THE COUNTY COMMISSIONER OF CARROLL COUNTY, MARYLAND, A BODY CORPORATE AND POLITIC OF THE STATE OF MARYLAND
225 North Center Street
Westminster, Maryland 21157,

Plaintiff,

v.

ALLERGAN PLC
Clonshaugh Business & Technology Park,
Dublin, D17 E400, Ireland,

ACTAVIS PLC
5 Giralda Farms
Madison, New Jersey 07940,

ACTAVIS, INC.
5 Giralda Farms
Madison, New Jersey 07940,

WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.
5 Giralda Farms
Madison, New Jersey 07940,

WATSON LABORATORIES, INC.
5 Giralda Farms
Madison, New Jersey 07940,

ACTAVIS LLC
5 Giralda Farms
Madison, New Jersey 07940,

ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.
5 Giralda Farms
Madison, New Jersey 07940,
Serve: Corporate Creations Network Inc.
3411 Silverside Road
Tatnall Building, Suite 104
Wilmington, Delaware 19810

CARDINAL HEALTH 5, LLC
7000 Cardinal Place
Dublin, Ohio 43017,
Serve: The Corporation Trust, Incorporated
2405 York Road, Suite 201
Lutherville Timonium, Maryland 21093

IN THE

CIRCUIT COURT

FOR

CARROLL COUNTY

MARYLAND

Case No.:

CARDINAL HEALTH 100, INC.
7000 Cardinal Place
Dublin, Ohio 43017,
Serve: The Corporation Trust, Incorporated
2405 York Road, Suite 201
Lutherville Timonium, Maryland 21093

CARDINAL HEALTH 107, LLC
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CARDINAL HEALTH 122, LLC
7172 Columbia Gateway, Suite 200B
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THERESA SACKLER, an individual
Address Unknown

KATHE SACKLER, an individual
Address Unknown

JONATHAN SACKLER, an individual
Address Unknown

MORTIMER D.A. SACKLER, an individual
Address Unknown

BEVERLY SACKLER, an individual
Address Unknown

DAVID SACKLER, an individual
Address Unknown

ILENE SACKLER LEFCOURT, an individual
Address Unknown

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United Kingdom,

MALLINCKRODT, LLC,
3 Lotus Park
The Causeway
Staines-Upon-Thames, Surrey TW18 3AG
United Kingdom,

SPECGX, LLC,
Unknown
Serve: The Corporation Trust, Incorporated
351 West Camden Street
Baltimore, Maryland 21201,

JOHN KAPOOR, an individual
Serve: 6610 North 29th Place
Phoenix, Arizona 85016,

MICHAEL BABICH, an individual
Serve: 18391 North 97th Place
Scottsdale, Arizona 85255.

AMERISOURCEBERGEN DRUG CORPORATION
1300 Morris Drive
Chesterbrook, Pennsylvania 19087,
Serve: The Corporation Trust, Incorporated
2405 York Road, Suite 201
Lutherville Timonium, Maryland 21093

DOES 1 through 1000,

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff County Commissioner of Carroll County, Maryland, a Body Corporate and Politic of the State of Maryland ("Carroll County"), by its attorneys Paul Mark Sandler, Joel I. Sher, Eric R. Harlan, and Shapiro Sher Guinot & Sandler, P.A., and Jeffrey H. Reeves, Cheryl Priest Ainsworth, Kevin N. Royer, and Theodora Oringher PC, sue the above captioned Defendants and states as follows:

I. INTRODUCTION

1. Opiates[1] are killing people every day in this country and Marylanders have not been spared. Each of the Defendants in this action engaged in an industry-wide effort to downplay the dangerous and deadly potential effects of the misuse of prescription opioids. The opioid epidemic has hit every community in Maryland hard, including Carroll

[1] The term "opiate" technically refers only to chemicals that occur naturally in the opium plant, including morphine, codeine, thebaine and papaverine. "Opioid," by contrast, refers instead to compounds that have the same effect as opiates but do not occur naturally in the opium plant, such as heroin, oxycodone, hydrocodone, hydromorphone and oxymorphone ("semi-synthetic" opioids) as well as methadone, fentanyl, meperidine and tramadol ("synthetic" opioids).

County. Carroll County brings this complaint seeking redress for the societal and financial damage it has suffered at the hands of those directly responsible for the crisis—the manufacturers and distributors of prescription opioids.

2. This case is about corporate greed. Simply stated, each of the Defendants put their desire for profits above the health and well-being of Carroll County's residents. Carroll County and its citizens have paid dearly as a result.

3. This case is not about taking away medically-necessary opioids from the patients who need them. Plaintiff does not ask the Court to decide whether opioids are clinically appropriate, nor does Plaintiff seek to blame the well-meaning healthcare providers and suppliers who prescribed opioids to their patients in good faith. Instead, Plaintiff only asks that this Court hold the Defendants accountable for the damage they caused to Carroll County that Defendants were always in the best position to prevent.

A. The Manufacturer Defendants' Two-Part Scheme to Increase Opioid Sales

4. First, as part of a broader scheme to target municipalities in the United States where the elements most conducive to opioid addiction were prevalent, Defendants ALLERGAN PLC; ACTAVIS PLC; ACTAVIS, INC.; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT, PLC; MALLINCKRODT, LLC; SPECGX, LLC; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; and the

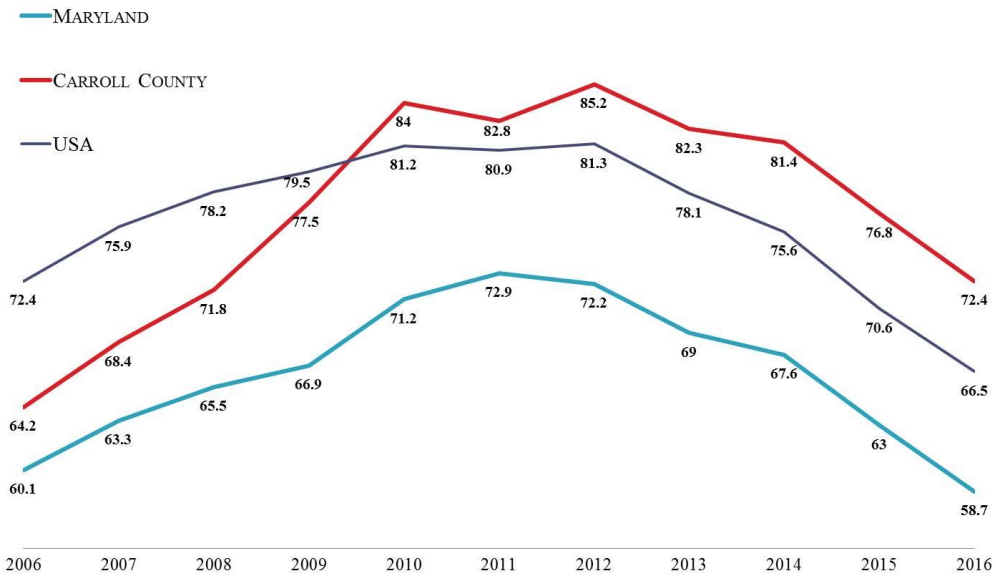
individual defendants JOHN KAPOOR and MICHAEL BABICH ("the Manufacturer Defendants"), targeted the State of Maryland, including the residents of Carroll County. The Manufacturer Defendants developed and engaged in a sophisticated, manipulative scheme designed to increase the number of opioid prescriptions written across the state, including in Carroll County. Defendants' scheme was particularly well-suited to Carroll County, because Carroll County is home to many economically and medically vulnerable populations that Defendants knew were uniquely predisposed to opioid addiction, including the elderly.

5. Second, the Manufacturer Defendants dramatically increased the number of opioid prescriptions in Carroll County and across the country by (1) concealing the truth about the risk of addiction and death associated with long-term use of their products, and (2) pressuring their respective sales forces to deceive (even bribe) local prescribers to flood Maryland—and Carroll County—with an abundance of opioids.

B. The Distributor Defendants Turned a Blind Eye to the Manufacturers' Scheme

6. Defendants AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH 5, LLC; CARDINAL HEALTH 100, INC.; CARDINAL HEALTH 107, LLC; CARDINAL HEALTH 108, LLC; CARDINAL HEALTH 110, LLC; CARDINAL HEALTH 121, LLC; CARDINAL HEALTH 122, LLC; CARDINAL HEALTH 128, LLC; CARDINAL HEALTH 132, LLC; CARDINAL HEALTH 200, LLC; and CARDINAL HEALTH PHARMACY SERVICES, LLC (the "Distributor Defendants") shipped prescription opioids throughout the country, including Maryland. Rather than meet their obligations under Maryland law to report suspicious orders of controlled substances, the Distributor Defendants willfully ignored impossibly large orders being shipped to locations where it was inconceivable that any legitimate medical need could have required the quantities shipped. They failed to report these suspicious shipments despite their clear statutory and common law obligations to do so, and in

contravention of their own internal policies and procedures. The Distributor Defendants' breaches of their respective reporting obligations were willful, motivated by their desire to maximize profits, and were committed without consideration of the cost to Carroll County or its citizenry.



Opioid RXs Dispensed Per 100 Persons in Maryland, Carroll County, and USA (2006-2016)[2]

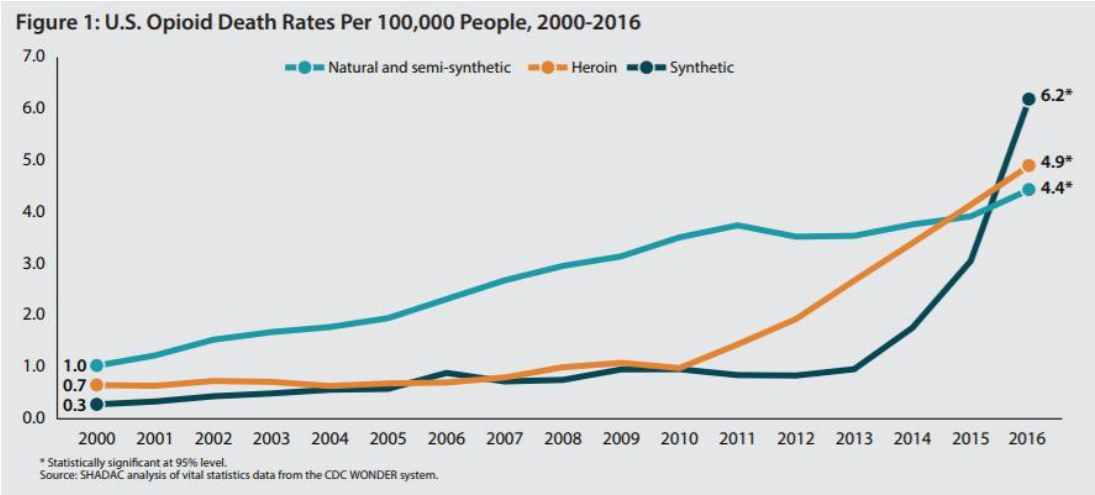
C. The Devastating Effects of Defendants' Conduct

7. Each of the Defendants was fully aware that their products placed patients at an unreasonable risk of opioid-related addiction and/or death. Despite this knowledge, the Manufacturer Defendants continue to misrepresent the risks associated with prescription opioids and their efforts to influence physicians with the goal of increasing sales of prescription opioids to Carroll County citizens. Likewise, the Distributor Defendants continue to breach their duties under Maryland law to monitor, report, and prevent

[2] Centers For Disease Control and Prevention, *U.S. Opioid Prescribing Rate Maps*, https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html

suspicious shipments of prescription opioids.

This conduct precipitated the opioid crisis that has ravaged Plaintiff's communities since the early 2000s, and will continue to do so for many years, even decades, to come. Defendants' scheme has succeeded—Defendants have made untold billions of dollars from prescription opioids. Meanwhile, the death toll they have caused in Carroll County and elsewhere is unconscionable.



8. Carroll County dedicates substantial portions of its tax revenues to provide and pay for a broad array of services for its population, including various public health and behavioral and mental health services, programs, and opioid-related task forces, law enforcement and corrections, courts and legal services, specialty services, citizen services, and other necessary public services and programs for adults, families, and children. However, as a result of the opioid epidemic, Carroll County has been severely hampered in its ability to continue to provide the requisite level of service in each of these categories. This creates a perverse dichotomy. The overburdened service areas require a *greater share* of Carroll County's scarce tax dollars, while at the same time, the crisis itself *decreases* the tax dollars Carroll County can generate. That is because opioid addiction takes productive members of society out of the economy, usually due to death or the inability to work. Simply put, most who become addicted to opioids are no longer able to work, and therefore are no longer able to care for their families, earn a paycheck or spend money in

the same way they did before they fell victim to addiction. This predictable downward spiral means Carroll County's tax revenues have suffered. These harms are the direct and proximate result of Defendants' scheme to increase their profits without regard for the end users of Defendants' drugs, or the municipalities that must bear the brunt of the increased demand for their services brought on by the epidemic.

9. In addition to its tax-related damages, an increasing number of Carroll County residents are entering local rehabilitation facilities and treatment programs for opioid-related addiction and, in addition to an influx in the number of facilities in neighboring counties, Carroll County is home to a handful of both inpatient and outpatient facilities that specialize in opioid-addiction.

10. Things were not always this way in Carroll County. Though Defendants have been manufacturing, marketing, and/or selling prescription opioids for decades—including brand-name drugs like OxyContin and Percocet, as well as generic formulations such as oxycodone and hydrocodone—only since the late 1990s have Defendants' powerful narcotic painkillers been used to treat more than just short-term, acute or cancer-related pain. Indeed, for the vast majority of the twentieth century, Defendants' drugs were considered too addictive and debilitating for patients suffering from long-term (chronic) pain due to non-cancer conditions like arthritis, fibromyalgia and migraines.[3]

11. In the late 1990s, however, and continuing today, Defendants began a sophisticated marketing and distribution scheme premised on deception to persuade patients that opioids can and should be used to treat chronic pain. Defendants spent, and some continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids and overstate the benefits of opioids. As to the risks, Defendants falsely and misleadingly: (1) downplayed the serious risk of addiction;[4] (2) promoted the concept of "pseudoaddiction," falsely claiming that signs of

[3] In this Complaint, "chronic pain" refers to non-cancer pain lasting three months or longer.

[4] Addiction is classified as a spectrum of "substance use disorders" that range from misuse

addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of abuse-deterrent opioid formulations to prevent abuse by—*inter alia*—falsely claiming these opioids "cannot be crushed." Defendants also falsely touted the benefits of long-term opioid use, including its supposed ability to improve function and quality of life, even though there was no good evidence to support those benefits—a fact that Defendants not only knew at all times relevant to this action, but effectively suppressed and concealed.

12. Indeed, at all times relevant to this action, Defendants knew their longstanding and ongoing misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Moreover, the U.S. Food and Drug Administration (the "FDA") and the Centers for Disease Control and Prevention (the "CDC") have recognized the serious risks posed by opioid pain medications, as evidenced by the CDC Guideline for Prescribing Opioids for Chronic Pain, which the CDC issued and the FDA approved in 2016 ("2016 CDC Guideline").[5] Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have also entered into agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint in other jurisdictions. Yet even now,

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and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on this spectrum. In this Complaint, "addiction" refers to the entire range of substance abuse disorders. (*See, e.g.*, American Society of Addiction Medicine ("ASAM"), Public Policy Statements, *Terminology Related to the Spectrum of Unhealthy Substance Use*, p. 1-2 (July 2013), https://www.asam.org/docs/default-source/public-policy-statements/1-terminology-spectrum-sud-7-13.pdf?sfvrsn=d93c69c2_2.

[5] *See generally* Deborah Dowell, MD, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, CDC.gov (Mar. 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htmhttps://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

Defendants continue to misrepresent the risks and benefits of long-term opioid use in Maryland, including in Carroll County, and continue to fail to correct their past misrepresentations.

13. Specifically, Defendants concealed what their own internal documents and communications show they already knew, and had known for decades: not only were Defendants' opioids both medically unnecessary and, in fact, life-threatening for non-cancer patients with chronic pain, but further, none of Defendants' representations about the manageability or prevention of opioid addiction were true. As set forth in detail below, for decades, the Manufacturer and Distributor Defendants have made and continue to make a series of inaccurate claims about the risks and benefits associated with their opioids, essentially bribing Key Opinion Leader ("KOL") group to substantiate the veracity of Defendants' false statements. In creating the illusion that prescription opioids were a low risk treatment option for chronic pain relative to non-opioid pharmacologic approaches. Defendants successfully targeted vulnerable patient populations like the elderly. Defendants further tainted the sources that many doctors and patients in Carroll County relied upon for guidance, including treatment guidelines, continuing medical education programs, medical conferences and seminars, and scientific articles. As a result, Defendants successfully transformed the way doctors treat chronic pain in Carroll County, opening the floodgates of opioid prescribing and use. This explosion in opioid prescriptions and use has padded Defendants' profit margins at the expense of chronic pain patients. As the CDC recently concluded, "for the vast majority of [those] patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits."[6]

14. The explosion in opioid prescriptions and use caused by Defendants has led to a public health crisis in Maryland and, in particular, Carroll County. Maryland faces

[6] Thomas R. Frieden et al., *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline,* 374 New Eng. J. Med. 1501-1504 (2016).

skyrocketing opioid addiction and opioid-related overdoses and deaths as well as devastating social and economic consequences. This public health crisis is a public nuisance because it significantly interferes with the public health, the public safety, the public peace, the public comfort, and the public convenience. The effects of Defendants' deceptive marketing scheme are catastrophic and are only getting worse. These effects are devastating in Maryland. Between 2015 and 2016 alone, the number of opioid-related deaths spiked 70% and continued to increase by 8% between 2016 and 2017.[7] In 2017, 88% of all intoxication deaths that occurred in Maryland were opioid-related.[8] Specifically, in 2017, there were approximately 1,985 opioid-related overdose deaths in Maryland at a rate of 32.2 deaths per 100,000 people, which is twofold greater than the national rate of 14.6 deaths per 100,0000 people, placing Maryland in the top five for opioid-related deaths in the United States.[9] As the FDA acknowledged in February 2016, "[t]hings are getting worse, not better, with the epidemic of opioid misuse, abuse and dependence."[10]

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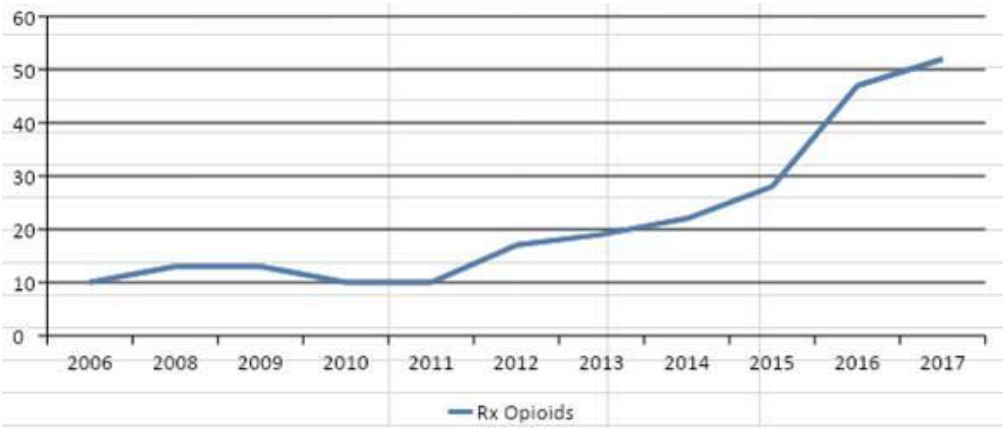
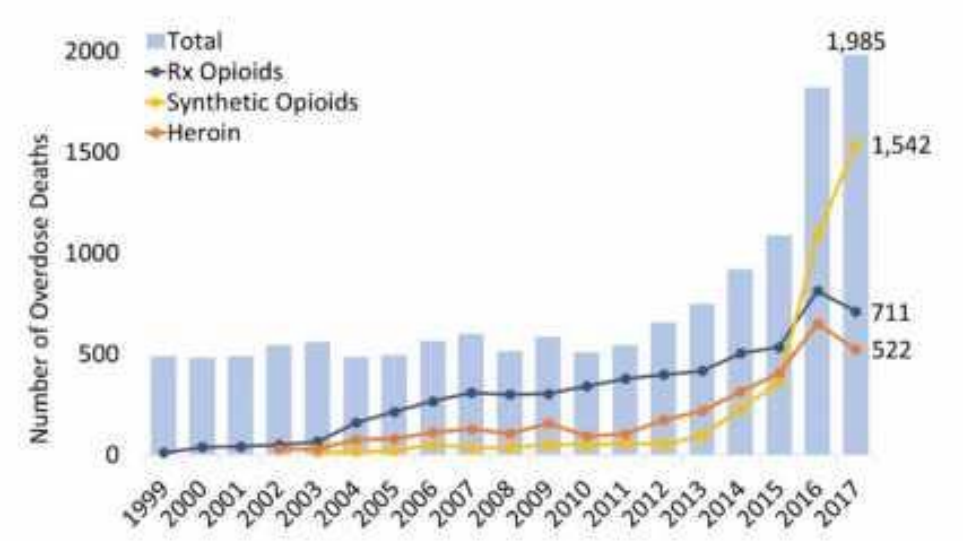
[7] Maryland Department of Health and Mental Hygiene, *Drug- and Alcohol-Related Intoxication Deaths in Maryland, 2017*, at 5, *available at* https://bha.health.maryland.gov/OVERDOSE_PREVENTION/Documents/Drug_Intox_Report_2017.pdf

[8] *Id.*

[9] National Institute on Drug Abuse, *Maryland Opioid Summary*, https://www.drugabuse.gov/opioid-summaries-by-state/maryland-opioid-summary

[10] FDA.gov, *Calif., FDA top officials call for sweeping review of agency opioids policies*, U.S. Food and Drug Administration ("FDA") News Release (Feb. 4, 2016), http://www.fda.gov/ NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.





