[*Submitting Counsel on Signature Page*]

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: MCKINSEY & CO., INC. NATIONAL PRESCRIPTION OPIATE CONSULTANT LITIGATION This Document Relates to: ALL SCHOOL DISTRICT ACTIONS	Case No. 21-md-02996-CRB (SK) **MASTER COMPLAINT (SCHOOL DISTRICTS)** **REDACTED** **JURY TRIAL DEMANDED**

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I. PREAMBLE

This Complaint is an administrative device as described in *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D.133, 142 (E.D. La. 2002), for the specific purposes of enabling the Court to address the threshold issues it articulated in its statements and Orders to date, and does not supersede the complaints filed in the individual actions consolidated in this multi-district litigation for pretrial proceedings only. *See Gelboim v. Bank of Am.*, 574 U.S. 405, 413 n.3 (2015). Upon the conclusion of pretrial proceedings, and absent agreement of any bellwether process to occur in this Court, the underlying cases will be remanded back to their transferor districts for trial.

This Complaint is not intended to consolidate for trial the separate claims of the Plaintiffs and the State Classes they seek to represent. This complaint does not include every Plaintiff-specific or State Class-specific fact alleged in the underlying complaints, including facts related to individual and State Class damages. This Complaint incorporates by reference the complaints filed by individual school districts pending in this MDL as of November 22, 2021: *Board of Educ. Of Mason County et al. v. McKinsey & Co., Inc.* No. 3:21-cv-00280 (S.D. W. Va.) and *Board of Educ. Of Jefferson County v. McKinsey & Co., Inc.*, No. 3:21-CV-282-DJH (W.D. Ky).

II. INTRODUCTION

1. For more than two decades, the opioid crisis has raged across this country. An opioid-related public health emergency was declared by the President in 2017. Last year was the worst on record, with drug overdoses soaring nearly 30%.[1] Today, there are increasingly few Americans whose lives have not been affected by the consequences of opioid dependency, addiction, and overdoses.

2. McKinsey is a management consulting firm with operations across the globe. It played a central role in the unfolding, propagation, and exploitation of the opioid crisis by advising multiple opioid manufacturers and other industry participants how to sell as many

[1] Betsy McKay, "U.S. Drug-Overdose Deaths Soared Nearly 30% in 2020, Driven by Synthetic Opioids," *Wall Street Journal*, July 14, 2021, *available at*: https://www.wsj.com/articles/u-s-drug-overdose-deaths-soared-nearly-30-in-2020-11626271200.

opioids as conceivably possible. Knowing that its clients' products were highly addictive, ineffective, and unsafe for the treatment of long-term chronic pain, non-acute pain, and non-cancer pain, McKinsey developed a singular focus on increasing opioid sales, no matter the resultant cost to society. McKinsey did this for well over a decade, despite knowing full well the risk to public health and safety and the widespread economic harm from developing and implementing the transformation of strictly-controlled substances into top-selling blockbuster drugs.

3. The purpose of McKinsey's work with its opioids clients was at all times to maximize return on investment. The whole point for those clients (and hence McKinsey) was to make as much money as possible. They all did. This relentless drive to increase sales and create greater availability of opioids was made with no concern about the parallel, known, and inevitable increase in opioid-related deaths, addiction, abuse, diversion, and misuse.

4. In the world of management consulting, McKinsey is preeminent. It is one of the world's oldest, largest, and most lucrative consulting firms and is generally seen as the most prestigious firm in the industry. More consiglieri than one-off advisor, McKinsey touts its model of engaging in "transformational partnerships" with its clients. McKinsey learns each client's business intimately, embeds itself into all levels of the corporate hierarchy, and provides granular strategies to achieve transformative goals for its clients.

5. Marvin Bower, the managing director of McKinsey from 1950 to 1967, was "the father of the consulting profession."[2] He "turned the business of selling management advice into a keystone of American corporate culture," and is "credited with taking a fledgling industry and setting its course not only as to the kinds of services it could sell but also the standards it must uphold for its work to be respected."[3] A lawyer by trade, Bower stressed that management consulting should be seen as an emergent profession, akin to the law or accounting, with obligations to clients and to the broader society that extend beyond the mere commercial.

