IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON,

Plaintiff,

v. **Civil Action No. 3:17-01362**

AMERISOURCEBERGEN DRUG CORPORATION, et al.,

Defendants.

CABELL COUNTY COMMISSION,

Plaintiff,

v. **Civil Action No. 3:17-01665**

AMERISOURCEBERGEN DRUG CORPORATION, et al.,

Defendants.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

These two cases are related to thousands of other lawsuits that have been filed throughout the country in recent years relating to the opioid crisis. The Opioid MDL (MDL 2804) was created by the Judicial Panel on Multidistrict Litigation (JPML) in December of 2017 after the JPML determined that a large number of cases should be centralized for pretrial proceedings in the Northern District of Ohio to coordinate the resolution of these actions. In re Nat'l Prescription Opiate Litig., 290 F.

Supp. 3d 1375, 1378 (J.P.M.L. 2017). These two cases, designated in the MDL as "Track Two" cases, were remanded to this court for further proceedings.

A bench trial was held on May 3, 2021, through July 12, 2021. Closing arguments were held on July 27 and July 28, 2021. Set forth herein are the court's findings of fact and conclusions of law pursuant to Fed. R. Civ. P. 52.

Because this case was tried before the court as a bench trial, the court's findings are presumed to be based on admissible evidence. See Fishing Fleet, Inc. v. Trident Ins., 598 F.2d 925, 929 (5th Cir. 1979); see also Harris v. Rivera, 454 U.S. 339, 346 (1981) ("In bench trials, judges routinely hear inadmissible evidence that they are presumed to ignore when making decisions."); Chicago Title Ins. v. IMG Exeter Assocs. Ltd., 985 F.2d 553, 1993 WL 27392 at *4 (4th Cir. 1993) ("[A] judge presiding over a bench trial is presumed to consider only relevant, admissible evidence.") (unpublished). Accordingly, the court finds it unnecessary to rule on each separate evidentiary objection raised by the parties. The court has considered those objections relating to the evidence supporting the findings contained herein and, to the extent such objections relate to the evidence which the court cites in support of its findings, such objections are hereby overruled.

Plaintiffs, a West Virginia city and a West Virginia county, proceeded in this case on a single cause of action, public nuisance, against three wholesale distributors of medical products. According to plaintiffs, defendants' wholesale distribution of prescription opioids in Huntington and Cabell County created an opioid epidemic, which has caused a public nuisance in those localities. Plaintiffs contend that they seek relief in the form of abatement of the alleged nuisance.

Though they may disagree as to certain particulars, the parties agree that there is an opioid epidemic in the United States, as well as the City of Huntington and Cabell County. The parties further agree that the epidemic was fueled, at least in part, by prescription opioids. As the MDL court described it:

> It is accurate to describe the opioid epidemic as a man-made plague, twenty years in the making. The pain, death, and heartache it has wrought cannot be overstated. As this Court has previously stated, it is hard to find anyone . . . who does not have a family member, a friend, a parent of a friend, or a child of a friend who has not been affected.

In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2018 WL 6628898, at *21 (N.D. Ohio Dec. 19, 2018).

FINDINGS OF FACT

I. Background

The plaintiffs are The City of Huntington ("City of Huntington" or "Huntington"), a West Virginia city, and the

County Commission of Cabell County ("Cabell County" or "Cabell"), a West Virginia county commission (collectively, "plaintiffs" or "Cabell/Huntington"). See Third Amend. Compl. ¶¶ 26-30 (ECF No. 80). The defendants are AmerisourceBergen Drug Corporation ("ABDC"), Cardinal Health, Inc. ("Cardinal Health" or "Cardinal"), and McKesson Corporation ("McKesson") (collectively, "defendants"). See id. at ¶¶ 127-30, 133-36, 140-43.[1]

[1] Plaintiffs' complaint also names as defendants the following entities that were severed from this trial but remain part of the litigation: Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Rhodes Pharmaceuticals L.P., Rhodes Technologies, Inc., Richard S. Sackler, M.D., Kathe A. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler, Allergan PLC f/k/a Actavis PLC f/k/a Allergan Inc., Allergan Finance LLC f/k/a Actavis Inc. f/k/a Watson Pharmaceuticals, Inc., Allergan Sales, LLC, Allergan USA, Inc., Watson Laboratories, Inc., Warner Chilcott Company, LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc., Actavis Laboratories FL, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc., Teva Pharmaceutical Industries LTD., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Mallinckrodt PLC, Mallinckrodt LLC, SpecGx LLC, KVK-Tech, Inc., Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals, Inc., Impax Laboratories, LLC, Amneal Pharmaceuticals of New York LLC, CVS Health Corporation, CVS Indiana L.L.C., CVS Rx Services, Inc., CVS Tennessee Distribution, L.L.C., CVS Pharmacy, Inc., West Virginia CVS Pharmacy, LLC, Rite Aid Corporation, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support

The Third Amended Complaint is the operative pleading.

Defendants are wholesale distributors of pharmaceutical and other products, including prescription and over-the-counter (OTC) medicines, as well as health and beauty aids. Defendants distribute a full line of medical products and supplies to pharmacies and hospitals across the United States.

Chris Zimmerman of ABDC described the important role that wholesale distributors play in maintaining an efficient supply chain between manufacturers and pharmacies:

> [T]here's 2,000 manufacturers . . . that we buy products from where we purchase - - we carry anywhere from 60,000 different items within our warehouses and . . . we have over 16,000 pharmacy customers.
>
> So, what we do, without a distributor, each one of those 2,000 manufacturers have to ship direct to the pharmacy. And those pharmacies would have to place 2,000 separate orders. They'd have to receive 2,000 separate receipts at the door each day. And that's just the product going out.
>
> There's also the setup of the customers. The manufacturers only have to set up a few distributors and sell their products to the distributors. And then, we handle all the pharmacies, making sure that they have an appropriate license . . .

Center, Inc., Rite Aid of West Virginia, Inc., Walgreens Boots Alliance, Inc., Walgreen Eastern Co., Inc., Walgreen Co., H.D. Smith Wholesale Drug Co., Kroger Limited Partnership I, Kroger Limited Partnership II, Walmart Inc., Wal-Mart Stores East d/b/a Wal-Mart Pharmacy Warehouse #46, Wal-Mart Pharmacy Warehouse #45, Wal-Mart Pharmacy Warehouse, Express Scripts Holding Company, Express Scripts, Inc., Caremark Rx, LLC, Optum, Inc., OptumRx Inc., and Tasmanian Alkaloids Pty. LTD. See Third Amend. Compl. ¶¶ 42-123, 146-299.

> [M]anufacturers couldn't handle it because they ship like once a week, where we ship every single day, and the pharmacies need those products the following day.

Zimmerman, 5/13/21, at 151.

Each defendant operates multiple distribution centers across the United States. ABDC has 27 distribution centers; Cardinal has more than 20; and McKesson has 28. See Zimmerman, 5/12/21, at 149; Moné, 5/20/21, at 167; Oriente, 5/25/21, at 13.

II. The Witnesses

Seventy witnesses testified at trial, either live or by designation. They are:

1. Robert "Corey" Waller is a physician and Associate Professor at Michigan State University. See Waller, 5/4/21, at 11-12. Dr. Waller was qualified as an expert in the fields of neuroscience, addiction, and pain. See id. at 20.

2. David Courtwright is a historian who taught at the University of North Florida and other institutions before retiring in 2019. See Courtwright, 5/5/21, at 10. Dr. Courtwright was qualified as an expert in the history of opiate use and abuse in drug policy. See id. at 18.

3. Rahul Gupta served as Physician Director, Local Health Officer, and Executive Director of the Kanawha-Charleston Health Department from March 2009 to December 2014. See Gupta, 5/5/21, at 47. Dr. Gupta also served as the Commissioner for the Bureau of Public Health and Human Resources and the State Health

Officer for the State of West Virginia from January 2015 to November 2018. See id. at 47.

4. Connie Priddy is the Director of Quality Compliance at Cabell County EMS and the Program Coordinator for the Huntington Quick Response Team ("QRT"). See Priddy, 5/6/21, at 182-83. Ms. Priddy is also a licensed nurse. See id. at 183-85.

5. Jan Rader is the Huntington Fire Chief and is also a nurse. See Rader, 5/7/21, at 27, 29. Chief Rader has been with the Huntington Fire Department for 27 years. See id. at 27-28.

6. Craig McCann is a data analyst at Securities Litigation and Consulting Group, Inc. See McCann, 5/10/21, at 9. Dr. McCann was qualified as an expert on data processing, validating, reconciling, and summarizing large datasets as they relate to ARCOS and related governmental datasets. See id. at 20.

7. Chris Zimmerman is the Senior Vice President of Corporate Security and Regulatory Affairs at ABDC. See Zimmerman, 5/12/21, at 128. He has been with ABDC (or its predecessor company) since 1990. See id.

8. Donna Kelley is employed at Discount Emporium, Inc., doing business as Drug Emporium. See Kelley, 5/13/21, at 229. She testified as a records custodian for Drug Emporium. See id.

9. David May is the Vice President of Diversion Control and Security for ABDC. See May, 5/14/21, at 13. He has been

with the company since 2014. See id. at 14. Prior to joining ABDC, he worked for the DEA for thirty years. See id. at 16-17.

10. Stephen Mays is the Vice President of Regulatory Affairs for ABDC. See 5/17/21, at 177-78. He has been an employee for ABDC or its predecessor companies since 1974. See Mays, 5/18/21, at 145-46.

11. Michael Perry was a Sales Executive with ABDC from 1996 until 2020, when he retired. See Perry, 5/19/21, at 67-68.

12. Michael Moné was employed by Cardinal Health from 2006 to 2012. See Moné, 5/19/21, at 203. In December of 2007, Mr. Moné assumed the position of Vice President of Anti-Diversion for Cardinal. See id. at 205. Mr. Moné has been a practicing pharmacist as well as a practicing attorney. See Moné, 5/20/21, at 152-53.

13. Joseph Werthammer is a pediatrician with a subspecialty in neonatology, and currently works as a full-time neonatologist. See Werthammer, 5/21/21, at 9-10. Dr. Werthammer practices at the Cabell-Huntington Hospital and the School of Medicine at Marshall University. See id. at 10.

14. Jesse Kave was employed by Cardinal Health as a business consultant in its sales department from 2006 to 2018. See Kave, 5/21/21, at 62-64.

15. Scott Lemley is the Director of Innovation for the City of Huntington. See Lemley, 5/21/21, at 112. He previously

worked as a Criminal Intelligence Analyst for the Huntington Police Department and as a member of the Mayor's Office of Drug Control Policy. See id. at 112-13.

16. Michael Oriente has been employed at McKesson since 2004. See Oriente, 5/25/21, at 18. He was a Director of Operations for one of McKesson's distribution centers for three years before becoming a Director of Regulatory Affairs. See id. at 18-19.

17. Timothy Ashworth is a Regional Sales Manager for McKesson. See Ashworth, 5/25/21, at 194. He has been with McKesson since 2005. See id. at 195.

18. James Rafalski previously was employed as a DEA Diversion Investigator from 2004 to 2017. See Rafalski, 5/26/21, at 15-16. The court granted in part and denied in part defendant's Daubert motion regarding Mr. Rafalski's testimony. See ECF No. 1529.

19. Charles "Chuck" Zerkle serves as Cabell County Sheriff and was first elected to that position in 2016. See Zerkle, 5/27/21, at 77, 84-85.

20. Lyn O'Connell works for the Joan C. Edwards School of Medicine as the Associate Director of Addiction Sciences. See O'Connell, 5/27/21, at 192.

21. Joseph Rannazzisi worked at the DEA from March 1986 to October 2015. See Rannazzisi, 6/7/21, at 165. He was Deputy

Assistant Administrator for the DEA's Office of Diversion Control for ten years, from July 2005 to October 2015. See id. at 165; see also Rannazzisi, 6/8/21, at 211-12.

22. Gordon Smith is a public health epidemiologist at the West Virginia University School of Public Health. See Smith, 6/10/21, at 97. Dr. Smith was qualified as an expert on epidemiology, drug overdoses, and overdose data and trends for the State of West Virginia and Cabell County. See id. at 114.

23. Jakki Mohr is a Professor of Marketing at the University of Montana. See Mohr, 6/10/21, at 227-28. Dr. Mohr was qualified as an expert in the field of marketing. See id. at 234.

24. Katherine Keyes is an Associate Professor of Epidemiology at Columbia University's Mailman School of Public Health. See Keyes, 6/11/21, at 150-51. Dr. Keyes was qualified as an expert in the field of epidemiology, specializing in opioid use, Opioid Use Disorder, and related harms. See id. at 160.

25. Lacey Keller is co-owner of MK Analytics, a data and analytics company. See Keller, 6/15/21, at 49, 51-52. Ms. Keller was qualified as an expert in the field of data analytics. See id. at 58.

26. Nancy Young is the Executive Director of Children and Family Futures, a non-profit organization that works on public

policy issues affecting children of parents with Substance Use Disorders. See Young, 6/16/21, at 9. Dr. Young was qualified as an expert on the impact of opioids on children and families and remedies to address their impact. See id. at 18.

27. Kevin Yingling is Chairman of the Board for the Cabell County Health Department and the Chairman of the Board of Tri-State Medical Missions. See Yingling, 6/16/21, at 133-34. Dr. Yingling also works at PROACT once a week providing medication-assisted treatment. See id. at 152.

28. Thomas McGuire is a health economist in the Department of Healthcare Policy at Harvard Medical School. See McGuire, 6/17/21, at 7-8. Dr. McGuire was qualified as an expert in the field of health economics. See id. at 12.

29. Judith Feinberg is an internist with special training in infectious diseases. See Feinberg, 6/17/21, at 88-89. She is employed at the West Virginia University School of Medicine as a Professor of Behavioral Medicine and Psychiatry, Professor of Medicine in the section of infectious diseases, and Doctor E.B. Flink Vice Chair of Medicine for Research. See id. Dr. Feinberg was qualified as an expert in the prevention and treatment of infectious diseases associated with opioid use disorder and injection opioid drug use. See id. at 106.

30. Skip Holbrook was Chief of the Huntington Police Department from 2007 to 2014, and he served on the Appalachia HIDTA Executive Board. See Holbrook, 6/17/21, at 189-90.

31. Caleb Alexander is the owner and co-founder of a consultancy called Monument Analytics, a Professor of Epidemiology and Medicine at Johns Hopkins University, and a general internist. See Alexander, 6/28/21, at 8-9. Dr. Alexander was qualified as an expert in the field of epidemiology and opioid abatement intervention. See id. at 18-19.

32. George Barrett is a forensic economist with the consulting firm of Brookshire Barrett & Associates. See Barrett, 6/29/21, at 55-56. Mr. Barrett was qualified as an expert in the field of forensic economics. See id. at 66.

33. Steve Williams is the Mayor of the City of Huntington, and he has served in that role since January 1, 2013. See Williams, 6/30/21, at 7-8.

34. Chris Gilligan is the Chief of the Division of Pain Medicine at Brigham & Women's Hospital in Boston, a teaching hospital for Harvard Medical School. See Gilligan, 7/2/21, at 8, 12-13. Dr. Gilligan was qualified as an expert in the field of pain management and the risks and benefits of prescription opioids. See id. at 26.

35. Timothy Deer is a practicing physician with a specialty in anesthesiology and pain medicine. See Deer, 7/7/21, at 8-9. Dr. Deer has practiced pain medicine in Charleston for twenty-seven years, and he runs the largest pain practice in West Virginia. See id. at 12-13, 22-23. Dr. Deer was qualified as an expert in pain management and the standard of care for pain management. See id. at 37.

36. James Hughes is an economist who specializes in microeconomics, particularly labor economics and health economics. See Hughes, 7/7/21, at 209. Dr. Hughes is a Professor of Economics Emeritus at Bates College. See id. at 212. Dr. Hughes was qualified as an expert in the fields of health economics and health insurance related to prescription medicines. See id. at 220.

37. Theodore Martens is a certified public accountant and specializes in forensic accounting. See Martens, 7/8/21, at 24-25, 27. Mr. Martens was qualified as an expert in the fields of forensic accounting and data analytics. See id. at 40.

38. Kevin M. Murphy is the George J. Stigler Distinguished Service Professor of Economics in the Graduate School of Business in the Department of Economics at the University of Chicago. See Murphy, 7/8/21, at 56. Dr. Murphy was qualified as an expert in the field of economics and especially in health economics. See id. at 63.

39. Peter Boberg is an economist at Charles River Associates, a Boston-based economic consulting firm. See Boberg, 7/8/21, at 151, 156. Dr. Boberg was qualified as an expert in the fields of econometrics, data analysis, and large datasets. See id. at 160.

40. John MacDonald is the Principal Executive Officer and President of Berkley Research Group, a global consulting firm. See MacDonald, 7/9/21, at 8-9. Mr. MacDonald was qualified as an expert in the fields of data analytics related to the pharmaceutical supply chain. See id. at 16.

41. Robert Rufus is a certified public accountant and a forensic accountant. See Rufus, 7/12/21, at 8-9, 11. Dr. Rufus was qualified as an expert in public and forensic accounting. See id. at 16.

42. Stephenie Colston is currently the President and Chief Executive Office of Colston Consulting Group, which offers consulting services related to both mental health and substance use disorder services. See Colston, 7/12/21, at 57. Ms. Colston was qualified as an expert in the area of systems, programs, and services that provide care for people with substance use disorder, the structure, financing, and how to assess them, and trends in the substances that are being abused. See id. at 79.

43. Vic Brown was the Executive Director of Appalachia HIDTA. See Brown, 5/17/21, at 247, 272-73.

44. Stacy Harper-Avilla testified on behalf of the DEA. See Harper-Avilla, 4/11/19, at 17. She is the Section Chief of the DEA's United Nations Reporting and Quota Section. See id. at 21.

45. Thomas Prevoznik is a 28-year veteran of the DEA testifying as a 30(b)(6) witness. See Prevoznik, 4/17/19, at 42, 71. He is the Acting Section Chief for Pharmaceutical Investigations in the Diversion Control Division. See id. at 42.

46. Matthew Strait is a 20-year veteran of the DEA who testified on its behalf. See Strait, 5/31/19, at 14-15. He is the Senior Policy Advisor to the Assistant Administrator for the Diversion Control Division. See id. at 16.

47. John Gray is the former president and CEO of Healthcare Distribution Alliance ("HDA"). See Gray, 7/30/20, at 19. He served as president and CEO of the HDA from April 2004 until May 2020. See id. at 20.

48. Patrick Kelly testified on behalf of the Healthcare Distribution Alliance in both his personal capacity and as a Rule 30(b)(6) witness for the organization. See Kelly, 5/10/19, at 31.

49. Eric Cherveny works in diversion control at ABDC. See Cherveny, 11/9/18, at 200.

50. Nathan Elkins works in Sales at ABDC and started in 2005 as a Retail Account Manager. See Elkins, 11/14/18, at 27.

51. Edward Hazewski started at ABDC in 2007 and is the Director of Diversion Control and Security. See Hazewski, 10/25/18, at 19.

52. Lisa Mash was the Vice President of Sales at ABDC for approximately 14 years. See Mash, 7/28/20 at 27.

53. Eric Brantley is a former Cardinal Health employee who worked there for eleven years from 2002 to 2013. See Brantley, 11/27/18, at 518. He worked in the Quality and Regulatory Affairs department for approximately three years. See id. at 18, 520.

54. Mark Hartman worked at Cardinal in a variety of positions for twelve years from 1998 until February 2010. See Hartman, 11/15/18, at 131, 356-59. For a time, he was the Senior Vice President of Supply Chain Integrity and Regulatory Operations. See id. at 19.

55. Kim Howenstein is the Director of Non-PD Customer Management at Cardinal Health. See Howenstein, 1/10/19, at 11.

56. Steve Lawrence is the Senior Vice President of Independent Sales at Cardinal Health. See Lawrence, 1/4/19, at 26.

57. Jennifer Norris testified as a 30(b)(6) witness for Cardinal. See Norris, 8/7/18, at 16-17. At the time she was deposed, she had been with Cardinal for eighteen years and held the position of Vice President & Associate General Counsel at Cardinal Health. See id. at 14.

58. Gilberto Quintero is an employee of Cardinal Health who started in December 2009 as Senior Vice President of Quality Regulatory Affairs. See Quintero, 12/6/18, at 12, 16-17.

59. Steve Reardon started at Cardinal Health in 1998 and retired in 2016. See Reardon, 11/30/18, at 498. From 2005 to 2007, he was the Vice President of Quality and Regulatory Affairs. See id. at 410-11.

60. Gary Boggs is the Vice President of Regulatory Affairs and Compliance at McKesson. See Boggs, 1/17/19, at 18. Prior to working for McKesson, he worked for the DEA from 1985 until he retired in 2012. See id. at 20.

61. Dave Gustin was a former Director of Regulatory Affairs at McKesson for approximately seven years until 2013. See Gustin, 8/17/18, at 22, 478-81. Gustin began working at McKesson in 1995. See id. at 478.

62. Nathan Hartle is the Vice President of Regulatory Affairs and Compliance at McKesson. See Hartle, 7/31/2018, at 15. He testified on behalf of McKesson as a 30(b)(6) witness. See id. at 16.

63. Nathan Hartle also testified as a fact witness. See Hartle, 8/1/18, at 15.

64. Gary Hilliard was the Director of Regulatory Affairs at McKesson from 1998 to 2016. See Hilliard, 1/10/19, at 17.

65. Donald Walker was the Senior Vice President of Distribution for McKesson from 1996 until he retired in June 2015. See Walker, 1/10/19, at 357-59. He started at McKesson in 1987. See id. at 357.

66. Darren Cox is a Special Agent with the Federal Bureau of Investigation ("FBI") who served as the coordinator of the Huntington Violent Crime and Drug Task Force from November 2012 to May 2015. See Cox, 7/15/20, at 10-11.

67. June Howard is Chief of the DEA's Reports Analysis Unit. See Howard, 4/25/19, at 17-18. She was formerly the Chief of the Targeting and Analysis Unit from 1996 to 2010. See id. at 19. Ms. Howard testified on behalf of the DEA. See id. at 15-17.

68. Robert Knittle was the Executive Director of West Virginia Board of Medicine from December 2005 to December 31, 2016. See Knittle, 8/27/20, at 25-26.

69. Michael Mapes worked for the DEA from 1977 to 2007 in various positions, all related to diversion. See Mapes, 7/11/19, at 47-48. He has worked in the pharmaceutical industry since retiring from the DEA. See id. at 349-50.

70. Beth Thompson testified as a 30(b)(6) witness on behalf of the Cabell County Commission. See Thompson, 7/23/20, at 5-7.

III. Opioid Epidemic in Huntington and Cabell

The court finds that there is and has been an opioid epidemic in the City of Huntington and Cabell County, West Virginia. See Keyes, 6/11/21, at 198. "The U.S. opioid crisis is an extraordinary public health crisis that started at least two decades ago and has accelerated over the past decade." Ex. MC-WV-02079 at 1. "Since 2000, more than 300,000 Americans have lost their lives to an opioid overdose." Ex. DEF-WV-01597 at 22. West Virginia likewise "has been experiencing a public health epidemic of drug overdose deaths for more than a decade." Ex. P-41213 at 4.

Former West Virginia Bureau of Public Health Commissioner, Dr. Rahul Gupta, described West Virginia as "ground zero" for the national opioid epidemic, the hardest-hit state in the country. Gupta, 5/5/21, at 74, 77; Gupta, 5/6/21, at 96. "Opioids were detected in 6,001 drug overdose deaths in West Virginia from 2001 through 2015." Ex. P-41213 at 7.

Huntington and Cabell are among the West Virginia communities hardest hit by the opioid epidemic. From 2001 to 2018, there were 1,151 overdose deaths in Cabell County, of which 1,002 were opioid-related. See Smith, 6/10/21, at 134-35.

From 2001 to 2017, the fatal overdose rate in Cabell County increased from 16.6 to 213.9 per 100,000. See id. at 139-40. Cabell County's opioid overdose rate is higher than that of West Virginia, which itself is above the national average. See Keyes, 6/11/21, at 201.

As of 2017, more than 10% of the population of the City of Huntington and Cabell County, and Wayne County are or have been addicted to opioids. See Ex. P-41850 at 7; Werthammer, 5/21/21, at 20. In 2018, the prevalence of opioid use disorder ("OUD") in Cabell and Huntington was 8.9%, which represents approximately 8,200 people. See Keyes, 6/11/21, at 212. Dr. Keyes estimated that approximately 7,109 of these OUD cases in Cabell and Huntington were directly or indirectly attributable to prescription opioids. See Keyes, 6/14/21, at 160, 175.

Over 600 pregnant women in Cabell and Huntington have been admitted to treatment with OUD. See Young, 6/16/21, at 34. "West Virginia has the highest incidence of Neonatal Abstinence Syndrome in the country." Werthammer, 5/21/21, at 16. Since 2010, approximately 2,500 newborns in Cabell County have been born with neonatal abstinence syndrome ("NAS"). See id. at 18. In 2012, one-third of Cabell and Huntington Hospital NICU patients were babies withdrawing from opioids. See id. at 14. The rate of babies being born with NAS at Cabell and Huntington Hospital has been as high as 10%. See id. at 16-18.

The number of children in West Virginia placed into foster care doubled over a ten-year period during the opioid epidemic, with 80% of placements involving substance abuse issues. See Young, 6/16/21, at 20, 42-43. In Cabell County, overdose deaths and foster care entries exceeded the national averages, resulting in demand for child placements not being met and increased placements outside of extended family, which can have adverse effects on a child's intellectual, social, and emotional development. See id. at 19-22, 33, 41-46, 58-59.

The opioid epidemic in Cabell/Huntington has resulted in sharply increased rates of infectious disease, including HIV, Hepatitis B and C, and complications due to Endocarditis. See Yingling, 6/16/21, at 156-58. Injection drug use introduces foreign organisms into the bloodstream, causing blood-borne infections that have high mortality and morbidity and are a substantial part of the public health crisis of the opioid epidemic. See Feinberg, 6/17/21, at 109, 112.

For people who inject drugs, there is a 1 in 160 chance of acquiring HIV with each injection, and an increasing risk with every additional injection. See id. at 115. In 2019, there were 69 new cases of HIV in Cabell County, of which 90% were among people who inject drugs. See id. at 117.

Hepatitis C is even more contagious than HIV among injection drug users, with approximately 40% of injection drug

users contracting Hepatitis C in their first year of use and 90% eventually contracting it. See id. at 128-29. As a result, West Virginia has, for the past two decades, been among the top two or three states for rate of Hepatitis C infection, while the rate in Cabell County is far higher still, reaching a rate of 10.3 cases per 100,000 people—more than double West Virginia's already-high statewide rate of 5.1 cases per 100,000 people. See id. at 129-30.