Maryland Opioid-Related Overdose Deaths By Category (1999-2017)[11]

Opioid RX-Related Deaths in Carroll County (2006-2017)[12]

15. There is little doubt that Defendants' deceptive marketing and distribution scheme has precipitated this public health crisis in Maryland, including in Carroll County, by dramatically increasing opioid prescriptions and use. An oversupply of prescription opioids has provided a source for illicit use or sale of opioids (the supply), while the

[11] National Institute on Drug Abuse, *Maryland Opioid Summary*, https://www.drugabuse.gov/opioid-summaries-by-state/maryland-opioid-summary.

[12] Maryland Department of Health, Table 6. Number of Opioid-Related Intoxication Deaths by Place of Occurrence, Maryland, 2007-2017.

widespread use of opioids has created a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

16. Defendants' deceptive marketing and distribution scheme have had further foreseeable impacts on Carroll County. As a result of Defendants' conduct, Carroll County must devote increased resources to the burden of the addicted homeless who commit drug and property crimes, to feed their addiction. For example, tax dollars are required to maintain public safety of places where the addicted homeless attempt to congregate, including parks, schools and public lands. Tax dollars are required to fight the infectious disease brought by the addicted and particularly the addicted homeless. Hepatitis B and C, HIV, sexually transmitted disease and methicillin-resistant Staphylococcus aureus ("MRSA") have been demonstrated to be spread by opioid abuse.

17. The role of Defendants' deceptive marketing and distribution scheme in causing this public health crisis has become well-recognized in recent years. In her May 2014 testimony to the Senate Caucus on International Narcotics Control on behalf of the National Institutes of Health ("NIH"), Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[13] In the years since her comments were initially published, Dr. Volkow's message has become the dominant view of the top experts and influencers in the medical community, who are finally realizing just how dangerous Defendants' opioids are, and how devastating the economic and social costs of Defendants intentional deception has been.[14]

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[13] N. Volkow, M.D., *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, National Institute on Drug Abuse, (May 14, 2014), available at: https://www.drugabuse.gov/about-nida/legislative-activities/testimony-tocongress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

[14] E. O'Brien, *Here's What it Would Cost to Fix the Opioid Crisis, According to 5 Experts*,

18. Absent the Manufacturer Defendants' deceptive marketing scheme and the Distributor Defendants' improper distribution, the opioid use, misuse, abuse, and addiction in Carroll County would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

19. By falsely downplaying the risks and grossly exaggerating the benefits of long-term opioid use through their deceptive marketing claims, despite their knowledge of the falsity of those claims, and by improperly distributing prescription opioids as set forth herein, Defendants have not only engaged in false advertising and unfair competition, but they have also created or assisted in the creation of a public nuisance and negligence.

20. Accordingly, Defendants' conduct, both individually and collectively, has violated and continues to violate Maryland's public nuisance laws. Carroll County does not ask this Court to weigh the risks and benefits of long-term opioid use. Instead, Carroll County seeks an order requiring Defendants to cease their unlawful promotion and distribution of opioids, to correct their misrepresentations, and to abate the public nuisance they have created. To redress and punish Defendants' previous and current violations of law that cause and continue to cause harm to Carroll County and its citizens, Carroll County seeks a judgment requiring Defendants to pay civil penalties, and any fees or costs permitted under law, in an amount to be determined at trial.

21. By this action, Carroll County further seeks to recoup tax dollars spent for the consequences of Defendants' wrongful conduct in causing the opioid epidemic and its impact on Carroll County, and to abate the opioid nuisance so Carroll County will not be required to spend further taxpayer dollars on the epidemic wrought by Defendants.

II. PARTIES

A. Plaintiff

22. Carroll County, Maryland, by and through its attorneys hereto, hereby brings

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Time Money (Nov. 27, 2017), http://time.com/money/5032445/cost-fix-opioid-crisis/

this action on behalf of the people of Carroll County to protect the public from false and misleading advertising, unlawful, unfair, and fraudulent business practices, and a public nuisance.

23. Carroll County, Maryland is located in Northern Maryland and is home to over 168,000 people. Carroll County is the eighth most populated county in the State of Maryland, out of 23 counties, and consists of eight incorporated municipalities: Hampstead, Manchester, Mount Airy, New Windsor, Sykesville, Taneytown, Union Bridge, and Westminster, which serves as the county seat. Carroll County is known as "a great place to live, a great place to work, a great place to play." For instance, Carroll County's top-ranked public school system is among the highest ranked in Maryland, and residents enjoy increasing high-quality business and employment opportunities. Carroll County also relies heavily on tourism, including attracting visitors to several museums, historical sites, an arts center, a multi-recreational park, and an environmental center. Carroll Hospital Center in Westminster services Carroll County's emergency department needs. Carroll County is also home to several substance abuse inpatient and outpatient treatment centers, including opioid and heroin addiction. Carroll County's fire protection and emergency medical services are primarily volunteer-based. However, Carroll County funds paid staff for medic units operated by 13 of the 14 member volunteer fire departments of the Carroll County Volunteer Emergency Services Association ("VESA"). VESA represents over 1,000 men and women volunteers at the Gamber, Hampstead, Harney, Lineboro, Manchester, Mt. Airy, New Windsor, Pleasant Valley, Reese, Sykesville-Freedom, Taneytown, Union Bridge, Westminster, and Winfield fire companies. Specifically, the county funds one paid medic unit at 11 of the fire companies, and two each at the Sykesville-Freedom and Westminster companies. Finally, Carroll County's Sheriff's Office operates out of Westminster with city police departments located in Hampstead, Manchester, Sykesville, Taneytown, and Westminster.

B. Manufacturer Defendants

1. Actavis/Allergan

24. Defendant Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in June 2015. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis PLC in October 2013. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Defendant Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Defendant Actavis PLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these Defendants is owned by Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to in this Complaint as "Actavis.")

25. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S. and Maryland. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

2. Cephalon

26. Defendant Cephalon, Inc. ("Cephalon") is a Delaware corporation with its

principal place of business in Frazer, Pennsylvania. Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania.

27. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain." Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

3. Teva

28. Teva Ltd., Teva USA, and Cephalon work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

29. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012—the year immediately following the Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to "the

inclusion of a full year of Cephalon's specialty sales," including *inter alia* sales of Fentora. Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva has engaged in consensual commercial dealings in Maryland, and has purposefully availed itself of the advantages of conducting business with and within Maryland. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon" for the remainder of this Complaint.

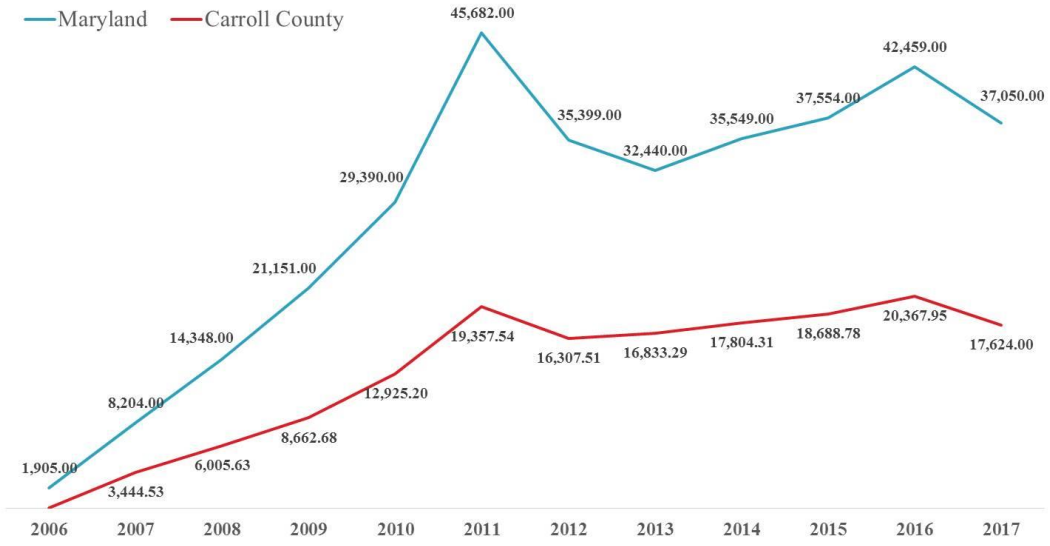
30. Notably, on May 26, 2019, Teva Pharmaceuticals agreed to settle its lawsuit brought by the Oklahoma Attorney General on behalf of the State of Oklahoma for $85 million dollars which accuses Teva (and other manufacturers) of creating a public nuisance through its production and marketing of prescription opioids.[15] Carroll County alleges similar claims against Teva and its subsidiaries in this Complaint.

4. Endo

31. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Defendant Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo").

[15] Oklahoma Attorney General, Press Release—*Attorney General Hunter Announces Settlement with Teva Pharmaceuticals*, (May 26, 2019), http://www.oag.ok.gov/attorney-general-hunter-announces-settlement-with-teva-pharmaceuticals.

32. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Maryland. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Maryland, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.



Milligrams of Oxymorphone Distributed to Maryland and Carroll County Zip Codes (2006-2017)[16]

5. Janssen

33. Defendant Janssen Pharmaceuticals, Inc. (formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceuticals, Inc.) is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Defendant Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. These entities, which are

[16] ARCOS Retail Drug Summary Reports, https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html.

collectively referred to herein as "Janssen," acted in concert with one another—as agents and/or principals of one another—in connection with the conduct described herein. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. The Janssen and J&J parties are collectively referred to as "Janssen."

34. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Maryland, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER, which also generated substantial sales revenue for the company, accounting for $172 million in sales in 2014 alone.

6. Johnson & Johnson

35. Defendant Johnson & Johnson ("J&J") imposes a code of conduct on Janssen as a pharmaceutical subsidiary of J&J. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "pharmaceutical Companies of Johnson and Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, and sales associates must certify that they have "read, understood and will abide by" the code of conduct. Thus, the code of conduct governs all forms of marketing at issue in this case.

36. In addition, J&J made payments to front groups, discussed herein, who perpetuated and disseminated Defendants' misleading marketing messages regarding the

risks and benefits of opioids.[17]

7. Purdue

37. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware and is registered to do business in Maryland. Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and Defendant The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

38. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,[18] and Targiniq ER in the U.S. and Maryland. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

8. The Purdue Individual Defendants: Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer D.A. Sackler, and Theresa Sackler

39. The Sackler family—Defendants Richard Sackler, Theresa Sackler, Kathe Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Beverly Sackler, David Sackler, and Ilene Sackler Lefcourt (collectively, "the Sacklers")—own Purdue, and they always held a majority of the seats on its Board. Because they controlled their own privately held drug company, the Sacklers had the power to decide how addictive narcotics were sold.

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[17] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, Staff Report, *Fueling an Epidemic, Report Two, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, n. 23 ("Payments from Janssen include payments from Johnson & Johnson Health Care Systems, Inc.")

[18] Long-acting or extended release (ER or ER/LA) opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release (IR) opioids, last for approximately 4-6 hours.

40. Beverly Sackler, Jonathan Sackler, and Kathe Sackler reside in Connecticut. David Sackler, Ilene Sackler Lefcourt, and Mortimer D.A. Sackler reside in New York. Richard Sackler resides in Florida and Theresa Sackler resides in the United Kingdom.

9. Mallinckrodt

41. Defendant Mallinckrodt PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt PLC was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien PLC, which was fully transferred to Mallinckrodt in June of that year. Mallinckrodt began as a U.S.-based company, with the founding of Mallinckrodt & Co. in 1867, Tyco International Ltd. acquired the company in 2000. In 2008, Tyco Healthcare Group separated from Tyco International Ltd. and renamed itself Covidien.

42. Defendant Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware and headquartered in St. Louis, Missouri.

43. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC.

44. Defendant SpecGX LLC is a limited liability company existing under the laws of the State of Delaware and headquartered in St. Louis, Missouri. SpecGX LLC is a wholly owned subsidiary of Mallinckrodt PLC and is registered to do business in Maryland.

45. Together, Mallinckrodt PLC, Mallinckrodt, LLC, and SpecGX LLC (collectively, "Mallinckrodt") manufacture, market, and sell drugs in the United States. As of 2012, it was the largest U.S. supplier of opioid pain medications. In particular, it is one of the largest manufacturers of oxycodone in the U.S. and Maryland.

46. Mallinckrodt currently manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In addition, Mallinckrodt previously developed, promoted, and sold the following branded

opioid products: Magnacet, TussiCaps, and Xartemis XR.

47. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that, in 2015, it received approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

48. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

10. The Insys Individual Defendants: John Kapoor and Michael Babich

49. Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys manufactures, markets, sells and distributes nationwide several types of opioids, including Subsys—a fentanyl sublingual spray and semi-synthetic opioid antagonist—as well as Syndros, a cannabinoid medicine used in adults to treat common side-effects of opioid use, particularly for patients whose nausea and vomiting have not improved with usual anti-nausea and vomiting medicines. The FDA approved Subsys in 2012, and Syndros in 2016.

50. Subsys is indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid

therapy for their underlying persistent cancer pain."[19] The indication also specifies that "Subsys is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." In addition, the indication provides that "[p]atients must remain on around-the-clock opioids when taking SUBSYS." Subsys is contraindicated for, among other ailments, the "[m]anagement of acute or postoperative pain including headache/migraine and dental pain." It is available in 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg dosage strengths.

51. Insys's revenue is derived almost entirely from Subsys. According to its Form 10-K for 2015, Insys reported revenues of $331 million. Of that total, $329.5 million was derived from sales of Subsys. The majority of Insys's sales of Subsys are through wholesalers, including Defendants AmerisourceBergen and Cardinal Health. In 2015, those wholesalers respectively comprised 20%, 17%, and 14% of Insys's total gross sales of Subsys.

52. On Friday, June 7, 2019, the pharmaceutical arm of Insys formally pled guilty to federal charges connected to allegations that the company bribed doctors to prescribe a powerful opioid to patients who did not need it, as part of a $225 million dollar deal entered into with the federal government in United States District Court for the District of Massachusetts.[20]

53. Defendant John Kapoor is the founder and majority owner of Insys. In October of 2017, Defendant Kapoor was arrested in Arizona and charged with RICO

[19] The indication provides that "[p]atients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer."

[20] https://www.law360.com/articles/1166925/insys-pleads-guilty-to-fraud-in-opioid-bribe-scheme

conspiracy, conspiracy to commit wire fraud, and conspiracy to violate the Anti-Kickback Law, for his alleged participation in a nationwide scheme to bribe healthcare providers in various states, including Maryland, to prescribe Subsys.[21] On May 2, 2019, he was found guilty of a racketeering conspiracy and running a nation-wide bribery scheme.[22] He is a resident of Phoenix, Arizona, and a current member of the Board of Directors of Insys.

54. Defendant Michael Babich is the former CEO and President of Insys. In 2017, he was also arrested in Arizona on charges of RICO conspiracy, conspiracy to commit wire fraud, and conspiracy to violate the Anti-Kickback Law. In January of 2019, Defendant Babich pleaded to these charges.[23] He is a resident of Scottsdale, Arizona.

B. Distributor Defendants

1. AmerisourceBergen

55. Defendant Distributor AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a publicly traded company headquartered in Pennsylvania and incorporated under the laws of Delaware. It is registered to do business in Maryland. AmerisourceBergen is in the chain of distribution of prescription opioids. At all relevant times, AmerisourceBergen was in the business of distributing substantial amounts of prescription opioids to providers and retailers. AmerisourceBergen has engaged in consensual commercial dealings in Carroll County, and has purposefully availed itself of the advantages of conducting business with and within Carroll County.

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[21] United States Department of Justice ("DOJ"), *Press Release—Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering*, U.S. Attny's Office Dist. of Mass. (Oct. 26, 2017), https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering

[22] Emanuel, Gabrielle, *Opioid Executive John Kapoor Found Guilty in Landmark Bribery Case* (May 2, 2019) https://www.npr.org/2019/05/02/711346081/opioid-executive-john-kapoor-found-guilty-in-landmark-bribery-case

[23] J. Saltzman, *Former CEO says Insys founder pushed for higher doses of opioid*, BOSTON GLOBE (Feb. 12, 2019), https://www2.bostonglobe.com/business/2019/02/12/former-ceo-says-insys-founder-pushed-for-higher-doses-opioid/aZhLcDEnayOO3dzPlFn9gN/story.html

2. Cardinal Health

56. Defendant Distributor Cardinal Health 121, LLC is a for-profit Delaware corporation with its principal place of business located in Columbia, Maryland. Defendant Distributor Cardinal Health 122, LLC is a for-profit Delaware corporation with its principal place of business located in Ellicott City, Maryland. Defendant Distributor Cardinal Health 100, Inc. is a for-profit Indiana corporation with its principal place of business located in Dublin, Ohio. Defendant Distributor Cardinal Health 108, LLC is a for-profit Delaware corporation with its principal place of business located in LaVergne, Tennessee. Defendant Distributor Cardinal Health 107, LLC is a for-profit Ohio corporation with its principal place of business located in Dublin, Ohio. Defendant Distributors Cardinal Health 110, LLC; Cardinal Health 128, LLC; Cardinal Health 200, LLC; and Cardinal Health 5, LLC are for-profit Delaware corporations with their principal place of business located in Dublin, Ohio. Defendant Distributors Cardinal Health 132, LLC and Cardinal Health Pharmacy Services, LLC are for-profit Delaware corporations with their principal place of business located in Houston, Texas. (Cardinal Health 121, LLC; Cardinal Health 122, LLC; Cardinal Health 100, Inc.; Cardinal Health 108, LLC; Cardinal Health 107, LLC; Cardinal Health 128, LLC; Cardinal Health 5, LLC; Cardinal Health 110, LLC; Cardinal Health 200, LLC; Cardinal Health Pharmacy Services, LLC; and Cardinal Health 132, LLC are all registered to do business in Maryland and shall collectively be referred to as "Cardinal Health.") At all relevant times, Cardinal Health was in the business of distributing substantial amounts of prescription opioids to providers and retailers. Cardinal Health has engaged in consensual commercial dealings in Carroll County, and has purposefully availed itself of the advantages of conducting business with and within Carroll County. Cardinal Health is in the chain of distribution of prescription opioids.

57. Defendants AmerisourceBergen and Cardinal Health are collectively referred to as the "Distributor Defendants." Manufacturers of opioids have transferred prescription opioids to the Distributor Defendants for years. The Distributor Defendants

dominate 85 to 90 percent of all revenues from drug distribution in the United States, estimated to be at $378.4 billion in 2015. The Distributor Defendants supplied opioids to hospitals, pharmacies, doctors and other healthcare providers, which then dispensed the drugs to patients in Maryland, including in Carroll County. The Distributor Defendants have had substantial contacts and business relationships with the citizens of Carroll County. The Distributor Defendants have purposefully availed themselves of business opportunities within Carroll County.

D. DOE Defendants

58. The true names and capacities, whether individual, plural, corporate, partnership, associate, or otherwise, of DOES 1 through 1000, inclusive, are unknown to Carroll County who therefore sues said Defendants by such fictitious names. The full extent of the facts linking such fictitiously sued Defendants is unknown to Carroll County. Carroll County is informed and believes and thereon alleges that each of the Defendants designated herein as a DOE was, and is, negligently, recklessly, and/or intentionally responsible for the events and happenings hereinafter referred to, and thereby negligently, recklessly, and/or intentionally legally and proximately caused the hereinafter described injuries and damages to Carroll County. Carroll County will hereafter seek leave of the Court to amend this Complaint to show the fictitiously sued Defendants' true names and capacities, after the same have been ascertained.

III. JURISDICTION AND VENUE

59. This Court has subject matter jurisdiction by grant of authority under the Constitution of the State of Maryland.

60. This Court has personal jurisdiction over Defendants under the long-arm statute of the State of Maryland, Md. Code Ann. §6-103, and the United States Constitution, because they have regularly transacted business in Maryland; have purposefully directed business activities to Maryland; and have engaged in unlawful practices and caused injury in Maryland. Each Defendant has promoted, marketed, sold,

and/or distributed prescription opioids in the State of Maryland or directed to the State of Maryland.

