated: 1/4/17

Paul J. Fishman
U.S. Attorney
District of New Jersey

THE UNITED STATES OF AMERICA

Dated: 1-3-17

A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: _____

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: _____

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

THE UNITED STATES OF AMERICA

Dated: _____

_____
A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: 1/5/17

_____
Eileen M. Decker
U.S. Attorney
Central District of California

Dated: _____

_____
Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

THE UNITED STATES OF AMERICA

Dated: _____

A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: _____

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: 1/5/17

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

McKESSON CORPORATION

Dated: 1/5/17

Lori A. Scheckter
Executive Vice President, General Counsel and
Chief Compliance Officer for
McKesson Corporation

Dated: 1/5/17

Geoffrey E. Hobart
Covington & Burling LLP
Counsel for McKesson Corporation

EXHIBIT E

SETTLEMENT AND RELEASE AGREEMENT AND ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Settlement and Release Agreement and Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and Cardinal Health, Inc., for itself and on behalf of its subsidiary entities which hold the registrations listed in Appendix A to this Agreement (collectively "Cardinal") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to Cardinal and all Cardinal DEA registered facilities identified in Appendix A.

BACKGROUND

1. Cardinal is registered with DEA at 27 facilities as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 et seq., ("CSA" of "the Act"). See Appendix A.

2. On November 28, 2007, the DEA, by its Deputy Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal, with respect to its distribution facility located at 801 C Street NW, Suite B, Auburn, Washington 98001 ("Auburn Facility"). See Appendix B.

3. On December 5, 2007, the DEA, by its Deputy Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal, with respect to its distribution facility located at 2045 Interstate Drive, Lakeland, Florida 33805 ("Lakeland Facility"). See Appendix C.

4. On December 7, 2007, the DEA, by its Deputy Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal, with respect to its distribution facility located at 1120 Commerce Boulevard, Swedesboro, New Jersey 08085 ("Swedesboro Facility"). See Appendix D.

5. On January 30, 2008, the DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued an Order to Show Cause to Cardinal, with respect to its distribution facility located at 13651 Dublin Court, Stafford, Texas 77477 ("Stafford Facility"). See Appendix E.

6. The Orders to Show Cause referenced above alleged, among other things, that Cardinal failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels as evidenced by sales to certain customers of Cardinal.

7. DEA also alleges that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located at the following addresses:

a. 500 Jerry Steele Lane, McDonough, Georgia 30253 ("McDonough Facility").

b. 27680 Avenue Mentry, Valencia, California 91355 ("Valencia Facility").

c. 4875 Florence Street, Denver, Colorado 80238 ("Denver Facility").

8. DEA alleges that Cardinal failed to report suspicious orders of controlled substances as more fully set forth in Appendix F, Paragraph 8 as required by 21 C.F.R. § 1301.74(b) .

9. The Parties believe that the continued cooperation between the Parties to reduce the potential for diversion is in the public interest, including but not limited to sharing of information related to the distribution of controlled substances.

STIPULATION AND AGREEMENT

The facts alleged in the Orders to Show Cause and the facts alleged in paragraphs 7 and 8 above as otherwise summarized above, if proven at an administrative hearing, could constitute grounds for revoking the DEA registrations of the facilities referenced in paragraphs 2-5 and 7 above. In lieu of continuing proceedings to revoke the DEA registrations for the facilities referenced in paragraphs 2-5 and 7 above, Cardinal and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement in this administrative matter is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, all outstanding administrative claims and/or issues with respect to the alleged failure of Cardinal to detect and report suspicious orders and the alleged failure of Cardinal to maintain adequate controls against the diversion of controlled substances on or prior to September 30, 2008, including but not limited to the conduct described in the Orders to Show Cause, and all outstanding claims and or issues with respect to the allegations set forth in paragraphs 7 and 8 above. The parties further believe that the terms and conditions of this settlement as set forth below represent a complete, just, and equitable resolution of this administrative matter.