Hepatitis B, too, is highly associated with injection drug use and, as a result, West Virginia has had the highest Hepatitis B rates in the United States for over a decade. See id. at 135-36. At present, the incidence of Hepatitis B in West Virginia is 14 times the national average, while Cabell County has among the highest rates of Hepatitis B infections among West Virginia's counties, measuring 17 cases per 100,000 people in 2016. See id. at 136.

Endocarditis is most commonly caused by the injection of bacteria through the skin. See id. at 140. Although Endocarditis is not actively surveilled, a recent study across four West Virginia hospitals that included two in Cabell and Huntington showed that a significant proportion of the 762 Endocarditis cases observed is concentrated among people living in or near Cabell and Huntington. See id. at 144.

The opioid epidemic has increased crime rates, decreased property values, and adversely affected neighborhoods throughout Cabell and Huntington. See Zerkle, 5/27/21, at 119-220 (addiction is draining Cabell County's workforce, reducing the population and tax base; Huntington owns 350-plus abandoned homes); Lemley, 5/21/21, at 118-19 (drug and property crime spiked in 2013-14). In 2004, only a small area of Huntington had drug offenses; by 2014, drug offenses had become prevalent throughout the city and by 2016 engulfed every neighborhood. See Lemley, 5/21/21, at 173-74.

Prescription opioids remain to this day an ongoing and significant cause of drug overdose deaths in Cabell and Huntington, with preliminary data showing sharp increases in opioid-related deaths throughout West Virginia in 2019 and 2020. See Smith, 6/10/21, at 141, 153-54.

IV. Controlled Substances Act and Closed System of Distribution

The Controlled Substances Act ("CSA") establishes a closed system for drugs classified as controlled substances. See Ex. DEF-WV-01597 at 11. Every party in the closed system must be registered by the Drug Enforcement Agency ("DEA"). Under the closed system, DEA-registered manufacturers may sell controlled substances only to DEA-registered distributors and pharmacies; DEA-registered distributors may distribute controlled substances only to DEA-registered dispensers (such as pharmacies and

hospitals); and DEA-registered dispensers may dispense controlled substances only pursuant to prescriptions written by DEA-registered prescribers. See Rafalski, 5/26/22, at 16-17; Rannazzisi, 6/7/22, at 175-76; Zimmerman, 5/13/22, at 152; Ex. DEF-WV-01597 at 6; see also 21 U.S.C. §§ 822(a)-(b); 21 C.F.R. § 1301.74(a).

The DEA is charged with regulating and overseeing the controlled system of distribution. The DEA's responsibilities in this regard begin with the registration process as only DEA-registered entities are permitted to participate in the controlled system. In this respect, the DEA acts as a "gatekeeper." Rannazzisi, 6/7/22, at 177; Rannazzisi, 6/8/22, at 210.

The DEA "shall register an applicant" unless it determines "that the issuance of such registration is inconsistent with the public interest." 21 U.S.C. § 823(b).

> In determining the public interest, the following factors shall be considered: (1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels; (2) compliance with applicable State and local law; (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances; (4) past experience in the distribution of controlled substances; and (5) such other factors as may be relevant to and consistent with the public health and safety.

Id.

The closed system allows the DEA to monitor the flow of controlled substances from the manufacturer to the patient with the goal of ensuring that prescription drugs do not flow into the illicit marketplace. See Rannazzisi, 6/7/22, at 174-75, 177. In order to monitor the flow of controlled substances within the closed system, the DEA maintains a database known as Automation of Reports and Consolidated Orders System ("ARCOS"). Registrants, like defendants, are required to report to ARCOS, on a routine basis, every shipment of prescription opioids. See Rafalski, 5/26/21, at 199-200.

Each distribution center operated by defendants is required to obtain its own DEA registration. See Zimmerman, 5/13/21, at 152-53, 171. The DEA inspects and audits every DEA-registered distributor and manufacturer. See Rannazzisi, 6/8/22, at 176-77. During these cyclical inspections, the DEA (1) reviews a registrant's policies and procedures for maintaining effective controls against diversion, (2) looks at customer due diligence files and recordkeeping, (3) performs a security sweep and security audit, (4) ensures alarm systems are up to date, (5) ensures that cages and vaults are compliant with federal regulations, and (6) audits certain products. See id. at 176-80. After an inspection is complete, the DEA communicates its findings to the distributor. See id. at 180.

A. Suspicious Order Monitoring Programs

The CSA and its implementing regulations require "[a]ll applicants and registrants [to] provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71(a). The regulations largely address the physical handling and security of controlled substances, including specifications for storage areas, cabinets, vaults, cages, alarms, compounding areas, and the like. See, e.g., 21 C.F.R. § 1301.72.

Wholesale distributors, like defendants, are also required to "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." 21 C.F.R. § 1301.74(b). The regulation goes on to define suspicious order to "include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." Id.; see also Rafalski, 5/26/21, at 82-83, 203; Rannazzisi, 6/9/21, at 9-10; Mapes, 7/11/19, at 80.

Substantial compliance with the relevant security requirements may be deemed sufficient by the DEA. 21 C.F.R. § 1301.71(b). "A registrant's regulatory obligations under the CSA, . . . and [its] implementing regulations do not require strict compliance. Only substantial compliance is required."

In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2021 WL 3917174, at *3 (N.D. Ohio Sept. 1, 2021). "A determination of substantial compliance . . . is a fact-intensive inquiry . . . and whether a defendant has substantially complied with the CSA is a question of fact." Id.; see also In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2022 WL 671219, at *6 (N.D. Ohio Mar. 7, 2022) ("[T]he ultimate determination of whether a defendants' compliance was substantial, or whether it falls somewhere short of that mark, is best left to a jury.").

The DEA does not and will not tell a distributor whether an order is suspicious but, rather, leaves that decision to the distributor. See Rafalski, 5/26/21, at 82; Rannazzisi, 6/9/21, at 11 ("It was up to the distributor to make the decision whether an order is suspicious or not.").

B. The Distributor Initiative

In 2005, the DEA convened individual meetings with distributors, referred to as the "Distributor Initiative." See Mapes, 7/11/19, at 129-30. These meetings were "started in response to the Internet pharmacy issue." Id. Mapes described the internet pharmacy issue as

> when websites were starting to offer their service to patients, doctors and pharmacies to put the three together so that patients could get a prescription filled by a pharmacy after completing a questionnaire on a website and getting that approved by a doctor for a prescription, and a pharmacy getting the

> prescriptions and filling those and sending them to patients.

Id. at 30.

Internet pharmacies were a concern to the DEA because there was no legitimate doctor-patient relationship and "the pharmacies were filling prescriptions for patients that they knew nothing about, for doctors that weren't within the geographic area, all for the same drug." Id. at 131.

Mr. Mapes was present at meetings between the DEA and all three defendants. See Exs. P-09112, P-09114, and P-12805. According to memoranda prepared by Mr. Mapes, the meetings concerned the growing internet pharmacy problem. See id.

The DEA provided ABDC with information, materials, and suggested tools to help with investigations of possible illegal internet pharmacies. See Ex. AM-WV-01079 at 1; Mays, 5/18/21, 193-94. The materials provided by the DEA included a questionnaire entitled "Internet Pharmacy – Decision Questions," which consisted of twelve questions designed to help identify customers engaged in illegal internet activity. See Ex. P-09112 at 17-18. Following the Distributor Initiative meeting, ABDC developed and implemented a new policy: CSRA 2.12: Possible Excessive/Suspicious Order Review. See Mays, 5/18/21, at 198-205; Ex. AM-WV-01079 at 1-11.

Mr. Reardon attended a presentation by the DEA to Cardinal Health as part of the Internet Pharmacy Initiative on August 22, 2005. See Reardon, 11/30/18, at 517; Ex. P-09114. Following this presentation, Mr. Reardon immediately started developing a process and program to identify and monitor Internet pharmacy activity. See Reardon, 11/30/18, at 517-18.

C. First Rannazzisi Letter

On September 27, 2006, the DEA issued a letter to distributors from DEA Deputy Assistant Administrator Joseph T. Rannazzisi. The letter's stated purpose was "to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces." Ex. P-00032. It reminded distributors that 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" and that registration also serves as "the primary incentive for compliance with the regulatory requirements of the CSA and DEA regulations." Id.

Mr. Rannazzisi referred to the statutory factors that the DEA must consider in deciding whether to revoke a distributor's registration, which are set forth in 21 U.S.C. § 823(e). See id. The first of those factors is "the duty of distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and

industrial channels." Id. The letter also cites distributors' additional obligation to report suspicious orders of controlled substances under 21 C.F.R. § 1301.74(b). See id.

After citing these two obligations, Mr. Rannazzisi continues:

> Thus, in addition to reporting all suspicious orders, a distributor has 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 would, 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 upon 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 requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

Id.

To determine whether an order is legitimate, Mr. Rannazzisi recommended that distributors pose a series of ten non-inclusive questions to the pharmacies that they supply. See id. All defendants received a copy of the letter. See Zimmerman, 5/12/21, at 212; Reardon, 11/30/18, 525-26; Hilliard, 1/10/19, at 53.

D. Second Rannazzisi Letter

On February 7, 2007, Mr. Rannazzisi sent a second letter to registrants. See Rannazzisi, 6/8/21, at 143-44; Ex. P-00032. According to Mr. Rannazzisi, the February letter was the same as the September letter and it was sent because the DEA "felt that there were some registrants who did not get the September letter, so we re-sent it." Rannazzisi, 6/8/21, at 144.

E. Third Rannazzisi Letter

On December 27, 2007, Rannazzisi sent a third letter that provided further guidance regarding distributors' obligations. It stated, for example, with respect to suspicious order monitoring systems 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.

Ex. P-00032.

According to the letter, "[f]iling a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the statutory requirement to report suspicious orders." Id. The letter also informed registrants, "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." Id.

The Rannazzisi letter concluded that

> 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.

Id. All three defendants reported receiving the third Rannazzisi letter. See Zimmerman, 5/13/21, at 20; Moné, 5/20/21, at 24; Oriente, 5/25/21, at 52.

V. Defendants Substantially Complied with Their Duties under the CSA to Design and Operate a SOM System and Report Suspicious Orders

As discussed in greater detail below, at all relevant times, defendants had in place suspicious order monitoring ("SOM") systems as required by the CSA and its implementing regulations.

A. ABDC

The evidence at trial showed that ABDC's Suspicious Order Monitoring Program has evolved and changed over the years. From 1998 through present, ABDC's program has taken three general forms:

1. Order Monitoring Program (OMP)

In 1996, ABDC began to develop a new suspicious order monitoring program. On September 30, 1996, Zimmerman wrote to Thomas Gitchel, the Chief of the Liaison and Policy Section of at the DEA, suggesting that ABDC's predecessor, Bergen Brunswig, work with DEA to develop a new "suspicious order reporting program that would provide better quality information to DEA in a more efficient manner" by detecting and reporting suspicious orders electronically. See Zimmerman, 5/13/21, at 174; Ex. AM-WV-00781, at 9-12.

ABDC's proposal to the DEA detailed the type of information about the suspicious orders that was to be included in the Excessive Purchase Reports:

> The summary report would show the customer name, address, DEA Number, Item Description, NDC Number, Order Date, Active Ingredient Volume Ordered, Active Ingredient Shipped and Customer "Allowance" (i.e. average of customers' prior four months orders).

Ex. AM-WV-00781 at 10. On October 29, 1996, Mr. Gitchel responded to Mr. Zimmerman's proposal, confirming the information that would be included in the Reports:

> As proposed, the summary report would include the customer's name, address, and DEA number; a description of the item ordered; the NDC number; date ordered; active ingredient volume ordered and shipped; and the customer's "allowance or average order."

Ex. AM-WV-00781 at 7. Over the next two years, Bergen Brunswig continued to develop and test the new SOM program. See Zimmerman, 5/12/21, at 219; Ex. AM-WV-00781 at 2-3, 7-8

The new program would set thresholds that applied a default multiplier of three to a customer's four-month purchasing average. See Zimmerman, 5/13/21, at 55. However, the program permitted the default multiplier to be adjusted for any given drug family, as needed. See id. at 55. Some DEA field offices asked that the default multiplier be adjusted upward. See id. at 55-56.

On July 23, 1998, Patricia M. Good, the DEA's Chief of the Liaison and Policy Section of the Office of Diversion Control, wrote to Bergen Brunswig stating, "This is to grant approval of your request to implement on a nationwide basis your newly developed system to identify and report suspicious orders for controlled substances and regulated chemicals, as required by Federal Regulation." Ex. AM-WV-00781 at 1; Ex. AM-WV-02658.

Ms. Good went on to write that "DEA managers who have been involved with the testing of the system have relayed their positive opinions regarding its ability to provide information in a fashion which is not only useful overall, but is also responsive to the needs of individual DEA offices." Id.

When Bergen Brunswig and Amerisource Health merged in 2001, the newly formed company, AmerisourceBergen, adopted and used

the Bergen Brunswig SOM program across all ABDC distribution centers nationwide. See Zimmerman, 5/12/21, at 192; Mays, 5/17/21, at 189. Prior to April 2007, the DEA never told ABDC that it should not ship suspicious orders or that ABDC should enhance or otherwise modify the suspicious order reports that ABDC was sending to the DEA. See Zimmerman, 5/13/21, at 196; Mays, 5/18/21, at 193-96.

On April 19, 2007, the DEA issued an Immediate Suspension Order ("ISO") for ABDC's Orlando, Florida distribution center. Ex. P-00049. The focus of the ISO was ABDC's Orlando distribution center's distribution of controlled substances to four Florida customers engaged in illicit internet pharmacy activity. See Ex. P-00049; see also Mays, 5/19/21, at 23; Zimmerman, 5/13/21, at 190-91. As part of the pharmacy investigations ABDC launched after the distributor initiative, ABDC had already cut off supplying controlled substances to three of the four pharmacies named in the ISO. See Zimmerman, 5/12/21, at 225; Zimmerman, 5/13/21, at 192.

Shortly after the ISO was served, ABDC met with the DEA in Washington, D.C. on April 25, 2007. See Mays, 5/19/21, at 26. DEA informed ABDC that it wanted ABDC to implement a program that blocked and did not ship the orders it identified as suspicious. See id. at 26-27. According to ABDC, before this point in time, DEA had not offered any guidance regarding a

registrant's obligations regarding suspicious orders that differed from ABDC's program—that is, DEA has never informed ABDC that it should not be shipping suspicious orders or that Excessive Purchase Reports were an insufficient means to report suspicious orders. See, e.g., Zimmerman, 5/13/21, at 196; Mays, 5/18/21, at 193-94, 195-96.

Between April 19 and June 22, 2007, ABDC worked to develop an enhanced diversion control program. See Mays, 5/19/21, at 29-30. ABDC and DEA had meetings at DEA headquarters and DEA personnel were on-site at ABDC's headquarters working alongside personnel from ABDC's Corporate Security and Regulatory Affairs (CSRA) in order to assist with the development of the new diversion control program. See id. at 26-29.

While on site, DEA personnel also provided additional input and guidance. Mr. Mapes, Mr. Wright, and Mr. Davis, at ABDC's request, reviewed due diligence files for several of its high-volume accounts so the DEA could advise whether these files raised any concerns that would justify ABDC cutting off these customers or warrant referral to DEA for investigation. See Mays, 5/19/21, at 30. The DEA never indicated to ABDC that any of these due diligence files were deficient. See Mays, 5/19/21, at 31. The DEA told ABDC that it had done everything it could have done in terms of due diligence for these customers,

including for certain "high volume" customers. See id. at 30-31.

The DEA and ABDC resolved the Orlando matter through a Settlement and Release Agreement on June 22, 2007. See Ex. P-00009. The Agreement did not include any fine or financial penalty. See id. The Agreement stated that it was not "an admission of liability by AmerisourceBergen" and "AmerisourceBergen expressly denies the DEA's allegations." Id. at 1; see also Mays, 5/19/21, at 36. ABDC's new diversion control program included an enhanced SOM program that would block and not ship suspicious orders.

The Agreement further required that that the Orlando distribution center's DEA-registration would be reinstated only after DEA "conduct[ed] reviews of the functionality of AmerisourceBergen's diversion compliance program ("Compliance Reviews") at up to five distribution centers of AmerisourceBergen." Ex. P-00009 at 3. The Compliance Reviews and audits were thorough, taking several days to complete and including the DEA's review of the order review process at the distribution center level. See Mays, 5/19/21, at 34.

The DEA also audited ABDC's order review process at the corporate level, looking, for instance, at the due diligence documents investigators relied on when adjudicating orders. See id. at 34-35. Each of these Compliance Reviews passed muster

and, as a result, the DEA permitted ABDC to file a renewal application for the Orlando distribution center's registration—and the DEA renewed the registration in August 2007. See id. at 35-36.

Mr. Zimmerman, alongside DEA personnel, made a presentation to the industry on ABDC's enhanced diversion control program. See Zimmerman, 5/13/21, at 198-205; Ex. DEF-WV-00001. ABDC understood that the DEA viewed ABDC's new enhanced program as the industry standard, and the DEA wanted other distributors to implement the same or similar program. See Ex. DEF-WV-02191; Ex. DEF-WV-00001; Mays, 5/19/21, at 40; Moné, 5/20, at 157-58 (Q: "Now, what is your understanding of what happened at the conference?" A: "My understanding of what happened at the conference was that a competitor had presented in conjunction with the DEA and explained their new electronic system for reporting suspicious orders and that the expectation of the DEA had changed relative to when Suspicious Order Reports would be sent to DEA.").

Mr. Mapes testified that the DEA asked ABDC to present at this conference because ABDC's newly developed system was compliant with the CSA. See Mapes, 7/11/19, at 178-82. A Cardinal representative who attended the conference said that the DEA referred to system as the new industry standard. See Reardon, 11/30/18, at 528 (Q: "Tell the jury what you remember

about the presentation." A: "That essentially this was going to be the new standard for the industry with respect to how suspicious orders were monitored, reported and handled.").

2. ABDC's 2007 Enhanced Diversion Control Program

ABDC implemented its enhanced diversion control program nationwide in June 2007. The program reported, rejected, and did not ship suspicious orders. See Mays, 5/19/21, at 31-32. Thus, ABDC already had stopped shipping orders identified as suspicious before Mr. Rannazzisi sent his December 2007 "Dear Registrant" letter. The 2007 program consisted of five "buckets" of activities that monitor suspicious orders and guard against diversion, which continue to be the cornerstones of the program through present day. See May, 5/17/21, 29-30.

First, ABDC enhanced its Suspicious Order Monitoring Program. Under the new program, ABDC created peer groups so it could compare like customers to like customers—i.e., retail to retail, hospital to hospital. See id. at 85-86. ABDC organized controlled substances into drug families, "sized" customers, and created new thresholds for each type and size of customer for each drug family, using a multiplier of three for ARCOS-reportable controlled substances. See generally id. at 203-04.

A computer program processes all controlled substances orders to determine if they exceeded the customer's threshold for that particular drug family. See id. at 31-32. Orders that

hit the thresholds, considered "orders of interest," are subject to human review and evaluation (using a totality of circumstances test comprised of many factors) to determine if the order met the statutory definition of "suspicious." See id. at 31-32, 36-39.

Second, ABDC enhanced its due diligence for onboarding new pharmacies by requiring all new pharmacy customers, except for chain customers, to complete a Form 590 during an on-site visit. See Mays, 5/19/21, at 38. After that, a diversion control team member reviewed and verified the customer's responses. See generally Mays, 5/19/21, at 19.

Third, ABDC enhanced its due diligence surrounding existing customers. ABDC implemented a "Do Not Ship List," which includes customers to which ABDC would no longer ship controlled substances or customers ABDC declined to onboard after new customer due diligence investigations. See May, 5/17/21, at 120. CSRA holds weekly meetings to analyze the previous week's suspicious orders, including the drug family, quantity, and other metrics related to each suspicious order. See May, 5/17/21, at 39-40.

Since approximately 2009, ABDC's ongoing customer due diligence efforts generated monthly trend reports containing a list of all customers purchasing controlled substances and data points that the diversion control team used to track and review

controlled substance purchasing. Id. at 96, 101. This suite of reports included both the Order Monitoring Program (OMP) size report and product specific drug trend reports. See Ex. AM-WV-00406; Ex. AM-WV-00398. The OMP size report compared each customer's purchase of controlled substances to its purchase of all products and identified the percentage of controlled substances purchased by that customer over time. See Ex. AM-WV-00406; May, 5/17/21 at 96. The drug trend reports identified each customer's month-over-month controlled substance purchases for specific products like oxycodone and hydrocodone and also provided a monthly average for the five-to-six-month time period covered by each report. See Ex. AM-WV-00398; May, 5/17/21, at 100.

Fourth, ABDC revised and supplemented its policies and procedures to reflect the enhancements it made to its diversion control program in 2007. See May, 5/17/21, at 28. When ABDC has made subsequent revisions to the program, its policies and procedures were revised accordingly. See id.

Finally, ABDC enhanced its training efforts with respect to diversion control. ABDC trains all employees involved in the Diversion Control Program, including associates at the distribution center and CSRA diversion control investigators. See id. at 28-29. ABDC also trains its sales staff. See id.

3. Enhanced Diversion Control Program

In 2014, ABDC began using Pharma Compliance Group, a compliance consulting company made up of former DEA diversion investigators and special agents, for certain pharmacy audits and investigations. See May, 5/14/21, at 55-56. Also in 2014, ABDC engaged FTI Consulting to evaluate its diversion control program, including its SOM program. See id. at 54-55, 63-64. Between 2014 and 2015, ABDC and FTI developed, tested, and refined enhancements to ABDC's SOM program. See id. at 54-55.

The resulting Revised SOM program (typically referred to by ABDC in the normal course as the "Revised OMP") incorporated user-friendly dashboards that visually present many advanced analytics, including customers' purchase history, and trends and developments related to drug use at the national, state, and local levels. See May, 5/17/21, at 50-55, 58-63, 65-68. Dashboards are supported by essentially the same voluminous amounts of information and data that has been available to CSRA investigators since 2007; the presentation of this data facilitates decision-making by diversion investigators on both order adjudication and ongoing customer due diligence efforts. See id. at 93-94.

B. Cardinal Health

The evidence at trial showed that Cardinal Health's Suspicious Order Monitoring Program has evolved and changed over

the years. From the 1990's through present, Cardinal Health's program has taken three general forms:

1. Cardinal Health's Suspicious Pre-2007

From the 1990s until late 2007, Cardinal Health operated a suspicious order monitoring system that included suspicious order reporting and due diligence on Cardinal Health's pharmacy customers. See Reardon, 11/30/18 Dep., at 505-08, 518. Cardinal Health had a two-step process for complying with the regulatory requirement to report suspicious orders. See id. at 506; Brantley 11/27/18, at 529-30; Ex. CAH-WV-00580.

First, Cardinal Health submitted monthly Ingredient Limit Reports ("ILRs") to DEA. See Reardon 11/30/18, at 424-25; Ex. CAH-WV-00580. The format and parameters for ILRs were developed around 1990 as part of a collaboration between the distributors' trade organization, then called the National Wholesale Druggists' Association ("NWDA"), and DEA. See id. at 421-22, 507-08; Brantley 11/27/18, at 521.

From the 1990s through 2007, Cardinal Health submitted ILRs on a monthly basis to the local DEA field office overseeing each distribution center. See Reardon 11/30/18, at 506. Each ILR was based on a computer program which monitored customers' controlled substance purchases for a month and compared those purchases to predetermined averages or limits. If a customer's purchase quantities exceeded the established parameters in that

month, the customer's activity was printed on the report. See Ex. CAH-WV-00580; Norris, 8/7/2018, at 134.

ILRs included customer names and DEA numbers, quantities of specific substances ordered, and the predetermined ingredient limits. If a customer exceeded the ingredient limit for that month, its total purchases were reflected on the ILR. See Reardon, 11/30/18, at 507-08. The predetermined ingredient limits that were applied and appeared on ILRs were based on a formula received from DEA. See Brantley, 11/27/18, at 521, 531-32.

Under that system, Cardinal Health shipped orders that it reported as suspicious or potentially suspicious on ILRs. See Norris, 8/7/2018, at 133. Thus, ILRs were generated after the orders had shipped. See Brantley, 11/27/18, at 368-69.

Second, and separately from the ILRs, Cardinal Health distribution center personnel—sometimes called "pickers and checkers"—would, as a matter of course, evaluate orders on a daily basis before they were shipped to customers. They were encouraged to investigate orders that appeared excessive and notify DEA "before the order [wa]s shipped." Ex. CAH-WV-00580; see also Reardon, 11/30/18 Dep., at 428-29, 437-39; Brantley, 11/27/18, at 369.

Cardinal Health submitted what it called "excessive purchase reports" to DEA reflecting orders identified by

distribution personnel as being of unusual size, pattern, or frequency. See Norris 8/7/18, at 134. In addition to reporting suspicious orders through the two processes outlined above, Cardinal Health also conducted due diligence on its customers before 2007, including by obtaining customer licenses and verifying addresses, see Ex. CAH-WV-00580, and by conducting additional diligence, including site visits to some customers that appeared on ILRs. See Brantley, 11/27/18, at 20.

Mr. Reardon hired Eric Brantley in 2005 to conduct due diligence site visit inspections of pharmacies based on ILRs. See Reardon, 11/30/18, at 517-18; Brantley 11/27/18, at 18-20, 522-23. Mr. Brantley and his team decided whether pharmacy customers posed an unreasonable risk of diversion. If a customer did pose such an unreasonable risk, it was terminated and DEA agent Kyle Wright was notified. See Brantley, 11/27/18, at 20, 522-23. Likewise, when Cardinal Health came to believe a customer might be involved in internet activity, it discontinued shipments of controlled substances to that customer and reported that customer to the DEA. See id. at 544.

Mr. Brantley also trained members of Cardinal Health's senior management, sales force, and the QRA team on anti-diversion policies. See Brantley, 11/27/18, at 547-48. Cardinal Health believed that the DEA approved of the changes to

its SOM program. See Reardon, 11/30/18, at 520-25; Brantley 11/27/18, at 548-50.

Mr. Reardon had conversations in 2006 with Kyle Wright, the DEA agent who received Cardinal Health's notifications of terminated customers. Mr. Reardon understood from those conversations that the DEA thought Cardinal Health was headed in the right direction and that Mr. Brantley had established a great working relationship with Mr. Wright. See Reardon 11/30/18, at 520.

Mr. Wright never told Mr. Reardon or Mr. Brantley that Cardinal Health's anti-diversion program was deficient in any way. See Reardon, 11/30/18, at 521; Brantley, 11/27/18, at 549-50. On April 26, 2007, Mr. Reardon spoke to Mr. Wright by telephone. During that conversation, Mr. Wright indicated that Cardinal Health was "doing the right things and heading in the right direction." Reardon, 11/30/18, at 521-25; Brantley 11/27/18, at 550-52.