61. The Manufacturer and Distributor Defendants are each registered to do business in Maryland and have generated substantial sums of money through the sale of prescription opioids in Maryland. The Manufacturer Defendants have also unlawfully promoted their opioids in Maryland, through conduct within the State of Maryland and through other business activities directed into Maryland. Defendant Distributors Cardinal Health 121, LLC and Cardinal Health 122, LLC each reside in Maryland and do business in Maryland.

62. Venue in this Court is proper because Carroll County's claims arise, in part, in Carroll County and each of the Defendants conduct business there.

IV. FACTUAL ALLEGATIONS

A. Background on Pain Medicine

63. The practice of medicine centers on informed risk management. Prescribers must weigh the potential risks and benefits of each treatment option, as well as risk of non-treatment. Accordingly, the safe and effective treatment of chronic pain requires that a physician be able to weigh the relative risk of prescribing opioids against both (a) the relative benefits that may be expected during the course of opioid treatment and (b) the risks and benefits of alternatives.

64. Opium has been recognized as a tool to relieve pain for millennia; so has the magnitude of its potential for abuse, addiction, and its dangers. Opioids are related to illegal drugs like opium and heroin. In fact, some types of fentanyl, a widely-distributed opioid in the United States, have now been made illegal in China.

65. During the Civil War, opioids gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain—particularly on the battlefield—and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants and beverages. By 1900, an estimated

300,000 people were addicted to opioids in the United States. Both the number of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

66. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an excessive dose.

67. Studies and articles from the 1970s and 1980s also made the reasons to avoid opioids clear. Scientists observed poor outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, and even prohibited, the use of opioid therapy for chronic pain.

68. Despite the fact that opioids are now routinely prescribed, there has never been evidence of their safety and efficacy for long-term use. On the contrary, evidence shows that opioid drugs are not effective to treat chronic pain, and may worsen patients' health. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

69. Opioids are highly addictive. Patients using opioids for more than a few days can experience severe withdrawal symptoms if they stop taking the drugs, including: anxiety, insomnia, pain, blurry vision, rapid heartbeat, chills, panic attacks, nausea, vomiting, and tremors. Withdrawal can last so long and be so painful that it is difficult to stop taking opioids.

70. Putting patients on opioids puts them at risk. Patients who take opioids at higher doses and for longer periods face higher and higher risk of addiction and death. Relative to the general population, the risk of opioid-death is 35-times higher for patients receiving three consecutive months of opioid therapy. Each of the Defendants named in this Complaint disregarded the well-known and frightening statistics regarding opioid abuse and chose to ignore them in the name of profits.

B. The Manufacturer Defendants' Impact on the Perception and Prescribing of Opioids

71. Before the Manufacturer Defendants began the marketing campaign complained of herein, the generally accepted standards of medical practice dictated that opioids should only be used short-term, for acute pain, or for patients nearing the end of life. The Manufacturer Defendants changed this perception and took advantage of addiction to make money. The Manufacturer Defendants' marketing campaign resulted in skyrocketing opioid prescriptions. The shocking increase in prescriptions has been a gold mine for the Manufacturer Defendants. It has been a tragedy for patients and Carroll County's citizenry. Carroll County has lost citizens young and old to the opioid epidemic – too many children in Carroll County have lost their parents and too many parents have buried their children. Too many grandparents are raising their grandchildren.

72. Patients who survive addiction need lengthy, difficult, and expensive treatment. People who are addicted to opioids are often unable to work. The addiction of parents can force their children into foster care. Babies are born addicted to opioids, a condition known as Neonatal Abstinence Syndrome ("NAS"), because they are exposed to the drugs in the womb. The rate of babies born with NAS increased by 50% in Maryland between 1999 and 2012.[24]

[24] Centers for Disease Control and Prevention, *Incidence of Neonatal Abstinence Syndrome—28 States, 1999-2013* (Aug. 12, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm

C. The Manufacturer Defendants Engaged in a Deceptive Marketing Scheme to Increase Profits

73. To profit from their dangerous drugs, the Manufacturer Defendants engaged in deadly and illegal practices to deceive doctors and patients. First, the Manufacturer Defendants deceived Carroll County doctors and patients to get more people on their dangerous drugs. Second, the Manufacturer Defendants misled them to take higher and more dangerous doses. Third, the Manufacturer Defendants deceived them to stay on their drugs for longer and more harmful periods of time.

74. The Manufacturer Defendants targeted vulnerable people who could be introduced to opioids, including elderly patients and people who had never taken opioids before. The Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observed that existing evidence showed that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concluded that there are "special risks of long-term opioid use for elderly patients" and recommended that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.

75. All the while, the Manufacturer Defendants peddled falsehoods to keep patients away from safer alternatives. Even when the Manufacturer Defendants knew people in Carroll County were addicted and dying, the Manufacturer Defendants treated doctors and patients as "targets" to sell more drugs.

76. Each part of the scheme earned the Manufacturer Defendants more money from opioid sales and caused more addiction and death in Carroll County. From 2012 to 2016, the total economic cost for opioid-related fatalities in Maryland, which includes

Carroll County, was over $55 billion.[25] In 2016 alone, the economic cost of the opioid epidemic in Maryland, which includes Carroll County, was over $21.19 billion.[26] Each Manufacturer Defendant participated in and profited from the opioid scheme in Maryland, and specifically in Carroll County, as set forth below.

D. The Manufacturer Defendants Funneled Misrepresentations Through Sales Representatives, Advertisements, and Third-Parties

77. Carroll County patients continue to visit emergency rooms and/or die after taking the Manufacturer Defendants' drugs because Carroll County was subject to the Manufacturer Defendants' massive deceptive sales campaign. The Manufacturer Defendants deceptively marketed their branded opioids directly to doctors and patients in Carroll County. The Manufacturer Defendants also deployed sales representatives to spread their false and misleading statements about the risks and benefits of opioids for the treatment of chronic pain throughout Maryland and, specifically, in Carroll County.

78. These representatives were the Manufacturer Defendants' most powerful tools of deception by using them to conduct face to face meetings with Carroll County healthcare providers and pharmacists in an effort to promote opioids. During sales visits, the Manufacturer Defendants' representatives made false and misleading claims directly to the professionals who care for Carroll County patients. The Manufacturer Defendants assigned representatives to Carroll County and gave them lists of Carroll County doctors to visit. The 'scripts' used by these representatives were approved and closely monitored by Manufacturer Defendants.

79. Each of these visits cost the Manufacturer Defendants money. But the Manufacturer Defendants made this money back many times over, because they convinced

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[25] Minority Staff, Senate Committee on Health, Education, Labor, and Pensions, *The Economic Cost of the Opioid Epidemic in Maryland*, https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Economic%20Cost%20of%20the%20Opioid%20Epidemic%20in%20Maryland.pdf

[26] *Id*.

doctors to prescribe their addictive drugs. The Manufacturer Defendants rewarded high prescribing doctors with meals, money, and gifts. The Manufacturer Defendants' sales representatives who generated the most prescriptions won bonuses and prizes. These representatives have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors, and other healthcare providers, including those in Carroll County.

80. The Manufacturer Defendants' representatives have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

81. The Manufacturer Defendants also conducted and continue to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, the Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

82. A number of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, since at least May 21, 2011, Endo has distributed and made available on its website, opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction workers and chefs, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year old

writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they continue to disseminate them in Maryland.

83. Similarly, despite Subsys' limited indication and the potent danger associated with fentanyl, Insys falsely and misleadingly marketed Subsys to doctors as an effective treatment for back pain, neck pain and other off-label breakthrough pain conditions. As of June 2012, Insys defined "breakthrough pain" in cancer patients to include mild pain: a "flare of mild-to-severe pain in patients with otherwise stable persistent pain," based on a misleading citation to a paper written by Dr. Russell Portenoy.[27] Insys trained and instructed its sales representatives to use the false definition of breakthrough pain and specifically to use a core visual aid, including the improper definition, whenever they detailed Subsys to a healthcare provider or provider's office.

84. According to a 2014 article in *The New York Times*, only 1% of prescriptions for Subsys were written by oncologists. Approximately half the prescriptions were written by pain specialists, with others, including dentists and podiatrists, writing prescriptions as well.[28]

85. On September 6, 2017, Senator Claire McCaskill's report, "Fueling an Epidemic: Insys Therapeutics and the System Manipulation of Prior Authorization" was published. The report found that Insys manipulated the prior authorization process [29] by

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[27] Portenoy's paper, which was featured in the 1990 issue of Pain, actually defined breakthrough pain as "a transitory increase in pain to greater than moderate intensity—i.e., to an intensity of 'severe' or 'excruciating') . . . on a baseline pain of moderate intensity or less." Russell K. Portenoy & Neil A. Hagen, *Breakthrough pain: Definition, prevalence and characteristics*, 41(3) Pain 273-81 (July 1990).

[28] Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller*, N.Y. TIMES (May 13, 2014), https://www.nytimes.com/2014/05/14/ business/doubts-raised-aboutoff-label-use-of-subsys-a-strong-painkiller.html.

[29] Prior authorization (PA) is any process by which physicians and other health care

misleading pharmacy benefit managers about the role of Insys in the prior authorization process and the presence of breakthrough cancer pain in potential Subsys patients.[30]

86. On September 12, 2017, Senator McCaskill convened a Roundtable Discussion on Opioid Marketing. During the hearing, Senator McCaskill stated:

> "The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out these messages were exaggerations at best and outright lies at worst.
>
> * * *
>
> "Our national opioid epidemic is complex, but one explanation for this crisis is simple, pure greed."[31]

87. Less than two years later, Insys' former chief executive officer pleaded guilty to participating in a nationwide scheme to bribe doctors in exchange for prescribing Sybsys.[32]

88. The Manufacturer Defendants[33] also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Manufacturer Defendants. These speaker programs provided: (1) an incentive for doctors

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providers must obtain advance approval from a health plan before a specific procedure, service, device, supply or medication is delivered to the patient to qualify for payment coverage. (American Medical Association, *Prior authorization: The current landscape*, p. 1 (2015), https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/premium/ psa/prior-authorization-toolkit_0.pdf

[30] HSGAC Minority Staff Report, Insys Therapeutics and the Systemic Manipulation of Prior Authorization (2017).

[31] *See*, *LIVESTREAM: Insys Opioid Sales and Marketing Practices Roundtable*, September 12, 2017, at 31:03-31:37, https://www.youtube.com/watch?v=k9mrQa8_vAo (last accessed Mar. 17, 2019).

[32] Nate Raymon, Former Insys CEO pleads guilty to opioid kickback scheme, REUTERS (Jan. 9, 2019), https://www.reuters.com/article/us-insys-opioids/former-insys-ceo-pleads-guilty-to-opioid-kickback-scheme-idUSKCN1P312L.

[33] Upon information and belief, Actavis continued to carry out speaker programs after it acquired Kadian.

to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by the Manufacturer Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids.

89. Each Manufacturer Defendant devoted and continues to devote massive resources to direct sales contacts ("detailing") with doctors. In 2014 alone, the Manufacturer Defendants spent $168 million on detailing branded opioids to doctors. This amount is twice as much as the Manufacturer Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $10 million by Endo, and $2 million by Actavis.

90. The Manufacturer Defendants also deceptively marketed opioids in Maryland through unbranded advertising—*i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain.[34]

91. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from

[34] The phrase "acted in concert" includes conspiring to achieve some end and aiding and abetting in the commission of acts necessary to achieve some end.

an independent and objective source. Like tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

92. The Manufacturer Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	**Opana ER Advertisement (Branded)**
"People who take opioids **as prescribed usually do not become addicted**."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

93. The Manufacturer Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by the Manufacturer Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." The Manufacturer Defendants paid these KOLs to serve as consultants or on their advisory boards and to give talks or present continuing medical education programs ("CMEs"), and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the Manufacturer Defendants.

94. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and misleading statements about the risks and benefits of long-term opioid use for chronic pain. The Manufacturer Defendants know that doctors rely heavily and more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the New York Attorney General ("NY AG") found in its settlement with Purdue that through March 2015, the Purdue website, "In the Face of Pain," failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials. KOLs have written, consulted on, edited, and lent their names to books and articles, and have given speeches and CMEs supportive of chronic opioid therapy. The Manufacturer Defendants created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, the Manufacturer Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

95. The Manufacturer Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they were created, and they are not supported by the scientific evidence today. The Manufacturer Defendants were able to direct and exert control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

96. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front

Groups"—which include, but are not limited to, the American Pain Foundation ("APF") and the American Academy of Pain Medicine—generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. These guidelines, materials, and programs were not supported by the evidence at the time they were created, and they are not supported by the scientific evidence today. Indeed, they stand in marked contrast to the 2016 CDC Guideline. These Front Groups also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

97. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. For example, Purdue's consulting agreement with APF gave it direct, contractual control over APF's work. In doing so, the Manufacturer Defendants ensured the Groups would generate only the messages the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members—whether patients were suffering from pain or doctors were treating those patients.

98. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, the Manufacturer Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Endo, Janssen/J&J, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require

mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing. PCF also worked to address a perceived "lack of coordination" among its members and developed "key" messages that were disseminated in programs and industry-run websites.

E. The Manufacturer Defendants Deceived Doctors and Patients to Get More People on Dangerous Drugs, at Higher Doses, for Longer Periods

99. To convince doctors and patients around the country, including in Maryland, that opioids can and should be used to treat chronic pain, the Manufacturer Defendants had to convince them that long-term opioid use is both safe and beneficial. The Manufacturer Defendants deceived those doctors and patients about the risks and benefits of long-term opioid use. The Manufacturer Defendants, through Front Groups, KOLS, and advertisements, made claims that were not supported by or were contrary to the scientific evidence—most frequently, these claims downplayed the risks of addiction in order to convince patients and doctors alike that prescription opioids should be used more regularly. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and misleading, Carroll County is informed and believes that the Manufacturer Defendants have not corrected them and continue to spread them today, including as set forth specifically below.

1. Deception About Addiction

100. The Manufacturer Defendants always knew that their opioids carry grave risks of addiction and death. Instead of being honest about these risks, the Manufacturer Defendants obscured them, including by falsely stating and implying that "appropriate patients" won't get addicted. To convince doctors and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC.

101. First, the Manufacturer Defendants falsely claimed that the risk of addiction

is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and misleading claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after May 21, 2011, are described below:

a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

b. Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft.

c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

d. Endo and Cephalon distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

e. Janssen/J&J reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen ran a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children

prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]."

h. Detailers for Purdue, Endo, Teva, and Janssen in Maryland have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in Maryland, including Carroll County, about the risk of addiction; falsely claiming that abuse-deterrent formulations "cannot be crushed," downplaying the potential that these opioids could be abused; and routinely did not correct the misrepresentations noted above.

102. Moreover, Purdue, in a pamphlet for doctors, *Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substance Prescribing Practices*, wrote that addiction "is not caused by drugs." Instead, Purdue assured doctors that addiction happens when the wrong patients get drugs and abuse them: "it is triggered in a susceptible individual by exposure to drugs, most commonly through abuse."[35]

103. Purdue also promoted its opioids to Carroll County patients with marketing that was designed to obscure the risk of addiction and even the fact that Purdue was behind the campaign. Purdue created a website, *In the Face of Pain*, that promoted pain treatment by urging patients to "overcome" their "concerns about addiction." Testimonials on the website that were presented as personal stories were in fact by Purdue consultants, whom Purdue had paid tens of thousands of dollars to promote its drugs.[36]

104. Another Purdue publication, the *Resource Guide for People with Pain*, falsely assured patients and doctors that opioid medications are not addictive:

> "*Many people living with pain and even some healthcare providers believe that opioid medications are addictive. The truth is that when properly prescribed by a healthcare professional and taken*

[35] Purdue Pharma LP, *Providing Relief, Preventing Abuse* (2008), pg. 12; *see also* K. Nelson, *Purdue Pharma lawsuit: Terms you need to know to understand OxyContin blitz*, Knox News (July 13, 2018), https://www.knoxnews.com/story/news/health/2018/07/13/purdue-pharma-lawsuit-terms-know-understand-oxycontin-blitz/779173002/

[36] Purdue Pharma LP, *In the Face of Pain* (Oct. 24, 2011).

as directed, these medications give relief – not a 'high'."[37]

105. Purdue falsely denied the risk of addiction, falsely implied that addiction requires patients to get "high," and falsely promised that patients would not get addicted if they took opioids as prescribed.

106. Purdue funded and distributed many more publications that were similarly misleading. *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and their Families* misleadingly claimed: "Long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."[38]

107. *Responsible Opioid Prescribing* told doctors that only a "small minority of people seeking treatment may not be reliable or trustworthy" and not suitable for addictive opioid drugs.[39]

108. Similarly, while Janssen/J&J repeatedly disclaimed responsibility for its part in causing the opioid crisis, insisting that "[e]verything that we have done with our products when we've promoted opioid products . . . was appropriate and responsible," internal memoranda and communications between high-level executives at Janssen show the company funded and pushed bogus research to lend false credibility to a series of dangerous fictions, claiming that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain," and enabling "Janssen's representatives [to] promote[] Nucynta and Nucynta ER as safer, milder, and less addictive than competitor opioids like OxyContin."[40]

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[37] Purdue Pharma LP, *Resource Guide for People with Pain*, p. 8 (2009).

[38] Purdue Pharma LP, *Exit Wounds*, p. 107 (2009).

[39] Purdue Pharma LP, *Responsible Opioid Prescribing*, p. 11 (2007).

[40] M. Aron, *deceptively marketing opioids*, NJTV News (Nov. 13, 2018), https://www.njtvonline.org/news/video/state-sues-johnson-johnson-subsidiary-for-deceptively-marketing-opioids/

109. In 2017, Mallinckrodt agreed to settle for $35 million the Department of Justice's allegations regarding excessive sales of oxycodone in Florida. The Department of Justice alleged that, even though Mallinckrodt knew that its oxycodone was being diverted for illicit use, it nonetheless continued to incentivize and supply these suspicious sales, and it failed to notify the DEA of the suspicious orders in violation of its obligations as a registrant under the Controlled Substances Act, 21 U.S.C. § 801 et seq. ("CSA"). Similarly, in 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million.

110. Over and over, Defendants said opioids could be given to "trusted" patients without risk of addiction. To promote their drugs, the Manufacturer Defendants pushed the myth that addiction is a character flaw, and "trustworthy" people do not get addicted to drugs.

111. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline approved by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder." (Emphasis added.)

112. The FDA further exposed the falsity of the Manufacturer Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at

recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

113. The New York Attorney General, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed until at least April 2012 on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the NY AG found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo has not been restricted from making these statements in Maryland yet.

2. Deception to Get Vulnerable Patients on Opioids

114. To expand the market for opioids, the Manufacturer Defendants also trained their representatives to target vulnerable populations and encourage doctors to put them on opioids, without disclosing the risks. The Manufacturer Defendants deceptively promoted opioids for elderly patients, patients who had never taken opioids, and patients with osteoarthritis—putting thousands of more patients at risk.

Elderly Patients

115. The Manufacturer Defendants knew that prescribing opioids to elderly patients increase their risk of death. Elderly patients are at a greater risk of dangerous interactions between drugs. They are also at a greater risk of respiratory depression—in which patients suffocate and die. But the Manufacturer Defendants saw the opportunity to

earn millions of dollars by getting elderly patients on opioids because the public would pay through Medicare. For instance, Purdue's internal documents show it targeted "Patients over the age of 65 as more Medicare Part D coverage is achieved."[41]

Opioid-Naïve Patients

116. The Manufacturer Defendants also targeted patients who were not already taking opioids, described in the field as "opioid-naïve." The Manufacturer Defendants unfairly and deceptively marketed their drugs as appropriate treatments for opioid-naïve patients, without disclosing that they face even higher risks of overdose and death.

CLOSE #1
Opioid-naïve (5 mcg/hour):
- "Doctor, either today or tomorrow, do you anticipate seeing this commercially insured, opioid-naïve patient with moderate to severe chronic pain, who you believe would benefit from Butrans?

Purdue sales script from 2011

117. For instance, Purdue trained its sales reps to promote their drugs specifically for opioid-naïve patients. In training calls, Purdue managers instructed:

- *"Your opportunity here is with the naïve community, let's use the naïve trial to make the case."*
- *"You created an epiphany with the doctor today (potentially) by reviewing the opiate naïve patient profile. What made him more apt to write this for his patient, being an amiable doctor, is the fact that he would not have to talk patients out of their short-acting [opioids]."*
- *"This was an example of what a good call looks like … [Dr.] was particularly interested in the RM case study of Marjorie, which generated a robust discussion of opioid naïve patients …"*

118. Purdue also promoted its drugs for opioid-naïve patients using the deceptive term "first line opioid." "First line" is a medical term for the preferred first step in treating a patient. Opioids are not an appropriate first line therapy.