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[2] Douglas Martin, *Marvin Bower, 99; Built McKinsey & Co.*, N.Y. Times, Jan. 24, 2003, *available at*: https://www.nytimes.com/2003/01/24/business/marvin-bower-99-built-mckinsey-co.html

[3] *Id.*

6. Bower instilled an ethos at McKinsey that has been reinforced throughout the decades as a core value of the firm: "Deliver the bad news if you must, but deliver it properly."[4] Bower's principles, and the values he imparted within McKinsey, are said to guide the firm to the present day. "In many ways, certainly in spirit and soul, Marvin continued to lead it after he retired, and he leads it still," eulogized Rajat Gupta, McKinsey's then-global managing partner, at Bower's funeral in 2003.[5]

7. This case is, in large part, about the firm's failure to adhere to Bower's simple, foundational tenet. It arises instead from the firm's steadfast and continual work to maximize opioid sales in partnership with numerous clients during the pendency of the worst man-made epidemic in modern medical history. It is about McKinsey never delivering the "bad news" of opioids' devastating impact on Plaintiffs and the public, properly or otherwise, and instead looking the other way for money.

8. When it came to opioids, McKinsey did far more than just give advice. Not only did it suggest courses of action that its clients should adopt, the firm remained in place and worked collaboratively alongside its clients to actually implement McKinsey's recommendations to achieve objectives jointly identified by the clients and McKinsey. McKinsey stood alongside its clients in the arena doing the deeds.

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[4] Duff McDonald, *The Firm* 35 (2014).

[5] *Id.* at 270. In many ways, Gupta was an interesting figure to opine on Bower's legacy. Indeed, Gupta's leadership of McKinsey is in many respects to be *contrasted* with Bower's legacy. Many of the values Bower emphasized—an emphasis on professionalism over commercial exploitation, for example—were jettisoned under Gupta's tenure as managing partner of the firm, which ended in 2003. "Under his watch, McKinsey began to chase top billings in a way it never had before." *Id.* at 234. For instance, McKinsey first began accepting equity stakes in clients as a form of incentive compensation during Gupta's tenure. Previously, McKinsey only charged standard fees for its consulting services as Bower disdained the notion of taking equity stakes in clients. *Id.* at 234. Under Gupta, McKinsey also began to allow consultants' compensation to be tied to client performance. *Id.*

Consistent with Gupta's efforts to monetize McKinsey's consulting business in ways previous firm leadership had not, McKinsey also began to expand its client base. "While the firm would never admit as much, under Gupta, McKinsey began working for just about anyone with a fat bank account and a checkbook." *Id*. at 266.

Institutions age, and by the time Gupta came to lead the firm in 1994, McKinsey was a mature institution. It had built up significant value in its *reputation* by historically advising *only* "blue chip" companies "at the top of the corporate pyramid." *Id*. Under Gupta, McKinsey began the process of realizing that value. For McKinsey, the way to monetize an elite reputation was to start advising those it historically may have shunned as clients—to start offering its *imprimatur*, in addition to its services, for money. McKinsey's work with opioid manufacturers began under Gupta's leadership.

9. The deceptive marketing strategies that McKinsey and its clients invented, developed, deployed, and continually refined for years to expand the market for opioids are foundational to the epidemic.

10. McKinsey worked hand-in-hand with major opioid manufacturers, including Purdue Pharma L.P., Endo Pharmaceuticals,[6] Johnson & Johnson,[7] and Mallinckrodt[8] for years. At the same time, McKinsey advised other participants in the opioid supply chain, including distributors, pharmacies, and even regulators.

11. In particular, McKinsey advised the Sackler family and their company, Purdue, for years while Purdue aggressively marketed OxyContin, widely viewed as the taproot of the opioid crisis. The relationship began no later than 2004. In the years following Purdue's 2007 guilty plea for misleadingly marketing OxyContin, McKinsey continued to work closely with Purdue to dramatically increase OxyContin sales, notwithstanding the existence of a five-year Corporate Integrity Agreement that Purdue entered as part of its guilty plea.

12. McKinsey knew of the dangers of opioids and in particular the prior misconduct of Purdue but nonetheless advised Purdue and other opioid manufacturers to improperly market and sell OxyContin and other prescription opioids, supplying granular sales and marketing strategies and remaining intimately involved throughout implementation of those strategies. McKinsey's actions resulted in a surge in sales of OxyContin and other opioids that fueled and prolonged the opioid crisis.

13. For years, McKinsey advised Purdue on, designed, and helped to implement various strategies to raise sales of OxyContin by focusing on high dose sales and deceptively messaging to physicians that OxyContin would improve function and quality of life. For example, McKinsey urged Purdue to maximize sales by dictating, to a greater degree, which prescribers its sales representatives would target, exploring ways to increase the amount of time those sales

[6] "Endo Pharmaceuticals" or "Endo" refers to Endo Health Solutions Inc., Endo International plc, and Endo Pharmaceuticals Inc., collectively.