Mr. Reardon attended the DEA Pharmaceutical Industry Conference on September 11, 2007. See Reardon, 11/30/18, at 528; Ex. P-00069. At that conference, AmerisourceBergen and DEA jointly presented a new suspicious order monitoring program that AmerisourceBergen recently had developed and implemented. Ex. P-00069.

Following that presentation, Mr. Reardon sent the slides from that presentation to colleagues at Cardinal Health and informed them that "DEA is setting a new standard with which we must comply," and that DEA referred to ABDC's program as they presented it as the "new industry standard." Ex. P-00069. This presentation was the first time Mr. Reardon understood DEA to be providing guidance to distributors not to ship orders they reported as suspicious. See Reardon, 11/30/18, at 529. Immediately upon his return to Cardinal Health's corporate office following the presentation by ABDC and the DEA, Mr. Reardon began creating a new team to develop a new SOM program. See Reardon, 11/30/18, at 529-30.

2. Cardinal Health's Suspicious Order Monitoring System: 2008-2012

In late 2007, Cardinal Health revised its SOM program to take account of and conform to DEA's guidance and expectations. Cardinal Health implemented that revised program in early 2008 and operated that system until 2012.

Cardinal Health enhanced its SOM system to incorporate the three main components discussed in the DEA-AmerisourceBergen presentation: (1) "Know Your Customer," (2) electronic order monitoring, and (3) investigations. See Moné, 5/20/21, at 158, 173-74. "Know Your Customer" involved thorough evaluation of new customers (i.e., review of detailed questionnaires) and

continuing diligence regarding existing customers. See id. at 173, 182. Approval of new customers was not automatic: Cardinal Health refused to approve certain prospective customers due to diversion concerns. See id. at 221-22.

With electronic order monitoring, Cardinal Health established customized thresholds (or limits) for each customer and each drug family. See id. at 184-85; Norris, 8/7/18, at 226. This system automatically blocked orders that exceeded a customer's threshold, pending evaluation by the anti-diversion team comprised of in-house pharmacists who reviewed any information that they believed was necessary to make an appropriate assessment. See Moné, 5/20/21, at 185-87. If the anti-diversion team cleared the order after the assessment, the order was shipped. See id. at 63. If the anti-diversion team determined that an order was in fact suspicious, Cardinal Health reported the order to the DEA and did not ship it. See id. at 189

In setting thresholds, Cardinal segmented customers by type and size. See Moné, 5/20/21, at 59-60. It consulted with experts, including Deloitte, IBM Watson, and a Ph.D. at Ohio State, each of whom concluded that the assumptions underlying the threshold calculations were appropriate. See id. at 139, 143. Cardinal Health also relied in part on the DEA's Chemical Handlers Manual, which provided a framework for identifying

excessive orders of List I chemicals, which include certain controlled substances, using a multiplier. See id. at 93-94.

Over time the anti-diversion team would evaluate thresholds and determine whether or not to make changes to thresholds. See id. at 64-65. Cardinal Health, under Mr. Moné's direction, also created an Analytics team to support the SOM system in establishing thresholds and running reports. See id. at 83, 174, 199.

The investigations component of Cardinal Health's suspicious order monitoring system involved site visits of pharmacy customers conducted by former police and former DEA-diversion, Medicaid-fraud, and Board of Pharmacy investigators. See id. at 174, 187-88. Cardinal Health adopted comprehensive Standard Operating Procedures ("SOPs") regarding the SOM system, and periodically updated those procedures. See, e.g., Ex. CAH-WV-00030 (SOP for the new account approval process); Ex. CAH-WV-00745 (SOP to establish SOM threshold limits); Ex. CAH-WV-00743 (SOP for threshold event review, self-verification; decision making and threshold outcome communication); Ex. CAH-WV-00740 (updated SOP for detecting and reporting suspicious orders and responding to threshold events); Ex. CAH-WV-00026 (SOP for on-site investigations); Ex. CAH-WV-00747 (updated SOP for on-site investigations). Cardinal Health trained and tested all

employees involved in anti-diversion activities on the SOPs. See Moné, 5/20/21, at 192, 196.

From 2007 to 2012, Mr. Moné regularly communicated with the DEA about Cardinal Health's SOM system. See id. at 217-19. In early 2009, Mr. Moné met with Barbara Boockholdt (Chief of the Regulatory Section of the DEA's Office of Diversion Control) and several DEA diversion investigators. Over the course of a week, Mr. Moné reviewed with them the company's SOM system, as revamped in light of the DEA's new expectations. See id. at 219-20.

That discussion included reviewing the procedures for setting customer thresholds—including any multipliers used—and how Cardinal Health identified and reported suspicious orders. See id. at 220. Cardinal Health shared with the DEA its policies and procedures and demonstrated the kinds of reports that could be generated by the SOM system. See id. at 220-21. At the end of that weeklong meeting, the DEA did not ask Cardinal Health to change the system or fault it in any way. See id. ; Quintero, 12/6/18, at 90-91.

Following the 2009 meeting, the DEA inspected a number of Cardinal Health distribution centers, doing "a deep dive into the SOM system" for the purpose of verifying that the SOM system worked as indicated. Moné, 5/20/21, at 223-24. At the

conclusion of the inspections, the DEA did not identify any flaws in the system. Quintero, 12/6/18, at 90-91.

3. Cardinal Health's Suspicious Order Monitoring System: 2012-Present

In 2012, Todd Cameron assumed responsibility for the company's anti-diversion efforts and enhanced the program again. See Moné, 5/20/21, at 16. Cardinal Health developed a new analytical methodology to set thresholds for customers. That methodology calculates how busy a pharmacy is based on the total number of prescriptions it dispenses for all medications. Cardinal Health then uses national pharmacy data purchased from a third-party data aggregation company to determine what a normal dispensing product mix looks like, and then applies that data to the customer's overall prescription count. It further considers information about the specific pharmacy gathered in due diligence to set customer-specific and drug-specific threshold limits. Ex. CAH-WV-00476 ("Enhancing our anti-diversion program" memo); Quintero, 12/6/18, at 70-74.

Orders that hit thresholds are held for review by analysts on the anti-diversion team. Analysts first familiarize themselves with background due diligence on the customer, including previous held orders and resolutions thereof, the location of the customer, the customer's class of trade, and comments in the Anti-Diversion Centralization database.

Analysts then review the specific held order, including the drug family, order size, threshold, and accrual amount to determine whether the order should be cleared for shipment or cancelled and reported to the DEA. Ex. P-14290_00825 (QRA SOM Customer Analytics General Work Instructions).

Cardinal Health implemented what it calls "objective criteria" to quantitatively assess its customers across a variety of data metrics. Cardinal Health collects data about its customers across the objective criteria—which include the percentage of prescriptions dispensed that are for controlled substances and more specifically for opioids—and compares that data to national averages. Ex. CAH-WV-00476 ("Enhancing our anti-diversion program" memo); Ex. P-14290_00884 (Objective Criteria Working Guidelines).

Cardinal Health developed the Large Volume Tactical and Analytical Committee ("LVTAC"), which is a group of anti-diversion professionals, including senior leadership, which analyzes and makes decisions about customers that purchase large volumes of controlled substances from Cardinal Health. See Ex. CAH-WV-00065 (LVTAC SOP); Ex. CAH-WV-00564 (two-person approval SOP).

Cardinal Health continues to do regular site investigations of its customers, visiting them in person, looking for any signs of possible diversion, and requesting and analyzing pharmacy

data. Ex. P-14290_00860 (QRA Investigations SOP); Quintero 12/6/18, at 98-101. This data-driven, analytical methodology requires orders to be reported to DEA anytime they hit a threshold and cannot be promptly cleared for shipment based on due diligence information on hand, even if Cardinal Health doesn't believe that diversion is occurring at the pharmacy. See Quintero, 12/6/18, at 84-85, 94-97; Ex. CAH-WV-00104 (Detecting and Reporting Suspicious Orders SOP); Ex. CAH-WV-00562 (DMQ Working Guidelines); Ex. P-14290_00825 (QRA SOM Customer Analytics General Work Instructions). Accordingly, Cardinal Health submitted more suspicious order reports for customers in Cabell County and the City of Huntington starting in 2012, compared with previous years. See Ex. P-42071.

C. McKesson

The evidence at trial showed that McKesson's SOM program has evolved and changed over the years. From the 1990's through present, McKesson's program has taken three general forms:

1. Section 55

Prior to 2008, McKesson operated a SOM program that was set out in Section 55 of McKesson's Drug Operations Manual ("Section 55"). See Ex. MC-WV-00451 (Section 55 Manual). Under Section 55, each McKesson distribution center submitted daily faxes to DEA, called "DU-45" reports, which "listed all suspicious orders

identified from [its] customers' purchasing patterns." Oriente, 5/25/21, at 42.

Under Section 55, McKesson used an algorithm to identify suspicious orders that utilized a "three times monthly average for Schedule[] II and III" prescription opioids. Oriente, 5/25/21, at 44; see also Ex. MC-WV-00451 (Section 55 Manual) at .00047. This three-times criterion for identifying suspicious orders was identical to another monitoring system that DEA had reviewed. Oriente testified as to his understanding that Section 55 was "based on DEA approved guidelines." Oriente, 5/25/21, at 50.

McKesson's Section 55 Manual includes a copy of the 1984 letter that DEA sent after reviewing this SOM system using a three-times modifier, which stated that the SOM system would "provide effective customer verification and suspicious and/or excess order monitoring system" and "appear[s] appropriate for implementation." Ex. MC-WV-00451 at 204-05. McKesson relied on the DEA's statements in this 1984 letter and, based on it, McKesson informed its employees that "these guidelines [in Section 55] have been accepted by the DEA" and "compliance with them is mandatory." Id. at 46.

McKesson's DU-45 report included text expressly informing DEA that the submission was made "[p]ursuant to CFR 21 [§] 1301.74(B)" and "reflect[ed] purchases from customers for

schedules II-V controlled substance which exceed the monthly average" used by McKesson to identify potentially suspicious orders. See, e.g., Ex. MC-WV-02143 at 2.

Section 55 of McKesson's Drug Operations Manual states that the "Daily Controlled Substance Suspicious Order Warning Report . . . can be faxed to your local DEA district office before the order is shipped." Ex. MC-WV-00451 at 48. DU-45 reports were created and sent by "each distribution center" operated by McKesson. Oriente, 5/25/21, at 43. McKesson submitted DU-45 reports from each distribution center until early 2009. See id. at 43. Under Section 55, McKesson did not systematically block all orders identified as suspicious under the DEA's regulatory definition. See Oriente, 5/25/21, at 9. Any blocking would have been manual. See id.

2. Lifestyle Drug Monitoring Program

In 2007, McKesson adopted a Lifestyle Drug Monitoring Program ("LDMP") that was an immediate precursor to McKesson's 2008 Controlled Substance Monitoring Program ("CSMP"). See Oriente, 5/25/21, at 59. The LDMP operated in conjunction with, but did not replace, Section 55. See id. at 43 (testifying that McKesson submitted DU-45 reports "up to about 2009"); see id. at 59 (confirming that the LDMP overlapped with Section 55). Under the LDMP, in addition to continued operation of Section 55 and DU-45 reporting, McKesson conducted additional monitoring of

four substances, including hydrocodone and oxycodone. See Ex. DEF-WV-01527 at 3.

The LDMP "target[ed] controlled substances that the DEA consider[ed] 'lifestyle' drugs." Id. "Lifestyle drug" was a term McKesson adopted from the DEA. See Oriente, 5/25/21, at 59-60. Where any customer's purchases of one of the substances monitored under the LDMP exceeded 8,000, the LDMP set forth a process to conduct additional review of the customer's purchasing patterns, culminating in potentially terminating the customer and reporting that customer to the DEA. See Ex. DEF-WV-01527 at 3-7.

3. Controlled Substance Monitoring Program (2008–2013)

McKesson implemented a new SOM program, the Controlled Substance Monitoring Program ("CSMP"), in May 2008. See Oriente, 5/25/21, at 55, 58-59; Ex. MC-WV-00381. With the advent of the CSMP, McKesson began automatically blocking all orders that it identified as suspicious. See Ex. MC-WV-00381 at 6; Oriente, 5/25/21, at 9, 55. In addition to blocking of all orders identified as suspicious, Mr. Oriente confirmed that McKesson continued to block all orders that it believed were likely to be diverted. See Oriente, 5/25/21, at 55.

In order to identify orders as suspicious and block those orders, McKesson employed a system of setting customer-specific maximum monthly thresholds for each DEA drug base code. Mr.

Oriente testified that under the CSMP, a monthly order limit, or "threshold," was determined for each controlled substance base code at each pharmacy. See Oriente, 5/25/21, at 62.

Under the CSMP, if a customer ordered above its threshold that order would be automatically blocked and would not be shipped. See id. Under the CSMP, after a customer met its monthly threshold, all further orders for any product containing that DEA base code were blocked for the remainder of the month. See id. at 74; Ex. MC-WV-00381 at 6-7.

There was no process for further review and potential shipment of any order in excess of a threshold. Under the CSMP as operated by McKesson, these blocked orders could not later be released. See Ex. MC-WV-00381 at 7; Oriente, 5/25/21, at 62 ("It was blocked for all time. There was not further review for releasing. It ceased to exist.").

Thresholds under the CSMP were set in a manner to account for each customer's individual needs and ordering variability. Mr. Oriente testified that thresholds were set on a customer-specific basis in order to account for the individualized nature of that pharmacy customer's business, in recognition of the fact that there is wide variability in needs and business models across McKesson's network of customers. See Oriente, 5/25/21, at 63-64. Mr. Oriente explained that thresholds were set using a customer's historical purchasing in order to account for that

customer's individualized needs and business model. See id. at 63.

In order to account for natural ordering variability, Mr. Oriente testified that McKesson also applied small "buffers" as a reasonable measure to "offset . . . variability where pharmacies order more or less each month." Id. at 103. Initially, McKesson notified a customer when it was approaching its threshold. This was to ensure that, if a threshold adjustment was appropriate, McKesson could review a pharmacy's request to modify its threshold before orders to fill legitimate prescriptions were blocked. See id. at 108. Mr. Ashworth testified that when a customer requested a change in its threshold after receiving notice from McKesson, that customer would still have to satisfy the "whole threshold request procedure." Ashworth, 5/25/21, at 219.

McKesson's Regulatory Affairs Department reviewed all customer requests to adjust thresholds after receiving a request from the customer that set forth reasons and data supporting the adjustment. Mr. Oriente testified that a customer that wished to have a threshold adjusted would have to submit a TCR form for review by regulatory affairs personnel at McKesson. See Oriente, 5/25/21, at 75.

Mr. Oriente confirmed that McKesson's Directors of Regulatory Affairs were responsible for approving all TCRs

submitted by customers. See Oriente, 5/25/21, at 75:18-20. Mr. Oriente testified that each TCR would receive due diligence prior to approval or rejection. See id. at 65. Mr. Oriente further testified that, in evaluating a request for an increased threshold, McKesson would receive and consider the customer's dispensing data, as well as the customer's stated reason for the increase. See Oriente, 5/25/21, at 75. McKesson would also request prescriber information as part of its due diligence when necessary. See id. at 69.

Under the CSMP, McKesson also conducted customer due diligence proactively throughout its relationship with a customer, including during customer onboarding and for existing customers. See Oriente, 5/24/21, at 181; Oriente, 5/25/21, at 65-66. In the context of onboarding a new customer, McKesson undertook specific diligence to vet that customer prior to approving that customer to purchase controlled substances. See Oriente, 5/25/21, at 82. McKesson's 2008 CSMP Manual made clear that each new customer had to undergo a customer onboarding process, including providing information to McKesson about its business practices and that "[a]t no time is there a guarantee, implied or otherwise, that any customer will be able to purchase controlled substances based upon information received during this process." Ex. MC-WV-00381 at 9.

The 2008 CSMP Manual further specified that "[a] complete customer questionnaire is mandatory for every new McKesson customer prior to them receiving controlled substances" and that "it is necessary to obtain past purchasing information" from the customer in order to "understand the new customer[']s current controlled substance purchase requirements." Ex. MC-WV-00381 at 11, 13. Mr. Oriente testified that as part of McKesson's onboarding process for new customers, McKesson would administer a customer questionnaire, ask for dispensing data, and do a site visit. See Oriente, 5/25/21, at 83:7-24.

The customer questionnaire required a potential new pharmacy customer to provide information on its licensing status, the identity of its personnel that would handle controlled substances, its average amount of purchases, and its customer base and business model. See Ex. MC-WV-00381 at 11-14. The questionnaire also included a section for a physical inspection completed by a McKesson employee. See Oriente, 5/25/21, at 89-90 (describing physical inspection of new pharmacy customers). In addition to the above diligence, McKesson verified DEA and state licenses of pharmacies as part of its onboarding process. See id. at 86-87.

Under the CSMP, McKesson also conducted ongoing due diligence of its existing customers. See id. at 90-91, 94; Ex. MC-WV-00381 at 5. Mr. Oriente testified that he would

proactively review customers and select pharmacies for site visits based on markers such as size, purchasing level, number of blocked orders, or other "red flags." See Oriente, 5/25/21, at 92. "Red flags" are items that McKesson's Regulatory Affairs team would pay attention to as they evaluated customers. However, the presence of a red flag, by itself, does not mean diversion has occurred or will occur.

Red flags can be resolved through additional diligence. See id. at 96. McKesson provided guidance to its employees about the types of "red flags" to look for when evaluating pharmacies. See, e.g., Ex. P-12643. Mr. Oriente testified that "red flags" changed over time "[a]s different diversion trends evolved . . . and came to light . . . and [were] added to our red flag list." Oriente, 5/25/21, at 98. During on-site visits to current customers, McKesson would look for "red flags" such as out-of-state plates on cars, security guards on site, or unusually long lines. See id. at 89, 93-94. McKesson would also consider how customers paid for their prescriptions, and the range of products sold by the pharmacy. See id. at 94. Where "red flags" or other issues could not be resolved, McKesson would terminate existing customers. See id.

Under the CSMP, McKesson used a three-level review process to investigate suspicious orders. A Level I review would be conducted for customers who had an order blocked. See Ex. MC-

WV-00381 at 7 ("A level 1 review is required for every threshold excursion," resulting in a blocked order); Oriente, 5/25/21, at 77, 81 (Q: "Just to orient ourselves . . . what level would blocking occur at?" A: "Prior to Level 1."). A Level I review consisted of a McKesson employee contacting a customer to ask why that customer had attempted to order above its threshold, triggering a blocked order. See id. at 77. If a Level I review resolved suspicions, the order would not be treated as suspicious or reported to DEA. See id. at 78; Ex. MC-WV-00381 at 7.

Even if a Level I review resolved any suspicions, the ordered item would remain "blocked for the remainder of the month" unless the customers separately submitted a TCR form that was approved by a Director of Regulatory Affairs. Oriente, 5/25/21, at 77. The two review processes, Level I and TCR review, are distinct. See Ex. MC-WV-00381 at 7 (at the conclusion of a Level I, McKesson will "[c]ontinue to block item until the beginning of [the] new month," absent a "[r]equest [for] a temporary/permanent threshold change"). If the Level I review did not resolve suspicions, then McKesson would escalate the customer to a Level II review. See Oriente, 5/25/21, at 78.

A Level II review would involve escalation to a member of the Regulatory Affairs team at McKesson "to do a review of that pharmacy. Id. at 78-79; Ex. MC-WV-00381 at 7-8. An order could

be resolved at a Level II review, but if suspicions remained the order would be escalated to a Level III review. See Oriente, 5/25/21, at 79; Ex. MC-WV-00381 at 8 ("If after the Level I and Level II reviews have been conducted and the transactions are deemed 'suspicious' a Level III review is necessary.").

McKesson's policy manual states, and Mr. Oriente confirmed, that "[u]pon escalation to Level III, ALL control[led substance orders] will be blocked." Ex. MC-WV-00381 at 8; Oriente, 5/25/21, at 79 ("[T]he customer would be blocked from all controlled substances."). This includes other controlled substance base codes, in addition to the base code for the order triggering the review. See id. at 79 ("[A]ll controlled substances for that customer, not just that specific base code that was [already] blocked, would be blocked.").

Upon reaching a Level III review, McKesson would also notify the DEA about the terminated customer and report the customer and its orders as "suspicious." See id. at 79-80; Ex. MC-WV-00381 at 8 ("The customer / transaction(s) are reported to DEA Headquarters as 'suspicious'"). Mr. Oriente testified that Level III reviews and accompanying terminations could happen with or without a preceding Level I or II review. See Oriente, 5/25/21, at 95:14-20.

Based upon what it believed the DEA wanted, McKesson adopted the CSMP system that reported orders as suspicious at a

Level III review, despite having already blocked that order prior to a Level I review. See id. at 81. As a result, McKesson reported fewer suspicious orders than it blocked during this period of time. See id. Mr. Oriente confirmed that all suspicious orders "would be blocked" under McKesson's CSMP, even if blocked orders that did not escalate to Level III review were not reported. Id.

Mr. Oriente gave a presentation on its CSMP program to DEA in November 2008 in order to make DEA aware of McKesson's new SOM Program and receive feedback. See Oriente, 5/25/21, at 101-02; Ex. P-42657. Mr. Oriente told DEA that McKesson's CSMP would block orders prior to a Level I review, but that McKesson would not report those orders as suspicious until a Level III review. See Oriente, 5/25/21, at 109-10; Ex. P-42657 at 16.

DEA did not express any disagreement to Mr. Oriente upon being told about this three-level reporting process. See Oriente, 5/25/21, at 110. McKesson's Senior Vice President of Distribution Operations, Donald Walker, gave a similar presentation to DEA in July 2008. See id. at 110-12; Ex. MC-WV-00397. Mr. Walker's presentation also laid out McKesson's three-level reporting structure, that showed blocking of orders occurring prior to Level I review and DEA reporting occurring at Level III review. See Ex. MC-WV-00397 at 10-12; see also Oriente, 5/25/21, at 112-13. In this same presentation,

McKesson told the DEA that it would stop submitting DU-45 reports to local field offices. See Oriente, 5/25/21, at 113; Ex. MC-WV-00397 at 13.

4. Controlled Substance Monitoring Program (2013–present)

From 2013 through the present, McKesson has continued to systematically block all suspicious orders, and it has also blocked all orders it identified as likely to be diverted. See Oriente, 5/25/21, at 126. In 2013, McKesson increased the volume of suspicious order reporting to cover all orders that McKesson was blocking, not just those that reached a Level III. See id. at 125-26, 130, 133.

In 2013, McKesson made other modifications and enhancements to its CSMP. In 2013, McKesson made enhancements to its due diligence processes, including less frequent threshold modifications. See id. at 126, 129, 132. In 2013, McKesson increased the number of personnel in the regulatory affairs department, including hiring individuals with prior DEA experience. See id. at 129. By 2015, this department included approximately 26 people. See id. at 132; Ex. MC-WV-00199 at 6. In 2013, McKesson began using enhanced data reports and a more rigorous process for threshold change requests. See id. at 129. In 2013, McKesson implemented additional training for employees. See id. at 130; Ex. P-13737 (email regarding training).

Since 2015, McKesson has also used an algorithm developed by an outside data analytics firm, Analysis Group, Inc. ("AGI"), to set and monitor customer thresholds. See Oriente, 5/25/21, at 134-35, 136. AGI's algorithm reviews each customer's prior purchasing and also compares each customer's purchases against the purchases of similar customers in a geographic area to create dynamic thresholds that track customer purchases over time. See id. at 135.

VI. Plaintiffs Have Not Proved Diversion-control Failures by Defendants

Plaintiffs did not prove that defendants failed to maintain effective controls against diversion and design and operate sufficient SOM systems to do so. Relatedly, plaintiffs did not prove that defendants' due diligence with respect to suspicious orders was inadequate.

The evidence that defendants did not maintain effective controls against diversion or operate systems sufficient to do so was unpersuasive. Plaintiffs attempted to prove such failures through their expert witness James Rafalski ("Rafalski"). From 2004 to 2017, Mr. Rafalski was employed as a DEA Diversion Investigator. See Rafalski, 5/26/21, at 15–16, 124. When he joined the DEA in 2004, Mr. Rafalksi brought with him twenty-six years of law enforcement experience. Plaintiffs presented Mr. Rafalski as "an expert in the field of diversion

control investigations, Suspicious Order Monitoring Systems, and maintenance of effective control to prevent diversion of controlled substances into the illicit market." Id. at 30.

Defendants objected to the court's recognition of Mr. Rafalski as an expert on causation between purported failures in defendants' efforts to maintain effective controls against diversion and diversion itself and the opioid epidemic. Moreover, Mr. Raflaksi was the subject of a Daubert motion, which the court deferred a ruling on until the close of Mr. Rafalski's testimony. Defendants renewed their motion after Mr. Rafalski's testimony.

Ultimately, the court ruled that, as a matter of Daubert and Federal Rule of Evidence 702, Mr. Rafalski's opinions regarding potential flagging criteria that defendants conceivably could have used in their suspicious order monitoring systems ("SOMS"), and the results thereof, were admissible. See ECF No. 1529. The court also found admissible Mr. Rafalski's opinions that defendants failed to design effective systems to prevent diversion and failed to maintain effective controls against diversion, and that such failures were systemic in nature. See id.

The court found inadmissible (for lack of a reliable methodology) Mr. Rafalski's opinions regarding causation. This includes his opinion that the opioid epidemic in the City of

Huntington and Cabell County can be traced to defendants' purported deficiencies in maintaining effective controls against diversion and designing and operating effective SOM programs (that the deficiencies were a "substantial factor" in causing the epidemic). See id. The court also found unreliable and inadmissible Mr. Rafalski's conclusion that certain swaths of shipments that he believed defendants knew or should have known were suspicious, and yet still shipped, were more likely than not diverted. See id.

A. Flagging Methods and Results Thereof

Mr. Rafalski provided a list of six sets of flagging criteria (from among a "huge number" of possible sets of criteria) that defendants could have used in their SOM programs. Rafalski, 5/26/21, at 83-85. He referred to these sets of criteria as Methods A through F. Id. The court finds that Methods A through F represent sets of flagging criteria that are among the innumerable possibilities that defendants could have used. As explained below, the methods were not convincing ways to achieve accurate results of the number of orders that should have been flagged or blocked.

The shipment data available to Mr. Rafalski included McKesson from 2004 through 2018; AmerisourceBergen from 2002 through 2018; Cardinal Health from 1996 through 2018 and ARCOS data from 2006 through 2014. Id. at 45. The following is a

description of Methods A through F and the results of applying them to that shipment data.