2. No Admission or Concession. This Agreement is neither an admission by Cardinal of liability or of the veracity of any allegation made by DEA in the Orders to Show Cause, this Agreement or any investigation, nor a concession by DEA that its allegations in the Orders to Show Cause and investigations are not well-founded.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:

a. the conduct alleged in the Orders to Show Cause (Appendices B-E);

b. the alleged failure of Cardinal to maintain adequate controls against the diversion of controlled substances, on or prior to September 30, 2008, at all distribution facilities listed in Appendix A operated, owned, or controlled by it;

c. the conduct described in Appendix F, Paragraph 8 to this Agreement; and

d. the alleged failure of Cardinal to detect and report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b) on or before September 30, 2008.

II. Terms and Conditions

1. Obligations of Cardinal.

a. Cardinal agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders that exceed established thresholds and criteria will be reviewed by a Cardinal employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should be not filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels. Orders identified as suspicious will be reported to the DEA as discussed in subsection II(1)(c). This compliance program shall apply to all current and future Cardinal distribution centers registered with the DEA in the United States and its territories and possessions. Cardinal acknowledges and agrees that the obligations undertaken in this subparagraph do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.

b. On a monthly basis, Cardinal shall provide DEA Headquarters with a report of all sales transactions of controlled substances, carisoprodol, and tramadol through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. The data shall be due by the 15th of each month for the previous month's report. This information will be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for Cardinal's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5). Cardinal shall begin transmitting this information for all controlled substances no later than 90 days after the Parties have mutually agreed upon a format and as soon as practicable

for carisoprodol and tramadol. The obligations contained in this paragraph shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination of the obligations contained in this paragraph.

c. Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, Cardinal shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA agrees to notify all of the DEA Field Offices within 30 days of the Effective Date of this Agreement that Cardinal will no longer be required to provide suspicious order reports or any other type of report regarding excessive purchases of controlled substances to the DEA Field Offices and that this Agreement shall supersede any DEA regulatory requirements to report suspicious orders to DEA. The obligations contained in this paragraph shall be and remain in full force and effect from the Effective Date of this Agreement, and thereafter shall remain in full force and effect unless terminated and revoked by DEA with 30 days written notice.

d. Cardinal agrees to the continued suspension of its authority to handle controlled substances at its Lakeland, Auburn, and Swedesboro facilities until October 1, 2008, or until such time that the parties execute this Agreement and the Settlement Agreement at Appendix F, whichever is later.

e. Cardinal agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to Cardinal's obligations to detect and report suspicious orders in accordance with 21 C.F.R. §1301.74(b).

f. Cardinal agrees that within 180 days of the Effective Date of this Agreement it will review distributions of oxycodone, hydrocodone, alprazolam, and phentermine to retail pharmacy customers and physicians for the 18-month period immediately preceding the execution of this Agreement and identify any current customer whose purchases of oxycodone, hydrocodone, alprazolam, and phentermine exceeded the thresholds established in its compliance program on the date of such review. To the extent it has not otherwise done so, Cardinal shall conduct an investigation for each customer where such review reveals purchasing patterns substantially deviating from the normal purchasing patterns, and take appropriate action as required by this Agreement, DEA regulations and other procedures established under Cardinal's compliance program.

g. Cardinal's policy and procedure is to cooperate with the government in any investigation. Cardinal agrees to reasonably cooperate with DEA, the United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting Cardinal's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the

rights or obligations of Cardinal in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement authorities. However, nothing in this paragraph shall be construed as a waiver by Cardinal or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

h. Cardinal agrees to pay to the United States of America under 21 U.S.C. § 842(c) for violations of 21 U.S.C. § 842(a)(5) the amount of $34,000,000.00 in settlement of claims or potential claims for civil penalties made by the United States of America for failing to report suspicious orders of controlled substances. Payment of said amounts shall be made by Cardinal in the amounts indicated and as directed by the United States Attorneys' Offices set forth in Appendix F, Paragraph 13. Cardinal agrees to execute the Settlement Agreement at Appendix F simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said amounts within 30 days of the Effective Date of this Agreement.

i. Any material breach by any Cardinal facility of subsections II(1)(a)-(h) of this Agreement by Cardinal after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of Cardinal's DEA certificate(s) of registration for that facility.