[7] "Johnson & Johnson" refers to Johnson & Johnson Services, Inc. and its wholly-owned subsidiary Janssen Pharmaceuticals, Inc. ("Janssen").

[8] "Mallinckrodt" refers to Mallinckrodt LLC and Mallinckrodt plc, together.

representatives spent in the field increasing opioid sales and prioritizing OxyContin in incentive compensation targets.[9]

14. McKinsey's partnership with Purdue reached its fever pitch in the summer of 2013. In January of that year, Purdue's Corporate Integrity Agreement expired, and Purdue was no longer bound by its constraints. Within months, the Sacklers tasked McKinsey with transforming Purdue's approach to OxyContin sales in order to extract as much money as possible from the remaining patent life of the drug.[10]

15. In response, McKinsey developed and proposed Project Turbocharge, a series of transformational changes that McKinsey proposed to implement at Purdue to dramatically increase OxyContin sales by re-tooling Purdue's sales force and investing large amounts of capital to "turbocharge" it. "[O]ur recommendation is that Purdue makes a clear go-no-go decision to 'Turbocharge the Sales Engine'," McKinsey told Purdue on August 8, 2013.

16. The Sacklers chose "go," and McKinsey subsequently implemented and continually refined Project Turbocharge at Purdue over the course of years, to devastating, but profitable, effect.

17. McKinsey has recently been the subject of scrutiny for its various business practices, including its work facilitating the opioid crisis with Purdue.[11] On March 7, 2019, Kevin Sneader, McKinsey's then-global managing partner, addressed all McKinsey employees regarding this scrutiny. Drawing inspiration from Theodore Roosevelt, Sneader stated,

> [W]e cannot return to a time when we were in the background and unobserved. Those days have gone. Indeed, I have little doubt that scrutiny—fair and unfair—will continue. It is the price we pay for being "in the arena" and working on what matters.[12]

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[9] PPLPC012000437346

[10] OxyContin, like any branded pharmaceutical, is subject to eventual patent expiration and competition from generic opioid manufacturers.

[11] *See* Michael Forsythe and Walt Bogdanich, *McKinsey Advised Purdue Pharma How to 'Turbocharge' Opioid Sales, Lawsuit Says*, N.Y. Times, Feb. 1, 2019, *available at:* https://www.nytimes.com/2019/02/01/business/purdue-pharma-mckinsey-oxycontin-opiods.html.

[12] *See "The Price We Pay for Being 'In the Arena'": McKinsey's Chief Writes to Staff About Media Scrutiny and Scandal*, Fortune Magazine, March 8, 2019, *available at* https://fortune.com/2019/03/08/mckinsey-staff-letter-kevin-sneader/. The "arena" reference is to *Citizenship in a Republic*, a speech delivered by Theodore Roosevelt at the *Sorbonne* on April 23, 1910:

> It is not the critic who counts; not the man who points out how the strong man stumbles, or where the doers of deeds could have done them better. The credit belongs to the man who is actually in the

18. Weeks later, McKinsey announced that it would no longer work for any opioid manufacturer. "Opioid abuse and addiction are having a tragic and devastating impact on our communities. We are no longer advising clients on any opioid-specific business and are continuing to support key stakeholders working to combat the crisis."[13]

19. The price for being in the arena is more than mere scrutiny. McKinsey is liable for its misconduct and the harms it caused or exacerbated. McKinsey is liable for its successful efforts to increase opioid sales for years. It continued this work unabated and with alacrity despite events as stunning as Purdue's 2007 guilty plea for misbranding OxyContin, Purdue's 2015 settlement with the State of Kentucky, and numerous other enforcement actions related to opioid sales and marketing by McKinsey clients. Through it all, McKinsey remained steadfast in its efforts to promote opioid sales for all of its clients for the purpose of maximizing return on investment without regard to the obvious implications of what they were doing. Indeed, the firm endeavored alongside its clients to increase the size of the *overall* opioid market for *nearly two decades*, until as late as March 22, 2019, despite increasingly blood-red flags along the way.[14]

20. American public schools perform an indispensable function, central to the health of American democracy, by providing a free education to every student who comes through their doors. But, for the last decade at least, public schools' ability to succeed has been taxed by the devastation of the opioid epidemic.