[41] Purdue Pharma LP, *Pain Products Presentation*, p. 12 (Jan. 28, 2015).

Purdue opioid promotion from 2015[12]

119. The Manufacturer Defendants also found vulnerable opioid-naïve patients by targeting prescribers with the least training in the risks of opioids. The Manufacturer Defendants determined that nurse practitioners, physician assistants, and primary care doctors were especially responsive to sales reps, so it targeted them to sell more drugs.

Osteoarthritis Patients

120. The Manufacturer Defendants knew that opioids were not appropriate to treat nonmalignant pain in non-cancer patients, including patients suffering from osteoarthritis. Opioids are not approved to treat osteoarthritis. For instance, Purdue conducted a single study on osteoarthritis for Butrans, and it failed. Purdue admitted in internal documents that its opioids "are not indicated for a specific disease" and "it is very important that you never suggest to your HCP [health care professional] that OxyContin is indicated for the treatment of a specific disease state such as Rheumatoid Arthritis or Osteoarthritis."

121. Nevertheless, to meet their business goals, the Manufacturer Defendants

trained their sales representatives to mislead doctors by promoting opioids for osteoarthritis. For instance, a Purdue marketing presentation concluded that its sales reps were "identifying appropriate patients" because osteoarthritis was specifically mentioned during at least 35% of sales visits.

122. The Manufacturer Defendants also directed their sales reps to use marketing materials that highlight patients with osteoarthritis, even though their drugs were never indicated for that disease.

3. The Manufacturer Defendants Deceived Doctors and Patients to Use Higher and Higher Doses

123. The impetus behind the Manufacturer Defendants' scheme is as simple as it is nefarious. Enticed by the exponentially greater profits that would result from increases in opioid dose mix, the Manufacturer Defendants deceived (or bribed) Carroll County's local prescribers in order to increase the supply of prescription opioids in Plaintiff's territory and drown Plaintiff's community in a sea of highly addictive, prescription drugs.

124. The Manufacturer Defendants—including, but not limited to, Defendant Purdue and Defendant Endo—also falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudoaddiction"—a made-up, misleading and scientifically unsubstantiated term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Endo, Janssen, Teva, and Purdue. Through aggressive marketing campaigns to Carroll County prescribers and patients, the Manufacturer Defendants used the concept of "pseudoaddiction" as a lever to mislead prescribers and their patients into believing that certain warning signs of opioid addiction [42] were neither indicative of "true" addiction nor cause for alarm. To the

[42] *E.g.*, demanding more opioids, engaging in manipulative behavior to obtain drugs, requesting specific drugs, hoarding drugs during periods of reduced symptoms, using drugs to treat another symptom, etc.

contrary, the Manufacturer Defendants repeatedly claimed these warning signs were manifestations of undertreated pain, which should be addressed by prescribing more opioids. Importantly, at all times relevant to this action, the Manufacturer Defendants both knew the concept of "pseudoaddiction" was false and yet actively sought to conceal the truth from Carroll County's physicians and patients, sabotaging these prescribers' ability to protect their patients from opioid addiction and concomitant injuries. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants are described below:

a. Purdue, Cephalon and Endo sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name", "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online.

b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

e. Purdue sponsored a CME program entitled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse" in 2011. In a role play exercise, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor

should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

f. Detailers for Purdue have directed doctors and their medical staff in Maryland, including Carroll County, to PartnersAgainstPain.com, which contained false and misleading materials describing pseudoaddiction.

g. Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which states: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." (emphasis added.)

125. The 2016 CDC Guideline rejects the concept of pseudoaddiction. Nowhere in the Guideline does it recommend that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

126. Even one of the Manufacturer Defendants has effectively repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the NY AG, in its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.' "[43] Consistent with this testimony, Endo agreed not to "use the term 'pseudoaddiction' in any training or

[43] In the Matter of Endo Health Solutions Inc., *et al*., Assurance No. 15-228, p. 7, ¶ 23 (NY AG, Mar. 1, 2016), https://www.ag.ny.gov/pdfs/ENDO_AOD_030116-Fully_Executed.pdf

marketing" in New York.[44]

127. The Manufacturer Defendants also falsely promised prescribers and their patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies would both allow these prescribers to reliably identify and safely prescribe opioids to patients who are predisposed to addiction and be efficacious enough to essentially rule out the risk of opioid addiction (even in the context of long-term opioid therapy). These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after March 21, 2011 are described below:

a. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue sponsored a November 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

d. Since at least May 21, 2011, detailers for Purdue have touted and continue

[44] *Id.*, p. 15, ¶ 41.e.

> to tout to doctors in Maryland, including Carroll County, the reliability and effectiveness of screening or monitoring patients as a tool that would virtually eliminate the risks of opioid abuse and addiction.

128. Consistent with what the Manufacturer Defendants already knew—but failed to disclose—at all times relevant to this action, the 2016 CDC Guideline confirms that the Manufacturer Defendants' statements were false, misleading, and unsupported at the time they were made by the Manufacturer Defendants. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse—"for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that prescribers "*should not overestimate* the ability of these tools to rule out risks from long-term opioid therapy." (Emphasis added.)

4. The Manufacturer Defendants Peddled Falsehoods to Keep Patients Away from Safer Alternatives

A. Deception about Quality of Life

129. The Manufacturer Defendants also steered patients away from safer alternatives with the false claim that its opioids improve patients' "quality of life." For instance, Purdue's internal documents admit that "Purdue has no clinical studies or other substantial evidence demonstrating that a Purdue Product will improve the quality of a person's life." Nevertheless, Purdue sales reps repeatedly claimed that its opioids improve quality of life. Purdue also devised and funded third-party publications to say that opioids give patients the "quality of life we deserve."

B. Deception about Risk of Abuse

130. In addition to visiting prescribers and pharmacists hundreds of thousands of times, the Manufacturer Defendants distributed thousands of copies of its deceptive

publications, including *Providing Relief, Preventing Abuse*; *Resource Guide for People with Pain*; *Exit Wounds*; *Opioid Prescribing: Clinical Tools and Risk Management Strategies*; *Responsible Opioid Prescribing*; *Clinical Issues in Opioid Prescribing;* and *In The Face of Pain*.

5. The Manufacturer Defendants Downplayed Opioids Withdrawal

131. To downplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use. For example, a 2011 non-credit educational program sponsored by Endo, entitled "Persistent Pain in the Older Adult," claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur. This publication was available on APF's website until the organization dissolved in May 2012. Detailers for Janssen have told and continue to tell doctors in Maryland, including Carroll County, that their patients would not experience withdrawal if they stopped using opioids.

132. The Manufacturer Defendants deceptively minimized the significant symptoms of opioid withdrawal—which, as explained in the 2016 CDC Guideline, include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, rapid heartbeat, spontaneous abortion and premature labor in pregnant women, and the unmasking or exacerbating of anxiety, depression, and addiction—and grossly understated the difficulty of tapering, particularly after long-term opioid use. The 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant

withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

133. Some prescribers and many patients in Carroll County relied on the truth of the Manufacturers Defendants' representations about both the benefits of opioid analgesics and the risks of opioid addiction. Because each of the Manufacturer Defendants willfully concealed the truth about their products and knew their representations were false at the time they were made, Carroll County's citizens are forced to pay the price for Defendants' misconduct.

6. The Manufacturer Defendants Hid the Greater Risks to Patients at Higher Dosages of Opioids

134. The Manufacturer Defendants were in the best position to know, and in fact did know, that—relative to the general population—the risk of opioid-related death increases exponentially after a patient takes opioids for several consecutive months.

135. Specifically, the Manufacturer Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or

have not been corrected by the Manufacturer Defendants after May 21, 2011, are described below:

a. Actavis' predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis' acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

b. Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.[45]

c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain." The website was still accessible online after May 21, 2011.

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was still available after May 21, 2011 on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of

[45] The Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See, e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids); *Finding Relief: Pain Management for Older Adults* (Janssen) (NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation).)

increased opioid dosages.

f. Through March 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.

h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.

j. Since at least May 21, 2011, Purdue's detailers have told doctors in Maryland, including in Carroll County, that they should increase the dose of OxyContin, rather than the frequency of use, to address early failure.

136. Through a series of internal strategy presentations and other communications with its sales force and prescriber-accomplices, Purdue aimed to "drive" patients toward higher doses of opioids for longer periods by dramatically increasing the supply. Purdue also sought to increase consumer demand for opioids, namely by offering discounts to patients on their first prescriptions. These discounts ultimately proved to be one of Purdue's most powerful tactics to keep patients on opioids longer, as Purdue's return on investment from these discounts was a staggering 4.28—*i.e.*, every $1,000,000 Purdue gave away in first-time patient discounts came back to Purdue as $4,280,000 in revenue.

Purdue internal strategy presentation from 2012

137. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

138. The 2016 CDC Guidelines reinforce earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." In fact, a recent study found that 92% of persons who died from an opioid-related overdose were initially prescribed opioids for chronic pain.

139. Finally, the Manufacturer Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

140. These abuse deterrent formulations ("AD opioids") are harder (but not impossible) to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Though at all times relevant to this action the Manufacturer

Defendants falsely claimed that AD opioids "cannot be crushed," the FDA found in 2015 that AD opioids are, in fact, "not impossible" to abuse.[46] They can be defeated—often quickly and easily—by those determined to do so. Moreover, they do not stop oral intake, the most common avenue for opioid misuse and abuse, and do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses.

141. Because of these significant limitations on AD opioids and because of the heightened risk for misconceptions and for the false belief that AD opioids can be prescribed safely, the FDA has cautioned that any communications from the sponsor companies regarding AD properties must be truthful and not misleading (based on a product's labeling), and supported by sound science taking into consideration the totality of the data for the particular drug. Claims for AD opioid products that are false, misleading, and/or insufficiently proven do not serve the public health.[47]

142. Despite this admonition, the Manufacturer Defendants have made and continue to make misleading claims about the extent to which their AD opioids can prevent or reduce abuse and addiction.

143. For example, Endo has marketed Opana ER as tamper- or crush-resistant and less prone to misuse and abuse since at least May 21, 2011 even though: (1) the FDA rejected Endo's petition to approve Opana ER as abuse-deterrent in 2012; (2) the FDA warned in a 2013 letter that there was no evidence that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse"; and (3) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that Opana ER

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[46] *See* U.S. Food and Drug Administration ("FDA"). *Abuse-Deterrent Opioids—Evaluation and Labeling: Guidance for Industry*, p. 23 (Apr. 2015), https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf

[47] *Ibid*.

could not be crushed, suggesting it was more difficult to abuse. On information and belief, detailers for Endo continue to reiterate these false statements to Maryland prescribers, including in Carroll County.

144. In the 2016 settlement with the NY AG, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The NY AG found those statements false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

145. Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market.[48]

146. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids—*i.e.*, reformulated Oxycontin and Hysingla—since at least May 21, 2011. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, Maryland prescribers report that detailers from Purdue have regularly used the so-called abuse deterrent properties of Purdue's opioid products as a primary selling point to differentiate those products from their competitors. Specifically, these detailers: (1) claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) claim that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (3) Purdue's AD opioids are "safer" than other opioids; and (4) fail to disclose

[48] FDA News Release, *FDA requests removal of Opana ER for risks related to abuse* (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm

that Purdue's AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

147. These statements and omissions by Purdue are false and misleading and conflict with or are inconsistent with the FDA-approved label for Purdue's AD opioids—which indicates that abusers do seek them because of their high likability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse deterrent properties and which does not indicate that AD opioids prevent or reduce abuse, misuse, or diversion.

148. To the contrary, testimony in litigation against Purdue and other evidence indicates that Purdue knew and should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin" and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a study it conducted that found continued abuse of OxyContin with so-called abuse deterrent properties. Finally, there are no reliable studies indicating that Purdue's AD opioids are safer than any other opioid products.

149. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, one-third of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such as heroin.[49] Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in

[49] Cicero, Theodore J., and Matthew S. Ellis, *Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin*, 72.5 JAMA Psychiatry, 424-30 (2015).

2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.

150. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes." Tom Frieden, the Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death."[50]

151. These false and misleading claims about the abuse deterrent properties of their opioids are especially troubling. First, the Manufacturer Defendants are using these claims in a spurious attempt to rehabilitate their image as responsible opioid manufacturers. Indeed, Purdue has conveyed that its sale of AD opioids is "atonement" for its earlier sins even though its true motive was to preserve the profits it would have lost when its patent for OxyContin expired. Purdue introduced its first AD opioid days before that patent would have expired and petitioned the FDA to withdraw its non-AD opioid as unsafe and; thereby, preventing generic competition. Second, these claims are falsely targeting doctors' concerns about the toll caused by the explosion in opioid prescriptions and use and encouraging doctors to prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe more AD opioids—which are far more expensive than other opioid products even though they provide little or no additional benefit.

152. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

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[50] Perrone, *Drugmakers push profitable, but unproven, opioid solution* (Dec. 15, 2016).

7. The Manufacturer Defendants Grossly Overstated the Benefits of Chronic Opioid Therapy

153. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." (Emphasis added.) In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, the Manufacturer Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturer Defendants failed to correct these false and misleading claims, they continue to make them today.

154. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after May 21, 2011 are described below:

a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled *Finding*

Relief: Pain Management for Older Adults (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo, Cephalon and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.

f. Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."

g. Endo's NIPC website painknowledge.com claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

h. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

i. Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

j. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are

effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients."

k. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic pain patients' "quality of life," and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.

l. Since at least May 21, 2011, Purdue's, Endo's, Teva's and Janssen's sales representatives have conveyed and continue to convey to prescribers in Maryland, including in Carroll County, the message that opioids will improve patient function.

155. These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. The 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." The CDC reinforced this conclusion throughout its 2016 Guideline:

- *"No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."*

- *"Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."*

- *"[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."*

156. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

157. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described above, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience … results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

158. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants, before and after May 21, 2011, have overstated the number of deaths from NSAIDS and have prominently featured the risks of NSAIDS, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

8. The Manufacturer Defendants Engaged in Other Unlawful and Unfair Misconduct

159. Since at least 2010, Defendant Purdue's sales representatives have pressed

doctors to prescribe its opioids in order to be rewarded with talks paid by Purdue.

160. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed Purdue about its legal "obligation to design and operate a system to disclose . . . suspicious orders of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs after 2010, despite knowing about it for years.

161. For over a decade, Purdue has been able to track the distribution and prescribing of its opioids down to the retail and prescriber levels. Through its extensive network of sales representatives, Purdue had and continues to have knowledge of the prescribing practices of thousands of doctors in Maryland and could identify Maryland doctors who displayed red flags. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused.

162. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action—even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite Purdue's knowledge of illegal prescribing, Purdue did not report until after law enforcement shut down clinics that overprescribed OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

163. This misconduct by Purdue is ongoing. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015, Purdue's sales representatives, at various

times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a "no-call" list.

164. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a Los Angeles Times article, "[a]ny drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it." The NY AG's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prescribers in Maryland, including in Carroll County.

165. Like Purdue, Defendant Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY AG found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal prescribing of opioids after May 21, 2011, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so.

F. Although the Manufacturer Defendants Knew That Their Marketing of Opioids Was False and Misleading, They Fraudulently Concealed Their Misconduct

166. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and misleading. The history of opioids, as well as research and clinical experience over the last

20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned the Manufacturer Defendants of this, and Purdue entered into settlements in the hundreds of millions of dollars to address similar misconduct that occurred before 2008. The Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

167. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants fraudulently concealed their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.

168. The Manufacturer Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar

websites that masked their own direct role.

169. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for the Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by Plaintiff.

170. Thus, the Manufacturer Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that Plaintiff now asserts. Plaintiff did not know of the existence or scope of the Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

171. As detailed in the allegations below, the Sacklers were intimately aware of the potential liabilities against the Purdue entities because the Sacklers controlled the companies. The Sacklers personally participated in the misconduct or at least acquiesced to the misconduct by way of their knowledge of the wrongful acts combined with their failure to act. The Sacklers also performed multiple fraudulent transfers of billions of dollars to enrich themselves while leaving the Purdue entities hopelessly undercapitalized if ever forced to pay for the injuries they had caused.

G. By Knowingly Causing an Explosion in Opioid Prescribing, Use, Misuse, Abuse, and Addiction Through Their Deceptive Marketing Schemes and Unlawful and Unfair Business Practices, Each Manufacturer Defendant Has Created or Assisted in the Creation of a Public Nuisance in Carroll County

1. The Manufacturer Defendants' Deceptive Marketing Scheme Has Caused and Continues to Cause a Huge Increase in Opioid Prescriptions and Use in Carroll County

172. The Manufacturer Defendants' misrepresentations deceived and continue to deceive doctors and patients in Carroll County about the risks and benefits of long-term opioid use. Studies also reveal that some doctors and many patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive. No doubt, Maryland residents in treatment for opioid addiction, including residents of Carroll County, were never told that they might become addicted to opioids when they started taking them, were told that they could easily stop using opioids, or were told that the opioids they were prescribed were less addictive than other opioids.

173. The Manufacturer Defendants knew and should have known that their misrepresentations about the risks and benefits of long-term opioid use were false and misleading when they made them.

174. The Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices caused and continue to cause doctors and other clinicians in Carroll County to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent the Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices, these doctors

would not have prescribed as many opioids to as many patients, and there would not have been as many opioids available for misuse and abuse or as much demand for those opioids.

175. The Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices also caused and continue to cause patients in Maryland, including patients in Carroll County, to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them. The Manufacturer Defendants' deceptive marketing and their unlawful and unfair business practices have caused and continue to cause the prescribing and use of opioids to explode in Carroll County.

176. In Carroll County, the Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of their opioids during the past few years has been particularly effective. For example, one survey reports that pain specialists were more likely to recognize that OxyContin had abuse deterrent properties and to prescribe OxyContin specifically because of those properties. Further, prescribers who knew of OxyContin's abuse deterrent properties were using more of it than those who did not know it was an AD opioid. Although sales of AD opioids still represent only a small fraction of opioids sold (less than 5% of all opioids sold in 2015), they represent a disproportionate share of opioid sales revenue ($2.4 billion or approximately 25% in opioid sales revenue in 2015).

177. The dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in the Manufacturer Defendants' spending on their deceptive marketing scheme. The Manufacturer Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

2. By Causing an Explosion in Opioid Prescriptions and Use, the Manufacturer Defendants Have Created or Assisted in the Creation of a Public Nuisance in Carroll County

178. The escalating number of opioid prescriptions written by doctors who were deceived by the Manufacturer Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Maryland, including in Carroll County.

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

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

181. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

182. Contrary to the Manufacturer Defendants' misrepresentations, most opioid addiction begins with legitimately prescribed opioids. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers

or the internet. Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic. As the FDA observed in 2016, the opioid epidemic is getting worse, not better.

183. The Manufacturer Defendants' creation, through false and misleading advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed Carroll County. The Manufacturer Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

184. The rise in opioid addiction caused by the Manufacturer Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription opioids.

185. Many patients who become addicted to opioids will lose their jobs. Some will lose their homes and their families. Some will get treatment and fewer will successfully complete it; many of those patients will relapse, returning to opioids or some other drug. Of those who continue to take opioids, some will overdose—some fatally, some not. Others will die prematurely from related causes—falling or getting into traffic accidents due to opioid-induced somnolence; dying in their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit drug transactions; or dying from opioid-induced heart or neurological disease.

186. Absent each Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices, the public health crisis caused by opioid misuse, abuse, and addiction in Carroll County, would have been averted or much less severe.

187. These harms in Carroll County, caused by the Manufacturer Defendants'

deceptive marketing schemes and unlawful and unfair business practices are a public nuisance because they significantly interfere with the public health, safety, peace, comfort, and convenience, are substantial and unreasonable, and has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit.

3. The Manufacturer Defendants Knew and Should Have Known That Their Deceptive Marketing Schemes Would Create or Assist in the Creation of This Public Nuisance in Carroll County

188. The Manufacturer Defendants knew and should have known about these harms that their deceptive marketing and unlawful and unfair business practices have caused and continue to cause in Carroll County. The Manufacturer Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. The Manufacturer Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew—and, indeed, intended—that their misrepresentations would persuade doctors in Carroll County to prescribe, and patients in Carroll County to use, their opioids for chronic pain.

4. The Manufacturer Defendants' Conduct and Role in Creating or Assisting in the Creation of the Public Nuisance Is Not Excused by the Actions of any Third Parties

189. The Manufacturer Defendants' actions are not permitted nor excused by the fact that their drug labels may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give the Manufacturer Defendants license to misrepresent the risks and benefits of opioids. Indeed, the Manufacturer Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

190. Nor is the Manufacturer Defendants' causal role broken by the involvement

of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. The Manufacturer Defendants also were able to harness and hijack what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

H. The Manufacturer Defendants' Fraudulent Marketing Has Led To Record Profits

191. While the use of opioids has taken an enormous toll on Carroll County and its residents, the Manufacturer Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like the Manufacturer Defendants. Indeed, financial information indicates that each Manufacturer Defendant experienced a material increase in sales, revenue, and profits from the false and misleading advertising and other unlawful and unfair conduct described above.