2. Obligations of DEA.

a. At Cardinal's request, DEA shall provide diversion prevention and awareness training, as practicable, to retail pharmacy industry members and Cardinal employees at Cardinal trade shows, or at Cardinal internal training sessions, and through written materials. The frequency and content of such training shall be at DEA's sole discretion.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. §1301.74(b) and described in subsection II(1)(c) of this Agreement. DEA agrees that this procedure is consistent with DEA regulatory requirements and hereby waives the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Division Offices.

c. Within 150 days of the Effective Date of this Agreement, but not earlier than the later of 90 days after the Effective Date of this Agreement, or 30 days after the previously suspended distribution center re-commences distribution of controlled substances, DEA shall conduct reviews of the functionality of Cardinal's diversion compliance program ("Compliance Reviews") at up to seven Cardinal

distribution centers, consisting of the Auburn Facility; the Lakeland Facility; the Stafford Facility; the Swedesboro facility; and two other Cardinal distribution centers selected by DEA, as well as the Controlled Substance Anti-Diversion investigatory files and processes maintained at Cardinal's Dublin, Ohio headquarters. DEA shall also review the investigatory files maintained by Cardinal of the customers serviced by the distribution centers subject to the Compliance Reviews. DEA shall notify Cardinal no less than 48 hours prior to commencing a Compliance Review at a distribution center or at Cardinal's Dublin, Ohio headquarters. DEA shall issue a Notice of Inspection to Cardinal upon commencement of a Compliance Review. During the course of a Compliance Review, if requested, Cardinal shall provide DEA with information in a form reasonably agreed to related to the sales of controlled substances, non-controlled drugs, and listed chemicals from Effective Date of Agreement, to the date of the Compliance Review by the particular distribution center being reviewed. At the conclusion of each Compliance Review, DEA shall conduct an exit interview with an appropriate Cardinal representative to provide DEA's preliminary conclusions regarding the Compliance Review. The parties agree that, at Cardinal's option, Cardinal may be represented by counsel at such Compliance Reviews and that DEA shall neither object to nor limit the number of counsel present at such Compliance Reviews.

d. The Compliance Reviews will be deemed satisfactory unless DEA determines that one or more of the facilities being inspected has (i) failed to maintain effective controls against diversion regarding the distribution of any controlled substance; (ii) failed to detect and report to DEA suspicious orders of controlled substances; or (iii) failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances. The Compliance Reviews shall be deemed "not satisfactory" if DEA provides written notice with specificity to Cardinal on or before 165 days from the Effective Date of Agreement, stating that Cardinal failed to meet any of the requirements in either subsections II(2)(d)(i), (ii), or (iii) of this Agreement. DEA shall not find a Compliance Review "not satisfactory" unless the failure(s) are sufficient to provide DEA with a factual and legal basis for issuing an Order to Show Cause under 21 U.S.C. § 824(a) against one or more of the inspected facilities. In the event that DEA provides such written notice of a Compliance Review Failure(s), DEA shall meet and confer with Cardinal within 48 hours regarding such a finding. DEA shall consider remedial measures that Cardinal has instituted in determining whether the Compliance Reviews are satisfactory. A finding of "satisfactory" does not otherwise express DEA's approval of the compliance program implemented at any particular distribution center.

e. DEA shall execute this Agreement only upon obtaining a fully executed copy of the Settlement Agreement at Appendix F.

f. In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA

shall favorably consider Cardinal's entry into this Agreement; all actions taken by Cardinal pursuant to this Agreement; any remedial actions taken by Cardinal to address the alleged or perceived violative conduct; and the compliance history of Cardinal at the particular facility, and at other Cardinal facilities.

g. DEA represents that it has reviewed its records for investigations or inspections, initiated or conducted prior to September 30, 2008, which may allege that Cardinal failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA further represents that it has reviewed reports and records submitted by Cardinal to DEA on or before September 30, 2008, for indications that Cardinal may have failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA has not referred and agrees to not refer any conduct (other than conduct in Appendix F, Paragraph 8) occurring before September 30, 2008, for civil penalty proceedings under to 21 U.S.C. § 842(a)(5) that would be based on the Covered Conduct, to any other agency within the Department of Justice.

h. DEA represents that upon execution of this Agreement, Cardinal's pending application for renewals of the controlled substance registrations of the Auburn, Swedesboro, Lakeland, and Stafford facilities will be granted.