> arena [here, McKinsey; and the arena, opioid sales], whose face is marred by dust and sweat and blood; who strives valiantly; who errs, who comes short again and again, because there is no effort without error and shortcoming; but who does actually strive to do the deeds; who knows great enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in the end the triumph of high achievement, and who at the worst, if he fails, at least fails while daring greatly, so that his place shall never be with those cold and timid souls who neither know victory nor defeat.

As it happens, Mr. Sneader is not the only McKinsey person to draw inspiration from Roosevelt. *Citizenship in a Republic* similarly inspired Dominic Barton, the man Mr. Sneader succeeded as McKinsey's global managing partner. It served as the basis for his 2017 address to the Ivey Business School in Canada. *See* Dominic Barton *In the Arena: Leadership in an Age of Disruption*, October 17, 2017, *available at*: https://www.ivey.uwo.ca/media/3780710/daquino_lecture2017.pdf. While McKinsey continues to preach the values of corporate integrity from the Bower area, its actions show that it has moved far afield from its professed moral compass.

[13] *See* Paul La Monica, *Consulting firm McKinsey no longer working with opioid maker Purdue Pharma*, CNN, May 24, 2019, *available at*: https://www.cnn.com/2019/05/24/business/mckinsey-purdue-pharma-oxycontin/index.html. The statement was attributed to McKinsey as an entity. No individual's name was attributed.

[14] *See* "About McKinsey's past work for opioid manufacturers," *last updated March 22, 2021, available at:* https://www.mckinseyopioidfacts.com ("We decided nearly two years ago to end all work on opioid-specific business . . . .")

21. The connection between McKinsey's role as the architect of a scheme to "turbocharge" opioid sales and substantial harms to public schools is direct and proximate. As a result of McKinsey's actions, the market was flooded with opioids. That increased the number of women using opioids during pregnancy—and the number of women giving birth to infants born with Neonatal Opioid Withdrawal Syndrome ("NOWS"). NOWS is a group of adverse neurodevelopmental conditions that occur when infants are born with opioid withdrawal symptoms.[15] Four or five years after birth, those children enter the schools. Because of the adverse neurodevelopmental consequences of NOWS, they disproportionately need and receive mandated costly "special education" services, 34 C.F.R. §§ 300.320-300.328, often from pre-kindergarten all the way through high school. The average per pupil expenditure on special education services is almost twice the per pupil cost for other students.[16] By "turbocharging" opioid sales, McKinsey increased NOWS births, saddling many public schools with large, increased, unfunded costs.

22. The effect of McKinsey's efforts to increase opioid sales has been staggering. Between 1999 and 2014, the number of women using opioids during pregnancy increased by 333%.[17] A newborn is now diagnosed with NOWS every 15-25 minutes in the United States.[18] The incidence of NOWS increased more than fivefold among infants covered by Medicaid.[19] The financial and other consequences for public schools as a result of the increased incidence of NOWS have been very serious—and were foreseeable.

23. For years, research has reported that fetal exposure to opioids can produce adverse changes in brain structure and function.[20] And the link between those problems and educational

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[15] Neonatal Opioid Withdrawal Syndrome ("NOWS") is also referred to as Neonatal Abstinence Syndrome ("NAS"). For present purposes, the two labels—NOWS and NAS—refer to the same diagnosed medical condition.

[16] Jay G. Chambers et al., *Total Expenditures for Students with Disabilities, 1999-2000: Spending Variation by Disability*, Special Education Expenditure Project 4 (June 2003), https://www.air.org/sites/default/files/SEEP5-Total-Expenditures.pdf.

[17] Sarah C. Haight et al., *Opioid Use Disorder Documented at Delivery Hospitalization - United States, 1999-2014*, 67 Morbidity and Mortality Weekly Report 845, 846 (2018).

[18] Saminathan Anbalagan & Magda D. Mendez, *Neonatal Abstinence Syndrome* (2021), https://www.ncbi.nlm.nih.gov/books/NBK551498/.

[19] Tyler N. A. Winkelman et al., *Incidence and Costs of Neonatal Abstinence Syndrome Among Infants With Medicaid: 2004-2014*, 141 Pediatrics e20173520 (2018).