I. The Sacklers Led Purdue's Misconduct

192. Maryland laws against both the creation of a public nuisance as well as unfair and deceptive conduct in commerce apply to individuals regardless of whether they are officers, directors, or employees. Holding individuals personally liable for their misconduct does not require piercing a corporate veil. Maryland law maintains that a corporation's officers and directors are jointly and severally liable for their misconduct.[51] Individuals are personally liable if: (a) they participated in the misconduct; or (b) they knew about the misconduct and failed to stop it; or (c) they should have known about the misconduct and they failed to stop it. In this case, the Purdue Individual Defendants made the decisions to break the law; they controlled the unfair and deceptive conduct; and they personally collected many millions of dollars from the deception.

[51] MD Corp & Assn Code §2-417

193. Each individual defendant knowingly and intentionally sent sales representatives to promote opioids to prescribers in Maryland thousands of times.

194. Each individual defendant knew and intended that the sales reps in Maryland would unfairly and deceptively promote opioid sales that are risky for patients, including by:

- falsely blaming the dangers of opioids on patients instead of the addictive drugs;
- pushing opioids for elderly patients, without properly disclosing the higher risks;
- pushing opioids for patients who had never taken them before, without disclosing the higher risks;
- pushing opioids as substitutes for safer medications, with improper comparative claims;
- falsely assuring doctors and patients that reformulated OxyContin was so safe;
- pushing doctors and patients to use higher doses of opioids, without disclosing the higher risks;
- pushing doctors and patients to use opioids for longer periods of time, without disclosing the higher risks; and
- pushing opioid prescriptions by doctors that Purdue knew were writing dangerous prescriptions.

195. Each individual defendant knew and intended that the sales representatives would not tell doctors and patients in Maryland and Carroll County about the truth about Purdue's opioids. Indeed, they knew and intended these unfair and deceptive tactics achieved their purpose by concealing the truth.

196. Each individual defendant knew and intended that prescribers, pharmacists, and patients in Maryland would rely on Purdue's deceptive sales campaign to prescribe, dispense, and take Purdue opioids. Securing that reliance was the purpose of the sales campaign.

197. Each individual defendant knew and intended that staff reporting to them would pay top prescribers tens of thousands of dollars to encourage other doctors to write

dangerous prescriptions across the State of Maryland as well as in Carroll County.

198. Each individual defendant knew and intended that staff reporting to them would reinforce these misleading acts through thousands of additional acts in Carroll County including by sending deceptive publications to Plaintiff's local doctors and deceptively promoting Purdue opioids at Plaintiff's local healthcare facilities and other institutions.

199. Each individual defendant knew and intended that staff reporting to them would reinforce these misleading acts through thousands of additional acts in Maryland, including by sending deceptive publications to Maryland doctors and deceptively promoting Purdue's opioids in Carroll County.

200. Each individual defendant knowingly and intentionally took money from Purdue's deceptive business in Maryland.

201. Each individual defendant knowingly and intentionally sought to conceal his or her misconduct.

1. Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler

202. The opioid epidemic can be largely traced back to eight people in a single family—the Sacklers—who made decisions for their own pecuniary benefit that caused much of the opioid epidemic. The Sackler family owns Purdue, and has always held a majority of the seats on its Board. They controlled their own privately held drug company, and as a result, the Sacklers had the power to decide how their addictive narcotics were sold. They hired hundreds of workers to carry out their plan, and they fired those who failed to sell enough drugs. They got more patients on opioids, at higher doses, and for longer, than ever before. And to reward themselves, they paid themselves billions of dollars. They should be held accountable now.

2. The Sacklers' Misconduct Leading To The 2007 Judgment

203. The misconduct of Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler was neither new, nor accidental. Indeed, it was particularly unfair, deceptive, unreasonable, and unlawful because they already had been given a second chance. From the 1990s until 2007, they presided over a decade of illegal and immoral conduct, which led to criminal convictions, a judgment of this Court, and commitments that Purdue would not deceive doctors and patients again. That background confirms that their subsequent and sustained misconduct was knowing and intentional.

204. Purdue Frederick Company, the Sacklers' first drug company, was purchased by them in 1952. In 1990, they created Purdue Pharma Inc. and Purdue Pharma L.P. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler took seats on the Board.[52] For events before July 2012, this Complaint uses "the Sacklers" to refer to them. David Sackler joined the Board in July 2012. From that time forward, "the Sacklers" includes him as well.

205. The Sacklers insisted that the family control Purdue at all times. From 1990 until today, the family has consistently held the majority of seats on the Board. In 1994, Jonathan Sackler issued a memorandum to Purdue staff requiring that the Sacklers should receive "all Quarterly Reports and any other reports directed to the Board."

206. Purdue launched OxyContin in 1996. It quickly earned the superlative "honor" of becoming one of the deadliest drugs of all time. The FDA scientist, Curtis Wright, who evaluated OxyContin wrote in his original review: "Care should be taken to

[52] Purdue Pharma Inc.'s 1991 filings with the Secretary of State of Connecticut state that it was incorporated in New York on October 2, 1990. Richard, Ilene, Jonathan, and Kathe Sackler are all listed as directors on the earliest (1991) report. Beverly, Mortimer, and Theresa all appear on the 1995 report. (*See* The Office of Secretary of State Denise W. Merill, https://www.concord-sots.ct.gov/CONCORD/online?sn=PublicInquiry&eid=9740.)

limit competitive promotion."[53] The Sacklers disagreed.

207. The Sacklers were—and have always been—behind Purdue's decision to deceive doctors and patients about the risks and benefits of Purdue's opioids. In 1997, Richard Sackler, Kathe Sackler, and other Purdue executives determined that doctors had the beneficial but crucial misconception that OxyContin was weaker than morphine, which led them to prescribe OxyContin much more often, even as a substitute for Tylenol. The truth was that OxyContin is more potent than morphine. Richard directed Purdue staff not to tell doctors the truth, because the truth would reduce OxyContin sales.

208. In 1999, Richard Sackler became the President of Purdue. Jonathan, Kathe, and Mortimer were Vice Presidents. The company hired hundreds of sales representatives and taught them all the false claims they would need to sell drugs. Purdue managers tested the sales representatives on the most important false statements during training at company headquarters. On the crucial issue of addiction, which would destroy so many lives, Purdue trained its sales representatives to deceive doctors by insisting that the risk of addiction was "less than one percent."[54] In February of 2001, a federal prosecutor reported 59 deaths from OxyContin in a single state. Meanwhile, Richard Sackler came up with Purdue's plan to blame and stigmatize people who become addicted to opioids. Sackler wrote, "We have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals."

209. The Sacklers delighted in their success by landing on the front page of the *New York Times* which reported that "OxyContin's sales have hit $1 billion, more than even Viagra's." The only dark spot? The article reported that "OxyContin has been a factor in the deaths of at least 120 people, and medical examiners are still counting."[55]

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[53] Curtis Wright, ultimately approved OxyContin for wide use. Shortly after approval, he left the FDA, joining Purdue within two years of his departure.

[54] Barry Meier, *Pain Killer* (1 ed. 2003) at 99.

[55] Meier, Barry, *Sales of Painkiller Grew Rapidly, But Success Brought a High Cost* (March 5, 2001) https://www.nytimes.com/2001/03/05/business/sales-of-painkiller-grew-

210. When *Time* magazine published an article about OxyContin deaths, Purdue employees told Richard Sackler they were worried. Richard responded with his thematic message to the staff: *Time*'s coverage of people who lost their lives to OxyContin was not "balanced," and the deaths were the fault of "the drug addicts," instead of Purdue. "We intend to stay the course and speak out for people in pain—who far outnumber the drug addicts abusing our product."

211. Meanwhile, Purdue kept pushing opioids and people kept dying. Soon, the company was engulfed in a wave of investigations by state attorneys general, the DEA, and the U.S. Department of Justice. In 2003, Richard Sackler left his position as President of Purdue. After a few more years of investigation, Jonathan, Kathe, and Mortimer Sackler resigned from their positions as Vice Presidents. But those resignations were superficial. The Sacklers remained in control of the company and continued to direct Purdue's deceptive marketing campaign.

212. By 2006, prosecutors found damning evidence that Purdue intentionally deceived doctors and patients about its opioids.[56] In May 2007, The Purdue Frederick Company confessed to a felony and effectively went out of business. However, the Sacklers continued their opioid business in two other companies: Purdue Pharma Inc. and Purdue Pharma L.P.

213. The Sacklers voted to admit in an Agreed Statement of Facts that, for more than six years, supervisors and employees *intentionally* used to deceive doctors about OxyContin: "Beginning on or about December 12, 1995, and continuing until on or about June 30, 2000, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and

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rapidly-but-success-brought-a-high-cost.html

[56] U.S. Department of Justice, *Statement of U.S. Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executes for Illegally Misbranding OxyContin* (Oct. 25, 2006), https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf

diversion, and less likely to cause tolerance and withdrawal than other pain medications."[57]

214. The Sacklers entered into a plea agreement that stated: "Purdue is pleading guilty as described above because Purdue is in fact guilty."[58] Those intentional violations of the law happened while Richard Sackler was President; Jonathan, Kathe, and Mortimer were Vice Presidents; and Richard, Jonathan, Kathe, Mortimer, Ilene, Beverly, and Theresa Sackler were all on the Board.

215. The Sacklers also voted for Purdue to enter a Corporate Integrity Agreement with the U.S. government. The agreement required the Sacklers to ensure that Purdue did not deceive doctors and patients again. As part of the agreement, the family promised to comply with rules that prohibit deception about Purdue opioids. They were required to complete hours of training to ensure that they understood the rules. They were required to report any deception. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler each certified in writing to the government that he or she had read and understood the rules and would obey them.[59]

216. Finally, the Sacklers voted to enter into a Consent Judgment in this Court ("2007 Judgment"). The 2007 Judgment ordered that Purdue "shall not make any written or oral claim that is false, misleading, or deceptive" in the promotion or marketing of OxyContin. The judgment further required that Purdue provide balance regarding risks and benefits in all promotion of OxyContin. That judgment required balance in presentation of the risks of taking higher doses for longer periods and the risks of addiction, overdose, and death.[60]

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[57] *See, e.g.*, Attachment B to Plea Agreement in *United States v. The Purdue Frederick Co., Inc.*, Case No. 1:07-cr-00029-JPJ: Purdue Agreed Statement of Facts, ("PASF") at ¶20.

[58] 2007-05-09 Plea Agreement. https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf

[59] 2007-05-09 Plea Agreement. https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf

[60] 2007-05-15 Consent Judgment, *Commonwealth v. Purdue Pharma L.P. et al.*, No. 07-

217. The 2007 Judgment also required that Purdue establish and follow an abuse and diversion detection program to identify high-prescribing doctors who show signs of inappropriate prescribing, stop promoting drugs to them, and report them to the authorities:

> "Upon identification of potential abuse or diversion," Purdue must conduct an inquiry and take appropriate action, "which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities."[61]

218. The 2007 Judgment and related agreements should have ended the Sacklers' misconduct for good. Instead, the Sacklers decided to expand their deceptive sales campaign to make more money from more patients on more dangerous doses of opioids.

3. The Sacklers Continue Their Misconduct From The 2007 Judgment

219. From the 2007 Judgment to 2018, the Sackler family controlled Purdue's deceptive sales campaign. They directed the company to hire hundreds more sales representatives to visit doctors thousands more times than they otherwise could. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied and adopted unlawful tactics to keep patients on opioids longer and then ordered staff to use them. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. The family was well informed: They sometimes demanded more detail than anyone else in the entire company, so staff had to create special reports just for them. Richard Sackler even went into the field to promote opioids to doctors and supervise representatives face-to-face.

1967(B), Mass. Super. Ct.

[61] *Id*.

220. The Sacklers' iron rule impacted everyone in the company from the top down. When they berated sales managers, the managers turned around and passed angry messages to the sales representatives in the field. When Richard Sackler complained to sales managers, sales managers threatened their sales representatives with termination.

221. In July 2007, staff informed the Sacklers that more than 5,000 cases of "adverse events" had been reported to Purdue in just the first three months of 2007. Staff also told the Sacklers that Purdue received 572 "Reports of Concern" about abuse and diversion of Purdue opioids during Q2 2007. Shockingly, staff reported to the Sacklers that they completed only 21 field inquiries in response to these reports. Staff also told the Sacklers that they received more than 100 calls to Purdue's compliance hotline during the quarter, which was a "significant increase," but Purdue did not report any of the hotline calls or Reports of Concern to the FDA, DEA, Department of Justice, or state authorities.

222. Purdue's intentional failure to report abuse and diversion continued unabated, even though the 2007 Judgment required Purdue to report "potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities." Instead of reporting dangerous prescribers, or even directing sales representatives to stop visiting them, the Sacklers chose to keep pushing opioids to whoever prescribed the most.

223. The Sacklers were further aware that Purdue staff members continued to mail out thousands of deceptive marketing materials. The single most-distributed material was volume #1 of Purdue's "*Focused and Customized Education Topic Selections in Pain Management*" (FACETS). In FACETS, Purdue falsely instructed doctors and patients that physical dependence on opioids is not dangerous and instead improves patients' "quality of life." In the same material, Purdue also falsely told doctors and patients that signs of addiction are actually "pseudoaddiction," and that doctors should respond by prescribing more opioids. Staff told the Sacklers that another of the publications they had sent most often to doctors was "*Complexities in Caring for People in Pain*." In it, Purdue repeated again its false claim that warning signs of addiction are really "pseudoaddiction" that

should be treated in the worse way possible: with more opioids.

224. At the same time, Purdue was making more money than expected. A few months earlier, there had been a projected profit of $407,000,000; now it expected more than $600,000,000. The Sacklers had every reason to know that Purdue employed 301 sales representatives to promote opioids and that sales representatives were the largest group of Purdue employees by far. In comparison, Purdue employed only 34 people in drug discovery.

225. As a result of Purdue's overwhelming number of sales representatives—which varied from a low of 300 representatives in mid-2007 to a peak of over 700 representatives in 2015—the impact of Purdue on Maryland and Carroll County was significant and direct—from the 2007 felony conviction to 2018, Purdue sales representatives visited Plaintiff's local prescribers regularly.

226. In August of 2007, Howard Udell was serving as Purdue's top lawyer, even after his 2007 criminal conviction for assisting Purdue in misleading doctors and patients by claiming that OxyContin was less prone to abuse than similar drugs. He warned the Sacklers about the negative press OxyContin was receiving.

227. In October of 2007, the Sacklers learned that Purdue received 284 Reports of Concern about abuse and diversion of Purdue's opioids in Q3 2007, and they conducted only 46 field inquiries in response. Moreover, they received 39 tips to Purdue's compliance hotline during the quarter, but Purdue did not report any of them to the authorities.

228. By late 2007, Purdue expected to collect more than half its total revenue from sales of 80mg OxyContin—its most powerful, most profitable, and most dangerous pill.

229. In January 2008, the Sacklers had every reason to know that Purdue still employed 304 sales representatives and they were succeeding at the goal of promoting higher doses of opioids. Purdue's net sales were just over $1 billion in 2007, almost double what the company had projected. OxyContin accounted for more than 90% of those sales.

230. Purdue received 689 Reports of Concern about abuse and diversion of

Purdue's opioids in Q4 2007, and they conducted only 21 field inquiries in response. Purdue received 83 tips to Purdue's compliance hotline during the quarter, but Purdue did not report any of them to the authorities. The Sacklers did nothing to comply with their obligations.

231. Instead of complying with their legal obligations, the Sacklers wanted more details on tactics for pushing sales, including the distribution and use of savings cards for Purdue opioids.

232. The Sacklers made it a point to become personally involved in various decision-making process of the company, ranging from selling opioids door-to-door and arranging in-person visits to doctor's offices and hospitals, to pressuring Purdue's sales forces to increase orders—whatever the cost.

233. The Sacklers also ensured that their top-performing sales representatives were rewarded. For example, top sales representatives were rewarded with bonuses and lavish, all-expense-paid vacations to tropical islands, hoping all the while that Purdue's relatively less productive sales representatives would hone in on the perks of increasing their sales, and ignore the clear risks of pushing higher doses of Purdue's opioids on vulnerable patients.

234. By 2008, Purdue was working on a crush-proof reformulation of OxyContin to extend Purdue's patent monopoly. The Sacklers learned that another company was planning clinical research to test whether crush-proof opioids were actually safer for patients. The Sacklers decided not to do the research because they wanted the profits from a new product.

235. In March of 2008, Richard Sackler focused on Purdue's strategy for selling more OxyContin. In response to clear indications that Purdue's VP of Sales, Russell Gasdia, had doubts about the company's increasingly aggressive sales tactics, Richard Sackler immediately ramped up the pressure, both pushing staff to sell more of the highest doses of opioids and get more pills in each prescription, as well as seeking to identify tactics

for exceeding prior sales numbers. Under Sackler's direction, Purdue began preparing plans for how adding sales representatives, opioid savings cards, and promoting more intermediate doses of OxyContin could help increase sales.

236. Staff told these Sacklers that they would use opioid savings cards to meet the challenge of keeping OxyContin scripts at the same level in 2008 as in 2007.

237. In April of 2008, staff told the Sacklers that Purdue employed 304 sales representatives and that the representatives had obtained data showing which pharmacies stocked higher strengths of OxyContin, which helped them convince area doctors to prescribe the highest doses. At that time, the Sacklers learned that Purdue received 853 Reports of Concern about abuse and diversion of Purdue opioids in Q1 2008, and they had conducted only 17 field inquiries in response. Staff also reported to the Sacklers that they received 83 tips to Purdue's compliance hotline during the quarter, but did not report any of them to the authorities.

238. On April 18, 2008, Richard Sackler felt it important to install a CEO who would be loyal to the family. He recommended John Stewart for the position because of his loyalty. Richard also proposed that the family should either sell Purdue in 2008 or, if they could not find a buyer, milk the profits out of the business and "distribute more free cash flow" to themselves.

239. When the Sacklers directed Purdue to pay their family, they knew and intended that they were paying themselves from opioid sales in Maryland. Purdue and the Sacklers tracked revenue and staff reported to the Sacklers that prescriptions of Purdue's highest doses provided seven-figure revenues per year and represented a significant percentage of Purdue's overall revenues from high-dose opioids.

240. In May of 2008, the Sacklers received more ideas from Purdue staff about ways to promote Purdue's opioids. One strategy that particularly pleased the Sacklers was to deflect blame from Purdue's addictive drugs by stigmatizing people who become addicted. "KEY MESSAGES THAT WORK" included this dangerous lie: "It's not

addiction, it's abuse. It's about personal responsibility." This blame-the-victim approach has characterized the Sacklers' response to the opioid crisis they helped create.

241. Meanwhile, Richard Sackler pushed Purdue's opioid savings cards. 67,951 patients had used Purdue's opioid savings cards, and that the cards provided a discount on a patient's first five prescriptions. Predictably, after five prescriptions, many patients would face significant withdrawal symptoms if they tried to stop taking opioids. 27% of patients (more than 18,000 people) had used the cards for all five prescriptions.

242. In July of 2008, Purdue's Fleet Department reported to the Sacklers that Purdue had bought one hundred new Pontiac Vibes for the expanded sales force. Staff also told the Sacklers that Purdue received 890 Reports of Concern regarding abuse and diversion of Purdue's opioids in Q2 2008 and had conducted only 25 field inquiries in response. Staff reported to the Sacklers that they received 93 tips to Purdue's compliance hotline during the quarter, but did not report any of them to the authorities.

243. Staff also told the Sacklers that they promoted Purdue opioids in various presentations, which echoed the company's messaging from presentations such as "*The Assessment and Management of Chronic Pain with an Emphasis on the Appropriate Use of Opioid Analgesics*" and "*The Role of Urine Drug and other Biofluid Assays in Pain Management*." Through these presentations, the Sacklers intentionally ensured that a dangerous (and false) message would be disseminated to Maryland doctors and elsewhere—*i.e.*, Purdue opioids were the best way to manage chronic pain and that urine tests protected patients from addiction were both part of Purdue's unfair and deceptive scheme.

244. In October of 2008, surveillance data monitored by Purdue indicated a "wide geographic dispersion" of abuse and diversion of OxyContin "throughout the United States." The Sacklers learned that "availability of the product" and "prescribing practices" were key factors driving abuse and diversion of OxyContin. On the same day, Purdue had begun a new "Toppers Club sales contest" for sales representatives to win bonuses, based

on how much a representative increased OxyContin use in her territory and how much the representative increased the broader prescribing of opioids—the same "availability of product" and "prescribing practices" factors that worsen the risk of diversion and abuse. Purdue also knew it received 163 tips to Purdue's compliance hotline during Q3 2008, but did not report any of them to the authorities.