3. Joint Obligations of the Parties.

a. Cardinal and DEA agree that upon the execution of this Agreement, DEA and Cardinal shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against the Auburn, Lakeland, Swedesboro, and Stafford facilities.

4. Release by DEA. (i) In consideration of the fulfillment of the obligations of Cardinal under this Agreement, DEA agrees to:

a. Release Cardinal, together with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any administrative claims within DEA's enforcement authority for the conduct alleged in the Orders to Show Cause and this Agreement; and

b. Refrain from filing any administrative claims against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823, 824 and 842, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of September 30, 2008, and the review of the reports and records Cardinal submitted to DEA prior to September 30, 2008.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-covered conduct. Further,

nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof ("law enforcement agency"), from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any law enforcement agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At Cardinal's request, DEA agrees to disclose the terms of this Agreement to any other law enforcement agency and will represent that Cardinal's compliance with this Agreement adequately addressed the administrative and civil allegations raised by DEA as defined in the Covered Conduct. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

5. Release by Cardinal. Cardinal fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Cardinal has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Cardinal) are the following:

a. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct subject to Paragraph II.4 of this Agreement; or

c. Any liability based upon such obligations as are created by this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on Cardinal, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than

those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. Cardinal represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Cardinal further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify Cardinal immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices pursuant to paragraphs II(2)(c) and (d) of this Agreement to Cardinal shall be made in writing to the following individuals, which notice information may be altered from time to time by Cardinal providing written notification to DEA:

a. Mark Hartman, Senior Vice President, Supply Chain Integrity and Regulatory Operations, 7000 Cardinal Place, Dublin, Ohio 43017; fax: 614 757 6597; email: mark.hartman@cardinalhealth.com;
b. With copy to: Steve Falk, General Counsel – HSCS, 7000 Cardinal Place, Dublin, Ohio 43017, fax: 614 757 5051; email: steve.falk@cardinalhealth.com.

7. Disclosure. Cardinal and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.

8. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

9. Authorizations. The individuals signing this Agreement on behalf of Cardinal represent and warrant that they are authorized by Cardinal to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

10. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties under subsections II(2)(a-d) of this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Cardinal distribution facility(s) at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Settlement and Release Agreement as of the date written above.

On Behalf of Cardinal Health:

R. Kerry Clark
Chairman and Chief Executive Officer

Dated: 9/30/2008

Ivan K. Fong
Chief Legal Officer and Secretary

Dated: Sept. 30, 2008

John J. Carney, Esq.
Baker & Hostetler LLP
45 Rockefeller Plaza
11th Floor
New York, NY 10111
Counsel for Cardinal Health

Dated: 09-30-08

Jodi L. Avergun, Esq.
Cadwalader, Wickersham & Taft LLP
1201 F Street, NW
Washington, DC 20004
Counsel for Cardinal Health

Dated: 9/30/08

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

Michele M. Leonhart
Acting Administrator

Dated:

Wendy H. Goggin
Chief Counsel

Dated:

EXHIBIT F

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and Cardinal Health, Inc., ("Cardinal") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to Cardinal and all 28 Cardinal DEA registered distribution facilities.

BACKGROUND

1. Cardinal is registered with DEA at 28 facilities as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 et seq., ("CSA" or "the Act"). See Appendix A.

2. In September 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA"). See Appendix B.

3. Cardinal's Lakeland distribution facility ("Cardinal Lakeland") is registered with DEA as a distributor of Schedule II-V controlled substances at 2045 Interstate Drive, Lakeland, Florida 33805, with an expiration date of May 31, 2012.