Method A

This method looks back at six months of data for the pharmacy and sets the threshold at the highest order amount in the prior six months. Id. at 87-88. If an order exceeds the highest order amount in the prior six months, the system triggers or flags the order and holds the order pending review or the execution of due diligence sufficient to dispel the suspicion of the order having been flagged. Id. at 88-89. Because Mr. Rafalski assumes that due diligence did not dispel the suspicion, all future shipments are flagged as suspicious and unable to be shipped. Id. at 89. If defendants' distributions are imagined as a line, this method flags the point at which the flagging criteria is first met and the rest of the line into the future.

ABDC

Oxycodone dosage units flagged: 11,610,920 – 90.6%

Hydrocodone dosage units flagged: 20,621,360 – 91.1%

Cardinal

Oxycodone dosage units flagged: 15,997,400 – 93.1%

Hydrocodone dosage units flagged: 14,795,350 – 82.5%

McKesson

Oxycodone dosage units flagged: 3,501,970 – 87.9%

Hydrocodone dosage units flagged: 3,261,250 – 87.4%

Id. at 96-97.

Method B

This method is similar to Method A in that the trigger or cap is set in the same manner: a six month look-back. Id. at 89. However, rather than stop all future orders once the trigger is initiated by an order over the highest order in the last six months, future orders are shipped up to the cap and all orders over the cap or trigger are held or blocked. Id.

ABDC

Oxycodone dosage units flagged: 3,763,580 – 29.4%

Hydrocodone dosage units flagged: 5,616,380 – 24.8%

Cardinal Health

Oxycodone dosage units flagged: 11,325,200 – 65.9%

Hydrocodone dosage units flagged: 7,252,580 – 40.5%

McKesson

Oxycodone dosage units flagged 805,300 – 20.2%

Hydrocodone dosage units flagged 2,390,800 – 64%

Id. 98.

Method C

This method looks back twelve months to identify an average number of pills distributed in either the state of West Virginia or nationally (depending on the available data). Each month, the trigger is recalculated based upon the prior twelve months.

Id. at 92-93. This method would then calculate the trigger as double the prior twelve-month average. Id.

ABDC

Oxycodone dosage units flagged: 10,477,680 – 81.8%

Hydrocodone dosage units flagged: 18,877,140 – 83.4%

Cardinal Health

Oxycodone dosage units flagged: 14,011,880 – 81.5%

Hydrocodone dosage units flagged: 16,593,780 – 92.6%

McKesson

Oxycodone dosage units flagged: 2,405,620 – 60.4%

Hydrocodone dosage units flagged: 2,362,420 – 63.3%

Id. at 98.

Method D

This method is similar to Method C except that rather than doubling the prior twelve-month average order of pills, the trigger is set at triple or three times the prior twelve-month average. Id. at 85, 93.

ABDC

Oxycodone dosage units flagged: 8,360,740 – 65.3%

Hydrocodone dosage units flagged: 15,701,930– 69.4%

Cardinal Health

Oxycodone dosage units flagged: 9,567,580 – 55.7%

Hydrocodone dosage units flagged: 14,957,360 – 83.5%

McKesson

Oxycodone dosage units flagged: 1,005,320 – 25.2%

Hydrocodone dosage units flagged: 1,245,640 – 33.4%

Id. at 99-100.

Method E

This method sets the trigger at 8,000 dosage units per customer, per month. McKesson used an 8,000 flagging criterion, but for less than a year. Id. at 93-94; Rafalski, 5/27/21, at 10.

ABDC

Oxycodone dosage units flagged: 10,446,280 – 81.5%

Hydrocodone dosage units flagged: 21,679,760– 95.8%

Cardinal Health

Oxycodone dosage units flagged: 13,274,080 – 77.2%

Hydrocodone dosage units flagged: 16,159,150 – 90.2%

McKesson

Oxycodone dosage units flagged: 2,098560 – 52.7%

Hydrocodone dosage units flagged: 2,484,640 – 66.6%

Rafalski, 5/26/21, at 100-01.

Method F

With this method, there is a maximum daily dosage unit order on a list in the cage or vault where the packers work, and anything above the amount on the list in the vault is not shipped. The amounts from the list of one of the defendants was used for the calculations. Id. at 94-95.

ABDC

Oxycodone dosage units flagged: 12,459,020 – 97.3%

Hydrocodone dosage units flagged: 22,582,020 – 99.8%

Cardinal Health

Oxycodone dosage units flagged: 16,527,880 – 96.2%

Hydrocodone dosage units flagged: 17,688,100 – 98%

McKesson

Oxycodone dosage units flagged 3,713,000 – 93.2%

Hydrocodone dosage units flagged 3,648,650 – 97.9%

Id. at 101.

B. Results of Methods A through F Unpersuasive

The results of the flagging methods were unpersuasive indicators of the level of suspicious orders that defendants allegedly received and fulfilled. In large part, this is because, as explained below, the court rejects as factually unsupported Mr. Rafalski's assumption that for every single order Methods A through F flagged, no due diligence was done to clear the suspicion.

The results of Methods A through F were unpersuasive for additional reasons. Method A, for example, employs an assumption that once an order is flagged, all future orders are permanently and automatically to be flagged as suspicious as well. Id. at 96, 226-27. This assumption, together with Mr. Rafalski's assumption that due diligence was never done, means

that after the flagging criteria is met once, Method A deems every subsequent order suspicious and unable to be shipped (in perpetuity). Id.; Boberg, 7/8/21, at 169.

Ninety-six percent of all orders flagged by Method A are flagged solely due to the application of the assumption that all future orders must be flagged, not due to the actual application of the Method A criteria itself. See Boberg, 7/8/21, at 173-74. Piling assumption upon assumption, Method A leads to an entirely unpersuasive result.

Methods C through F were unconvincing, as an initial matter, because Mr. Rafalski himself stated that he would not use them. Rafalski, 5/26/21, at 224-25. These methods were also not clearly explained. For example, the record is unclear as to whether Mr. Rafalski asked Dr. McCann to employ an assumption with Methods C through F that once an order is flagged, all subsequent orders must also be flagged (as with Method A), and if he did not do so, why not.

The results of Method B were less obviously flawed, but these too were entirely unpersuasive. Using Method B, Mr. Rafalski testified that defendants should have blocked and not shipped 20-66% of their oxycodone and hydrocodone shipments into the City of Huntington and Cabell County. Id. at 89, 91, 97.

Under Method B, a fixed threshold is established based on the maximum monthly volume of the first six months of shipments.

See id. at 89. Method B assumes that any order exceeding that fixed threshold should be blocked as suspicious and not shipped. See id. at 89, 91, 97. The fixed threshold assumed by Method B never changes or increases based on any subsequent developments, including particularly increased levels of prescribing or changes in the standards of care. See id. at 241.

Of the orders flagged by Method B, 89% are flagged solely due to the application of the "fixed threshold assumption," not due to the actual application of the underlying Method B criteria. See Boberg, 7/8/21, at 176-77.

Methods A through F represent sets of flagging criteria that were only roughly equivalent to those used in the real world. See Rafalski, 5/26/21, at 220-21. Methods A and B (which produced vastly different results) were both framed as being based on the systems that the distributor-defendant in Masters Pharm., Inc. v. DEA, 861 F.3d 206, 216 (D.C. Cir. 2017) had used. Id. at 225-26. Method C was framed as being based on what a drug manufacturer (Mallinckrodt) had used. See id. at 85.

Methods D through F were framed as being based on SOM programs Mr. Rafalski believes that one or more defendants used at various times, although there was no persuasive evidence linking any method (to any reasonable degree of similitude) to any defendant for any substantial portion of the time. See id.

at 85, 240; Rafalski, 5/27/21, at 10. That is to say, the evidence established no more than that the methods were only roughly based on what some defendants used some of the time.

Although it was advertised as such, Method A is not consistent with the methodology described in Masters given that it uses shipment data instead of order data, and because it applies an additional assumption not present in Masters. See Boberg, 7/8/21, at 188–89. The assumption is that once one order is flagged, all future orders must also be flagged. Rafalski, 5/26/21, at 88-89, 97, 101-02. Mr. Rafalski acknowledged that Method A and the Masters system differ "in important regards." Id. at 225-26.

Likewise, although it was also advertised as such, Method B is not consistent with the flagging methodology described in Masters given that it too is applied to shipment data, not order data. See Boberg, 7/8/21, at 188-89. Furthermore, Mr. Rafalski described Method B as merely "similar" to the Masters system. Rafalski, 5/26/21, at 238.

Regardless, even assuming Method A or B matched the system in Masters, applying those systems to the defendants here, none of whom used them, is inconsistent with the analysis in Masters itself. In Masters, the distributor's conduct was judged against the failures evident when applying its own SOM program. See 861 F.3d at 214-16. The court noted that Masters

Pharmaceutical's SOM program flagged orders that could be considered suspicious "[a]s a matter of common sense and ordinary language," but the court did not purport to mandate that SOM program for other distributors. Id. at 216-17.

By contrast, Mr. Rafalski's analysis does not judge defendants' conduct against their own SOMS. This is obvious for Methods A and B, but it is also true for the remaining methods because the evidence did not show that those methods came reasonably close to replicating what was happening in the real world with defendants' SOM programs.

Furthermore, Mr. Rafalski did not arrive at his conclusions regarding each defendant's purported diversion-control failures with any particular regard to whatever method(s) he thought matched each defendant's own SOM program (at various times). That is, Mr. Rafalski's testimony did not emphasize the results of a method based on its supposed closeness to what a given defendant had used. Instead, Mr. Rafalski expressed a preference for Method A, which no defendant had used. Id. at 85, 219. Additionally, it was not clear whether Mr. Rafalski deemed the results of Method A sufficient to sustain his opinion that each defendant failed to maintain effective controls against diversion and run a sufficient SOM system, or whether the results of the other methods were necessary for him to reach those opinions.

Mr. Rafalski did not actually review any of the orders flagged by his methods before issuing his expert report in this case. See id. at 214-15, 227-28. This lack of review extended even to the initial flagged orders, and even when the results after those initial flagged orders hinge entirely on whether the initial orders were suspicious (as in Method A). Id. Mr. Rafalski also did not know what percentage of the orders he identified as likely to be diverted "were actually investigated and . . . cleared" by defendants. See id. at 228-29.

Mr. Rafalski testified that the millions of orders flagged by his methods were not necessarily "suspicious orders" within the meaning of the federal regulations. See id. at 229-30. He did not know how many of the orders flagged by his methodologies went to fill legitimate medical needs. See id. 216:13-18. He did not perform any analysis of the medical needs for prescription opioids in the City of Huntington or Cabell County relative to the national average, and the results of his methods do not take account of any estimate of medical needs. See id. at 129, 216-17.

C. Assumption That No Due Diligence Dispelled the Suspicion Unsupported

The court finds unsupported Mr. Rafalski's assumption that defendants failed to dispel the suspicion of any flagged order with the exercise of due diligence. To the extent Mr. Rafalski

offered the more limited, vague opinion that defendants systematically failed to conduct due diligence, the court does not find that opinion persuasive either.

In determining how many suspicious orders that he believes defendants shipped, Mr. Rafalski adopted the assumption that defendants never conducted due diligence to dispel the suspicion of any order that his methods flagged. Id. at 97, 101-02, 217. Applying this assumption means that every order flagged should not be shipped because no due diligence was done to dispel the suspicion.[2] Id. at 76, 97, 217.

Thus, the assumption that due diligence was not done drives Mr. Rafalksi's opinion that defendants wrongfully shipped the orders that his methods flagged and that, accordingly, defendants failed to maintain effective controls against diversion. The court finds Mr. Rafalski's assumption that no due diligence cleared any flagged order entirely unsupported both because of the way he justified this assumption and in light of the extensive, persuasive evidence that defendants conducted due diligence.

[2] Because it does not affect the outcome of this case under the evidence presented at trial, the court assumes without deciding that "the CSA statutory and regulatory duties to maintain effective controls against diversion includes a duty not to ship suspicious orders." In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2019 WL 3917575, at *9 (N.D. Ohio Aug. 19, 2019).

Mr. Rafalski stakes his assumption that no due diligence occurred on a lack of existing records in the discovery materials that would allow him to clear the suspicion of any order many years after it was shipped. Id. at 102. In his records review, Mr. Rafalski did not find sufficient evidence to dispel the suspicion of orders "that were or should have been flagged." Id. In other words, Mr. Rafalski did not explicitly testify that he found defendants' due diligence nonexistent, but merely that, in his after-the-fact review of defendants' records, he did not find sufficient evidence to dispel the suspicion himself.[3] Id.

Importantly, Mr. Rafalski conceded on cross-examination that the fact such diligence files are not still available is not necessarily indicative of whether the diligence was previously done and recorded. See Rafalski, 5/27/21, at 15 ("Q. And you don't have any knowledge to say these [diligence records] were never done for Huntington/Cabell or they were done and just not kept; correct? A. I don't have any knowledge either way, Your Honor.").

As a former DEA diversion investigator, Mr. Rafalski confirmed that federal law does not require that pharmacy

[3] There is a conflict in the evidence as to whether Mr. Rafalski reviewed all of the due diligence files or just some of them. Rafalski, 5/26/21, at 228. The court finds that Mr. Rafalski reviewed all of the due diligence files that were produced.

diligence files or suspicious order reports be maintained for any minimum period of time. See Rafalski, 5/26/21, at 269. Mr. Rafalski was not aware of any policy from the DEA indicating that diligence files must be maintained for a set period of time. See Rafalski, 5/27/21, at 17–18. The fact that defendants do not currently maintain copies of certain due diligence files (many years later) is not a very persuasive indicator that due diligence was not completed or that the files did not previously exist.

Moreover, Mr. Rafalski's assumption regarding the systematic (or complete) lack of due diligence is in sharp conflict with evidence that each defendant engaged in extensive due diligence. In other words, the evidence of defendants' consistent due diligence substantially outweighs the permissible inference that a lack of records means adequate due diligence was not done. The court finds the following evidence of defendants' due diligence efforts persuasive.

1. ABDC Due Diligence

The ABDC witnesses whom plaintiffs called in their case-in-chief described ABDC's customer due diligence program, how the program evolved over the years. They also provided testimony specific to customers in Cabell and Huntington. The court found their testimony credible.

Mr. Mays provided detailed and extensive testimony on the investigations ABDC conducted between October 2005 and August 2007—a program ABDC put in place after the 2005 distributor initiative meeting. Mays, 5/18/21, at 202-05. As part of that program, ABDC investigators validated and analyzed customers' one-year controlled substance purchase reports, site visit results, photos, Form 590 Questionnaires, and publicly available documents. Id.; Ex. AM-WV-01079. Mr. Mays further testified regarding the new program developed in 2007—which included customer due diligence—with input from the DEA. Mays, 5/19/21, at 29-32.

Mr. Zimmerman similarly explained the improvements ABDC made to its due diligence program in 2005 and 2007, as well as ABDC's due diligence policies and procedures generally. Zimmerman, 5/13/21, at 189-90 (improvements made in 2005); 194 (enhancements made in 2007).

Mr. May explained ABDC's customer due diligence, including its use of Tableau files to track and analyze all available data regarding every individual customer who purchased controlled substances, as well as nationwide trends. See May, 5/17/21, at 28-29; 50-55; 58-63; 65-68; 93-94.

Beginning in 2009, ABDC also utilized Order Monitoring Program ("OMP") size reports and drug trend reports as part of its ongoing due diligence efforts. See id. at 96; 100; Ex. AM-

WV-00406; Ex. AM-WV-00398. The OMP size report compared each customer's purchase of controlled substances to its purchase of all products and identified the percentage of controlled substances purchased by that customer over time. See May, 5/17/21, at 96; Ex. AM-WV-00406. The drug trend reports identified each customer's month-over-month controlled substance purchases for specific products like oxycodone and hydrocodone and also provided a monthly average for the five to six month time period covered by each report. See May, 5/17/21, at 100; Ex. AM-WV-00398.

a. ABDC's Due Diligence Re: Safescript

Plaintiffs focused much of their case against ABDC on a pharmacy called Safescript, which was an ABDC customer from 2004 to 2012 (when it was raided by the DEA and shut down). Perry, 5/19/21, at 108, 144-45. There was no evidence, however, that a single pill from Safescript was diverted; no evidence of any actual harm tied to Safescript; no evidence that the West Virginia Board of Pharmacy took any action against Safescript; no evidence that Safescript ever failed a West Virginia Board of Pharmacy inspection; and no evidence that the owner of Safescript, or any pharmacist who worked at Safescript, was ever prosecuted. In sum, the evidence did not show that ABDC's due diligence of Safescript was inadequate.

ABDC's CSRA personnel opened an investigation following their own review of Safescript's hydrocodone purchases in April 2007. Ex. AM-WV-01418; Ex. AM-WV-01444. Mr. Perry, the local account manager, provided a CSRA Form 590 and photographs to ABDC's compliance personnel, and also provided compliance personnel with a detailed description of Safescript. Ex. AM-WV-01444. CSRA personnel then evaluated the due diligence Mr. Perry collected along with its independent online research on Safescript, and concluded that Safescript "did not indicate any type of diversion." Ex. AM-WV-01444.

In addition, Mr. Perry—the only trial witness who actually visited Safescript—provided a first-hand account on the pharmacy. He described Safescript as a "normal practice," which had a full line of pharmaceuticals on their shelves and was located in an "okay" part of Huntington. Perry, 5/19/21, at 184-85. And Mr. Perry, who visited Safescript approximately every other week for a period of several years, testified that he did not observe any red flags there. Id. at 185-87.

With the information obtained from their 2007 investigation, monthly trend reports and other ongoing due diligence efforts, and Mr. Perry's first-hand accounts in hand, ABDC adjusted Safescript's threshold both up and down over the years in response to the pharmacy's needs. See Mays 5/18/21, at 86; Ex. AM-WV-01444; Ex. AM-WV-00406; Ex. AM-WV-00398.

Dr. McCann noted that oxycodone purchasing actually dropped after the threshold increase. McCann, 5/11/21, at 90-91. And Dr. McCann observed that an ABDC email "seem[ed] to have been effective" in lowering Safescript's purchasing. Id.

Finally, ABDC reported to the DEA suspicious orders placed by Safescript every year from 2007 to 2011—the same period of time during which thresholds were adjusted. See Ex. P-44766.

b. ABDC Due Diligence Re: Drug Emporium and McCloud

ABDC undertook due diligence with respect to both Drug Emporium and McCloud Family Pharmacy in 2007. Ex. AM-WV-01410; Ex. AM-WV-01999. Consistent with ABDC's customer investigation program, Mr. Perry obtained Form 590s and photographs and submitted them to CSRA personnel. Ex. AM-WV-01410; Ex. AM-WV-01999.

Mr. Perry testified that he did not observe any "red flags" during his frequent visits to these customers. Perry, 5/19/21, 191-92 (McCloud Family Pharmacy), 194 (Drug Emporium). ABDC's investigations concluded that there was no indication of diversion occurring at either pharmacy. Id.

In addition to records of investigations and monthly trend reports for McCloud and Drug Emporium, ABDC introduced evidence of customer-specific Tableau files for both Drug Emporium and McCloud (files that represented due diligence of these

pharmacies from April 2015). Ex. AM-WV-01040E; see also May, 5/17/21, at 176.

2. Cardinal Health Due Diligence

Mr. Moné testified that his team investigated every order that exceeded that pharmacy's threshold. Moné, 5/20/21, at 62 ("[E]very order that triggers is going to have some sort of due diligence."). Cardinal Health also required its sales staff, who visited pharmacy customers regularly, to look for and report any potential signs that diversion might be occurring. Kave, 5/21/21, at 95. Sales representatives at Cardinal Health received frequent and regular training on anti-diversion and red flags for potential signs of diversions. Id. at 70-71.

The investigations component of Cardinal Health's SOMS involved site visits of pharmacy customers conducted by former police and former DEA-diversion, Medicaid-fraud, and Board of Pharmacy investigators. Moné, 5/20/21, at 174, 187-88.

Cardinal Health adopted comprehensive Standard Operating Procedures ("SOPs") regarding the SOM system, and periodically updated those procedures. See, e.g., Ex. CAH-WV-00001 (SOP for a new retail independent customer survey process); Ex. CAH-WV-00030 (SOP for the new account approval process); Ex. CAH-WV-00745 (SOP to establish SOM threshold limits); Ex. CAH-WV-00743 (SOP for threshold event review, self-verification; decision making and threshold outcome communication); Ex. CAH-WV-00740

(updated SOP for detecting and reporting suspicious orders and responding to threshold events); Ex. CAH-WV-00026 (SOP for on-site investigations); Ex. CAH-WV-00747 (updated SOP for on-site investigations).

Cardinal Health trained and tested all employees involved in anti-diversion activities on the SOPs. Moné, 5/20/21, at 192-96. These employees numbered in the hundreds—all employees in the centralized anti-diversion group, QRA more broadly, and in the twenty-six distribution centers, sales managers, and sales directors. Mr. Rafalski did not identify any specific pharmacy within plaintiffs' borders for which he claims Cardinal did not conduct sufficient due diligence.

a. Cardinal Health Due Diligence Re: Medicine Shoppe

Of Cardinal Health's 37 customers in the City of Huntington and Cabell County, the only specific one that plaintiffs focused on at trial was T&J Enterprises, Inc., doing business as The Medicine Shoppe, located in Huntington ("Medicine Shoppe"). But there was no evidence that Medicine Shoppe was engaged in diversion of opioids and no evidence that Cardinal failed to report or block shipment of any suspicious orders placed by Medicine Shoppe.

The due diligence file for Medicine Shoppe was hundreds of pages and included material dating back to 2008 when Medicine Shoppe first became a Cardinal Health customer. See Ex. P-

42116. The file contained several Anti-Diversion Customer Profiles and information regarding overall controlled substances percentages, volumes of particular categories of drugs, the number of previous threshold events, and overall purchase data by month for that drug family. Id.

Cardinal Health conducted a full site visit in August 2012. During that visit, the site investigator found no evidence of diversion. Moné, 5/20/21, at 215-16; Ex. CAH-WV-00770. The site visit report included explanations for the pharmacy's increased purchases of oxycodone, including that "prescribers in the area prefer oxycodone 15 mg and 30 mg strengths for pain management" and "the pain management population consists of a high number of coal miners and truckers with job related injuries." Ex. CAH-WV-00770 at Section 2.

It also concluded that the pharmacist-in-charge understood his corresponding responsibility, only filled controlled substance scripts for local residents and local prescribers, and took advantage of the state's prescription monitoring program to ensure that patients filling controlled substance scripts did not appear to be engaged in diversion. Id. at Section 5.

The only individuals who testified at trial with any significant knowledge of Medicine Shoppe were former Cardinal Health employees Mr. Moné and Mr. Kave. Mr. Kave, the sales representative who called on Medicine Shoppe for twelve years,

testified that he knew the pharmacists there and found them to be professional. Kave, 5/21/21, at 107-09. Mr. Kave did not testify that he ever witnessed signs of diversion at Medicine Shoppe.

3. McKesson Due Diligence

As detailed below, McKesson's Regulatory Affairs Department reviewed all customer requests to adjust thresholds after receiving a request from the customer that set forth reasons and data supporting the adjustment. Mr. Oriente testified regarding McKesson's due diligence, and the court found his testimony reliable in all respects.

Mr. Oriente testified that a pharmacy customer that wished to have a threshold adjusted would have to submit a TCR form for review by regulatory affairs personnel at McKesson. See Oriente, 5/25/21, at 75; see also Ex. P-13714 (exemplar TCR form). Mr. Oriente confirmed that McKesson's Directors of Regulatory Affairs were responsible for approving all TCRs submitted by customers. See Oriente, 5/25/21, at 75. Each TCR would receive due diligence prior to approval or rejection. See id. at 65.

In evaluating a request for an increased threshold, McKesson would receive and consider the customer's dispensing data, as well as the customer's stated reason for the increase. See id. at 75. McKesson would also request prescriber

information as part of its due diligence when necessary. See id. at 69.

Mr. Oriente testified that in the 2008-2013 time period, the Directors of Regulatory Affairs were able to do their due diligence even if they were busy at times. See id. at 67. If Mr. Oriente received too many TCR forms to conduct diligence on them all before the end of a month, then some requests would roll over into the next month. See id. at 67-68.

Under the CSMP, McKesson also conducted customer due diligence proactively throughout its relationship with a customer, including during customer onboarding and for existing customers. See id. at 65-66; Oriente, 5/24/21, at 181. Under the CSMP, McKesson also conducted ongoing due diligence of its existing customers. See Oriente, 5/25/21, at 90-91, 94; Ex. MC-WV-00381 (2008 CSMP Manual) at .00015.

a. McKesson Due Diligence Re: Rite Aid

McKesson operated its due diligence program for retail national chain pharmacies, like Rite Aid, differently than its program for independent pharmacies in recognition of the fact that national chain pharmacies have their own corporate regulatory affairs departments that monitor compliance at their stores. See Oriente, 5/25/21, at 134; see also Ex. MC-WV-00243 (Controlled Substance Monitoring Program for Retail National Chains).

In his role, Mr. Oriente was aware that Rite Aid had an internal set of policies and procedures on the filling of controlled substances. See Oriente, 5/25/21, at 141. He worked directly with members of Rite Aid's corporate regulatory affairs department. See id. His experience working with Rite Aid led him to conclude that "Rite Aid was conducting their due diligence" in relation to orders by specific Rite Aid stores. Id.

When McKesson flagged concerns about pharmacies to Rite Aid, Rite Aid reviewed those stores and reported back to McKesson with findings and additional information to resolve McKesson's concerns. See id. at 141-42. Mr. Oriente testified that Rite Aid would also, at times, raise and report issues to McKesson on its own volition. See id. at 142.

D. Mr. Rafalski's Diversion-control Opinions

Mr. Rafalski offered the following opinions regarding diversion-control failures by defendants: (1) defendants failed to maintain effective controls against diversion of prescription opioids into the illicit market in Huntington-Cabell County, West Virginia; (2) defendants failed to design and operate an effective system to identify, block and report suspicious orders arising out of Huntington-Cabell County, West Virginia; and (3) these failures were systemic. Rafalski, 5/26/21, at 107-10.

The results of Methods A through F, including the assumption that defendants did not complete due diligence, were entirely unpersuasive. Because Mr. Rafalski's diversion-control opinions hinge on those results, those opinions are likewise entirely unpersuasive. Mr. Rafalski's diversion-control opinions are also unpersuasive because it is apparent that he employed an overbroad understanding of distributors' duty to maintain effective controls against diversion.