245. To the contrary, the Sacklers decided to expand Purdue's sales forces, which effectively increased both the number of in-person visits to Maryland prescribers, as well as the disastrous consequences that would follow.

246. The Sacklers wanted to hire a new staff member who would contact prescribers electronically and would promote Purdue opioids through the deceptive website, *Partners Against Pain*.

247. Purdue received 122 tips to Purdue's compliance hotline during the first quarter of 2009, one of which was from an outside monitor. The Sacklers did nothing to stop the compliance problems, including the improper use of OxyContin marketing materials and opioid savings cards.

248. In addition to disregarding non-compliance, the Sacklers further instructed Purdue management to disregard supervision requirements under federal law mandating that—in order to mitigate the high risk of misconduct by sales representatives—Purdue managers needed to supervise sales representatives in-person at least five days each year.[62]

249. Still, the Sacklers and Purdue created new sales territories and expanded sales staff. The expansion was focused on the most prolific opioid prescribers, because "there are a significant number of the top prescribers" that Purdue had not been able to visit with its smaller force of sales representatives.

250. By July of 2009, Purdue employed 429 sales representatives. Richard Sackler was not satisfied with that number, wanting more.

[62] Purdue Corporate Integrity Agreement, section III.K.

251. By August of 2009, the 80mg OxyContin pill was far-and-away Purdue's best performing drug. Purdue sold many more kilograms of active ingredient in the 80mg dose than any other dose (about 1,000 kilograms: literally a ton of oxycodone).

252. Purdue and the Sacklers reviewed their newest OxyContin sales campaign, with the slogan: *Options*. The *Options* campaign exemplified the strategy that Purdue would follow for years to come—pushing doctors and patients up the ladder to higher doses. To make it easy for sales representatives to promote higher doses, suggesting that doctors could or should adjust the patient's dose as frequently as every one-to-two days. They planned to advertise the *Options* campaign in medical journals reaching 245,000 doctors.

253. By 2009, more than 160,000 patients had used Purdue's opioid savings cards, more than doubling the result reported to the Sacklers the summer before. Purdue and the Sacklers also decided to advertise OxyContin using a special television network and that thousands of doctors would be given free digital video recorders for their home televisions, in exchange for watching advertisements for drugs.

254. As set forth throughout this Complaint, the Purdue Individual Defendants paved the way for the opioid epidemic in Carroll County by organizing and ensuring the execution of an intentional, underhanded strategy to combine strong-arm sales tactics with misrepresentation about the benefits and risks of Purdue's opioids. The Sacklers accomplished their goal through not only their individual and combined actions, but also through the actions of their executive-agents, including Peter Boer, Judith Lewent, Cecil Pickett, Paulo Costa, Ralph Snyderman, John Stewart, Russel Gasdia, Mark Timney, and Craig Landau. And they did so while making themselves extraordinarily wealthy. Ultimately a single family, the Sacklers drove much of the opioid epidemic, at the expense of Carroll County, Maryland, as well as the entire nation.

J. John Kapoor and Michael Babich Led Insys's Misconduct

255. John Kapoor ("Kapoor"), the founder and majority owner of Insys, and

Michael Babich ("Babich"), the former CEO and President of Insys, led a nationwide conspiracy to profit using bribes and fraud to cause the illegal distribution of Subsys.

256. Kapoor and Babich conspired to bribe practitioners in various states, including in Maryland, many of whom operated pain clinics, in order to get them to prescribe Subsys. In exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for patients, many of whom were not diagnosed with cancer, and therefore did not need Subsys.

257. Kapoor and Babich also conspired to mislead and defraud health insurance providers who were reluctant to approve payment for the drug when it was prescribed for non-cancer patients. They achieved this goal by setting up a "reimbursement unit" which was dedicated to obtaining prior authorization directly from insurers and pharmacy benefit managers.

258. Kapoor and Babich fueled the opioid epidemic by paying doctors to needlessly prescribe Subsys for patients who did not need it, and without complying with FDA requirements, thus putting patients at risk and contributing to the current opioid crisis. Kapoor and Babich committed fraud, placing profit before patient safety, to sell a highly potent and addictive opioid.

K. Distributor Defendants' Violation of Duty

259. Distributor Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

260. Specifically, under the Code of Maryland Regulations 10.19.03.03, manufacturers, distributors, and dispensers are required to monitor and report suspicious orders of "controlled dangerous substances" and register with the Maryland Department of Health. Each of the Manufacturer and Distributor Defendants are obligated to monitor and

report suspicious orders of controlled substances, especially opioids. Additionally, pursuant to Code of Maryland Regulations 10.19.03.12, all such "registrants" are required to "guard against theft and unlawful diversion of controlled substances" and importing the security requirements set forth.

L. Distributor Defendants Knew or should have Known they were Facilitating Widespread Opioid Diversion

261. Opioid diversion in the supply chain has always been a widespread problem and has been highly publicized. Numerous publications, studies, federal agencies, Maryland agencies, and professional health organizations have highlighted the epidemic rate of opioid abuse and overdose rates in Carroll County, as well as throughout the United States.

262. Prescription drug abuse is the fastest-growing drug problem in the United States, and particularly in Maryland.

263. To combat the problem of opioid diversion, the DEA has provided guidance to distributors on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions.

264. Since 2006, the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, their due diligence responsibilities, and their legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA). The DEA provided distributors with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The distributors were also given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA pointed out "red flags" distributors should look for in order to identify potential diversion. This initiative was created to help distributors understand their duties with respect to diversion control.

265. Since 2007, the DEA has hosted at least five conferences to provide registrants with updated information about diversion trends and regulatory changes that affect the drug supply chain, the distributor initiative, and suspicious order reporting. Both of the Distributor Defendants - AmerisourceBergen and Cardinal Health—attended at least one of these conferences. The conferences allowed the registrants to ask questions and raise concerns. These registrants could also request clarification on DEA policies and procedures.

266. Since 2008, the DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association ("HDMA"), now known as the Healthcare Distribution Alliance ("HDA"), an industry trade association for wholesalers and distributors. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances.[63] (HDMA, "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," (2008).

267. On September 27, 2006 and again on December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion. These letters reminded registrants that they were required by law to exercise due diligence to avoid filling orders that may be diverted into the illicit market. These letters explained that as part of the legal

[63] *See*, *e.g.*, HDA.org, Issues in Distribution, *Prescription Drug Abuse and Diversion* (2018) (describing various resources "address[ing] the industry's approach to countering diversion and ensuring the safe supply of medicines to licensed entities across the supply chain"), https://www.hda.org/issues/prescription-drug-abuse-and-diversion

obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of all orders prior to filling.

268. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The December 2007 letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious order prior to the sale to determine if controlled substances would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility.

269. The Distributor Defendants were on notice that their own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" that stressed the critical role of each member of the supply chain in distributing controlled substances.

270. Opioid distributors themselves recognized the magnitude of the problem and, at least rhetorically, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

271. For example, a Cardinal executive recently claimed that it uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

272. These assurances, in addition to obligations imposed by law, show that Distributor Defendants understand and have undertaken a duty to protect the public against diversion from their supply chains, and to curb the opioid epidemic.

273. However, despite these statements and duties, Distributor Defendants have knowingly or negligently allowed diversion. Their misconduct has resulted in numerous civil fines and other penalties recovered by state and federal agencies, including actions by the DEA.

274. In 2008, Cardinal Health paid a $34 million penalty to settle allegations about opioid diversion taking place at seven warehouses around the United States. Again in 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. Even very recently, in December 2016, a Department of Justice press release announced that, in connection with CSA violations, the United States reached a $34 million settlement for civil penalties under the CSA. During the investigation of Cardinal, the DEA discovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Florida that was suspected of opioid diversion. Cardinal took no action and failed to notify the DEA or cut off the supply of drugs to the pharmacy. Instead, Cardinal's opioid shipments to the pharmacy increased to almost 2 million doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

275. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against the diversion of particular controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

276. Although these Distributor Defendants have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as

a cost of doing business in an industry which generates billions of dollars in revenue.

277. Plaintiff does not bring causes of action based on violations of federal statutes and regulations. However, the existence of these complicated regulatory schemes shows Defendants' intimate knowledge of the dangers of diversion of prescription opioids and the existence of a thriving illicit market for these drugs. Defendants breached their duties to Plaintiff despite this knowledge and longstanding regulatory guidance of how to deter and prevent diversion of prescription opioids.

M. Each of the Defendant's Misconduct Has Injured and Continues to Injure Carroll County and Its Citizens

278. In addition to the significant social costs associated with illicit drug use, Defendants' predatory and willful misrepresentations in manufacturing, marketing and/or distributing opioids have imposed enormous tax-based economic damages on Carroll County, including tax revenue expended for various public services Carroll County is required to provide to its citizens under Maryland law, including healthcare and crime-related costs, as well as for special programs and services aimed at addressing and combating Carroll County's opioid crisis on its own accord. These revenues would not have been expended but for the opioid crisis that Defendants willfully and foreseeably caused in Maryland generally and Carroll County specifically.

279. Carroll County officials have regularly kept their citizens informed of the devastating effects of the opioid epidemic and the efforts the County has taken to combat these issues in a series of press releases. For example:

- On March 24, 2015, Carroll County issued a press release proposing that the County implement an aggressive initiative to attack the drug and heroin overdose problems in its community. In the release, Commissioner Doug Howard stated: "Illegal drugs in our community are a threat to our economic development, our school system, our children, and our way of life. We must address this issue with a serious commitment of resources and the resolve to

see it through." "The program will cost [Carroll] County approximately 2.2 million dollars; with approximately $400,000 in start-up costs for equipment, vehicles, uniforms, and training, and another $600,000 a year for 3 years, for manpower and fringe benefits. The program will create 8 new positions (5 officers in the Sheriff's Office and 3 dedicated personnel in the State's Attorney's Office.)"[64]

- On August 7, 2015, Carroll County issued a press release informing its residents about an upcoming roundtable discussion regarding the next steps in implementing an aggressive initiative to attack the drug and heroin overdose problems in Carroll County.[65]
- On July 19, 2016, the Carroll County Health Department issued a press release inviting the public to attend a Town Hall meeting entitled "From Pills to Street Drugs: The Heroin Epidemic."[66] This meeting allowed residents to ask questions and share stories about their own experiences with heroin and opioids and to encourage its residents to join the ongoing discussion about Carroll County's efforts to combat the ever-evolving opioid drug problem.
- On December 30, 2016, the Carroll County Board of Commissioners issued a press release addressing a final list of Carroll County long-term goals, one of which included the County's efforts to combat drug abuse through

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[64] Carroll County Press Release, *Commissioners' Drug Enforcement Support Program* (Mar. 24, 2015), http://ccgovernment.carr.org/ccg/releases/Drug%20Presentation.pdf?x=1562717973662

[65] Carroll County, MD Press Release, *Drug Enforcement Roundtable* (Aug. 7, 2015), http://ccgovernment.carr.org/ccg/releases/Drug%20Enforcement%20Roundtable%20Scheduled.pdf?x=1562717914827

[66] Carroll County, MD Press Release, *Residents Invited to Participate in Town Hall Meeting about Drugs* (Jul. 19, 2016), http://ccgovernment.carr.org/ccg/releases/Press%20release%20Town%20Hall%20meeting%20heroin%206.27.16.pdf?x=1562717527055

education, treatment, and enforcement.[67]

- On January 27, 2017, the Carroll County Health Department issued a press release alerting its residents that "**seven drug overdoses…occurred today**, Friday, January 27, 2017, between 10:00 a.m. and 12 noon. So many overdoses in a short period of time often indicates that the illegal or prescription drugs currently being sold are very potent and more likely to cause an overdose." [Emphasis added].[68]
- On June 8, 2017, the Carroll County Health Department issued a press release "alerting the community that there ha[d] been an **increase in opioid overdoses** [that] week in Maryland and in other parts of the country. This could be due to a number of causes, but such spikes are often related to heroin laced with fentanyl or carfentanil…**The pills are disguised to look like frequently-prescribed and commonly abused medications such as…oxycodone**." [Emphasis added].[69] The press release also provided information regarding the "signs of an opioid overdose," how to properly administer naloxone, and further information regarding Maryland's Good Samaritan Law, drug treatment resources, and free opioid overdose rescue training with Naloxone provided by the Access Carroll program.
- On November 1, 2018, the Carroll County Board of Commissioners issued a press release informing its residents that over $100,000 had been voted on to

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[67] Carroll County, MD Press Release, *Carroll County Board of Commissioners Approve Long Term Goals* (Dec. 30, 2016), http://ccgovernment.carr.org/ccg/releases/Goals%2012.28.16.pdf?x=1562717292943

[68] Carroll County, MD Press Release, *Community Overdose Alert* (Jan. 27, 2017), http://ccgovernment.carr.org/ccg/releases/CCHD%20press%20release%20overdoses%201.27.17.pdf?x=1562713679516

[69] Carroll County, MD Press Release, *Opioid Alert* (Jun. 8, 2017), http://ccgovernment.carr.org/ccg/releases/CCHD%20press%20release%20opioid%20alert%206.8.17.pdf?x=1562713579191

be allocated to programs supporting opioid prevention issues.[70] Commissioner Dennis Frazier, District 3, stated that "these four programs represent an excellent multi-tiered strategy to expand our tools for fighting opioid addiction in Carroll County." The four approved programs were:

(1) Sources of Strength Program: An evidence-based peer leadership program, initiated by Carroll County Public Schools, to develop relationships among students and adults;

(2) Behavioral Health Resource Guide: A guide developed by the Partnership for a Healthier Carroll County and community partners to be widely utilized by emergency medical services, law enforcement, providers, CCPS, and other community partners;

(3) Pilot Street Smart Program in Westminster Boys and Girls Club: Programming related to the prevention of risky behaviors which will be used to develop a local curriculum to expand programs in the areas of prevention; and

(4) Vehicle for Youth Service Bureau: Funding to purchase an additional vehicle to help the Carroll County Youth Service Bureau's Assertive Community Treatment team to provide comprehensive, recovery-oriented, mental health/substance use treatment to individuals with severe and persistent mental illness.

280. More recently, in February 2019, the Carroll County Health Department reported between four and six overdoses over a single weekend due to opioid use.[71]

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[70] Carroll County, MD Press Release, *Commissioners Allocate $108K for Opioid Programs* (Nov. 1, 2018), http://ccgovernment.carr.org/ccg/releases/OpioidAllocation11.1.18%20(2).pdf?x=1562710169031

[71] Kelvey, Jon, Carroll County Times, *Carroll County Health Department issues opioid alert after at least four people overdose over weekend* (Feb. 11, 2019),

281. As Defendants' opioids continue to wreak havoc on Carroll County's community and incapacitate and/or kill Carroll County's citizens, Carroll County has also been deprived of the benefits these citizens would have conferred to Carroll County's community but for Defendants' wrongful conduct. Carroll County has lost both the productivity of Carroll County's citizens who have been hospitalized, incarcerated, killed, or otherwise incapacitated by Defendants' dangerous products, including the property and/or sales taxes these citizens would have paid had Defendants simply told the truth about the risks and benefits of opioids.

1. Tax Revenue Expended—Healthcare-Related Costs

282. While Defendants reaped billions of dollars in profits from their deceptive conduct, Carroll County has suffered—and continues to suffer—irreparable damage in the form of increased healthcare-related costs, which Maryland law requires that Carroll County pay to protect the health and safety of its citizenry. Carroll County would not have incurred these costs had Defendants not concealed the dangers (and misrepresented the benefits) of the relevant opioids.

283. In particular, each of the Defendants has directly and proximately caused Carroll County to divert precious tax dollars and local resources from Carroll County's general and special revenue funds, in order to address its citizens' ever-increasing need for county-funded, opioid-related health services, including: (a) hospital and emergency services; and (b) specialty treatment and health and human services—e.g., mental health treatment, family counseling, drug education, rehabilitation, etc. These services are provided and arranged by the Carroll County Health Department which depends on Plaintiff's general and special revenues in order to meet the medical needs of its residents.

284. Carroll County also makes financial contributions from its Special Revenue Funds to provide its citizens with several healthcare services as described below. These

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https://www.baltimoresun.com/maryland/carroll/news/cc-2019-overdoses-alert-20190211-story.html

programs are geared toward particularly vulnerable populations—such as the elderly and low-income persons, as well as individuals suffering from certain disabilities or other serious medical conditions.

(b) Emergency Medical Treatment—Opioid-Related Emergencies

285. In 2017, Maryland had the nation's highest rate of hospitalizations for opioid use, according to federal data that illustrates the depth of the addiction problem in a state where many people have died from overdoses of the drugs.[72] Between 2010 to 2015, there were approximately 2,531.1 inpatient stays resulting from opioid use per 100,000 people compared to the 1,304.9 figure reflecting opioid-related inpatient stays across the United States.[73] It is clear that opioids have a significant impact upon Maryland's medical care system due to the volume of encounters involving opioids, and the costs of these encounters. While the full economic burden of opioids upon the healthcare system is difficult to precisely calculate, a reasonable measure may be derived using emergency department visits and charges provided by the Maryland Department of Health and Mental Hygiene. In 2014, there were 1,564 heroin-related emergency department visits in Maryland.[74] Using this approach, the cost of 1,564 heroin-related emergency department visits totaled $1.55 million dollars.[75] Thus, in 2014, the average cost per heroin-related emergency department visit in Maryland amounted to approximately $991. In 2014, there

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[72] Cohn, Meredith, The Baltimore Sun, *Opioid users filling Maryland hospital beds and emergency rooms* (Jan. 6, 2017), https://www.baltimoresun.com/health/bs-hs-opioid-hospitalizations-20170106-story.html

[73] amfAR, Opioid & Health Indicators Database, *Maryland Opioid Epidemic*, https://opioid.amfar.org/MD

[74] Maryland Department of Health and Mental Hygiene, *Data Report, Drug and Alcohol-Related Emergency Department Visits in Maryland 2008-2014* (Sep. 2015), p. 39, https://bha.health.maryland.gov/OVERDOSE_PREVENTION/Documents/Drug%20and%20Alcohol-related%20ED%20Visits_2008-2014.pdf

[75] *Id*., at p. 43

were 1,101 prescription opioid-related emergency department visits in Maryland.[76] Using this approach, the cost of 1,101 prescription opioid-related emergency department visits totaled $1.5 million dollars.[77] Thus, in 2014, the average cost per prescription opioid-related emergency department visit in Maryland amounted to approximately $1,362.

286. On information and belief, the incidence of opioid-related hospitalizations in Carroll County—which can be tracked by various medical billing and documentation codes, such as the Healthcare Common Procedure Coding System ("HCPCS") and the American Medical Association's Current Procedural Terminology (CPT), including National Drug Codes (NDCs) and International Classification of Diseases ("ICD") codes—increased during the relevant period.

287. As the number of opioid-related hospital encounters in Carroll County has ballooned, the costs of treatment and supplies have also increased. This increase has strained—and continues to strain—Plaintiff's General and Special Revenue Funds, which provide necessary funding to respond appropriately to an increasingly large demand for opioid-related emergency medical services in Carroll County.

288. At the same time, the costs of providing 911 dispatch, fire services, emergency medical services, and other 911 services for opioid emergencies have likewise increased. Additionally, Carroll County regularly works with first responders to address burn out and compassion fatigue associated with the opioid epidemic by providing educational seminars, outreach, training on the importance of self-care, and hosting appreciation dinners where first responders are reunited with former opioid addicts that are now in recovery.

(b) Specialty Treatment and Health and Human Services

289. Defendants' actions that fueled the opioid crisis have also devastated many

[76] *Id.*, at p. 46

[77] *Id.*, at p. 50

families and individuals across the country and, specifically, in Carroll County, Maryland. In response, Plaintiff has provided, and continues to provide, a variety of services and programs to help protect the health, safety, and welfare of Carroll County's children, families, and individuals afflicted by the opioid epidemic which has caused Plaintiff to expend substantial resources on such programs and services as:

- **Not in Carroll:** The 60th Board of County Commissioners established the "Not in Carroll" initiative which is a comprehensive approach to address and combat the drug epidemic in Carroll County through education, treatment, law enforcement, and prosecution by providing annual, ongoing funding to the Sheriff's Office, State's Attorney's Office, and Youth Services Bureau.
- **Recovery Support Services:** This program provides Residential Support and Crisis Service programs for Carroll County individuals who have substance use or co-occurring substance use and mental health disorders, to improve their quality of life, and to foster self-sufficiency, dignity, and respect.
- **Access Carroll:** This program provides quality, integrated health care services for low-income residents of Carroll County. Due to the increase in opioid use within Carroll County, Access Carroll now offers daily Ambulatory Detox services and free opioid overdose rescue training with Naloxone.
- **Human Services Program:** This program offers Carroll County residents assistance with basic needs, advocacy, and links to resources with its services involving three main divisions: emergency assistance, housing and shelters for the homeless, and a family support center.
- **Mosaic Community Services:** This non-profit program is Carroll County's largest provider of mental health services to adults and older teens. Mosaic Community Services' two primary services include a mental health clinic

and group practice, as well as the Psychiatric Rehabilitation Program.