4. On February 2, 2012, the DEA, by its Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal Lakeland. See Appendix C.

5. The Order to Show Cause referenced above alleged, among other things, that:

   a. Despite the 2008 MOA, Cardinal Lakeland failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels as evidenced by sales to certain customers of Cardinal;

   b. Cardinal Lakeland failed to report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b); and

   c. Cardinal Lakeland failed to conduct meaningful due diligence of its retail pharmacies, including its retail chain pharmacy customers to ensure that controlled substances were not diverted into other than legitimate channels.

STIPULATION AND AGREEMENT

The facts alleged in the Order to Show Cause, as well as the facts alleged in the Government's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D, constitute grounds under which DEA could revoke the DEA registration of Cardinal Lakeland. Cardinal admits that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate. In lieu of continuing proceedings to revoke the DEA registration of Cardinal Lakeland, Cardinal and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement in this administrative matter is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters involving the conduct described in the Order to Show Cause, as well as DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D. The parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this administrative matter.

2. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:

a. Conduct alleged in the February 2, 2012 Order to Show Cause ("Order to Show Cause"), and in DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D;

b. Failure to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted into other than legitimate channels, including failing to conduct site visits of its retail pharmacy chain customers on or before May 14, 2012;

c. Failure to detect and report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b) on or before May 14, 2012; and

d. Failure to adhere to the provisions of the 2008 MOA, on or before May 14, 2012.

3. Effect of 2008 MOA. The obligations contained in the 2008 MOA are superseded by the obligations contained within this Agreement.

4. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II. Terms and Conditions

1. Obligations of Cardinal.

   a. Cardinal agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders identified as suspicious will be reported to the DEA as discussed in subsection II.1.f. This compliance program shall apply to all current and future Cardinal distribution centers registered with the DEA in the United States and its territories and possessions. Cardinal acknowledges and agrees that the obligations undertaken in this Agreement do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.

   b. Within 120 days of the Effective Date of this Agreement, for all states, excluding Florida, Cardinal will commence procedures to ensure that any pharmacy, chain or retail, placing orders of controlled substances that are known to be diverted, or should be known to be diverted, at the time of the orders that Cardinal knows or should know are suspicious in nature, given the totality of the circumstances, will receive a site visit or an anonymous site inspection by a Cardinal employee or a qualified third-party inspector to provide an independent assessment of whether that customer's orders are being diverted. For Florida pharmacies, retail and chain, Cardinal, within 20 days of the Effective Date of this Agreement, will commence these site visit procedures. Cardinal will also employ additional field inspectors to perform investigations of Florida pharmacies.

      Cardinal will review and enhance its Quality and Regulatory Affairs ("QRA") processes and practices for establishing and increasing thresholds, including thresholds for Florida retail and chain pharmacies. Under the new processes and practices, two-person concurrence will be required before increasing thresholds for higher volume customers for specific drug classes. Cardinal understands that DEA does not endorse or otherwise approve threshold procedures, and that thresholds do not necessarily determine whether an order is suspicious.

   c. Cardinal will create a Large Volume-Tactical and Analytical Committee to review and make decisions regarding higher-volume retail and chain pharmacy customers, including higher-volume pharmacies in Florida. The committee will include the SVP of QRA (chair), VP Supply Chain Integrity, Regulatory Counsel, and the Director of QRA Analytics or designated equivalent officers.

d. Cardinal will enhance existing processes and practices for conducting due diligence reviews of pharmacies, chain and retail, including those located in Florida.

e. On a monthly basis, Cardinal shall provide DEA Headquarters with a report of all sales transactions of controlled substances, as well as tramadol, through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. The data shall be due by the 15th of each month for the previous month's report. This information will be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for Cardinal's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

f. Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, Cardinal shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA has previously notified all of the DEA Field Offices that Cardinal is not required to provide suspicious order reports or any other type of report regarding suspicious purchases of controlled substances to the DEA Field Offices. Execution of this Agreement by DEA shall waive the DEA regulatory requirements to report suspicious orders to DEA Field Offices for the duration of the Agreement.