E. No Pharmacy-level Diversion

Plaintiffs' diversion control expert, Mr. Rafalksi, could not identify a single pharmacy customer of defendants that was engaged in diversion. See Rafalski, 5/26/21, at 130-35. Mr. Rafalski could not identify any pills shipped by defendants that went to a pill-mill doctor or to fill an improper prescription. See id. at 130-32. Mr. Rafalksi did not evaluate whether any pharmacies within plaintiffs' borders were neglecting their legal obligations with regards to effective controls against diversion. See id. at 134-35. Mr. Rafalski did not know whether the pharmacies to which defendants distributed "helped cause the opioid crisis in Huntington/Cabell." Id. at 137.

Plaintiffs offered no evidence of any diversion from Defendants' pharmacy customers in Cabell/Huntington. Mr. Rafalski testified that he was "not offering any opinions about whether diversion occurred at a pharmacy level" in the City of

Huntington or Cabell County. Id. at 135. Mr. Rafalski further testified that he was not aware of the DEA ever telling one of the defendants not to distribute to a pharmacy in the City of Huntington or Cabell County. See id. at 162. Dr. Keyes testified that she did not identify any sources of diversion in relation to shipments between distributors and pharmacies. See Keyes, 6/14/21, at 68-69.

The only evidence of pharmacy-level diversion in the City of Huntington or Cabell County is with respect to A-Plus Care Pharmacy in Barboursville, which was "a major source of supply for pharmaceutical diversion to the tri-state area and beyond" and was shut down by local law enforcement in 2014. See Ex. P-41220 (Huntington Police Department 2014 Annual Report) at .00019-20; see also Lemley, 5/21/21, at 256. No defendant ever supplied the A-Plus Care Pharmacy. See, e.g., Rafalski, 5/26/21, at 15 (acknowledging that Miami-Luken was the only supplier of the A-Plus Care Pharmacy); McCann, 5/12/21, at 27.[4]

Any diversion of prescription opioids that occurred in the City of Huntington or Cabell County after the medicines were

[4] To the extent plaintiffs attempt to rely on purported examples of shipments to pharmacies engaged in diversion outside the City of Huntington and Cabell County, there was no persuasive evidence establishing a nexus between defendants' shipments to those pharmacies and any diversion or harm in the City of Huntington or Cabell County.

distributed to and dispensed by bona fide pharmacies involved criminal actions of third parties over whom defendants had no control, including the persons to whom the medicines were prescribed and those involved in diverting the prescription opioids. The court finds that plaintiffs did not prove that defendants supplied opioids to pharmacies engaged in diversion.[5]

VII. Failure to Prove Unreasonable Conduct

Plaintiffs failed to show that the volume of prescription opioids distributed in Cabell/Huntington was because of unreasonable conduct on the part of defendants. Plaintiffs argue that the volume of prescription opioids distributed by these defendants in Cabell/Huntington is per se unreasonable and, therefore, defendants are liable. Between 2006 and 2014, defendants distributed 51,349,150 dosage units of oxycodone and hydrocodone to retail pharmacies in Cabell County and the City of Huntington.[6] See P-44711. However, plaintiffs must show more

[5] Plaintiffs rely on a breach of a no-shipping duty to prove diversion and creation of an opioid epidemic. To the extent they also rely on the reporting requirement, plaintiffs failed to show that any alleged violations based upon a failure to report suspicious orders by defendants contributed to the volume of opioids distributed in Cabell/Huntington. Put another way, plaintiffs did not show that had defendants reported more suspicious orders that the DEA would have closed any of the pharmacies that defendants serviced in Cabell/Huntington.

[6] Plaintiffs aver that "[b]etween 2006 and 2014 alone . . . Defendants distributed 81,239,625 dosage units of oxycodone and hydrocodone to retail pharmacies in Cabell and Huntington." ECF No. 1493 at 13 (emphasis deleted). However, that figure is

than a volume of distribution which they allege, in retrospect, is unreasonable. They must show that the distribution was because of unreasonable conduct on the part of defendants. As discussed in greater detail below, there is nothing unreasonable about distributing controlled substances to fulfill legally written prescriptions.

A. The Role of Pain in the Opioid Crisis

In 2019, Dr. Wilson M. Compton of the National Institutes of Health ("NIH") observed that "[t]he roots of the remarkably lethal U.S. opioid crisis are complex and inextricably entangled with healthcare, especially in its treatment of another serious health problem: pain." Ex. MC-WV-02079 at 1. Chronic pain is a common, debilitating medical condition that can have a severe impact on patients. See Keyes, 6/14/21, at 111; Deer, 7/7/2021, at 14-15.

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incorrect. That figure represents ABDC's shipments from June 2002 through December 2018, Cardinal's shipments from January 1996 through May 2018, and McKesson's shipments from October 2004 through December 2018. See id; see also McCann, 5/10/21, at 92. Therefore, the figure is not especially helpful to the court because it is not an accurate summary of these defendants' distributions during any time period, much less the relevant one. For example, it is not a true reflection of these defendants' distributions from 1996 to 2018 because it does not include the full distribution amounts of ABDC or McKesson for the same period. And, as stated above, it overstates (to the tune of 30 million dosage units) the actual amount of oxycodone and hydrocodone distributed by defendants between 2006 and 2014.

A 2011 report authored by the Institute of Medicine, entitled Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research, found that pain was a "public health challenge" that "affects tens of millions of Americans and contributes substantially to morbidity, mortality, disability, demands on the health care system, and significant economic burdens for the nation. The prevalence of chronic pain is growing and likely to continue to do so." Ex. MC-WV-1170 at 74. Generally speaking, "opioids" help to ease pain by binding to opioid receptors in the body. See Waller, 5/4/21, at 20.

Opioids that naturally occur in the body, such as endorphins, are referred to as endogenous opioids. See id. at 24-29, 49. Whereas opioids that are produced outside the body are exogenous opioids. See id. at 29, 31. Exogenous opioids take three major forms. Naturally occurring opioids, such as morphine and codeine, are derived by extracting opium from the poppy plant. See id. at 31. Semisynthetic opioids start naturally but are later modified in a lab. Examples of semisynthetic opioids are heroin, oxycodone, and hydrocodone. Synthetic opioids, like fentanyl, are wholly produced in a lab. See id.

Prescription opioids are medicines approved by FDA. See Werthammer, 5/21/21, at 35; Keyes, 6/14/21, at 51. Prescription opioids are approved as safe and effective for the treatment of

pain, including for acute pain following injury or surgery, for cancer pain, for easing pain through palliative care at the end of life, and for chronic pain in appropriate circumstances. See Waller, 5/4/21, at 80-87; Priddy, 5/6/21, at 215-22.

They are a "Schedule II" drug, pursuant to U.S. Drug Enforcement Administration regulation, which means that they have a recognized medical use, but they also have a high potential for addiction. See Waller, 5/4/21, at 37. "Prescription opioids and illicit opioids, such as heroin and fentanyl, are pharmacologically quite similar . . . [and t]hey interact with endogenous opioid systems. . . ." MC-WV-02079 at 4.

B. Changes in the Standard of Care for the Treatment of Pain.

"Beginning in the 1980s, there were calls from some physicians and patient advocacy groups that not enough was being done to treat pain, both in cancer and palliative-care patients, and even more generally." Ex. MC-WV-02079 at 5; see also Waller, 5/4/21, at 172.

In a 1982 editorial titled "The Quality of Mercy" and published in the New England Journal of Medicine, Dr. Marcia Angell stated that pain treatment was "regularly and systematically inadequate," that "most pain, no matter how severe, can be effectively relieved by narcotic analgesics,"

that "a more important factor is a disproportionate sometimes irrational fear on the part of the medical profession and the public alike that patients will become addicted," and that "[p]ain is soul destroying." Ex. MC-WV-01135 at .00002–.00003; see also Gilligan, 7/2/21, at 78–79, 82–88. According to Dr. Gilligan, Dr. Angell's editorial reflected an emerging viewpoint within the medical community that more should be done to treat pain. See Gilligan, 7/2/21, at 84.

This notion that the medical community was not doing enough to treat pain persisted into the 2000s. In his 2007 book, Responsible Opioid Prescribing, Dr. Scott Fishman wrote that "[t]here is no debate among public health experts about the undertreatment of pain, which has been recognized as a public health crisis for decades." Ex. MC-WV-02111 at 111; see also Waller, 5/4/21, at 163.

For most of the 20th century, medical professionals prescribed opioid pain medicines only for acute and cancer pain. See, e.g., Ex. MC-WV-02079 at 5 (stating that before the 1980s, physicians and other healthcare providers were "reluctant to use [opioid drugs] to treat most pain conditions"); Yingling, 6/16/21, at 176 (agreeing that "[u]p until the 1990s, prescription opioids were primarily used for acute pain and cancer pain."); Deer, 7/7/21, at 68 (testifying that doctors did

not regularly prescribe opioids for chronic non-malignant pain prior to 1997).

As Dr. Gilligan described it,

> So in the period around the 1990s in particular, . . ., 1980s as well, there was an emphasis on the concept that we were under-treating pain in this country and that we were placing too much emphasis - - that we were exaggerating, would have been the argument, the potential risks of opioids, that we were under-utilizing them and we were leaving too many patients with pain that could have [and] should have been treated with opioids.

Gilligan, 7/2/21, at 76-77.

Plaintiffs' witness Dr. Yingling acknowledged this shift in thinking and testified that, during the 1990s, he too came to believe that pain was undertreated. See Yingling, 6/16/21, at 177-78. In 1986, the World Health Organization released a document called "Cancer Pain Relief" that said opioids were "under-use[d]" and introduced a highly influential pain ladder that called for progression toward more powerful opioids as pain became more severe. It also said that "cancer pain is often not treated adequately" and "[a]n analysis of 11 reports covering nearly 2000 patients in developed countries suggests that 50–80% of patients did not have satisfactory [pain] relief." Ex. DEF-WV-03699 at 10, 15, 20-21; see also Gilligan, 7/2/21, at 88-89, 89-94.

According to Dr. Gilligan, "this document was very, was very significant because it's the document where the World

Health Organization introduced their cancer pain treatment [ladder] which became very well-known throughout medicine and, and had a very significant influence on the practice of treating pain across fields of medicine." Gilligan, 7/2/21, at 88-89. Dr. Gilligan further described the WHO's statement regarding the under-use of opioid analgesics as

> meaningful . . . [b]ecause doctors know the World Health Organization. You would be hard-pressed to find a doctor who doesn't know the World Health Organization. And when they make a statement that's that clear saying that we're under-treating cancer pain and we should use opioids more often, more aggressively to, frankly, do a better job of treating cancer pain, that's a powerful statement coming from an organization of that stature.

Id. at 92.

The "standard of care" is what reasonable doctors would adhere to within their field of medicine in a given situation. See Deer, 7/7/21, at 48; see also Gilligan, 7/2/21, at 76 (testifying that the "standard of care in medical practice means the quality of care, the thoroughness, the safety of care that doctors expect to maintain in his or her fields"). The standard of care changes over time based on research, development, and new information. See Deer, 7/7/21, at 34, 49, 129 ("Sometimes we learn things that later prove to be untrue based on new research and development. So that's why the standard of care changes. I may have an opinion in 1997 that in 2015 you see

that was incorrect looking backward. So it changes based on new information.").

Doctors prescribe medications based on the then-prevailing standard of care, and doctors who do not follow the then-prevailing standard of care can lose their license or face civil or criminal consequences. See Deer, 7/7/21, at 49-50. Beginning in the 1990s, the standard of care changed to recognize a broader range of appropriate uses for prescription opioids nationwide, including for the long-term treatment of chronic non-cancer pain. See Ex. MC-WV-02079 at 6 (noting that as a result in "shifts in practice, the supply of prescription opioids increased fourfold between 1999 and 2010").

Dr. Gilligan testified that the standard of care surrounding the use of prescription opioids has changed over the past several decades. See Gilligan, 7/2/21, at 76 (noting that opioid prescribing went up through the 2000s and peaked around 2011).

Dr. Waller testified that there was a "sea change" in opioid medication prescribing that began in the mid-1990s and "hit its peak between 2010 and 2012." Waller, 5/4/21, at 94; see also Ex. MC-WV-02079 at 5 ("It was, and is, through pain suffering and the shifting philosophies of pain treatment that today's opioid crises first took root.").

C. OxyContin Introduced

Against this backdrop, the FDA approved Purdue Pharma's controlled-release pain reliever OxyContin in 1995. See MC-WV-01764 at 6-7 ("Amid the heightened awareness that many people were suffering from undertreated pain, in 1995 the Food and Drug Administration (FDA) approved the new drug OxyContin, a controlled-release semisynthetic opioid analgesic manufactured by Purdue Pharma L.P., for the treatment of moderate-to-severe pain lasting more than a few days.

According to Purdue, OxyContin provides patients with continuous relief from pain over a 12-hour period, . . . and allows a physician to increase the OxyContin dose for a patient as needed to relieve pain."). As of 2001, the FDA was saying that "there is no known limit to the amount of oxycodone, the active ingredient in OxyContin, that can be used to treat pain." Id. at 7 n.3. OxyContin was released to the market in 1996. See id. at 6; see also Ex. MC-WV-02079 at 5 ("These clinical practice and regulatory changes coincided with business decisions that fueled a marked increase in opioid prescribing and subsequent public health harms. For instance, pharmaceutical companies were developing a new generation of extended-release opioid analgesics that contained more opioid per pill but were promised to be less addicting; Purdue Pharma's

OxyContin (oxycodone) was approved and went on the market in 1996" (citation omitted)).

D. The Standard of Care Continues to Evolve

Dr. Deer testified that the standard of care for the use of prescription opioids has changed over time, and that this change has affected the rate at which doctors prescribed opioids in West Virginia. See Deer, 7/7/21, at 129. Dr. Deer further testified that there were "three main phases" of the standard of care surrounding opioid prescribing in West Virginia. Id. at 39.

"[P]ain advocacy organizations and some in the medical community began to seek state-based regulatory changes to reverse the perceived underuse of opioids to address chronic, noncancer pain. These organizations successfully lobbied state medical boards and state legislatures to revise statutes and regulatory policies to enable more permissive use of opioids outside of cancer or palliative care, and to reduce the risk of sanction for prescribers who prescribed opioids." Ex. MC-WV-02079 at 6.

According to Dr. Gilligan, state medical boards "play a role . . . in setting the standard of care." Gilligan, 7/2/21, at 96 ("So for a doctor to practice, you need your license from your state medical board. And if you were practicing inappropriately, for example, they would be the folks who could

pull your license. So, therefore, as, as a doctor, one tends to pay attention to what the state medical board is calling for in terms of appropriate practice."); see also Knittle, 8/27/20, at 32 (testifying that the "main purpose" of the West Virginia Board of Medicine "is to protect the public" by the "licensing and disciplining of physicians").

The State of West Virginia was one state approving of the use of prescription opioids to treat non-cancer pain. See MC-WV-01219 at 1. In 1997, the West Virginia Board of Medicine issued a position statement that read:

> Recent national guidelines have clarified the use of opioids in the management of acute pain and cancer pain. There is general consensus that opioids have a place in relieving intractable pain and suffering in the terminally ill when other measures fail, regardless of diagnosis. However, the problem of treatment of chronic non-malignant pain in the non-terminal patient is a controversial and difficult area, and guidelines are needed. The Board of Medicine appreciates the significance of this problem and urges that high priority be given to the suffering patient.
>
> The purpose of this statement is to clarify the Board of Medicine's position on the appropriate use of opioids for patients with chronic non-malignant pain so that these patients will receive quality pain management and so that their physicians will not fear legal consequences, including disciplinary action by the Board, when they prescribe opioids in a manner described in this statement. It should be understood that the Board recognizes that opioids are appropriate treatment for chronic non-malignant pain in selected patients.

* * *

> A physician need not fear disciplinary action by the Board if complete documentation of prescribing of opioids in chronic non-malignant pain, even in large doses, is contained in the medical records.
>
> Nothing in this statement should be interpreted as endorsing inappropriate or imprudent prescribing of opioids for chronic non-malignant pain.

Ex. MC-WV-01219 at 1.

Dr. Gilligan testified that this statement by the West Virginia Board of Medicine was consistent with the change in national standards. See Gilligan, 7/2/21, at 99. He further stated that the position statement sent a "clear message" to doctors in West Virginia "that if you prescribe opioids even in large doses for non-cancer pain . . . you need not fear disciplinary action." Id. at 100.

As Dr. Deer put it, guidance like this made doctors feel "comfortable just going up on the dose" and "upping the dose until someone got better or got a side effect." Deer, 7/7/21, at 69. Dr. Deer further testified that all doctors in West Virginia received a copy of the position statement and that it changed their perspectives. See Deer, 7/7/21, at 74-76; Ex. DEF-WV-03003.

The Federation of State Medical Boards ("FSMB") is an umbrella organization for state medical boards, including the West Virginia Board of Medicine. See Waller, 5/4/21, at 107; see also ECF No. 80 (Third Amended Complaint) at ¶ 565 ("The

Federation of State Medical Boards . . . is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.").[7] The FSMB writes guidelines that are often adopted by medical boards in different states. See Gilligan, 7/2/21, at 100-01.

In May 1998, the FSMB adopted "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain" wherein it laid out that body's "guidelines for the appropriate use of controlled substances to treat pain." Gilligan, 7/2/21, at 101-02; DEF-WV-02937. According to the FSMB's Model Guidelines, "principles of quality medical practice dictate that the people

[7] "The general rule is that 'a party is bound by the admissions of his pleadings.'" Lucas v. Burnley, 879 F.2d 1240 (4th Cir. 1989) (quoting Best Canvas Prods. & Supplies v. Ploof Truck Lines, 713 F.2d 618, 621 (11th Cir. 1983)); see also Butts v. Prince William Cnty. School Bd., 844 F.3d 424, 432 (4th Cir. 2016) (party bound by factual allegations in complaint); Everett v. Pitt Cnty. Bd. of Educ., 788 F.3d 132, 141 (4th Cir. 2015) ("A judicial admission is a representation made by a party that, unless allowed by the court to be withdrawn, is conclusive in the case.") (internal quotation and citation omitted). "A judicial admission is usually treated as absolutely binding, [and] such admissions go to matters of fact which, otherwise, would require evidentiary proof." New Amsterdam Cas. Co. v. Waller, 323 F.2d 20, 24 (4th Cir. 1963). Therefore, plaintiffs are bound by the factual assertions made in the Third Amended Complaint, see ECF No. 80, as they have not offered any reason for the court to relieve them of those admissions. See Yates v. Ford Motor Co., No. 5:12-CV-752-FL, 2015 WL 3932687, at *5 (E.D.N.C. June 26, 2015) (holding plaintiffs "bound by their judicial admissions in the nature of factual assertions").

. . . have access to appropriate and effective pain relief." DEF-WV-02937.

The Model Guidelines also "encourage[] physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic" and "recognize[] that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins." Id.

The Model Guidelines state that "[p]hysicians should not fear disciplinary action from the Board for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice." Id.; see also Gilligan, 7/2/21 at 101-05. Plaintiffs admit that the FSMB Guidelines approved the use of opioids to treat chronic pain. See ECF No. 80 at ¶ 567 ("The 1998 [FSMB] Guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were 'essential' for treatment of chronic pain, including as a first prescription option.").

According to Dr. Gilligan, the Model Guidelines "are examples of the evolution of [the] standard of care, but they reflect a broad discussion across pain medicine, and actually

medicine in general, about what's the appropriate way for us to treat pain and what's the appropriate way for us to use opioid pain medications to treat pain." Gilligan, 7/2/21, at 105.

The FSMB's 1998 guidelines were endorsed by various organizations, including state medical boards, medical professional organizations, healthcare regulatory boards, and the DEA. See Gilligan, 7/2/21, at 119-120; see also Ex. DEF-WV-03605 at 1.

The Joint Commission on Accreditation of Healthcare Organizations ("Joint Commission" or "JCAHO") is the body that accredits hospitals and other healthcare organizations. See Gilligan, 7/2/21, at 105-06. Of the importance of JCAHO accreditation, Dr. Gilligan testified that "accreditation is very important to us to continue to be able to operate our hospitals. An accredited hospital has implications for reimbursement, et cetera." Id. at 106. Dr. Waller testified that the concept of "Pain as the Fifth Vital Sign" originated with the Joint Commission, which is the regulatory body that the government uses to identify and evaluate hospitals for safety. See Waller, 5/4/21, at 96. A hospital may participate in federal healthcare programs like Medicaid and Medicare only if it is accredited by the Joint Commission. See id. at 96-97.

In 2001, the Joint Commission issued Pain Standards evincing a more aggressive stance at identifying and treating

pain. See AM-WV-02693. One such standard was that "[p]atients have the right to appropriate assessment and management of pain." Id. at 12; see also Gilligan, 7/2/21, at 109-10. That standard goes on to state that "[p]ain is considered a fifth vital sign in the hospital's care of patients. Pain intensity ratings are recorded during the admission assessment along with temperature, pulse, respiration and blood presure." AM-WV-02693 at 12. According to Dr. Gilligan, the Joint Commission's statement was a "significant consideration" in the standard of care in medicine because "to add pain as a fifth vital sign was a very clear message about the great importance of measuring pain and, by implication, of treating pain." Gilligan, 7/2/21, at 111.

The Joint Commission's 2001 Pain Standards emphasized the importance of treating pain, and provided examples for implementing its standards that included asking every patient "a 'screening' question regarding pain on admission" and posting a "statement on pain management . . . in all patient care areas" stating that "[a]ll patients have a right to pain relief." See Ex. AM-WV-02693 at 12; see also Gilligan, 7/2/21, at 105-12.

Of the significance of complying with the Joint Commission's pain standards, Dr. Gilligan testified that "it's very, very important to us to maintain our accreditation, and very important for us not to have findings where we're not

meeting their standards beyond how we treat pain or other things." Gilligan, 7/2/21, at 106; see also Yingling, 6/16/21, at 180 (Q: "And now, if we turn down to the third bullet, it reads, 'In 2001' - - '2001 pain management standards by JCAHO effective pain management from admission to discharge.' Do you see that?" A: "I do." Q: "This references that doctors were reminded to to ask their patients about pain and to treat that pain, correct?" A: "Yes. I'm only smiling, Counselor, because JCAHO does not really remind people. I mean, they're a regulatory agency, so remind just seems not quite appropriate, but thank you." Q: Perhaps remind was too gentle. Let me see if I can . . . respond to that. JCAHO mandated that doctors ask their patients about pain and treat that pain, correct." A: "That sounds like the JCAHO I know, yeah.").

Dr. Gilligan testified that JCAHO's 2001 pain standards were

> influential because they set standards for measuring pain as the fifth vital sign . . . which was extremely important because if you think of vital signs, the name, the name says a lot; heart rate, blood pressure, et cetera, key things. And to then add pain as a fifth vital sign was a very clear message of how important JCAHO felt measuring pain and, by implication, treating pain was and so, therefore, the expectation that hospitals who are going to be inspected by JCAHO would, would meet those sort of standards.

Id. at 106-07.

The change in the standard of care discussed above was reflected in the widespread adoption of "Pain as the Fifth Vital Sign." See, e.g., Ex. DEF-WV-02395, Ex. DEF-WV-03074. Dr. Deer testified that "Pain as the Fifth Vital Sign" became an important factor because every patient that walked into a hospital, inpatient or outpatient, had to be asked about their pain level, and that pain level had to be followed and addressed throughout their care. See Deer, 7/7/21, at 53.

Dr. Deer further testified that "Pain as the Fifth Vital Sign" was promoted by the American Pain Society and the Joint Commission, among others, and that "Pain as the Fifth Vital Sign" contributed to the change in the standard of care towards more opioid prescribing. See id. at 53-54, 57, 60-62; see also Ex. MC-WV-02079 at ("[I]n the early 1990s, advocacy groups, including the American Pain Society, encouraged physicians to treat pain as a 'fifth vital sign,' and the Joint Commission began to require hospitals to assess all patients' pain. . . . [As a result,] [p]ain rating scales became ubiquitous in doctor's offices and emergency rooms.").

Plaintiffs' witnesses corroborated the change in the standard of care wrought by "Pain as the Fifth Vital Sign" and the fact that it led to an increase in opioid prescribing. Dr. Waller testified that "Pain as the Fifth Vital Sign" embraced addressing pain more aggressively. See Waller, 5/4/21, at 96.

Dr. Waller further testified that "Pain as the Fifth Vital Sign" had an effect on the prescribing of opioids by some doctors. See id. at 97.

Dr. Waller testified that, in the early-to-mid 2000s, the Joint Commission made implementing "Pain as the Fifth Vital Sign" a criteria for accreditation, and that doctors practicing in a hospital accredited by the Joint Commission had to comply with these standards. See id. at 97. Dr. Keyes published an article in April 2021 stating that one of the two forces that led to the proliferation of opioid prescribing in the 1990s "was a shift in treatment approaches for chronic non-cancer pain, including a campaign by professional pain societies and the U.S. Joint Commission, the nation's largest accrediting body for healthcare organizations, to consider pain as the fifth vital sign and to improve the quality of care for chronic pain." See Keyes, 6/14/21, at 34.

Dr. Keyes testified that the Joint Commission's endorsement of "Pain as the Fifth Vital Sign" contributed to increases in opioid use disorder in West Virginia. See id. at 49. Ms. Priddy testified that "Pain as the Fifth Vital Sign" involved putting pain on the same level of importance as a patient's temperature or respiration, and that under "Pain as the Fifth Vital Sign," if a patient indicated pain, the attending medical

professional needed to address the patient's pain. See Priddy, at 217-18.

Dr. Werthammer testified that "Pain as a Fifth Vital Sign" came from organizations like the Joint Commission, and that opioids were prescribed more liberally at the time when pain was considered the "fifth vital sign." See Werthammer, 5/21/21, at 27. In a February 2016 e-mail thread discussing the opioid crisis, Dr. Werthammer wrote "it was not big pharma who wrote the prescriptions, it was me and my colleagues." Ex. DEF-WV-00473. Dr. Shapiro responded, "We had some help. Pain as the '5th vital sign' comes to mind. . . ." Id.

As well, Dr. Yingling testified that the American Pain Society designated "Pain as the Fifth Vital Sign" in 1995, and that the Joint Commission mandated hospitals ask their patients about pain and treat that pain beginning in 2001. See Yingling, 6/16/21, at 179-81. Dr. Yingling further testified that the designation of pain as the fifth vital sign had the effect of increasing net prescribing of pain medications. See id. at 182.

A separate lawsuit filed by the City of Huntington against the Joint Commission alleged that the Joint Commission played a key role in the concept of "Pain as the Fifth Vital Sign," which led to increasing prescribing of pain medications. See Ex. DEF-WV-01102; Ex. DEF-WV-02124 (Joint Commission Complaint); see also Williams, 6/30/21, at 92-103.

In particular, Huntington alleged that "[i]n 2001, Defendant JCAHO . . . teamed with Purdue Pharma L.P., and its affiliates ("Purdue"), as well as other opioid manufacturers, to issue Pain Management Standards . . . that grossly misrepresented the addictive qualities of opioids and fostered dangerous pain control practices, the result of which was often the inappropriate provision of opioids with disastrous adverse consequences. . . ." Ex. DEF-WV-02124 at 2.