- **Youth Services Bureau:** This program provides a continuum of community-based mental health and substance abuse services for children, adults, and families in Carroll County. Some example of the many services provided by the Youth Services Bureau include: alcohol and substance abuse services, parenting education workshops, and interactive group therapy. From 2016-2019, this program has seen regular $75,000 increases in its funding and is planned to increase to a cumulative $500,000 in 2022.[78]

(c) County Tax Expenditures for Public Health Department Services

290. In addition to the many services offered to Carroll County's citizens as described above, the Carroll County Health Department's office of prevention and the nonprofit, Families Against the Stigma of Addiction, have sponsored screenings of the Carroll County-produced film, "Heroin Still Kills" at the Carroll County Public Library. [79] "Heroin Still Kills" is a contemporary revisit of "Heroin Kills," the original Carroll County-produced film created to address the slew of heroin overdoses in the late 1990s. "Heroin Still Kills" has been updated to include the salient features of the current opioid addiction epidemic, such as the risks of an addiction beginning with opioid pain medications.

291. As a direct, proximate result of the Defendants' misdeeds as described in this Complaint, Plaintiff's allocations to the Carroll County Health Department —which, *inter*

[78] Carroll County Maryland, Department of Management & Budget, Adopted Budget, Operating Budget Fiscal Year 2019, p. 196, https://ccgovernment.carr.org/ccg/budget/19-abudget/entire.pdf?x=1563308711333

[79] Kelvey, Jon, Carroll County Times, *Drug education film covering opioids, fentanyl and heroin to be screened at Taneytown library* (Apr. 6, 2019), https://www.baltimoresun.com/maryland/carroll/news/cc-heroin-kills-taneytown-story.html

alia, protects the health and safety of Plaintiff's citizenry by providing and arranging for health and social services—have increased significantly over the arc of the opioid epidemic in Carroll County.

2. Tax Revenue Expended—Crime-Related Costs

292. In addition to imposing on Plaintiff increasing healthcare-related costs, Defendants' scheme has spread thin Plaintiff's resources by causing a significant increase in crime-related costs, including those associated with opioid-related arrests, investigations, and other criminal justice programs. The funds necessary to maintain the day-to-day operating expenses and equipment for these services and programs come from Plaintiff's general and special revenues, including Plaintiff's revenues from Plaintiff's privilege (sales) taxes and property taxes.

(a) Arrests and Investigations to Protect Public Health and Safety

293. The effects of Defendants' deceptive marketing and distribution scheme has further impacted Plaintiff by creating various public nuisances—including public health and safety hazards—which Plaintiff is obligated to abate. Plaintiff has dedicated substantial tax dollars to maintain the public safety of places, such as community parks, schools and public lands, where patients-turned-addicts may congregate as well as mitigating the increase in drug and property crimes committed by opioid addicts who are both actively looking to feed their addictions, as well as suffering from serious medical conditions associated with the spread opioid abuse, such as Hepatitis B and C, HIV, sexually transmitted diseases and methicillin-resistant staphylococcus aureus ("MRSA"), among other conditions.

294. The Carroll County Sheriff's Department has expended funds and exerted effort to investigate and respond to opioid-related calls and crimes. Specifically, over the past 4 years, Carroll County has prioritized additional resources towards public safety to the tune of $6 million dollars for Sheriff Services alone, approximately a 32% increase

from prior years.[80] Further, Carroll County has incurred significant costs in training 44 officers as part of the "County In Crisis Intervention Team" which helps officers assess and deescalate potentially dangerous opioid-related calls, create behavioral health referrals, and link patients to resources. To become a member of the County In Crisis Intervention Team, officers must undergo 40 hours of training and are required to participate in two yearly refresher courses. Additionally, Carroll County has incurred significant costs due to an increase in the administration of Naloxone for emergency overdoses. From January 2019 to July 1, 2019, alone, Naloxone was administered approximately 20 times by the Carroll County Sheriff's Office.[81] In an effort to further educate its citizens on the increasing use of Naloxone/NARCAN in emergency overdose situations, Carroll County offers its residents free training courses at Plaintiff's expense through the Access Carroll program, as previously mentioned herein.

295. From January 2019 to July 1, 2019, alone, there have been at least 194 overdose cases that were investigated by the Carroll County Sheriff's Office.[82] At least 23 of these overdose calls resulted in death and approximately 56% of those deaths were opioid-related.[83]

296. In abating the opioid nuisance to protect the health and safety of citizens of Carroll County, Plaintiff has suffered pecuniary damages, proximately caused by Defendants' misrepresentations and omissions of material fact.

(b) Carroll County's Court System

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[80] Carroll County Maryland, Department of Management & Budget, Adopted Budget, Operating Budget Fiscal Year 2019, p. 8, https://ccgovernment.carr.org/ccg/budget/19-abudget/entire.pdf?x=1563308711333

[81] Carroll County Sheriff's Office, Carroll County Crime Analysis Unit, *2019-2nd Qtr Overdose Report* (Jul. 3, 2019).

[82] Carroll County Sheriff's Office, Carroll County Crime Analysis Unit, *2019-2nd Qtr Overdose Report* (Jul. 3, 2019).

[83] *Id*.

297. As the Defendants' misconduct continues to frustrate Carroll County's efforts to protect the health and safety of its citizens, Carroll County has allocated and continues to allocate substantial sums to finance the operation of its Circuit Courts and Juvenile Courts.

298. Further, Carroll County now operates a Drug Treatment Court which provides treatment for adults that are convicted of drug- and alcohol-related offenses who have committed non-violent crimes.

(c) Carroll County's Sheriff's Office and Detention Center

299. While Carroll County has expended significant funds to abate the opioid epidemic through its services provided by the Sheriff's Office and Detention Center—ignited and continually fueled by Defendants' ongoing misconduct—the epidemic remains a constant threat to the health and safety of Carroll County citizens.

300. Additionally, Carroll County now has funding from a High Intensity Drug Trafficking Area grant in order to provide additional assistance in critical drug-trafficking areas.

(d) Carroll County's Attorney Costs

301. In abating the public nuisance that the Defendants created and/or exacerbated in Carroll County—which remains ongoing—Carroll County has incurred significant costs in both the State's Attorney's Office and the County Attorney in combatting the opioid epidemic.

302. The State's Attorney's Office has a constitutional and statutory mandate to effectively prosecute all cases arising in Carroll County. In 2018, Carroll County hired an additional Drug Treatment and Education Liaison and there were further personnel increases due to the addition of a full-time Drug Court Prosecutor. The Drug Treatment and Education division of the Carroll County's State's Attorney's Office actively hosts educational programming in Carroll County schools. For example, former addicts have met with Carroll County students to get a first-hand account of the dangers of heroin and

opioid abuse and learn about the sobering statistics of overdose deaths.[84]

303. The Department of the County Attorney provides legal representation and advice to all matters affecting Carroll County and also has incurred increases in its operating costs.

304. As the utilization of public safety services by Carroll County's citizens has increased over the years of the opioid crisis, so too have Plaintiff's allocations to maintain these important public programs and maintain the health, safety, and welfare of Plaintiff's citizens.

3. Tax Revenue Expended—Miscellaneous Carroll County Opioid-Response Programming

305. To summarize, as of the first quarter of 2019, Carroll County has either fully implemented, or is in the planning stages of implementing, several programs strictly dedicated to combatting the opioid crisis as follows:

(1) Community Awareness Programming

306. Carroll County has fully implemented: (a) opioid information campaigns geared towards accessing treatment and support; (b) safe drug disposal programs; (c) prescriber education; and (d) compassion/fatigue prevention. Carroll County is in the process of implementing: (a) opioid information campaigns geared toward combatting the stigma associated with opioid use; and (b) employer support programs.

(2) Youth and School Programming

307. Carroll County has fully implemented: (a) a substance-use and prevention curriculum geared towards guiding students to make good choices, preventing drug use, developing healthy beliefs and clear standards, avoiding trouble and learning refusal skills, managing conflict and expressing anger constructively, and strengthening family bonds;

[84] Kramer, Anne, WBAL NewsRadio 1090 (Dec. 11, 2017), https://www.wbal.com/article/281856/3/carroll-county-officials-describe-opioid-problem-as-horrible

(b) youth identification and support programs; and (c) youth impact programs that provide early prevention and intervention. Carroll County is also in the process of implementing after- school programs for its students.

(3) Law Enforcement Programming

308. Carroll County is beginning to implement: (a) heroin coordinator programs; and (b) law enforcement diversion.

(4) Criminal Justice Programming

309. Carroll County provides substance use treatment and assessments to incarcerated inmates as well as re-entry services for people with substance use-related disorders. Upon an inmate's release, Carroll County facilitates referrals to seek further treatment. Additionally, Carroll County is beginning to implement recovery-housing transition support.

(5) Crisis Intervention Systems

310. Carroll County has fully implemented: (a) mobile crisis teams with limited hours but with immediate response from law enforcement, fire/ems, hospitals, schools, other community organizations, family members/friends, and self-referrals; (b) walk-in crisis centers, with limited hours, that provide counseling, referrals to treatment, initiation of Medication Assisted Treatment ("MAT"), and providing a safe environment for its clientele; and (c) peer-recovery specialists that work in emergency rooms, OB/GYN offices, recovery centers, street outreach, other healthcare settings, crisis response, drug court, and other community organizations. In addition, Carroll County is planning to implement a crisis stabilization system outside of the emergency department.

(6) Harm Reduction Programming

311. Carroll County has fully implemented Naloxone training and distribution and is beginning to implement: (a) employment training; (b) other harm-reduction strategies; (c) and an EMS leave behind program.

(7) Access to Treatment and Recovery

312. Carroll County is beginning to implement case-management support to provide access to treatment and recovery programs.

(8) Information Sharing Programming

313. Finally, Carroll County has fully implemented: (a) local agency communications; (b) program monitoring and evaluation; and (c) annual spike alerts which trigger the Mobile Crisis Team, media campaigns, and communications with law enforcement and EMS services.

314. In 2018 and 2019 combined, Carroll County received just under $1 million dollars for Opioid Emergency Funding by way of state Opioid Intervention Team ("OIT") grants and other state and federal emergency funding.

4. Tax Revenue Forgone

315. Tax revenue forgone is a consequence of incapacitation. The principal events associated with incapacitation include specialty treatment admission, hospitalization, and death. As a result of such incapacitation, the citizens of Carroll County who became addicted to Defendants' opioids are unable to work or contribute to Carroll County's financial health through sales, property, and other taxes.

316. The lost tax revenue attributable to these patients is especially significant for Plaintiff, as the vast majority of such patients would—but for their addiction—be productive members of Plaintiff's community.

317. The opioid epidemic and public nuisance that resulted from Defendants' deceptive strategy continues to frustrate Plaintiff's ability to recover from the crisis.

318. Leading up to and following the peak years of the opioid crisis, Plaintiff's total local property taxes collected fell each year from 2011 to 2015. In 2017, Plaintiff's total local property taxes were still 3.29% lower than in 2011.[85] As set forth below,

[85] Carroll County Maryland, Department of Management & Budget, Adopted Budget, Operating Budget Fiscal Year 2019, p. 38, https://ccgovernment.carr.org/ccg/budget/19-abudget/entire.pdf?x=1563308711333

Defendants' willful, dishonest scheme made it much more difficult—and significantly more expensive—for Plaintiff to ameliorate its tax-related damages associated with the incapacitation of both its citizens and others who either died in Carroll County, or were incapacitated in Carroll County.

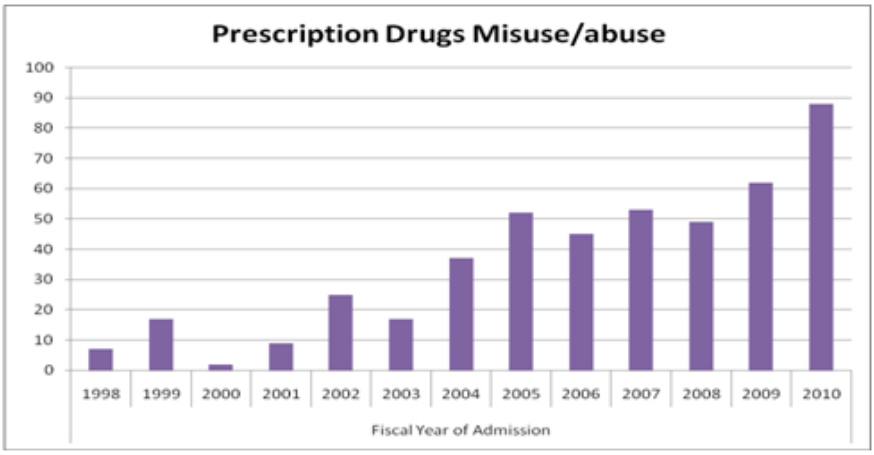
(a) Specialty Treatment

319. According to a 2016 Opioid Treatment Programs in Maryland Needs Assessment Report prepared by the University of Maryland Baltimore Systems Evaluation Center for the Maryland Behavioral Health Administration, between approximately 48,198 and 76,458 Marylanders age 12 or older are in need of treatment for a problem with opioid use.[86] Carroll County is no exception. Drug overdose and, in particular, opiate overdose has been a concerning, ongoing trend in Carroll County. The misuse of illicit and prescription narcotics is evidenced by an increase in treatment admissions as well as fatal and non-fatal overdoses. As a result, Carroll County residents that have become incapacitated by their addictions cannot meaningfully contribute to society because they are in treatment for the misuse/abuse of opioids. The lost tax revenue attributable to these patients is especially significant for Plaintiff, as the vast majority of such patients would—but for their addiction—be productive members of Plaintiff's community. Indeed, according to the inaugural Carroll County Opiate Overdose Prevention Plan, authored by the Carroll County Health Department in 2013, data collected by Carroll County showed a steady increase in prescription drugs misuse/abuse treatment admissions early on, from 1998 to 2010. In 2009, Carroll County began noting an increase in the number of persons admitted to Level II.D and Level III.7D treatment services who were acknowledging

[86] University of Maryland Baltimore Systems Evaluation Center, *Opioid Treatment Programs in Maryland Needs Assessment Report* (Sep. 2016), page 3, https://bha.health.maryland.gov/Documents/Combined%20OTP%20Needs%20Assessment%20Report%20and%20letter11.18.16.pdf

prescription drugs as their primary drug of choice.[87] In particular, Carroll County has seen an increase in the number of its residents in their prime working years (ages of 18-44), entering specialty treatment for opioid-related addiction.

320. Despite the fact that Carroll County has successfully initiated and continues to provide treatment resources to its citizens, the opioid epidemic and public nuisance that has resulted from Defendants' acts continue to frustrate Plaintiff's ability to recover from the crisis.



(b) Hospitalization

321. Patients who are hospitalized in connection with opioid-related emergencies are likewise unable to contribute to Carroll County's financial health with their labor or through the payment of taxes. From 2008 to 2014, Maryland emergency department visits for heroin- or prescription opioid-related emergencies increased by over 227% and

[87] The American Society of Addiction Medicine (ASAM) has established five main levels in a continuum of care for substance abuse treatment: Level 0.5: Early intervention services; Level I: Outpatient services; Level II: Intensive outpatient/Partial hospitalization services (Level II is subdivided into levels II.1 and II.5); Level III: Residential/Inpatient services (Level III is subdivided into levels III.1, III.3, III.5, and III.7) and Level IV: Medically managed intensive inpatient services. These levels should be thought of not as discrete levels of care but rather as points in a continuum of treatment services.

continues to be on the rise.[88] Moreover, according to a 2018 report published by DHHS, opioid-related hospital stays were consistently longer than those attributable to both hallucinogens and stimulants, including cocaine and methamphetamine.[89] Longer hospital stays are usually more expensive and lead to larger losses of productivity for the hospitalized patient.

(c) Death

322. According to government estimates, some 50,000 Americans died from an opioid overdose in 2016—*i.e.*, 137 people per day, and roughly one person every 12 minutes. [90] The emotional devastation caused by Defendants' despicable actions is impossible to quantify; however, as described above, the purely economic consequences of the opioid epidemic can and have been successfully tracked in terms of lives, lost productivity, healthcare, criminal justice and other costs. Accordingly, in 2017, President Donald Trump's Council of Economic Advisers estimated that the economic consequences to the nation of the opioid drug epidemic cost the United States $504 billion in 2015 alone, prompting the President to declare the opioid crisis a nationwide public health emergency.

323. Plaintiff has been hit even harder by the opioid crisis. From 2007 to 2018, approximately 12,087 Marylanders died from opioid-related intoxication causes.[91] During

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[88] Maryland Department of Health and Mental Hygiene, *Data Report, Drug and Alcohol-Related Emergency Department Visits in Maryland 2008-2014* (Sep. 2015), https://bha.health.maryland.gov/OVERDOSE_PREVENTION/Documents/Drug%20and%20Alcohol-related%20ED%20Visits_2008-2014.pdf

[89] Laura Radel, *Substance Use, the Opioid Epidemic, and the Child Welfare System: Key Findings from a Mixed Methods Study*, U.S. Dept. of Health and Human Services, p. 4 (Mar. 7, 2018), https://aspe.hhs.gov/system/files/pdf/258836/SubstanceUseChildWelfareOverview.pdf

[90] Money.com, *Here's What I Would Cost to Fix the Opioid Crisis, According to 5 Experts* (Nov. 27, 2017), http://money.com/money/5032445/cost-fix-opioid-crisis/.

[91] Maryland Department of Health data report, Table 6. Number of Opioid-Related Intoxication Deaths by Place of Occurrence, Maryland, 2007-2017; Opioid Operational Command Center ("OOCC") data report, Table 1. Comparison of Unintentional Opioid-Related Intoxication Deaths by Place of Occurrence, Maryland, 2017 and 2018.

that same period, approximately 335 Carroll County citizens died from opioid-related intoxication causes, who would not have died but for the Defendants' misconduct as described in this Complaint.[92]

WAIVER OF CERTAIN CLAIMS FOR RELIEF

324. Carroll County expressly disclaims and waives any and all right to recovery, whether financial, injunctive, or equitable, relating to or arising out of the distribution by any person of any product, or the provision of any service, pursuant to McKesson Corporation's ("McKesson") Pharmaceutical Prime Vendor Contract ("PPV Contract") with the United States Department of Veteran Affairs. Specifically, Carroll County expressly disclaims and waives any and all right to recover against any of the Distributor Defendants, including, but not limited to, Cardinal Health 121, LLC and Cardinal Health 122, LLC, under the terms and conditions of any PPV Contract or any similar contract.

325. Carroll County further commits that it will not, in any forum, rely on or raise the PPV Contract in connection with its allegations and/or prosecution in this matter.

326. Carroll County agrees that should Defendants present evidence sufficient for the trier of fact to determine that Carroll County's injuries were caused, in whole or in part, by the distribution of products or provision of services through the PPV, Defendants are entitled to a reduction of their liability proportionately by the extent to which the trier of fact determines that any injury to Carroll County was caused by goods or products distributed and/or services provided through the PPV.

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[92] Maryland Department of Health data report, Table 6. Number of Opioid-Related Intoxication Deaths by Place of Occurrence, Maryland, 2007-2017; Opioid Operational Command Center ("OOCC") data report, Table 1. Comparison of Unintentional Opioid-Related Intoxication Deaths by Place of Occurrence, Maryland, 2017 and 2018.

V. CAUSES OF ACTION

COUNT I

Public Nuisance

(Against All Defendants)

327. Carroll County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

328. Defendants, individually and in concert with each other, have contributed to, and/or assisted in creating and maintaining a condition that is a significant interference with the public health, the public safety, the public peace, the public comfort, and the public convenience.

329. The public nuisance created by Defendants' actions is substantial and unreasonable—it has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit.

330. This injury to the public includes, but is not limited to (a) widespread dissemination of false and misleading information regarding the risks, benefits, superiority, and appropriateness of opioids to treat chronic pain; (b) distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (c) high rates of opioid abuse, injury, overdose, and death, and their impact on Carroll County families and communities; (d) increased healthcare costs for individuals, families, employers, and Carroll County(e) lost employee productivity resulting from the cumulative effects of long-term opioid use, addiction, and death; (f) the creation and maintenance of a secondary, illicit market for opioids; and (g) greater demand for emergency services and law enforcement paid for by Carroll County at the ultimate cost of taxpayers.

331. Defendants knew or should have known that their promotion of opioid use would create a public nuisance.

332. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used. Absent Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

333. The health and safety of Carroll County's residents, including those who used, have used, or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to Carroll County and the entire state.

334. Defendants' conduct has injuriously affected, and continues to affect, Carroll County's property, patrons, employees, and a considerable number of people within Carroll County, and across the state.

335. Defendants' conduct also constitutes a nuisance per se because it independently violates other applicable statutes. As set forth below, the Manufacturing Defendants have violated the Maryland Consumer Protection Act and the Maryland False Claims Statute.