[20] See generally, Emily J. Ross et al., *Developmental Consequences of Fetal Exposure to Drugs: What We Know and What We Still Must Learn*, 40 Neuropsychopharmacology 61, 76 (2015) (discussing research results dating back to 1994).

outcomes is not surprising: there is a direct relationship between infants born with NOWS and the need for special education and related services once these children are in school.[21]

24. In addition, the need for special education services because of the opioid epidemic is not limited to children born with NOWS. Many children living in households battling addiction require special education interventions as well. The children of opioid abusing parents are at risk for a wide variety of adverse outcomes, even if they were not exposed to opioids in utero.[22]

25. The opioid epidemic has required many public school districts, including the Plaintiffs named in this Complaint, to expend or divert already scarce resources to support children born with NOWS or whose families are struggling with opioid addiction and death. These students disproportionately require mandated special education and related services or present behavioral and emotional challenges that disrupt classrooms, which in turn places burdens on schools.

III. JURISDICTION AND VENUE

26. This Court has subject matter jurisdiction over this action for the reasons stated in each underlying complaint.

27. This Court has personal jurisdiction over Defendants for the reasons stated in each underlying complaint.

28. Venue is appropriate for pretrial proceedings under *In re McKinsey & Co., Inc., Nat'l Prescription Opiate Consultant Litig.*, MDL No. 2996, 2021 WL 2351628 (J.P.M.L. June 7, 2021).

IV. PARTIES

A. School District Plaintiffs

29. **West Virginia**: The Boards of Education of Mason County, Marion County, and Wyoming County on behalf of themselves and all independent school districts of the State of West Virginia.[23]

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[21] Mary-Margaret A Fill et al., *Educational Disabilities Among Children Born With Neonatal Abstinence Syndrome*, 142 Pediatrics e20180562 (2018); *see also* Ju Lee Oei et al., *Neonatal Abstinence Syndrome and High School Performance*, 139 Pediatrics 2 (2017).

[22] Gemma Sanjuan Herranz et al., *Children Born to Heroin-Addicted Mothers: What's the Outcome 25 Years Later*, 5 J. Addiction Res. & Therapy 180 (2014).

[23] *Board of Educ. Of Mason County et al. v. McKinsey & Co., Inc.* No. 3:21-cv-00280 (S.D. W. Va.).

30. **Kentucky**: The Board of Education of Jefferson County on behalf of itself and all independent public school districts in the State of Kentucky.[24]

B. <u>Defendants</u>

31. Defendant McKinsey & Company, Inc. is a corporation organized under the laws of the state of New York. McKinsey's principal place of business is located at 711 Third Avenue, New York, NY 10017. It may be served with process via its registered agent, Corporation Service Company, at 80 State Street, Albany, NY 12207.

32. Defendant McKinsey Holdings, Inc. is a Delaware corporation with its principal place of business is located at 711 Third Avenue, New York, NY 10017. It may be served with process via its registered agent, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808

33. Defendant McKinsey & Company, Inc. United States is a Delaware corporation with its principal place of business is located at 711 Third Avenue, New York, NY 10017. It may be served with process via its registered agent, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808

34. Defendant McKinsey & Company, Inc. Washington D.C. is a Delaware corporation with its principal place of business is located at 711 Third Avenue, New York, NY 10017. It may be served with process via its registered agent, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

35. Upon information and belief, McKinsey & Company, Inc. is the parent company of McKinsey & Company Holdings, Inc., which is itself the parent company of both McKinsey & Company, Inc. United States and McKinsey & Company, Inc. Washington D.C. Upon information and belief, each subsidiary corporation is wholly-owned by its parent. Despite the corporate form, McKinsey began as a partnership and still refers to its senior employees as "partners." Those partners are the firm's shareholders. Collectively, these four Defendants are referenced throughout as "McKinsey."

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[24] *Board of Educ. Of Jefferson County v. McKinsey & Co., Inc.*, No. 3:21-CV-282-DJH (W.D. Ky).

36. McKinsey a is global management consultancy with offices in over 130 cities in 65 countries, including the following United States cities: Atlanta, GA; Austin, TX; Houston, TX; Dallas, TX; San Francisco, CA; Los Angeles, CA; Redwood City, CA; Boston, MA; Charlotte, NC; Chicago, IL; Cleveland, OH; Denver, CO; Detroit, MI; Miami, FL; Miramar, FL; Tampa, FL; Minneapolis, MN; Summit, NJ; New York, NY; Philadelphia, PA; Pittsburgh, PA; Seattle, WA; St. Louis, MO; Stamford, CT; Waltham, MA; and Washington, D.C.

37. McKinsey is registered to do business in all fifty states.

V. FACTUAL ALLEGATIONS APPLICABLE TO ALL CLAIMS

A. The Opioid Crisis

38. The term "opioid" refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from the opium poppy. Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

39. The opium poppy contains various opium alkaloids, three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine. Early use of opium in Western medicine was a tincture of opium and alcohol called laudanum, which contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

40. In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911: "The habit has this nation in its grip to an astonishing extent . . . . Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in the United States."