According to the City of Huntington, "[h]ospitals . . . were required to follow these Pain Management Standards to maintain JCAHO certification, which health care organizations deem essential to their continued operation." Id. According to the City of Huntington, "JCAHO's enforcement of its Pain Management Standards and . . . widespread misinformation campaign about the safety of opioids has also led to an overprescribing of opioids, not only in terms of doses and necessity, but also in terms of quantity." Id. at 4-5.6

Mayor Williams endorsed and agreed with Huntington's allegations against the Joint Commission, and testified that the Joint Commission is "one of the most culpable parties responsible for the opioid problem." Williams, 6/30/21 at 94.

In 2001, the DEA and 21 health organization, including the American Medical Association ("AMA"), released "A Joint Statement" on "Promoting Pain Relief and Preventing Abuse of

Pain Medications: A Critical Balancing Act." Ex. MC-WV-01522. The 2001 Joint Statement said, among other things, that "[u]ndertreatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death. Effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively." Id.

The statement continued: "For many patients, opioid analgesics-when used as recommended by established pain management guidelines-are the most effective way to treat their pain, and often the only treatment option that provides significant relief." Id. The statement acknowledged that "[d]rug abuse is a serious problem[,]" but maintained that "[f]ocusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated-generating a sense of fear rather than respect for their legitimate properties." *Id.*; see also Gilligan, 7/2/21 at 113-18.

Dr. Gilligan noted that this document was reflective of the changing standard of care. See Gilligan, 7/2/21, at 116. The AMA is the largest organization representing doctors in America, so it is "significant when they're endorsing a statement." Id. at 113, 117. Dr. Gilligan also testified that a statement from the DEA endorsing the use of opioid medications would be taken

seriously by doctors who might otherwise fear enforcement for prescribing opioids. See id. at 114, 117.

In 2004, the FSMB released an updated "Model Policy for the Use of Controlled Substances for the Treatment of Pain." See Ex. DEF-WV-03605. The 2004 FSMB Guidelines maintained "that both acute and chronic pain continue to be undertreated" and that "the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice." Id. The 2004 FSMB Guidelines further stated that "[t]he board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins." See id. at 3; see also Gilligan, 7/2/21 at 119-22.

The FSMB's 2004 Guidelines informed doctors that they would have failed to meet the standards of care if they did not adequately treat patients' pain. See DEF-WV-03605 at 2-3 ("[T]he Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations[.]"); see also Gilligan, 7/2/21 at 121-22.

Because the FSMB was involved with state medical boards and therefore medical licensing, such language had a significant influence on doctors. See Gilligan, 7/2/21, at 121-22 ("So what

the Federation of State Medical Boards is telling doctors there is that if you do not adequately treat patients' pain, you will have failed to meet the standards of care, or standard of practice care they use. And, again, where medical boards are the bodies that grant you your license and can take your license away, a recommendation of that sort from the Federation of State Medical Boards has a significant influence on doctors."); see also ECF No. 80 at ¶ 565.

FSMB guidelines had an impact on physician prescribing in West Virginia because FSMB materials were given to West Virginia physicians. See Deer, 7/7/21, at 90.

In 2005, the West Virginia Board of Medicine adopted a "Policy for the Use of Controlled Substances for the Treatment of Pain" that stated the "diagnosis and treatment of pain is integral to the practice of medicine[,]" encouraged doctors to "view pain management as a part of quality medical practice for all patients with pain, acute or chronic," and recognized that "controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins." Ex. MC-WV-01218 at 1-2; see also Gilligan, 7/2/21, at 123-24.

Dr. Deer testified that the policy statement was distributed to all licensed doctors in West Virginia and that

the policy statement reinforced and expanded the 1997 position statement. See Deer, 7/7/21, at 87-88. According to Dr. Deer, the policy statement "led to many complaints at that time against doctors for under-treatment of pain." Id. at 88.

In 2005, the West Virginia Board of Medicine reprinted in its newsletter sent to every licensed doctor in the state a letter from the West Virginia and other Attorneys General to DEA expressing their concern that there was too much focus on anti-diversion and not enough focus on the treatment of pain. See Ex. DEF-WV-3010 at .5 ("We are concerned that state and federal policies are diverging with respect to the relative emphasis on ensuring the availability of prescription pain medications to those who need them."); see also Deer, 7/7/21, at 90-91, 94.

In 2008, the West Virginia Board of Medicine distributed a copy of Responsible Opioid Prescribing to every doctor in West Virginia. See Ex. DEF-WV-03616 at 6 (stating that the West Virginia Board of Medicine, "in conjunction with the [FSMB]," among other organizations, "was able to distribute [Responsible Opioid Prescribing] to every licensed physician and physician assistant in West Virginia"); see also Deer, 7/7/21, at 102; Gilligan, 7/2/21, at 125. The West Virginia Board of Medicine concluded that Responsible Opioid Prescribing should be a guide for doctors' opioid prescribing, and even invited Dr. Fishman to

speak at a sponsored event in 2008. See Knittle, 8/27/20, at 135-37; see also Deer, 7/7/21, at 102.

Responsible Opioid Prescribing promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain. See, e.g., Ex. MC-WV-02111 at 8-9 (listing as "widely accepted" general principles that "[o]pioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins" and that "[p]atients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient"); see also Gilligan, 7/2/21, at 124-25.

Plaintiffs admit as much. See ECF No. 80 at ¶ 569 (admitting that Responsible Opioid Prescribing "asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient").

In 2013, the West Virginia Board of Medicine issued a "Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain," recognizing that "principles of high-quality medical practice dictate that the people of the State of West

Virginia have access to appropriate, safe and effective pain management" and that "opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes." Ex. DEF-WV-01935 at 3; see also Gilligan, 7/2/21, at 127-29.

The policy further states that "[p]hysicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances[.]" Ex. DEF-WV-01935 at 3. Dr. Gilligan once again confirmed that this statement would send physicians "a fairly clear message that they . . . shouldn't fear disciplinary action by the board as long as they practice meeting the standards of appropriate care." Gilligan, 7/2/21, at 129. The Board of Medicine adopted these guidelines from the FSMB, and reviewed the guidelines carefully before adopting. See Knittle, 8/27/20, at 163. Doctors practicing in West Virginia are expected to be familiar with and seek to follow the guidelines and policy statements issued by the West Virginia Board of Medicine. See Gupta, 5/6/21, at 54-55.

The State of West Virginia also passed laws that influenced doctors to prescribe more opioids to patients for chronic pain. In 1998, West Virginia passed the Intractable Pain Act. See generally Ex. DEF-WV-03106. The Intractable Pain Act made clear

to doctors that they could treat chronic non-cancer pain the same way they treated chronic cancer pain, with high doses of prescription drugs and without fear of retribution. See Deer, 7/7/21, at 80-81; see also Ex. DEF-WV-03106 at 2 ("In the case of intractable pain involving a patient who is not dying, the physician discharges his or her professional obligation to relieve the patient's intractable pain, even though the dosage exceeds the average dosage of a pain relieving controlled substance. . . .").

In 2009, West Virginia passed an amendment to the Intractable Pain Act. See Deer, 7/7/21, at 95-96; see also Ex. DEF-WV-03067 (2009 Amendment to Intractable Pain Act). The amendment removed the word "intractable" from the previous legislation, which, from Dr. Deer's perspective, had the effect of broadening the scope of the legislation and making it easier to treat patients with prescription opioids who did not have severe pain. See Deer, 7/7/21, at 97-98; see also Knittle, 8/27/20, at 141 (acknowledging that "the definitions of 'pain' is a bit broader than the definition of 'intractable pain'").

There was no evidence that defendants played any role in changing the standard of care for the treatment of pain or endorsed these changes. These changes in the standard of care led to an increase in the medical use of prescription opioids. Doctors began to prescribe opioids for a broader range of

conditions, most notably, for the long-term treatment of chronic pain.

According to Dr. Gilligan, physicians and other prescribing clinicians were the ones who drove the volume of opioids prescribed over the last thirty or so years. See Gilligan, 7/2/21, at 146. Plaintiffs admit as much: "by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions." ECF No. 80 at ¶ 375. Such prescribing, Dr. Waller testified, "was the general gestalt at the time given that pain as the fifth vital sign was being implemented in hospitals and as such that it was felt that that was the only lever we had to pull for the treatment of pain." Waller, 5/4/21, at 103.

Dr. Gupta testified that there was a "culture" of "attempting to reduce pain from a scale of whatever to zero for every American, every West Virginian, that they could possibly do." Gupta, 5/6/21, at 90. Dr. Gupta further testified that there was a "culture" of writing "several more days of prescriptions" than required to treat the given condition, and that it was "a common mistake in the medical profession" to prescribe too many opioid pills for a legitimate need. Id. at 89-90 ("It's probable for a good doctor to make a good sound judgment for the need of opioids, but make a mistake on the

duration of the need of opioids. So instead of three days, you write for 30 days, that's a problem. And not everybody who does that is necessarily a bad doctor or bad prescriber. That's what was happening.").

Dr. Keyes testified that, "starting in the late 1990s up through around 2010, doctors increased their prescribing of opioids." Keyes, 6/14/21, at 71 ("Pervasive over-prescribing resulted in unused prescription opioid medicines diverted for Monétary value, bartered for no cost among family and individuals in a shared social network."). Dr. Yingling testified that "the addition of pain as the fifth vital sign and the smiley face/happy face diagram shown to patients had the effect of increasing net prescribing of pain medications." Yingling, 6/16/21, at 182.

Dr. Deer testified that West Virginia laws and policies changed the standard of care in West Virginia and led to increased opioid prescribing around the state. See Deer, 7/7/21, at 100. Dr. Deer further testified that West Virginia prescribers prescribed opioid medications more freely in accordance with the guidance that was issued by various bodies in West Virginia, and that the vast majority of these prescribers were acting reasonably based on the information available to them at the time. See id. at 100-10.

The State of West Virginia's 2018 Opioid Response Plan stated that "[a] critical factor fueling the national opioid epidemic is the rapid rise in opioid prescriptions for pain. From 1999 to 2012, opioid prescribing increased fourfold . . . . West Virginia has experienced some of the highest rates of opioid prescribing in the nation." Ex. P-44223 at 9.

The changes in the standard of care led to a particular increase in opioid prescribing in West Virginia, which compared to the nation as a whole has an older population, more workers in industries that lead to pain and injuries, and more people who suffer from conditions that cause or contribute to chronic pain.

As of 2016, West Virginia ranked number one per capita in total annual prescriptions for all medicines. See Gupta, 5/6/21, at 32-33; see also Ex. DEF-WV-00747 at 39. States with large rural populations such as West Virginia have among the highest prescribing rates for opioid analgesics. See Keyes, 6/14/21, at 52-53.

The West Virginia population has a high relative prevalence of health conditions that could lead to increased pain, including arthritis, cancer, obesity, and other conditions. See, e.g., Gupta, 5/6/21, at 35-37 (ranked first in country for arthritis, cardiovascular disease, COPD, and hypertension; second in country for diabetes and depression; and third in

country for cancer); Keyes, 6/14/21, at 54, 60; Deer, 7/7/21, at 104-05; see also Ex. DEF-WV-00747 at 28.

The West Virginia population is relatively older and has relatively higher levels of obesity as well as a higher than average number of disabled persons, all of which tend to generate more needs for pain treatment. See, e.g., Gupta, 5/6/21, at 37-38, 50-53; Keyes, 6/14/21, at 59-60; Deer, 7/7/21, at 104-05; see also Keyes, 6/14/21, at 53-54 (testifying that rural populations are on average older than urban populations). Manual and physical labor is a significant component of the West Virginia economy and tends to generate more needs for pain treatment. See, e.g., Gupta, 5/6/21, at 47-50; Keyes, 6/14/21, at 60; Deer, 7/7/21, at 105-06. Given the older population and higher rates of chronic pain, Dr. Keyes "would expect to see higher levels of opioid prescribing in West Virginia than in many other states." See Keyes, 6/14/21, at 57.

The opioid crisis would not have occurred if prescribing opioids had not become standard practice in managing acute and chronic pain. See Keyes, 6/14/21, at 82 ("Q. And then, your view is that the opioid crisis would not have occurred if prescribing opioids had not become standard practice in managing acute and chronic pain, correct? A. That's right.").

Of the shaky science supporting this shift in the standard of care, Dr. Compton observed:

> Physicians and other healthcare providers had learned from historical experience of the dangerous addictiveness of opioid drugs, and for decades were therefore reluctant to treat most pain conditions. . . . A now notorious one-paragraph letter in the New England Journal of Medicine in 1980 stated that among a large sample of hospitalized patients who had been given opioids, only four developed addiction. Despite the fact that this report focused on inpatient administration of opioids, it was later cited widely to support less hesitation in using opioids in outpatient settings outside of end-of-life care. Other small case series in the mid-1980s suggested that patients with noncancer pain, if chosen appropriately, could take opioids long term safely and with few developing misuse or addiction.
>
> On the basis of these studies, pain advocacy organizations and some in the medical community began to seek state-based regulatory changes to reverse the perceived underuse of opioids to address chronic, non-cancer pain.
>
> * * *
>
> Opioids began to be increasingly prescribed for chronic non-cancer pain, despite a lack of evidence supporting opioids' efficacy or safety for patients with these conditions; for instance, the systematic review conducted for the 2014 National Institutes of Health Pathways to Prevention workshop found insufficient evidence "to determine the effectiveness of long-term opioid therapy for improving chronic pain and function" but did find evidence of a "dose-dependent risk for serious harms."

MC-WV-02079 at 5-6 (citations omitted).

Nevertheless, there was no evidence presented for the trier of fact to find that defendants had anything to do with changing the standard of care.

E. Manufacturers, Not Defendants, Exploited the New Standard of Care to Aggressively Market Prescription Opioids

Plaintiffs have alleged in their complaint, the manufacturers of prescription opioids "turned [the] consensus [that opioids were too addictive for chronic pain] on its head by designing and implementing a sophisticated and deceptive market strategy that, among other things, falsely denied the risk of addiction and overstated the benefits of using opioids long-term." ECF No. 80 at ¶ 372.

Plaintiffs maintain that manufacturers "marketing changed prescribers' willingness to prescribe opioids, lead them to prescribe more of their opioids, and persuaded them not to stop prescribing opioids." Id. at ¶ 663. Plaintiffs also allege and therefore admit that the change in the standard of care was influenced by a deceptive advertising campaign by the manufacturers of prescription opioids, which generally overstated the benefits and understated the risks of opioid treatment.

Plaintiffs judicially admit that a deceptive advertising campaign by the manufacturers of prescription opioids played a role in changing the standard of care. See ECF No. 80 ¶¶ 372–76. Plaintiffs judicially admit that manufacturers made false or misleading marketing claims about prescription opioids. See ECF No. 80 ¶¶ 378, 384–537.

Plaintiffs presented no evidence that distributors made any of these claims. Dr. Waller testified that marketing outreach to primary care physicians was done by manufacturers. See Waller, 5/4/21, at 218-19. Dr. Waller further testified that the manufacturers' marketing of OxyContin included high levels of targeted outreach to primary care physicians, outreach at national meetings, incentivized sales, and even illegal sales practices, all of which fueled the multi-billion-dollar medication sales increase starting in the 1990s.

Dr. Waller further testified that these practices found a particular niche in some rural areas where limited access to integrated pain treatment and high prevalence of pain conditions facilitated proliferation of prescription opioids and misuse. See id. at 199-201; see also Ex. MC-WV-02079 at 6.

Dr. Mohr testified that manufacturers, not distributors, engage in physician detailing, and maintain large sales detailing forces to consistently call on doctors and make representations about the risks and benefits of prescription opioids. See Mohr, 6/11/21, at 122-23. Dr. Mohr further testified that manufacturers, not distributors, detail physicians for the purpose of expanding sales of their products. See id. at 123 ("[D]istributors did not detail physicians.").

Dr. Werthammer testified that manufacturers of prescription opioids, like Purdue, detailed doctors about the benefits of

prescription opioids. See Werthammer, 5/21/21, at 30. Dr. Werthammer further testified that manufacturer marketing about the addiction potential of prescription opioids had the effect of increasing doctors' prescribing of opioids. See id. ("I agree with this, that the information promulgated by big pharma and that you cannot become addicted to opioids if you're truly in pain certainly contributed in physician's minds that there's safety in being able to prescribe opioids for pain without fearing the consequence of addiction.") see also 31 (Q: "[I]t was the prescribing that drove the demand, correct?" A: "Well, I think the prescribing and - - to some degree, and also some of th[ese] miscreants that we talked about like pharmaceutical pharmacy representatives and some physicians.").

Mr. Rafalski agreed with the GAO's conclusion that "Purdue conducted an extensive campaign to market and promote OxyContin using an expanded sales force and multiple promotional approaches to encourage physicians, including primary care specialists, to prescribe OxyContin as an initial opioid treatment for noncancer pain." Rafalski, 5/26/21, at 141-42; see also Ex. MC-WV-01764 at 9.

Mr. Rafalski further agreed with the GAO's conclusion that "DEA has expressed concern that Purdue's aggressive marketing of OxyContin focused on promoting the drugs to treat a wide range of conditions to physicians who may not have been adequately

trained in pain management." See Rafalski, 5/26/21, at 142; see also Ex. MC-WV-01764 at 9.

Dr. Keyes published an article in April 2021 stating one of the two forces that "led to the proliferation of opioid prescribing in the 1990s . . . [was] the pharmaceutical industry's concerted efforts to advocate for the long-term use of opioids as a safe, non-addictive, effective, and humane alternative to treat non-cancer pain," including "Purdue Pharma provid[ing] funds for educational campaigns supporting the use of opioids to treat chronic non-cancer pain." Keyes, 6/14/21, at 34-35. Mr. Knittle testified that pharmaceutical manufacturers promoted the idea that opioids were the "first and foremost" pain treatment. Knittle, 8/27/20, at 101-02.

Plaintiffs offered no evidence that defendants engaged in any false or misleading marketing activities that influenced the standard of care for the prescribing of opioids. Furthermore, any evidence plaintiffs presented about defendants' marketing activities had no impact on number of prescriptions written.

F. Good-Faith Prescribing Drove the Increased Volume of Prescription Opioids

To prescribe opioids, doctors must be registered with the DEA and licensed by the State. See 21 C.F.R. § 1306.03; see also Gilligan, 7/2/21, at 72, 96; Knittle, 8/27/20, at 39, 201. "The responsibility for the proper prescribing and dispensing of

controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a); see also Rafalski, 5/26/21, at 116-17. A prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a); see also Rafalski, 5/26/21, at 116.

Doctors in Cabell/Huntington determined the volume of prescription opioids that pharmacies in the community ordered from defendants and then dispensed pursuant to those prescriptions. Ms. Keller testified that prescribing and distribution in Cabell County matched almost perfectly—average opioid pills prescribed was 141.2 pills per person while opioid pills distributed was 142.19 pills per person. See Keller, 6/15/21, at 213-14.

Dr. Keller also testified that because ARCOS data "shows shipments by distributors to pharmacies" it is a "reflection of the prescribing because orders ultimately fill prescriptions that are written." Id. at 206. Dr. Gupta testified that the number of prescriptions going to pharmacies is based on the judgment of doctors and other healthcare providers, and that the total volume of prescriptions determines the total volume of pills that could leave pharmacies. See Gupta, 5/6/21, at 46-47.

Dr. Gupta further testified that a critical factor fueling the national opioid epidemic is the rapid rise in opioid prescriptions for pain. See id. at 85.

Dr. Keyes testified that the high volume of opioid prescriptions that doctors were writing "became the foundation for the overall expansion in the opioid supply and opioid-related harm." See 6/14/21, at 81. Dr. Keyes further testified that she is not aware of any occasion where McKesson, Cardinal, or AmerisourceBergen shipped opioids into Cabell/Huntington in excess of the levels prescribed by doctors. See id. at 27.

Mr. Rafalski testified that he is not aware of any pills shipped by defendants "other than in response to a licensed prescriber writing a prescription." Rafalski, 5/26/21, at 131. Mr. Rafalski further testified that there is "no other way" for distribution to increase other than for doctors to prescribe more opioids. Id. at 242. Mr. Rafalski further testified that pharmacies only dispense prescription opioids in response to prescriptions, and that the number of pills a pharmacy dispenses is directed by the number of prescriptions written by doctors. See id. at 131, 134.

According to Mr. Rannazzisi, the opioid crisis "started with prescriptions," and that "what drives demand for opioids is appropriate medical treatment," not opioid supply. See Rannazzisi, 6/9/21, at 87-89, 190. Dr. McCann testified that

prescribing and distribution volume are "two sides of the same coin." McCann, 5/11/21, at 134-35. Dr. McCann further testified that he was not aware of any evidence that distribution reflected in the ARCOS data exceeded prescriptions. See id. at 183.

Dr. Murphy testified that the volume of prescription opioids was determined by doctors, not distributors. See Murphy, 7/8/21, at 67 ("I think prescriptions - - if you wanted to think about market like this and what's going to determine the quantity, it's going to be the prescribing behavior . . . because in order to sell a prescription in this market place, you have to have a prescription. This is not like you go down to the grocery store and say, you know, oh, I see there's a stack of doughnuts. I'll buy some doughnuts. That's not how this works. You need a prescription to buy it. . . .").

Prescription opioids should remain on the pharmacy shelves unless and until prescriptions are written for them. Dr. Gupta testified that an opioid pill cannot leave a pharmacy lawfully unless a prescriber decides to write a prescription and a pharmacist decides to dispense it. See Gupta, 5/6/21, at 47.

Dr. Keyes confirmed that no matter how many opioids a distributor ships to a given pharmacy, those opioids are supposed to stay in the pharmacy and not go out to the public without a doctor's prescription. See Keyes, 6/14/21, at 83.

Dr. Gilligan testified that shipments prescription opioids have a one-to-one relationship with prescriptions, and that physicians and other prescribing clinicians drove the changes in prescribing both up and down over time. See Gilligan, 7/2/21, at 146.

The standard of care liberalizing the prescribing of opioids was multifaceted. First, more doctors were prescribing opioids than ever before. Second, they were prescribing opioids at higher doses and for longer durations. For example, Dr. Deer testified about seeing patients that were prescribed ten pills a day or 300 pills a month. See Deer, 7/7/21, at 41; see also 26 ("We had dentist [who] were prescribing a lot of opioids post-surgery for a tooth. Like they'd give you 90 pills for a tooth pull and things like that."); see also P-44223 at 9 (recounting West Virginia patient who stated, "A few years ago I had sinus surgery, and the doctor prescribed pain medication, which I filled on the way home while still groggy from the surgery. When I opened the medication, which was oxycodone, I found that there were 40 tablets. At my follow-up appointment I asked the doctor why on earth he prescribed 40 tablets. I only used one the first night just in case, and didn't need any more. He said it was the 'protocol.' So who decides the protocol? How can it be changed?").

Third, certain prominent doctors advanced the view that you upped the dosage of opioids until someone's pain got better. See Deer, 7/7/21, at 73 ("Many physicians adopted the philosophy that you upped the dose of opioids until someone got better, their pain below a 3 or a 4, or they had a side effect. And there was no ceiling, was what Dr. Portenoy always stated in his lectures and things around the country. And so, you should keep going up even to a thousand milligrams a day without any fear of problems in a patient."); see also id. at 43 (discussing Purdue's Medical Director speaking at an event where he stated "that no one was really addicted, they were undertreated, you give them more and more").

In Dr. Gilligan's opinion, even at the peak of opioid prescribing, "the great majority of the over-prescribing was well-intentioned." See Gilligan, 7/2/21, at 146. Id. ("I think there was a great majority of cases of well-intentioned clinicians trying to follow what they understood, or in some cases what they had been told, was the right way to treat patients." He further opined that distributors had no influence on doctors' prescribing decisions. See id. at 146-47.

The overwhelming majority of doctors were acting in good faith when they made the decision to prescribe opioids. See Gilligan, 7/2/21, at 146 (testifying that increased prescribing was driven by well-intentioned doctors, often primary care

doctors, trying to follow what they understood was the right way to treat patients). Dr. Deer also testified that doctors who prescribed more opioids in accordance with the changing standard of care were acting reasonably based on the information available. See Deer, 7/7/21, at 62.

Plaintiff's witnesses with a medical background, both expert and non-expert, confirmed as much. Dr. Gupta testified that there were more good doctors in West Virginia than bad doctors at any one point in time, and that most doctors' intent in prescribing opioids was to help their patient because "that was the culture. That was the education. That was the influence. That was their understanding." Gupta, 5/6/21, at 93-94. Dr. Keyes likewise testified that the "overwhelming majority of doctors prescribe opioids to their patients in good faith." Keyes, 6/14/21, at 71, 76. Dr. Keyes further testified that a doctor acting in good faith to prescribe an opioid may provide for more pills in the prescription than are needed to meet the medical need for which the pills are being prescribed. See id. at 74-77. Dr. Waller testified that doctors prescribing opioids for chronic non-cancer pain in the mid-2000s "were acting in good faith." Waller, 5/4/21, at 104.

The DEA agreed. Mr. Rannazzisi testified to Congress that "99 percent of the doctors are perfect" and "that the overwhelming majority of prescribing in America is conducted

responsibly." Rannazzisi, 6/9/21, at 102. Mr. Rannazzisi testified that an extremely small fraction of doctors were acting illegitimately, and testified that 99% of prescribers in the United States are treating their patients appropriately. See id. at 108; see also Rannazzisi, 6/8/21, at 184-85.

While serving as head of the DEA's Office of Diversion Control, Mr. Rannazzisi testified before Congress in 2014 that "99.5 percent of the prescribers . . . are not overprescribing." Rannazzisi, 6/9/21, at 99-100; see also Prevoznik, 4/17/19, at 402-03. In 2006, the DEA stated publicly that "nearly every prescription issued by a physician in the United States is for a legitimate medical purpose." Ex. DEF-WV-03076 at 7; see also Rannazzisi, 6/9/21, at 106-07.

Mr. Rafalski agreed with the DEA's assessment that "the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes," and that "the overwhelming majority of physicians who prescribe controlled substances do so in a legitimate manner that will never warrant scrutiny by federal or state law enforcement officials." Rafalski, 5/26/21, at 120-21. Mr. Rafalski further agreed with Mr. Rannazzisi's assessment that 99% of doctors prescribe opioids for legitimate medical purposes and testified that the vast majority of doctors are trying to do the right thing. See id. at 117-18.

Mr. Prevoznik testified on behalf of the DEA that the DEA believed that the overwhelming majority of prescribing in America is conducted responsibly. See Prevoznik, 4/17/19, at 401.