WHEREFORE, Plaintiff Carroll County demands judgment against all Defendants, jointly and severally, in excess of Seventy-Five Thousand Dollars ($75,000.00) in compensatory and punitive damages, plus interest, fees and costs, and for any other relief that is just and proper.

COUNT II

Negligence

(Against All Defendants)

336. Carroll County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

337. Each Defendant owed a duty of care to Plaintiff, including but not limited to, taking reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

338. In violation of this duty, Defendants, and each of them, failed to take

reasonable steps to prevent the misuse, abuse, and over-prescription of opioids by misrepresenting the risks and benefits associated with opioids and by distributing and prescribing dangerous quantities of opioids.

339. Each of the Manufacturing Defendants owed Carroll County a duty to promote and market opioids truthfully and to disclose the true risk of addiction associated with the risk of opioids. Each of the Manufacturing Defendants breached those duties by, among other things, circulating false and misleading information concerning the risks and benefits of opioids and downplaying or omitting the risks of addiction arising from their use. As set forth above in this Complaint, the Manufacturer Defendants' misrepresentations include falsely claiming that the risk of opioid addiction was negligible, falsely instructing doctors and patients that describing more opioids was appropriate when patients presented symptoms of addiction, falsely claiming that risk-mitigation strategies were so efficacious as to virtually negate concerns about addiction, falsely claiming that doctors and patients could increase opioid doses without significant added risk, and falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life without posing significant additional risks. Each of these misrepresentations made by Defendants violated duty of care to Carroll County.

340. Each of the Manufacturing Defendants and Distributor Defendants also owed the duties to report suspicious sales; to not fill suspicious orders; to abide by any government agreements entered into regarding the same and to comply with state regulations. (*See, e.g.*, COMAR 10.19.03.12.) Each of the Manufacturing Defendants and Distributor Defendants breached these duties by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances or by failing to report such suspicious orders to the appropriate regulators.

341. The Distributor Defendants knew of the serious problem posed by prescription opioid diversion and were under a legal obligation to take reasonable steps to prevent diversion.

342. The Distributor Defendants negligently distributed suspiciously large quantities of potent opioids and failed to report such distributions. As such, the Distributor Defendants violated their duty of care by moving these dangerous products into Carroll County in such quantities, facilitating misuse and abuse of opioids.

343. Plaintiff is not asserting a cause of action under the federal Controlled Substances Act or any other federal controlled substances laws, including—but not limited to—the federal laws cited above.

344. Defendants are liable for negligence *per se* in that the Defendants violated applicable Maryland laws, statutes, and regulations, in the manner in which they advertised, marketed, sold, and/or distributed opioid products. Plaintiff is a member of the class meant to be protected by the laws, statutes, and regulations which Defendants violated, and Plaintiff's injuries were caused by the violations.

345. As a direct and proximate cause of Defendants' unreasonable and negligent conduct, Carroll County has suffered and will continue to suffer harm, and is entitled to damages in an amount to be determined at trial. Indeed, Carroll County suffered both injuries and pecuniary losses proximately caused by the Defendants' breaches. Among other things, Carroll County has experienced an unprecedented opioid addiction and overdose epidemic costing millions in health insurance, government services, emergency visits, treatment for related illnesses and accidents, payments for fraudulent prescriptions, and lost productivity to Carroll County's workforce.

346. Plaintiff's damages were caused solely by the negligence of the Defendants without any negligence by Carroll County.

WHEREFORE, Plaintiff Carroll County demands judgment against all Defendants, jointly and severally, in excess of Seventy-Five Thousand Dollars ($75,000.00) in compensatory damages, plus interest, costs, and for any other relief that is just and proper.

COUNT III

Negligent Misrepresentation

(Against the Manufacturer Defendants)

347. Carroll County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

348. Defendants, individually and acting through their employees and agents, and jointly and severally, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail herein.

349. Defendants had a duty to exercise reasonable care in marketing and selling highly dangerous opioid drugs.

350. Defendants negligently asserted false statements and omitted material facts regarding the benefits of and evidence for the use of opioids for chronic pain as set forth herein, while understating their very serious risks, including the risk of addiction.

351. Defendants intended that Carroll County and its residents and / or employees or others affecting Carroll County or spending time therein would rely on their misrepresentations and omissions, knew that Carroll County and its residents would rely on their misrepresentations, and that such reliance would cause Carroll County to suffer loss.

352. Healthcare providers and residents in Carroll County reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants opioids, and Carroll County and its agents reasonably relied on these misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

353. Had Carroll County known that Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain Carroll County would

have undertaken efforts to avoid the damages suffered.

354. By reason of Defendants' misrepresentations and omissions of material fact Carroll County suffered actual pecuniary damage. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

WHEREFORE, Plaintiff Carroll County demands judgment against the Manufacturer Defendants, jointly and severally, in excess of Seventy-Five Thousand Dollars ($75,000.00) in compensatory damages, plus interest, costs, and for any other relief that is just and proper.

COUNT IV

Intentional Misrepresentation

(Against All Defendants)

355. Carroll County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

356. As set forth herein, Defendants, individually and acting through their employees and agents, made misrepresentations and omissions of material facts inducing the purchase, administration, payment for, and consumption of opioids as set forth in detail above.

357. In doing so, Defendants have engaged in misrepresentations and knowing omissions of material fact.

358. By engaging in the acts, omissions, and practices alleged herein, Defendants omitted material facts that they had a duty to disclose by virtue of Defendants' other representations and by virtue of their positions in manufacturing, marketing, selling, and distributing dangerous opioid drugs.

359. Defendants' statements about the use of opioids to treat chronic pain and/or non-cancer pain conditions were false and not supported by, or were contrary to, the

scientific evidence

360. Further, Defendants' omissions, which were false and misleading, rendered even seemingly truthful statements about opioids false and misleading and likely to mislead Carroll County prescribers and consumers.

361. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

362. Defendants intended that Carroll County and its residents and /or employees or others affecting Carroll County or spending time therein would rely on their misrepresentations and omissions, knew that Carroll County and its residents would rely on their misrepresentations, and that such reliance would cause Carroll County to suffer loss.

363. Healthcare providers and residents in Carroll County and / or employees or others affecting Carroll County or spending time therein reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants opioids, and Carroll County and its agents reasonably relied on these misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

364. Had Carroll County known of the Defendants' misrepresentations and false and tortious practices, Carroll County would have undertaken efforts to avoid payments of related claims or otherwise acted to mitigate or prevent damage.

365. By reason of their reliance on Defendants' misrepresentations and omissions of material fact Carroll County suffered actual pecuniary damage.

366. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

WHEREFORE, Plaintiff Carroll County demands judgment against all Defendants, jointly and severally, in excess of Seventy-Five Thousand Dollars ($75,000.00) in compensatory and punitive damages, plus interest, costs, and for any other relief that is just and proper.

COUNT V

Unjust Enrichment

(Against All Defendants)

367. Carroll County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

368. A claim for unjust enrichment in Maryland requires the defendant to be enriched by the receipt of a benefit; that the enrichment be at the expense of the plaintiff; and that it would be unjust to allow the defendant to retain the benefit.

369. Each Defendant was required to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

370. Rather than prevent or mitigate or wide proliferation of opioids into Carroll County, each Defendant instead chose to place its monetary interests first and each Defendant profited from prescription opioids sold in Carroll County.

371. Each Defendant also failed to maintain effective controls against the unintended and illegal use of the prescription opioids it or he manufactured, distributed, or prescribed, again choosing instead to place its or his monetary interests first.

372. Each Defendant therefore received a benefit from the sale, distribution, or prescription of prescription opioids to and in Carroll County, and these Defendants have been unjustly enriched at the expense of Carroll County.

373. As an expected and intended result of their wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid sales which have ultimately caused damage to the Carroll County, as alleged above.

374. Defendants have been unjustly enriched at the expense of Carroll County. it would be inequitable for Defendants to retain the profits and benefits they have reaped from the deceptive practices, misrepresentations, and unlawful conduct alleged herein.

WHEREFORE, Plaintiff Carroll County demands judgment against all Defendants, jointly and severally, in excess of Seventy-Five Thousand Dollars ($75,000.00) in compensatory and punitive damages, plus interest, costs, and for any other relief that is just and proper.

COUNT VI

Fraudulent Conveyance, Md. Code Ann., Com. Laws §§ 15-204 and 15-207

(Against The Sackler Defendants)

375. Carroll County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

376. As alleged herein, the Maryland Uniform Fraudulent Conveyance Act provides, inter alia, that (1)"[e]very conveyance made and every obligation incurred by a person who is or will be rendered insolvent by it is fraudulent as to creditors without regard to his actual intent, if the conveyance is made or the obligation is incurred without a fair consideration; and (2) Every conveyance made and every obligation incurred with actual intent, as distinguished from intent presumed in law, to hinder, delay, or defraud present or future creditors, is fraudulent as to both present and future creditors." (Md. Code. Ann., Com. Law § § 15-204, 15-207.)

377. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and fraudulent, entitling Carroll County to punitive damages.

378. As set forth above, Carroll County possesses a variety of causes of action against Purdue and the other Defendants, and as soon as final judgment is entered in this action, Carroll County will possess a right of payment from Purdue.

379. Carroll County has been harmed because Carroll County is informed and

believes that Purdue has been transferring assets to the Sacklers and other shareholders for years in order to avoid paying the judgment that will be owed to Carroll County, as well as the multitude of other plaintiffs that have commenced litigation against Purdue nationwide for its role in creating the opioid epidemic.

380. Carroll County is informed and believes that Purdue transferred assets to the Sacklers and other shareholders with the intent to hinder, delay, or defraud Purdue's creditors, including Carroll County.

381. Carroll County was harmed as a result of these transfers, and Carroll County is entitled to avoid them to the extent necessary to satisfy Carroll County's claims pursuant to Md. Code. Ann., Com. Law §§ 15-209 and 15-210 and an injunction against further disposition of assets by Purdue, the Sacklers, or both.

WHEREFORE, Plaintiff Carroll County requests that this Court enter an Order:

A. Setting aside all transfers by Defendant Purdue to the Sackler Defndants;

B. Enjoining any further disposition of assets by Defendant Purdue; and

C. Entering judgment in favor of Plaintiff Carroll County and against the Sackler Defendants, jointly and severally, in excess of Seventy-Five Thousand Dollars ($75,000.00) in compensatory and punitive damages, plus interest and costs; and

D. Granting Carroll County such other relief that is equitable, just and proper.

COUNT VII

Civil Conspiracy

(Against Defendant Purdue and The Sackler Defendants)

382. Carroll County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

383. As alleged above, Purdue and the Sacklers engaged in a knowing and willful conspiracy between themselves to fraudulently transfer assets from Purdue to the Individual Defendants and other shareholders in order to hinder, delay, and defraud Carroll

County in the collection of its judgment against Purdue entered in this action.

384. After the Sacklers became aware in or about 1999 that Purdue faced potential liability because of the addictive nature of OxyContin, Purdue and the Sacklers conspired to shield the proceeds of their wrongdoing from creditors like Carroll County by stripping Purdue every year of hundreds of millions of dollars of profits from the sale of OxyContin and other opioid-containing medications via distributions from Purdue to shareholders, including the Sacklers and their extended family.

385. Purdue and the Sacklers, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in a coordinated, common course of conduct to commit acts of fraud.

386. Purdue and the Sacklers acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and proximately caused the injuries alleged herein.

387. Purdue and the Sacklers acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

388. As a proximate result of Purdue and the Sacklers' conspiracy and the distributions of billions of dollars in profits to the Sacklers, Carroll County is informed and believes that Purdue lacks sufficient assets to satisfy its liabilities to Carroll County pursuant to the judgment entered in this action.

389. As a result of Purdue and the Sacklers' conspiracy, Carroll County is entitled to compensatory damages in an amount to be proved at trial.

390. As alleged herein, Purdue and the Sacklers' conspiracy was willful, malicious, oppressive, and fraudulent, entitling Carroll County to punitive damages.

WHEREFORE, Plaintiff Carroll County demands judgment against Defendant Purdue and the Sackler Defendants, jointly and severally, in excess of Seventy-Five Thousand Dollars ($75,000.00) in compensatory and punitive damages, plus interest, costs, and for any other relief that is just and proper.

COUNT VIII

Violations of Maryland False Claims Act, Md. Code Ann., Gen. Prov. §8-101, *et seq*.

(Against Manufacturing Defendants Only)

391. Carroll County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

392. A person is liable under Maryland's prohibition on submission of false claims, Md. Code Ann., Gen. Prov. § 8-102(b), when that person:

(1) knowingly present[s] or cause[s] to be presented a false or fraudulent claim for payment or approval; or

(2) knowingly make[s], use[s], or cause[s] to be made or used a false record or statement material to a false or fraudulent claim.

393. Pursuant to Md. Code Ann., Gen. Prov. § 8-101(b)(1), a "claim" is defined as "a request or demand, under a contract or otherwise, for money or other property, whether or not the governmental entity has title to the money or property, that is:

(i) presented to an officer, employee, or agent of a governmental entity; or

(ii) made to a contractor, grantee, or another recipient, if the money or other property is to be spent or used on a governmental entity's behalf or to advance an interest of a governmental entity, and the governmental entity:

1. provides or has provided any portion of the money or other

property requested or demanded; or

2. will reimburse the contractor, grantee, or other recipient for any portion of the money or other property that is requested or demanded.

394. A "governmental entity" includes "a municipal corporation." *Id*. § 8-101(e)(2). Moreover, "knowing" or "knowingly" explicitly does not require "proof of specific intent to defraud" but, instead, means that a person either "has actual knowledge that the information is false"; "acts in deliberate ignorance of the truth or falsity of the information"; or "acts in reckless disregard of the truth or falsity of the information." *Id*. § 8-101(f)(1).

395. The Manufacturing Defendants' practices, as described herein in this Complaint, violated Md. Code Ann., Gen. Prov. § 8-102(b). The Manufacturing Defendants, through their deceptive marketing of opioids for long-term use to treat chronic pain, presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used false statements to get false or fraudulent claims paid or approved by Carroll County.

396. The Manufacturing Defendants knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing such statements to be made and disseminated, that such statements were untrue, false, misleading, or unsupported by substantial and reliable scientific evidence, and were made for the purpose of inducing Carroll County, through its employees and contractors, to pay for opioids for long-term treatment of chronic pain. Manufacturing Defendants also knew or should have known that their marketing and promotional efforts had the effect of creating untrue, false, and misleading impressions regarding the risks, benefits, superiority, and appropriateness of using opioids on a long-term basis to treat chronic pain.

397. The Manufacturing Defendants' scheme caused prescribers to write prescriptions for opioids to treat chronic pain on a long-term basis that were presented to

Carroll County's employee health and workers' compensation plans for payment. Prescribers and other health care providers, and/or other agents of the health plans and workers' compensation program, expressly or impliedly certified to Carroll County that the opioids prescribed were medically necessary and reasonably required to treat chronic pain because those persons were influenced by the false and misleading statements disseminated by Manufacturing Defendants through the deceptive marketing campaign described above in this Complaint. To the extent such prescribing patterns were considered customary or consistent with then-generally accepted medical standards, those standards were influenced, dictated, and ultimately corrupted by the Manufacturing Defendants' deceptive marketing.

398. The Manufacturing Defendants knew that, as a natural and foreseeable consequence of their actions, governments such as Carroll County would necessarily end up paying for long-term prescriptions of opioids to treat chronic pain—prescriptions that were written and dispensed as a result of the Manufacturing Defendants' misrepresentations. Those misrepresentations—which were made and caused to be made by the Manufacturing Defendants—were material to Carroll County's decision to pay the costs of long-term opioid therapy to treat chronic pain because they falsely assured that such treatment was medically necessary.

399. Carroll County has as a result paid millions of dollars for opioid prescriptions that were represented to it as being medically necessary. These prescriptions would not have been written or covered or reimbursed but for the Manufacturing Defendants' deceptive, fraudulent, and unlawful marketing practices.

400. Carroll County has paid and will continue to pay consequential health care costs necessitated by the Manufacturing Defendants' deceptive, fraudulent, and unlawful marketing practices, in the form of drugs for persons who are physically dependent upon and addicted to opioids and in the form of treatment costs for those dealing with opioid use disorders, overdose, and other adverse effects.

WHEREFORE, Plaintiff Carroll County demands judgment against the Manufacturing Defendants, jointly and severally, in excess of Seventy-Five Thousand Dollars ($75,000.00) in compensatory and punitive damages, plus interest, fees and costs, and for any other relief that is just and proper.

COUNT IX

Violations of Maryland Consumer Protection Act, Md. Code Ann., Com. Law § 13-101, *et seq*.

(Against Manufacturing Defendants Only)

401. Carroll County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

402. Maryland's Consumer Protection Act ("CPA") makes it unlawful for any business to engage in "any unfair or deceptive trade practice," including making any "[f]alse, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers." Md. Code Ann., Com. Law §13-301(1). It also prohibits fraud-based deception, including "[d]eception, fraud, false pretense, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that a consumer rely on the same in connection with" the promotion or sale of any consumer goods or services. *Id*. §13-301(9).

403. The CPA authorizes a private right of action for "any person…to recover for injury or loss sustained [] as a result of" an unfair or deceptive trade practice. Md. Code Ann., Com. Law §13-408(a). "Person" is defined to include a "corporation…or any other legal or commercial entity." Md. Code Ann., Com. Law §13-101(h).

404. The Manufacturing Defendants are "persons" as defined in the CPA and are required to comply with the provisions of the CPA in their marketing, promotion, sale, and distribution of prescription drugs.

405. At all times relevant to this Complaint, the Manufacturing Defendants violated the CPA by engaging in the deceptive marketing and promotion of their products both by (1) making false and misleading statements which had the capacity, tendency, or effect of misleading consumers and by (2) making false representations and misleading omissions of material fact with the intent that consumers would rely on those representations. In particular, the Manufacturing Defendants engaged in deceptive marketing and promotion of their products by:

(1) making and disseminating false or misleading statements and other representations about the use of opioids to treat chronic pain which had the capacity, tendency, or effect of misleading customers;

(2) causing false or misleading statements about opioids to be made or disseminated;

(3) making statements to promote the use of opioids to treat chronic pain that omitted or concealed material facts; and

(4) failing to correct prior misrepresentation and omissions about the risks and benefits of opioids.

406. The Manufacturing Defendants' statements regarding the use of opioids on a long-term basis to treat chronic pain were not supported by, or were contrary to, substantial scientific evidence, as confirmed by recent pronouncement by the CDC and FDA based on such evidence. Moreover, false and misleading material omissions by Manufacturing Defendants rendered even seemingly truthful statements about opioids false and misleading because they were materially incomplete. At the time Manufacturing Defendants disseminated their false and misleading statements or caused such statements to be made or disseminated, they knowingly failed to include material facts regarding the risks and benefits of long-term use of opioids to treat chronic pain, and intended that recipients of their marketing messages would rely upon such omissions.

407. At all times relevant to this Complaint, Manufacturing Defendants violated

Md. Comm. L. § 13-303 by making misrepresentations including but nor limited to the following:

(1) Claiming or implying that opioids would improve patients' function and quality of life;

(2) Mischaracterizing the risk of opioid use disorders and abuse, including by stating or implying that "stead state" and abuse-deterrent properties meant that drugs were less likely to be addictive or abused, and that specific opioid drugs were less addictive or less likely to be abused than other opioids;

(3) Claiming or implying that addiction can be avoided or successfully managed through the use of screening and other tools;

(4) Promoting the misleading concept of pseudoaddiction and emphasizing the prevalence of dependence, thus obscuring the relationship between dependence and addiction and concealing the true risk of addiction;

(5) Claiming or implying that increasing the dose of opioids poses no significant additional risk to patients;

(6) Misleadingly depicting the safety of opioids by minimizing their risks and adverse effects while emphasizing the risks of competing products, including NSAIDs and acetaminophen; and

(7) As to Purdue, mischaracterizing OxyContin's onset of action and duration of efficacy to imply that the drug provides a full 12 hours of pain relief, when Purdue was aware that it does not.

408. By reason of the Manufacturing Defendants' foregoing deception, misrepresentations, and omissions of material fact, Manufacturing Defendants obtained income, profits, and other benefits it would not otherwise have obtained.

409. By reason of that same conduct, Carroll County incurred harm and was damaged in ways it would not otherwise have been, as described above.

WHEREFORE, Plaintiff Carroll County demands judgment against the Manufacturing Defendants, jointly and severally, in excess of Seventy-Five Thousand Dollars ($75,000.00) in compensatory and punitive damages, plus interest, fees and costs, and for any other relief that is just and proper.

Respectfully submitted,

Dated: July 25, 2019

/s/ *Paul Mark Sandler*

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DEMAND FOR JURY TRIAL

Pursuant to Maryland Rule 2-325(a), Plaintiff hereby demands a trial by jury on all issues.

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