g. Cardinal agrees to the continued suspension of its authority to handle controlled substances at Cardinal Lakeland until May 15, 2014, so long as the provisions of II.2.c are met.

h. Cardinal agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to Cardinal's obligations to detect and report suspicious orders in accordance with 21 C.F.R. § 1301.74(b).

i. Cardinal's policy and procedure is to cooperate with the government in any investigation. Cardinal agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting Cardinal's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of Cardinal in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement

authorities. However, nothing in this paragraph shall be construed as a waiver by Cardinal or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

j. Any material breach by any Cardinal facility of subsections II.1.a-f of this Agreement by Cardinal after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of Cardinal's DEA certificate of registration for that facility.

k. Cardinal agrees that it will dismiss, with prejudice, the pending appeal by Cardinal in Case No. 12-5061 as well as the pending petition for review by Cardinal in Case No. 12-1126 in the United States Court of Appeals for the District of Columbia Circuit. Cardinal agrees that it will also dismiss, with prejudice, Case No. 12-cv-185 in the United States District Court of the District of Columbia.

2. Obligations of DEA.

a. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. § 1301.74(b) and as described in subsection II.1.g. of this Agreement. DEA agrees to waive the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Offices.

b. In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider Cardinal's entry into this Agreement; all actions taken by Cardinal pursuant to this Agreement; any remedial actions taken by Cardinal to address the alleged or perceived violative conduct; and the compliance history of Cardinal at the particular facility, and at other Cardinal facilities.

c. If Cardinal is in compliance with the terms of this Agreement, DEA agrees that it will take appropriate steps to lift the suspension of Cardinal Lakeland's DEA registration and, if needed, to grant any requisite registration renewal on May 14, 2014.

3. Joint Obligations of the Parties.

a. Cardinal and DEA agree that upon the execution of this Agreement, DEA and Cardinal shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against Cardinal Lakeland in *The Matter of Cardinal Health*, DEA Docket No. 12-32.

4. Release by DEA. (i) In consideration of the fulfillment of the obligations of Cardinal under this Agreement, DEA agrees to:

a. Release Cardinal, together with its subsidiary entities, distribution facilities, and registrants that are listed in Appendix A, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 for the conduct alleged in the Order to Show Cause, DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D, and for the conduct alleged in this Agreement; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of May 14, 2012, and the review of the reports and records Cardinal submitted to DEA prior to May 14, 2012. This release applies only to administrative actions brought before or by the Agency.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-covered conduct. Further, nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. DEA expressly reserves the right to pursue civil action, through the United States Attorney's Office, against Cardinal for the "Covered Conduct" as described in this Agreement. At Cardinal's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming Cardinal is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

5. Release by Cardinal. Cardinal fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Cardinal has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Cardinal) are the following:

a. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any liability other than administrative claims released in Paragraph II.4.a. and b.; or

c. Any liability based upon such obligations as are created by this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on Cardinal, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. Cardinal represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Cardinal further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify Cardinal immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices to Cardinal pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by Cardinal providing written notification to DEA:

a. Gilberto Quintero, Senior Vice President, Supply Chain Integrity and Regulatory Operations, 7000 Cardinal Place, Dublin, Ohio 43017; fax: 614-757-6597; email: gilberto.quintero@cardinalhealth.com;

b. With copy to: Steve Falk, Executive Vice-President and General Counsel, 7000 Cardinal Place, Dublin, Ohio 43017, fax: 614-652-7325; email: steve.falk@cardinalhealth.com.

7. Disclosure. Cardinal and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.

8. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

9. Authorizations. The individuals signing this Agreement on behalf of Cardinal represent and warrant that they are authorized by Cardinal to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

10. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Cardinal distribution facility at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of Cardinal Health:

_____
Craig S. Morford
Chief Legal and Compliance Officer

Dated:

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

[redacted]

Dated: 5/14/12

[redacted]

Dated: 5/14/12