Mayor Williams testified that "the vast majority of doctors in Cabell County and Huntington thought they were prescribing opioids appropriately." Williams, 6/30/21, at 82. Mr. Knittle testified that the change in the standard of care caused addictions and death because "some physicians had believed that the best way to treat pain was for high and consistent amounts of opioids." Knittle, 8/27/20, at 106. He further testified that, at least in 2016, the West Virginia Board of Medicine's belief was "that the opioid epidemic was fueled primarily by doctors liberally prescribing opioids[.]" Knittle, 8/27/20, at 194.

G. The Increase in Prescribing of Opioids Is Reflected in the DEA's Average Production Quota over the Relevant Time Period

The DEA sets annual production quota (APQ) for each prescription opioid in the United States based on its determination of the legitimate medical, scientific, research, and industrial needs for prescription opioids. See 21 U.S.C. § 826(a)(1). The aggregate production quota is the maximum amount of a controlled substance that the United States needs for its legitimate medical, scientific, and research purposes,

and for export and inventory allowances. See Harper-Avilla, 4/11/19, at 35, 218.

The DEA evaluates prescription data as a factor when the setting the aggregate production quotas. See id. at 177. The DEA also considers diversion and abuse when setting the quota. See id. at 54-55, 73-74. The DEA admitted that if manufacturers of opioids had misled doctors and the public about the health benefits and the addictive nature of opioids causing sales to rise, then the DEA's estimate of the medical need could be above the actual medical need in the United States. See id. at 177.

From 2003 to 2013, the DEA raised the production quotas for prescription opioids by significant amounts. See Ex. DEF-WV-01597 at 18 (the DEA raised the APQ for oxycodone over 400 percent). Just as the DEA's establishment of production quotas reflect the prescriptions that were being written, so too did the defendants' distributions.

H. The Emergence of a More Conservative Approach to Prescribing Opioids

Dr. Gilligan testified that "around 2011 prescribing in the country peaked and started to go down." Gilligan, 7/2/21, at 77. He stated that this was due to an increased awareness regarding the risks of prescription opioids vis-à-vis their effectiveness. See id. Dr. Gilligan framed the current standard of care as more conservative with respect to

prescribing opioids. See id. at 77 and 139. According to him, since 2013, the standard of care for opioids has become more conservative, and opioid prescribing rates have decreased, and that this change was driven by the medical profession. See Gilligan, 7/2/21, at 138-39. Nevertheless, opioids continue to be prescribed for acute pain, cancer pain, and non-cancer chronic pain. See id. at 139.

Dr. Gupta testified that in recent years, there has been an effort to educate doctors in West Virginia to think more carefully about their prescribing of opioids. See Gupta, 5/6/21, at 57. Dr. Gupta further testified that over time, with more training and better use of databases like the CSMP, doctors in West Virginia are writing fewer prescriptions for opioids. See id. at 57-58.

Federal and state guidelines promulgated in 2016 [CDC and SEMP] advocating a more conservative approach to prescribing opioids, along with West Virginia's 2018 Opioid Reduction Act, changed the standard of care in West Virginia toward more conservative opioid prescribing. In 2018, West Virginia enacted the Opioid Reduction Act. See Ex. DEF-WV-03054; Deer, 7/7/21, at 117-18. The Opioid Reduction Act limited how many days' supply of an opioid medication doctors could prescribe to patients and required doctors to inform patients about alternatives to opioid medications and the risks associated with

opioid medications. See Deer, 7/7/21, at 118-20. Dr. Deer testified that the 2016 guidelines and the 2018 Opioid Reduction Act changed the standard of care in West Virginia. See id. at 121.

Prescription opioids continue to be widely prescribed today for the treatment of various forms of pain, but subject to new guidelines. Such prescribing occurs despite significant attention over the past decade to the risks of abuse and addiction associated with these medicines, reflecting the judgments of the medical community that these FDA-approved medications continue to play an important role in the treatment of pain despite the risks associated with their use. See, e.g., Keyes, 6/14/21, at 108 (testifying that "physicians are more concerned about addiction now than they were in the 1990s and 2000s").

In 2013, Dr. Keyes published a paper that stated "[w]hen used as prescribed under medical supervision, opioid analgesics are effective and used as standard practice in managing acute and chronic pain." Keyes, 6/14/21, at 15, 17. Dr. Keyes believed that statement was true based on the literature she had reviewed at the time. See id. at 17. Dr. Gilligan testified that it is the consensus of the medical community that the benefits of prescription opioids outweigh the risks for certain patients, and that is reflected in the fact that prescription

opioids are FDA-approved. See Gilligan, 7/2/21, at 38-39. Dr. Gilligan further testified that opioids play a central role in the treatment of chronic cancer pain. See id. at 32. Prescription opioids remain an option for certain people suffering from chronic non-cancer pain. See id. at 69-70. Dr. Deer testified that prescribing opioids is appropriate for the correct patient. See Deer, 7/7/21, at 37.

The DEA agrees there is a legitimate medical need under 21 U.S.C. § 801 for prescription opioids to treat pain. See Prevoznik, 4/17/19, at 393. The DEA further testified that it agrees that opioids are an appropriate medication for many Americans, and that prescription opioids are necessary to maintain the general welfare of American people who need them. See id. at 392-94.

I. There Is No Evidence That Defendants Distributed to Pill Mills in Cabell/Huntington

"The 1990s and 2000s also saw the development of rogue pain clinics (sometimes called pill mills) where opioids were prescribed and dispensed in large quantities but with few clinical indications." Ex. MC-WV-02079 at 6. There is no evidence that ties any of defendants' shipments to a pill mill in Cabell/Huntington.

Dr. McCann did not identify any of defendants' pharmacy customers as pill mills. See McCann, 5/11/21, at 183. Mr.

Rafalski could not identify any pills shipped by defendants that went to a pill mill doctor or to fill an improper prescription. See Rafalski, 5/26/21, at 130-32. Nor did he investigate any of the pharmacies in Cabell/Huntington. See id. at 134 ("I wasn't evaluating pharmacies."). In any event, according to Dr. Keyes, pill mills do not explain in any significant way the expansion of opioid prescribing and opioid-related harm in the U.S. See Keyes, 6/14/21, at 131.

Plaintiffs offered no evidence that Defendants ever distributed controlled substances to any entity that did not hold a proper registration from DEA or license from the West Virginia Board of Pharmacy. Dr. McCann was not aware of any evidence that Defendants distributed to pharmacies that were not licensed by DEA or the West Virginia Board of Pharmacy. See McCann, 5/11/21, at 69, 182-83; McCann, 5/12/21, at 65. Mr. Rafalski was not aware of Defendants ever supplying a pharmacy that was not licensed by DEA. See Rafalski, 5/26/21, at 131. Mr. Rannazzisi admitted that he could not identify any instance where any Defendant "supplied controlled substances to a Huntington or Cabell County pharmacy that was not registered with the DEA." Rannazzisi, 6/9/21, at 151.

None of the defendants ship opioids to pharmacies without a DEA registration or license. Mr. Mays testified that AmerisourceBergen does not ship to customers who are not

registered with DEA and licensed by the proper state entity. See Mays, 5/18/21, at 173. Mr. Moné testified that Cardinal Health does not ship to customers who are not registered with DEA and licensed by the State of West Virginia. See Moné, 5/20/21, at 180. Mr. Oriente testified that McKesson does not ship to customers who are not registered by DEA. See Oriente, 5/25/21, at 31.

Plaintiffs offered no evidence that defendants ever distributed controlled substances to any entity that it knew was dispensing for any purpose other than to fill legitimate prescriptions written by doctors. Mr. Zimmerman testified that if ABDC knew a pharmacy was diverting drugs "we wouldn't be selling [opioids] to them." Zimmerman, 5/12/21, at 203.

Mr. Moné testified that Cardinal Health did not ship any prescription opioids to a pharmacy in Cabell/Huntington that Cardinal Health knew or should have known was dispensing for a purpose other than to fill legitimate prescriptions written by doctors. Moné, 5/20/21, at 180. Mr. Moné further testified that Cardinal Health never shipped an order it believed would be used for other than legitimate medical purposes. See id. at 230. Mr. Oriente testified that, at all relevant times, McKesson blocked and did not ship orders that it identified as likely to be diverted. See Oriente, 5/25/21, at 48, 55, 126.

Although Plaintiffs allege that the volume of prescription opioids distributed in Cabell/Huntington was "excessive," they offered no evidence, expert or otherwise, of how many prescription opioids should have been distributed in Cabell/Huntington. Dr. McCann disavowed any opinion as to the "right" level of opioid supply in Cabell/Huntington. See McCann, 5/11/21, at 66 (Q: "[Y]ou have not studied the medical needs for Cabell County or the City of Huntington; correct?: A: "Correct." Q: "And you cannot tell this Court how many prescription opioids should have been distributed to Cabell County or the City of Huntington; correct?" A: "Correct.").

Mr. Rafalski also did not offer any opinion as to the "right" level of opioid supply in Cabell/Huntington. See Rafalski, 5/26/21, at 129 (Q: "You've not done any kind of analysis of the medical needs for prescription opioids in Cabell County or Huntington relative to the national average; correct?" A: "That's a correct statement. I did not do that.").

Ms. Keller likewise did not try to discern the "right" level of opioid supply in Cabell/Huntington. See Keller, 6/15/21, at 168 (Q: "So, you're not an expert who can come and tell the Court what volume of opioids was the right volume that should have been prescribed in Cabell-Huntington at any point in time, correct?" A: "Correct. . . . I don't offer the opinion

of what should be the volume. . . . I could tell you what was prescribed but not what should be prescribed.").

Dr. Keyes testified that she "ha[d] not undertaken a statistical evaluation" of how many prescription opioid pills were needed in Cabell/Huntington and "ha[d] not undertaken any analysis of the pain needs specifically in Cabell/Huntington." Keyes, 6/14/21, at 19-20.

There is a difference between "overprescribing" and "illegal prescribing." Boggs, 1/17/19, at 358-59. As Boggs explained,

> part of the opioid epidemic has been fueled by overprescribing. That's not illegal prescribing but it's overprescribing.
>
> Q: Can you explain what the difference - you just used two different terms, "overprescribing" and "illegal prescribing." Can you explain what you mean by those?
>
> A: Sure. Illegal prescribing would be when a doctor would be complicit in a scheme that they know the patient doesn't need it, the patient is paying in case the doctor writes a prescription for a patient they've never seen before or examined before. The doctor meets - meets someone in a parking lot. Those would be illegal prescriptions. Overprescribing, on the other hand, might be a situation where a doctor has a legitimate patient, has a legitimate need for the drugs, but instead of writing that prescription for, say, 15 days, they write it for 30 days. It's a perfectly legitimate prescription but its overprescribing. It's prescribing more than what the patient would need.
>
> Q: Can you give a - can you give the jury an example of a prescription that might be overprescription - that might be an overprescription without being diversion?

> A: Sure. You might have a patient go to a dentist and have a tooth - tooth extraction, and the patient needs the medication for maybe a couple of days, but the doctor writes it for 30 days. That's overprescribing.
>
> Q: So does the - does McKesson's compliance program target overprescribing, as you've just described it?
>
> A: It - it can't.
>
> Q: Why not?
>
> A: We don't see the prescriptions.

Id. at 358-60.

Therefore, even if there was some level of "illegal prescribing" in Cabell/Huntington, the court is unable to discern if it was significant enough to impact the overall volume of prescription opioids distributed by defendants. As Mr. Rannazzisi admitted, quantity alone might not indicate that there was illegal prescribing. See Rannazzisi, 6/9/21, at 112-13 (The DEA did not "investigate [doctors] based on quantities.").

Moreover, detecting and thwarting illegal prescribing is not the duty of distributors. Their role, instead, is to detect and avoid supplying pharmacies that are themselves not part of the "legitimate medical . . . channel[]." See 21 U.S.C. § 823(b)(1). The facts of this case do not support a failure to fulfill that role by defendants.

VIII. The Abatement Plan

Plaintiffs propose a 15-year "Abatement Plan" as their equitable remedy. Plaintiffs' expert Dr. Alexander developed the plan, see Alexander, 6/28/21, at 16-17, with inputs from plaintiffs' experts Dr. Young, see Young 6/16/21, at 104, and Dr. Keyes, see Alexander, 6/28/21, at 148-49. Plaintiffs' expert Mr. Barrett testified that the total cost of the plan over 15 years (in future dollars) is $2,544,446,548. See Barrett, 6/29/21, at 106. The court finds that plaintiffs' proposed "Abatement Plan" addresses harms caused by opioid abuse and addiction—it does not address defendants' conduct.

Virtually the entirety of the proposed Abatement Plan is addressed to programs and services to treat opioid addiction and abuse, and the attendant harms caused by opioid abuse and addiction. See Alexander, 6/28/21, at 29. Dr. Alexander testified that the Abatement Plan is intended to address the opioid epidemic as a whole, and is not limited to addressing prescription opioids. See id. at 29, 121.

Only one element of the Abatement Plan addresses the volume of prescription opioids in Cabell/Huntington and is arguably tailored to defendants' allegedly wrongful conduct: the "Safe Storage and Drug Disposal," which entails collection sites for unused pills that could remove excess prescription opioids from the community. See id. at 133. This program accounts for

$35,972 (in future dollars over 15 years), see Barrett 6/29/21, at 107, 110, representing 0.0014% of the total costs of the Abatement Plan.

The Abatement Plan does not include any provisions to constrain defendants' conduct generally or their distribution of prescription opioids in the City of Huntington or Cabell County specifically. Dr. Alexander acknowledged that the Abatement Plan (1) "does not recommend any new licensing requirements for distributors," (2) "does not propose any new reporting requirements for distributors," and (3) "does not propose any new physical security requirements for distributors." Alexander, 6/28/21, at 123-24.

CONCLUSIONS OF LAW

I. Jurisdiction and Venue

This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because the plaintiffs, City of Huntington and the Cabell County Commission, are both citizens of West Virginia, and all of the defendants are citizens of states other than West Virginia; and the amount in controversy exceeds $75,000 exclusive of interest and costs.

Venue is proper in the Southern District of West Virginia under 28 U.S.C. § 1391 because a substantial part of the acts or omissions giving rise to plaintiffs' claims occurred in this district.

II. Standing

Defendants have standing to bring this civil action. As this court previously held, in ruling on defendants' motion for summary judgment on the issue of standing, a municipality has standing to seek judicial redress to abate a condition alleged to be a public nuisance. See ECF No. 1248 at 11-14.

After trial of this action, the court finds no reason to alter or reverse its previous ruling on standing.

III. Statute of Limitations

Plaintiffs insist that they are seeking equitable relief, specifically abatement of the alleged nuisance. In West Virginia there is no statute of limitations for claims seeking equitable relief. See Dunn v. Rockwell, 689 S.E. 2d 255, 267 (W. Va. 2009). Where there is no statute of limitations that applies to equitable remedies, the court may apply the doctrine of laches to time bar a remedy. See Rodgers v. Rodgers, 399 S.E. 2d 664, 670 (W. Va. 1990).

Nuisance cases in West Virginia are characterized as either permanent or temporary for purposes of determining whether the suit is time barred. A permanent nuisance is one where, by one act, a permanent injury is done that at once produces all the damages than can ever result from it. A temporary nuisance, on the other hand, involves continuing or repeated injury. These principles were confirmed in State ex rel. Smith v. Kermit

Lumber & Pressure Treating Co., 488 S.E. 2d 901, 922 (1997). There, the Division of Environmental Protection of West Virginia brought suit against a lumber treatment business whose site was contaminated by chromium and arsenic. See id. at 905.

The toxic substances had spilled into the environment on multiple occasions over a period of time. See id. The Circuit Court of Mingo County dismissed the case on the theory that the statute of limitations had run. See id. at 907. The Supreme Court of Appeals of West Virginia reversed and held that the defendant had created a public nuisance subject to a one-year statute of limitations and that the period of limitations would not commence until the nuisance was abated. See id. at 925. The court held that, until the harm is abated, the public nuisance is continuing and the statute of limitations does not accrue. See id.

Kermit Lumber controls here, and this action is not barred by the statute of limitations or the doctrine of laches.

IV. The Law of Public Nuisance Does Not Afford Plaintiffs a Remedy upon the Facts of This Case

In an action based on diversity of citizenship, a federal court is, in most cases, required to follow established law of the forum state. A "State's highest court is the best authority on its own law." Commissioner of Internal Revenue v. Bosch, 387 U.S. 456, 465 (1967). If there is no decision on point by the

state's highest court, the federal court is to "predict" the law the state's highest court would likely apply. Knibbs v. Momphard, 30 F.4th 200, 213 (4th Cir. 2022) (quoting Rhodes v. E.I. du Pont de Nemours & Co., 636 F.3d 88, 96 (4th Cir. 2011)).

To forecast a decision of a state's highest court, a federal court may consider "canons of construction, restatements of the law, treatises, recent pronouncements of general rules or policies by the state's highest court, well considered dicta, and the state's trial court decisions." Wells v. Liddy, 186 F.3d 505, 528 (4th Cir. 1999).

The court may also consider "the practices of other states." St. Paul Fire Ins. v. Am. Intern. Spec. Lines, 365 F.3d 263, 272 (4th Cir. 2004) (internal citation and quotation omitted). The federal court should consider lower court decisions but is not bound to follow them if the federal court believes they would not be affirmed by the states' highest court. See Chemerinsky, Federal Jurisdiction, 6th ed., pp. 354-355. A federal court sitting in diversity is not bound by a state trial court decision on a matter of state law. See Twin City Fire Ins. v. Ben Arnold Sunbelt Beverage Co., 433 F.3d 365, 370 (4th Cir. 2005).

This court should "'respond conservatively when asked to discern governing principles of state law' and take care to avoid interpreting that law in a manner that 'has not been

approved'" by the West Virginia Supreme Court of Appeals. Knibbs, 30 F.4th at 213 (quoting Rhodes v. E.I. du Pont de Nemours & Co., 636 F.3d 88, 96 (4th Cir. 2011)).

The Supreme Court of Appeals of West Virginia has not ruled on the issue of whether the state's law of public nuisance affords a remedy in cases such as this. Lower court decisions so holding are not persuasive in view of decisions of West Virginia's highest court in cases involving other factual situations.

The Restatement of Torts (3d) states that public nuisance based on the sale and distribution of a product has been rejected by most courts because the common law of public nuisance is an inept vehicle for addressing such conduct. Restatement (Third) of Torts in Liability for Economic Harm, §8 cmt. g. In discussing the scope of public nuisance under West Virginia law, the Supreme Court of Appeals of West Virginia followed the Restatement of Torts. See Duff v. Morgantown Energy Association, 421 S.E. 2d 253, 257 n.6 (W. Va. 1992).

Consistent with the Restatement of Torts, the West Virginia Supreme Court has only applied public nuisance law in the context of conduct that interferes with public property or resources. In Sharon Steel Corp. v. City of Fairmont, 334 S.E. 2d 616 (W. Va. 1985), the court surveyed public nuisance cases in West Virginia from 1878 to 1982. Every case listed concerned

the misuse, or interference with, public property or resources. None of the cases cited held that distribution or sale of a product could constitute a public nuisance.

The extension of the law of nuisance to cover the marketing and sale of opioids is inconsistent with the history and traditional notions of nuisance. The original legal character of nuisance was a wrongful disturbance of the enjoyment of real property or of its appurtenances falling short of a forcible trespass or ouster. See Baker, An Introduction to English Legal History (4th ed. 2002), 422.

Professor James Oldham traced the development of the law of nuisance from the Twelfth Century and found its origins "closely and exclusively related to land law." Oldham, The Mansfield Manuscripts and the Growth of English Law in the Eighteenth Century, vol. 2, 882. The cases almost exclusively involved noxious odors, smoke and the obstruction of roads or waterways. See id. at 886-924.

Only one example in the list of nuisances identified by Oldham approaches the situation we have here. There, an act of Parliament prohibited the manufacturing, sale, or throwing of fireworks. The intent appears to be to eliminate fireworks entirely at their inception and not to apply the law of nuisance to manufacture and marketing of an otherwise beneficial product. See id. at 884.

Two lower court decisions in West Virginia that apply the law of public nuisance to sale and distribution of opioids are not persuasive and are inconsistent with the Restatement of Torts that has been favorably commented upon by the West Virginia Supreme Court of Appeals. The lower court cases are these: Brooke County Commission v. Purdue Pharma, No. 17-c-248 (Marshall County Circuit Court, Dec. 28, 2018); State ex rel. Morrisey v. Amerisource Bergen, No. 12-c-141 (Boone County Circuit Court, Dec. 12, 2014).

Both cases were decided on motions to dismiss the complaint which contained other causes of action besides public nuisance. While each case concluded that claims for public nuisance are not limited to property disputes, neither case contained an in-depth consideration of the question before concluding that the law of nuisance could be applied to opioid cases. Neither case considered the adverse economic consequences of extending the law of nuisance to the sale or distribution of opioids or the expansion of nuisance law to cover other dangerous products.

While the cases from other jurisdictions are conflicting, recent decisions deny extension of the public nuisance doctrine to the sale or manufacture of opioids, and sound public policy considerations support such denial. In 2019, the Superior Court of Connecticut, following Ganim v. Smith & Wesson Corp., 258

Conn. 313 (2001), dismissed an action against drug companies alleged to have caused the opioid crisis.

The court said:

> To keep order in law, government enforcement agencies must represent the indirect public interest in court, not a flurry of individual plaintiffs—even when they are local governments.
>
> To permit otherwise would risk letting everyone sue almost everyone else about pretty much everything that harms us.

City of New Haven v. Purdue Pharma, L.P., No. X07HHDCV176086134S, 2019 WL 423990, at *2 (Conn. Super. Ct. Jan. 8, 2019).

In State ex rel. Attorney General of Oklahoma v. Johnson & Johnson, the Supreme Court of Oklahoma declined to extend Oklahoma public nuisance law to the manufacturing, marketing and selling of prescription opioids. 499 P.3d 719, 730 (Okla. 2021). The court identified "a clear national trend to limit public nuisance to land or property use." Id. at 730. To hold otherwise, the court said, would convert almost every products liability action into a public nuisance claim. See id.

Additionally, the Oklahoma court noted that expansion of public nuisance law to cover the manufacture, marketing and sale of opioids would allow courts to manage public policy matters that should be dealt with by the legislative and executive branches of government—not by courts. See id. at 731.

In Tioga Public School District v. United States Gypsum Co., a school district sued a plastic manufacturer to recover the cost of removing asbestos-containing plastic used to coat the ceilings of the school. 984 F.2d 915 (8th Cir. 1993). Federal jurisdiction was based on diversity of citizenship. There was no controlling decision on point under North Dakota law, so the federal court was required, as the court is required here, to predict what law the Supreme Court of North Dakota would apply if called upon to decide the question. The federal court held that nuisance law does not afford a remedy against the manufacturer of an asbestos-containing product. See id. at 920.

The court said:

> Tioga has not presented us with any North Dakota cases extending the application of the nuisance statute to situations where one party has sold to the other a product that later is alleged to constitute a nuisance, nor has our research disclosed any such cases. North Dakota cases applying the state's nuisance statutes all appear to arise in the classic context of a landowner or other person in control of property conducting an activity on his land in such a manner as to interfere with the property rights of a neighbor.

Id. at 920.

In 2019, a lower court in North Dakota cited Tioga Public School District in an opioid case, holding that the law of nuisance cannot be extended to cases involving the sale of goods. See State Ex Rel. Stenehjem v. Purdue Pharma L.P., No.

08-2018-CV-01300, 2019 WL 2245743, at *13 (N.D. Dist. May 10, 2019). The court quoted with approval Tioga's observation that to extend the law of nuisance to cases involving the sale of goods would "totally rewrite North Dakota tort law" and "any inquiry would give rise a cause of action . . . regardless of the defendant's degree of culpability or the availability of other traditional tort law theories of recovery. Nuisance thus would become a monster that would devour in one gulp the entire law of tort . . . ." Id. at *13.

The phrase "opening the floodgates of litigation" is a canard often ridiculed with good cause. But here, it is applicable. To apply the law of public nuisance to the sale, marketing and distribution of products would invite litigation against any product with a known risk of harm, regardless of the benefits conferred on the public from proper use of the product. The economic harm and social costs associated with these new causes of action are difficult to measure but would obviously be extensive. If suits of this nature were permitted any product that involves a risk of harm would be open to suit under a public nuisance theory regardless of whether the product were misused or mishandled.

As the court states in City of Chicago v. Beretta U.S.A. Corp., such a public right so broad and undefined would subject any potentially dangerous instrumentality to suit. 821 N.E. 2d

1099 (Ill. 2004). Similarly, in In re Lead Paint Litigation, the court observed that to allow nuisance suits for the sale and distribution of a product would "supplement an ordinary product liability claim with a separate cause of action as to which there are apparently no bounds." 924 A.2d 484, 505 (N.J. 2007).

In People ex rel. Spitzer v. Sturm, Ruger & Co., the court concluded that "giving a green light to a common-law public nuisance cause of action today will, in our judgment, likely open the courthouse doors to a flood of limitless, similar theories of public nuisance." 761 N.Y.S. 2d 192, 196 (2003).

Based on the foregoing analysis, the court concludes that, if confronted with the option to extend the law of public nuisance to the sale, distribution, and manufacture of opioids, the Supreme Court of Appeals of West Virginia would decline with good reason to do so.

V. Plaintiffs Have Failed to Show That Defendants' Conduct Interfered with a Public Right

To establish a public nuisance, a plaintiff must prove "an unreasonable interference with a right common to the general public." Duff v. Morgantown Energy Assoc., 421 S.E. 2d 253, 257 n.6 (1992) (quoting Restatement (Second) of Torts § 821B(1) (1979)). The finder of fact in a public nuisance case must assess the gravity and avoidability of the harm, as well as the utility of defendants' conduct.

As stated in the Restatement (Second) of Torts, § 828, cmt. a:

> [I]n determining whether the gravity of the interference with a public right outweighs the utility of the actor's conduct, it is necessary to consider the social value the law attaches to the primary purpose of the conduct, the suitability of the conduct to the character of the locality and the impracticability of preventing or avoiding the invasion.

See Duff, 421 S.E.2d at 257 n.5 (discussing the court's adoption of this balancing test); see also In re Flood Litig. Coal River Watershed, 668 S.E.2d 203, 214 n.8 (W. Va. 2008) (noting that "in the context of nuisance law and related causes of action and doctrines, determining 'reasonableness' requires looking at the interests and conduct of both the plaintiff and the defendant").

Therefore, in determining the reasonableness of defendants' conduct and whether it interfered with a right common to the general public, the court must balance the danger of the harm with the social utility of the defendants' conduct. On one hand, the dangers of opioids are palpable, as abundantly proven by the social costs incurred by communities such as the City of Huntington and Cabell County. But the public benefits of responsible opioid use are likewise apparent. Opioids are essential to the effective treatment of chronic pain, particularly that suffered by terminal patients.

The volume of prescription opioids in Cabell/Huntington was determined by the good faith prescribing decisions of doctors in accordance with established medical standards. Defendants shipped prescription opioid pills to licensed pharmacies so patients could access the medication they were prescribed. Under the Restatement's formulation of a public nuisance, the distribution of medicine to support the legitimate medical needs of patients as determined by doctors exercising their medical judgment in good faith cannot be deemed an unreasonable interference with a right common to the general public. See Pope v. Edward M. Rude Carrier Corp., 75 S.E.2d 584, 589 (1953) (holding that conduct which the public convenience imperatively demands cannot be a public nuisance).

VI. No Causation

For alleged misconduct to be actionable, West Virginia law requires a plaintiff to establish proximate cause between the alleged culpable conduct and the alleged harm. See Sergent v. City of Charleston, 549 S.E. 2d 311, 320 (W. Va. 2001). "Proximate cause connotes a causal relation and not merely nearness in point of time." Evans v. Farmer, 133 S.E. 2d 710, 717 (W. Va. 1963). It necessitates a showing that but for the alleged wrongful conduct, the alleged harm would not have occurred. See White v. Wyeth, 705 S.E. 2d 828, 837 (W. Va. 2010). It "is the last negligent act contributing to the injury

and without which the injury would not have occurred." Sergent, 549 S.E. 2d 311, 320 (2001). To be proximate, a cause must not be "remote." Metro v. Smith, 124 S.E. 2d 460, 464 (W. Va. 1962).

The determination of causation is a question of fact. See Qura v. D.R. McClain & Son, 97 F. 3d 1448 (4th Cir. 1996); Aikens v. Debow, 541 S.E. 2d 576, 580 (W. Va. 2001). "[T]he law is clear that a mere possibility of causation is not sufficient to allow a reasonable jury to find causation." Spencer v. McClure, 618 S.E. 2d 451, 456 (2005).

A. Plaintiffs Have Failed to Prove That Defendants' Conduct Was a Proximate Cause of Diversion

No culpable acts by defendants caused an oversupply of opioids in Cabell/Huntington. Doctors, 99% of whom were acting in good faith, determined the total volume of prescription opioids that pharmacies ordered from defendants and dispensed pursuant to those prescriptions. Federal regulations require that a prescription for opioids be issued for a legitimate purpose by a medical practitioner acting the course of his practice. See 21 C.F.R. § 1306.04(a).

Therefore, doctors, in the exercise of their independent medical judgment, determined what opioids would be prescribed, in what doses, and for what purposes. Defendants shipped

prescription opioids only to licensed pharmacies in response to demand created by prescriptions.

At all relevant times, defendants' SOM systems were designed to identify suspicious orders. Their systems had imperfections, but defendants acted to correct these imperfections. By 2008, each defendant had in place a SOM program that blocked all suspicious orders they identified. Prior to that time, the DEA understood and accepted that wholesale distributions would ship any suspicious orders that they identified and reported to the DEA.

Plaintiffs' claim that defendants' purported violations of the CSA and its implementing regulations caused an opioid epidemic fails as a matter of law because there is no admissible evidence that any such violation caused opioid diversion, properly understood. Likewise, plaintiffs' claim that defendants' purportedly unreasonable volume of distributions caused an opioid epidemic fails as a matter of law for the same lack of admissible evidence that defendants' conduct caused diversion, properly understood.

The starting point in determining whether plaintiffs proved that defendants did not maintain effective controls against diversion is to define what diversion is in the context of distributors ("distributor diversion"). Plaintiffs have an extremely broad understanding of what constitutes distributor

diversion. Mr. Rafalski, plaintiff's diversion expert, provided the court with a definition of diversion without regard to when or how a controlled substance enters the illicit market:

> So, when we talk about a suspicious order, Your Honor, the suspicion is that this order could be diverted. In other words, it could fall into illicit hands.

Rafalski, 5/26, at 75-76 (emphasis added).

Mr. Rafalski's broad definition of diversion is consistent with plaintiffs' reliance in this case on proving (1) a very large amount of opioids distributed to retail and chain pharmacies within their borders; and (2) the existence of an opioid epidemic within their borders. Plaintiffs appear to take the position that these two conditions are sufficient to sustain a reasonable inference of distributor diversion.

From plaintiffs' perspective, the very high level of pills shows, on its face, that many of the prescriptions those pills went to fill should not have been written. To plaintiffs, the purported gap between what would have been sufficient to meet legitimate medical needs and what was distributed equals diversion. The implication is that to avoid liability, defendants must justify as medically necessary all prescriptions written and filled with opioids deriving from their warehouses.

Defendants, of course, have a much narrower understanding of diversion. To them, a match between distributions and prescriptions (which the evidence here shows, (see, e.g.,

Keller, 6/15/21, at 213-14)), precludes a finding of diversion. Their duties with regards to controlling against diversion end, they have suggested, when the pills are delivered to a DEA-registered pharmacy.

The CSA provides that in determining whether a distributor's federal registration is inconsistent with the public interest depends, in part, on the distributor's "maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823 (emphasis added).

Under implementing regulations, distributors are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71(a). The regulations also require as follows:

> 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.

21 C.F.R. § 1301.74(b).

Defendants frame distributor diversion too narrowly. As the cases discussed below illustrate, distributors must guard against diversion that occurs if they supply controlled

substances to diverting dispensers that operate under the guise of legitimacy (that is, with a DEA registration and pursuant to prescriptions). On the other hand, plaintiffs' conception of distributor diversion is far too broad. What distributors must guard against is handing over pills to pharmacies that are essentially acting as adjuncts of the illicit market, not against legitimate pharmacies dispensing a vague notion of too many opioids.

To see this, consider the major cases that plaintiffs have, at various times, tried to analogize to this one. In the first three cases (Masters Pharmaceutical, Inc. ("Masters I"), 80 Fed. Reg. 55418-01, 2015 WL 5320504 (DEA Sept. 15, 2015); Masters Pharm., Inc. v. DEA ("Masters II"), 861 F.3d 206, 214 (D.C. Cir. 2017); and Southwood Pharmaceuticals, Inc., 72 Fed. Reg. 36487-01, 36498, 2007 WL 1886484 (DEA July 3, 2007)), diversion involved distributors supplying dispensers that were essentially in the diversion business, not the legitimate dispensing business.

The fourth case (Direct Sales Co. v. United States, 319 U.S. 703, (1943)) comes from the criminal context and obviously does not define distributor diversion or plaintiffs' burden of proof here, and the court does not cite it for those uses. It is helpful simply as another example of what this case is not:

one where the wrongful conduct was supplying a dispenser that was not a legitimate operation.

Masters I was a revocation proceeding before the DEA. The DEA determined that the distributor was more interested in justifying continued orders than in "identifying those entities that were engaged in diversion." Masters I; 80 Fed. Reg. 55418-01, 55449 (emphasis added). The DEA asserted that distributors must "dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor 'inform' the [DEA] about the order." Id. at 55478 (emphasis added).

The relevant suspicion was not that portions of fulfilled orders were eventually making their way to the illicit market. Rather, it was that "each of the pharmacies was engaged in illegitimate dispensing practices." Id. at 55486 (emphasis added).

Masters II was the D.C. Circuit's review of the DEA's revocation order. The court distinguished between pills sent to "a bona fide retail pharmacy" and those sent to a "pharmacy [that] might be involved in illegal diversion." Masters II, 861 F.3d at 220 (emphasis added). The relevant "suspicion" that distributors are to be on the lookout for is that their own customers are engaged in diversion. Id. In other words, distributors are not charged with ferreting out and potentially

cutting off pharmacies that may have some suspicious customers. Rather, they are charged with ferreting out and potentially cutting off dispensers potentially engaged in diversion.

The D.C. Circuit noted that the distributor had (1) failed to clear with due diligence or report to the DEA orders that its own SOM system flagged (to the tune of hundreds of orders); (2) deleted or reduced flagged orders to get around its SOM system; and (3) shipped orders when customer explanations confirmed the suspicion that the orders were being diverted. Id. at 215.

Southwood was another revocation proceeding, and it also illustrates the kind of diversion against which distributors must guard. There, the distributor's "pharmacy customers were likely engaged in illegal activity," (not the pharmacy's customers). Southwood, 72 Fed. Reg. 36487-01, 36,499 (emphasis added).

Far from faulting a distributor for failing to guard against pills eventually falling into the wrong hands, the DEA faulted a distributor for supplying pharmacies in the business of diversion:

> As stated above, these websites and the pharmacies that fill the prescriptions issued by them, are nothing more than drug pushers operating under the patina of legitimate authority. Cutting off the supply sources of these pushers is of critical importance in protecting the American people from this extraordinary threat to public health and safety. In accomplishing this objective, this [DEA] cannot do it all itself. It must rely on registrants to fulfill

> their obligation under the Act to ensure that they do not supply controlled substances to entities which act as pushers.

Id. at 36,504 (emphasis added).

> Judge Polster has summarized Southwood's conduct well:
>
> In December of 2005, Southwood had begun selling large quantities of hydrocodone to internet pharmacies, many of which were dispensing illegal prescriptions for controlled substances. At the time, Southwood did not re-evaluate its criteria and procedures to determine whether these orders were suspicious; without inquiring into the nature of their internet businesses, Southwood sold its new customers large quantities of hydrocodone. Moreover, after learning substantial information which raised serious doubt as to the legality of their businesses, Southwood continued to supply extraordinarily large quantities of hydrocodone to these internet pharmacies.

In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2019 WL 3917575, at *4 (N.D. Ohio Aug. 19, 2019) (citations omitted).

Again, the diversion at issue was not some concept of pills eventually falling into the wrong hands—it was the distributor placing them in the wrong hands. The problem was not with diversion due to overprescribing or even doctor shopping, it was that the distributor's customers were in the business of filling prescriptions "issued outside of . . . legitimate doctor/patient relationship[s] and the safeguards that [those] relationship[s] provide[]." Southwood, 72 Fed. Reg. 36487-01, 36,504.

Finally, there is Direct Sales. The court's very limited point with this case is that, despite plaintiffs' attempts to analogize to it, the illegal distributions there were to a bad

dispenser, conduct which no persuasive evidence indicated the existence of here.

The Supreme Court summarized the facts as follows:

> Direct Sales sold morphine sulphate to Dr. Tate in such quantities, so frequently and over so long a period it must have known he could not dispense the amounts received in lawful practice and was therefore distributing the drug illegally. Not only so, but it actively stimulated Tate's purchases.

Direct Sales, 319 U.S. at 705.

The culpable conduct by the manufacturer-wholesaler was "working in prolonged cooperation with a physician's unlawful purpose to supply him with his stock in trade for his illicit enterprise." Id. at 713. Again, the problem was sending opioids to a diverting dispenser, not a legitimate dispenser, some of whose customers may have been diverters.

Plaintiffs cannot recover against defendants by proving only that they were injured as a result of the opioid epidemic. Plaintiffs' theory of harm is based on the diversion of prescription opioids, whether through illegal distributions of opioids or through distributing an unreasonable volume. Plaintiffs' theory is not that any prescription opioids entered the City of Huntington or Cabell County after being diverted while in defendants' custody or under their control. Nor does the record evidence support such a theory.

Nor does the record evidence support any assertion that defendants' pharmacy customers were engaging in diversion. The only record evidence of pharmacy-level diversion in the City of Huntington and Cabell County is A-Plus Care Pharmacy in Barboursville, which no defendant serviced. The lack of evidence of pharmacy-level diversion on the part of defendants' pharmacy customers is fatal to plaintiffs' claims.[8]

An overbroad understanding of diversion may require that whenever a distributor suspects that part of a dispensers' order may fill prescriptions for those who do not need them (or do not need as many dosage units), the distributor engages in diversion by filling the order. In this world, maintaining effective controls would require cutting off dispensers completely because the distributor (which is not a medical doctor or pharmacist) has a hunch that some of the pharmacy's customers may be engaged in misconduct such as doctor shopping, feigned injuries, and similar fraud to obtain an unnecessary prescription.

That is not a reasonable conception of what maintaining effective controls requires of distributors, and cases regarding

[8] To the extent plaintiffs attempt to rely on a showing of diversion at the pharmacy level outside the City of Huntington or Cabell County, such reliance fails as a matter of law. Plaintiffs presented no persuasive evidence establishing a "nexus" between those out-of-jurisdiction shipments and any diversion or harm occurring in the City of Huntington or Cabell County.

distributors engaged in diversion, such as Masters I, Masters II, and Southwood, confirm that it is too broad a conception of distributor diversion. These cases do not support the idea that distributors must prevent controlled substances from eventually falling into the wrong hands at some point in their existence.

Distributors have no control over the medical judgment of doctors. They do not see patients and are not tasked with deciding whether the patient ought to get pain medication. At best, distributors can detect upticks in dispensers' orders that may be traceable to doctors who may be intentionally or unintentionally violating medical standards. Distributors also are not pharmacists with expertise in assessing red flags that may be present in a prescription.

Indeed, the CSA "imposes duties on [pharmacies] to maintain systems, policies, or procedures to identify prescriptions that bear indicia ("red flags") that the prescription is invalid, or that the prescribed drugs may be diverted for illegitimate use." In re Nat'l Prescription Opiate Litig., 477 F. Supp. 3d 613, 629 (N.D. Ohio 2020), clarified on denial of reconsideration, No. 1:17-MD-2804, 2020 WL 5642173 (N.D. Ohio Sept. 22, 2020), and cert. denied, No. 18-OP-45032, 2022 WL 278954 (N.D. Ohio Jan. 31, 2022). "There is no question that dispensers of controlled substances are obligated to check for and conclusively resolve

red flags of possible diversion prior to dispensing those substances." Id.

Pharmacies are obviously best equipped to decide whether to fill prescriptions. Distributors' attempts to take on this duty indirectly would inevitably create supply problems for patients with legitimate needs for controlled substances. This is because distributors have at their disposal only the nuclear option of stopping a pharmacy order completely, not just the part of the order that possibly may go to diverting patients.

Not only do distributors have no ability to stop pills on a prescription-by-prescription basis and none of the expertise with which to determine whether prescriptions are good or bad, they also have none of the coercive powers of investigation that law enforcement has to determine whether pharmacies are fulfilling their duties under the CSA. All of this is to say, again, that while defendants may have a vantage point that allows them to detect orders from bad pharmacies and take appropriate, decisive action (cut off the diverting, illegitimate pharmacy), the duty to maintain effective controls does not charge distributors with blocking illegitimate customers of legitimate pharmacies from getting their prescriptions filled.

For the reasons stated above, plaintiffs cannot base their claim that defendants caused diversion on a theory of diversion

that occurred downstream from their pharmacy customers. There is no admissible evidence in this case of diversion at the pharmacy level. The CSA and its implementing regulations do not hold distributors responsible for supplying opioids to pharmacies not reasonably suspected of being diverters or adjuncts thereof.

Assuming that defendants could be responsible for diversion that does not fall within defendants' legal duties (diversion merely as a matter of fact), a concept of diversion that creates distributor liability for downstream conduct is unsupportable. Whether couched in terms of the CSA or not, there is no admissible evidence in this case that defendants caused diversion that resulted in an opioid epidemic. At most, there is only a reasonable inference that someday, somehow, some of the opioids that defendants shipped fell into the wrong hands. That is not enough to sustain a reasonable finding that defendants here caused diversion of opioids or an opioid epidemic.

The court therefore concludes that plaintiffs have failed to meet their burden of proving causation.

B. Under the Evidence Presented, the Harms That Plaintiffs Claim Defendants Caused Are Too Remote

Under West Virginia law, proximate cause is that cause which in actual sequence, unbroken by any independent cause,

produced the wrong complained of, without which the wrong would not have occurred. See Webb v. Sessler, 63 S.E. 2d 65, 68 (W. Va. 1950). The "proximate cause" of an injury is the last wrongful act contributing thereto, without which the injury would not have resulted. Id.

The proximate cause of an injury is the efficient, principal, superior or controlling agency from which springs the harm as contra-distinguished from those causes which are merely incidental or subsidiary to reach efficient, principal or controlling cause. See Yates v. Mancari, 168 S.E. 2d 746, 752-53 (W. Va. 1969). Thus, wrongful conduct may contribute to an injury without being the proximate cause of that injury.

Consider the following example: A driver who has broken the law by speeding stops at a red light and, while stopped, is "rear-ended" by a second vehicle. The first driver's wrongful act in speeding has placed him at the scene of the accident without which the accident would not have happened. Nevertheless, the proximate cause of the accident is the failure of the second driver to maintain control over his vehicle. Such failure to maintain control is the last wrongful act contributing to the injury and thus the sole proximate cause under the rule of Webb.

A remote cause of injury is insufficient to support a finding of proximate cause. See Metro v. Smith, 124 S.E. 2d

460, 464 (W. Va. 1962). An intervening event may break the chain of causation and preclude a finding of proximate cause. See Wal-Mart Stores E., L.P. v. Ankrom, 854 S.E.2d 257, 270 (W. Va. 2020). A defendant bears the burden of proving that intervening acts are a superseding cause. See Sydenstricker v. Mohan, 618 S.E. 2d 561, 568 (W. Va. 2005).

Intervening or superseding cause is illustrated by Employer Teamsters Local v. Bristol Myer Squibb, 969 F. Supp. 2d 463 (S.D.W. Va. 2013). This was an action against manufactures of prescription anticoagulant drug Plavix alleging that defendant engaged in a massive marketing campaign that was false and misleading. Id. at 466. Specifically, it was alleged that Plavix was not fit for its intended purpose of being a superior alternative to aspirin as a blood thinner, and that defendants' marketing campaign influenced doctors' decisions in prescribing the drug. Id. The court dismissed the case, and held, among other things, that the plaintiffs had failed to sufficiently plead proximate causation. Id. at 475.

The court adopted the "direct relation" standard of proximate cause established in Holmer v. Securities Investor Protection Corp., 503 U.S. 258 (1992). Id. at 472-73. This standard requires some direct relation between the injury asserted and defendants' injurious conduct. Id. at 473-74. The court in Employer Teamsters surveyed numerous cases on proximate

cause and found that "line-drawing" was necessary to limit this permissible scope of recovery when an injury involves a complex chain of causation with many intervening events. Id. The court concluded that "a vast array of intervening events including the 'independent medical judgement' of doctors" precluded a finding of proximate cause. Id. at 475-76.

A similar result was reached in City of Charleston v. Joint Commission, 473 F. Supp. 3d 596 (S.D.W. Va. 2020). This was an action by municipalities against an organization that accredited public and private health care organizations. Id. at 603-05. The plaintiffs alleged that the accrediting organization had collaborated with opioid manufacturers to issue pain management standards that misrepresented the addictive qualities of opioids and fostered dangerous pain control practices. Id. at 606. As a result, it was charged, the municipalities had suffered damages resulting from the opioid crisis—the same damages alleged by the plaintiffs in this case. See id. at 608, 615-16.

The court granted defendants' motion to dismiss and found no proximate causation because no injury would occur unless a doctor made a medical decision to prescribe opioids and because the claims relied upon various criminal acts of third parties. The court, citing Wehner v. Weinstein, 444 S.E. 2d 27 (W. Va. 1994), observed that where there is a sole, effective

intervening cause, there can be no other causes proximately resulting in the alleged injury. Id. at 627-31.

The core of plaintiffs' case is the assertion that the alleged nuisance within their borders was caused by oversupply and diversion of opioids from their legitimate channels, resulting in overuse, addiction and the "gateway" to malicious illegal substances such as heroin and fentanyl. Such oversupply and diversion were made possible, beyond the supply of opioids by defendants, by overprescribing by doctors, dispensing by pharmacists of the excessive prescriptions, and diversion of the drugs to illegal usage—all effective intervening causes beyond the control of defendants.

Accordingly, the court concludes that plaintiffs have failed to meet their burden to prove that defendants' conduct was the proximate cause of their injuries.

VII. No Abatement Remedy

Having waived all claims for damages, including punitive damages" plaintiffs seek "only the equitable remedy of abatement." See ECF No. 225, at 5. After trial, however, it is readily apparent that what plaintiffs seek is not relief from wrongful conduct; instead, plaintiffs "Abatement Plan" seeks recovery for the extensive harms of opioid abuse and addiction.

Under West Virginia law, a public nuisance consists of wrongful conduct. See Kermit Lumber, 488 S.E.2d 901, 925 n.28

(W. Va. 1997) (public nuisance is "the doing of or the failure to do something that injuriously affects the safety, health, or morals of the public, or works some substantial annoyance, inconvenience, or injury to the public[.]"). Plaintiffs cite several cases to support their contention that an "act or condition" may be a public nuisance. But each of those cases defined the nuisance at issue as the actionable conduct.

In Martin v. Williams, the court held that the operation of a used car lot in a residential neighborhood was a nuisance, and in that context stated that a "condition is a nuisance when it clearly appears that enjoyment of property is materially lessened, and physical comfort of persons in their homes is materially interfered with thereby." 93 S.E.2d 835, 844 (W. Va. 1956). The "condition" creating the nuisance and the "condition" subject to abatement was the defendant's conduct—the operation of its business. See id. ("[T]he carrying on of such business in such locality becomes a nuisance.").

In Burch v. Nedpower Mount Storm, LLC, the court held that "nuisance is the unreasonable, unusual, or unnatural use of one's property so that it substantially impairs the right of another to peacefully enjoy his or her property." 647 S.E.2d 879, 886 (W. Va. 2007).

In Hendricks v. Stalnaker, the court held "that the evidence presented clearly does not demonstrate that the water

well is an unreasonable use of land and, therefore, does not constitute a private nuisance." 380 S.E.2d 198, 203 (W. Va. 1989).

In Duff v. Morgantown Energy Associates, the court explained that "[i]t does not clearly appear from the record that conducting the proposed trucking in this locality will be unreasonable or that it is reasonably certain to cause serious harm" but that "the proposed trucking may constitute a public nuisance once it is operational." 421 S.E.2d 253, 262 (W. Va. 1992).

Plaintiffs' remedy is limited to "elimination of hazards to public health and safety" and "abate[ment]" of the alleged public nuisance. See W. Va. Code § 7-1-3kk (granting county commissions limited authority); W Va. Code § 8-12-5(23) (same for municipalities). "Under the traditional definition of abatement, nuisance claims seek court intervention to require one party to stop doing something that affects another . . . . Examples of conduct that may be enjoined include merry-go-rounds, and loud singing, talking, dancing, and opening and shutting doors." State ex rel. AmerisourceBergen Drug Corp. v. Moats, 859 S.E.2d 374, 389–90 (W. Va. 2021) (Armstead, J., concurring in part) (internal citations omitted)).

Equitable abatement has historically been limited to an injunction designed to eliminate allegedly tortious conduct or,

in certain environmental nuisance cases, an injunction to remove the contaminant from the environment. See, e.g., Duff, 421 S.E.2d at 257 (noting that "courts generally grant injunctions to abate existing nuisances").

As the Supreme Court of Appeals of West Virginia has recognized, the distinction between "abatement of nuisances and recovery of damages for injuries occasioned by wrongful acts, constituting nuisances," is both "apparent" and "vast." McMechen v. Hitchman-Glendale Consol. Coal Co., 107 S.E. 480, 482 (W. Va. 1921); see also Prosser and Keeton, The Law of Torts, § 631 (5th ed. 1984) (referring to the "fundamental distinction between entitlement to damages and entitlement to abatement of the nuisance").

Damages, unlike abatement, are directed to compensating a plaintiff for "the cost[s] of eliminating the nuisance effects." Dobbs, I Law of Remedies § 5.7(3). Plaintiffs, however, are not seeking to "abate" (enjoin or stop) the nuisance. Instead, plaintiffs are seeking remuneration for the costs of treating the horrendous downstream harms of opioid use and abuse. Those costs have no direct relation to any of defendants' alleged misconduct.

Plaintiffs' Abatement Plan, virtually in its entirety, is directed at treating or otherwise addressing drug use and addiction, not at any of defendants' alleged nuisance-causing

conduct. Only one element of the Abatement Plan, a safe drug disposal program for unused pills, is even arguably addressed at the volume of prescription opioids in the City of Huntington and Cabell County. This expense accounts for approximately 0.0014% of the total plan.

It is immaterial that plaintiffs have now termed their proposed relief "abatement damages," a term that finds no support in West Virginia law. The United States Supreme Court has cautioned that with "lawyerly inventiveness," any claim seeking legal relief can be phrased as one seeking equitable relief. Great-West Life & Annuity Ins. v. Knudson, 534 U.S. 204, 211 n.1 (2002). Courts appropriately focus on the substance of the claim asserted, not labels affixed by counsel. See, e.g., Gilbert v. City of Cambridge, 932 F.2d 51, 57-58 (1st Cir. 1991). Any such monetary award—whether styled as damages or "abatement damages"—is not properly an element of equitable abatement relief.

Plaintiffs have compared this case to Kermit Lumber and environmental nuisance cases more generally. But even under Kermit Lumber, plaintiffs' remedy fails. There, the relevant conduct was the depositing of arsenic "on the Kermit Lumber business site in amounts above the regulatory limits," which then "flow[ed] into the Tug Fork River." 488 S.E.2d at 925. Recognizing that "[t]he object of a public nuisance action is to

abate or stop the harm to the public health, safety, and the environment," the court held on the facts of that case that the nuisance "continue[d] until the hazardous waste is removed." Id. at 925 n.29.

The abatement in Kermit Lumber therefore consisted of removing the excessive or above-limits arsenic from the environment. See id. at 245. Tellingly, Kermit Lumber did not hold that the plaintiff could recover, as abatement, for downstream harms to the community resulting from the contamination in the Tug River, such as treatment for injuries from those who consumed or otherwise came in contact with contaminated water.

For the reasons stated above, and upon a full trial record, the court concludes that under the facts of this case, the relief that plaintiffs seek is not properly understood as in the nature of abatement.

VIII. Other Issues

In view of the conclusions made herein that compel entry of judgment for defendants, the court finds it unnecessary to consider other legal issues raised in the course of this litigation.

CONCLUSION

The opioid crisis has taken a considerable toll on the citizens of Cabell County and the City of Huntington. And while

there is a natural tendency to assign blame in such cases, they must be decided not based on sympathy, but on the facts and the law. In view of the court's findings and conclusions, the court finds that judgment should be entered in defendants' favor. A separate judgment has been entered, pursuant to Federal Rule of Civil Procedure 58, in accord with the foregoing findings of fact and conclusions of law.

The Clerk is directed to send a copy of these Findings of Fact and Conclusions of Law to those counsel of record who have registered to receive an electronic NEF.

IT IS SO ORDERED this 4th day of July, 2022.

ENTER:

David A. Faber
Senior United States District Judge