41. Pharmaceutical companies have long tried to develop substitutes for opium and morphine that would provide the same analgesic effects without the addictive properties. In 1898, Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of morphine) under the trade name “Heroin.” Bayer advertised heroin as a non-addictive cough and cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in the United States was limited to prescription only in 1914 and then banned altogether a decade later.

42. Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

43. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances by the Drug Enforcement Administration since 1970.

44. Throughout the twentieth century, pharmaceutical companies continued to develop prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally produced in combination with other drugs, with relatively low opioid content.

45. In contrast, OxyContin, the product whose launch in 1996 ushered in the modern opioid epidemic, is pure oxycodone. Purdue initially made it available in the following strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times that.

46. The effects of opioids vary by duration. Long-acting opioids, such as Purdue’s OxyContin and MS Contin, Janssen’s Nucynta ER and Duragesic, Endo’s Opana ER, and Actavis’s Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, twelve hours. Short-acting opioids, such as Cephalon’s Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address “episodic pain” (also referred to as “breakthrough pain”) and provide fast-acting, supplemental opioid

therapy lasting approximately four to six hours. Still other short-term opioids, such as Insys's Subsys, are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The opioid manufacturers promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough" pain.

47. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration and, at very high doses, can, and often do, arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

48. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

49. As one doctor put it, the widespread long-term use of opioids "was an experiment on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was collected until they started gathering death statistics."

50. The results were devastating, and the nation continues to reach ever grimmer milestones. In 2020, drug-overdose deaths in the United States soared nearly 30%, reaching all-time highs.[25]

[25] Betsy McKay, "U.S. Drug-Overdose Deaths Soared Nearly 30% in 2020, Driven by Synthetic Opioids," *Wall Street Journal*, July 14, 2020, *available at*: https://www.wsj.com/articles/u-s-drug-overdose-deaths-soared-nearly-30-in-2020-11626271200.

B. Marketing and the Origins of the Opioid Crisis

51. OxyContin, manufactured by Purdue Pharma L.P., was introduced to the market in 1996. Within six years of its introduction, the increasingly widespread misuse and abuse of OxyContin and similar opioids had drawn the attention of the United States Senate.

52. Two decades ago, Dr. Art Van Zee traveled from the rural coal town of St. Charles, in the southwestern corner of Virginia, to Washington D.C. to provide testimony to the United States Senate Committee on Health, Education, Labor and Pensions. On February 12, 2002, that Committee held a hearing entitled "Examining the Effects of the Painkiller OxyContin, Focusing on Federal, State, and Local Efforts to Decrease Abuse and Misuse of this Product While Assuring Availability for Patients Who Suffer Daily from Chronic Moderate to Severe Pain."[26]

53. Today, OxyContin—and the methods used to sell it—is widely seen as a principal taproot of the opioid crisis. In those early days of the unfolding opioid epidemic, Dr. Van Zee's medical practice in St. Charles put him in a position to offer informed, first-hand observations of the toll that the pharmaceutical industry's efforts to market opioids was exacting from his community. He testified:

> In the 25 years I have practiced as a general internist in St. Charles, which is a small Appalachian coal mining town, there has never been anything to compare to the epidemic of drug abuse and addiction that we have seen the last 3 years with OxyContin. Contrary to what is sometimes portrayed in the media as long-term addicts switching to the drug *du jour*, what we have seen for the most part is numerous young people recreationally using OxyContin and then becoming very rapidly addicted. Many of these kids are good kids, good families with bright, promising futures that are being destroyed in every way by their opioid addiction.[27]

54. Further, Dr. Van Zee identified the sales and marketing practices of the pharmaceutical industry when selling controlled substances as a primary cause of the problem:

> My own personal view of the complicated OxyContin abuse problem is that there are at least three major elements involved. First, there has been an obvious problem with physician misprescribing and overprescribing of this drug. Second, this epidemic has been a vicious indicator of the alarming degree of prescription drug abuse in our society. *Third and perhaps the one closest to this committee and the*

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[26] A transcript of the hearing is *available at*: https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm

[27] *See* https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm

FDA is that the promotion and marketing of OxyContin by Purdue Pharma has played a major role in this problem.[28]

55. Five years after Dr. Van Zee's testimony and eighty miles from his hometown of St. Charles, United States Attorney John Brownlee announced in Abingdon, Virginia, the guilty plea of the Purdue Frederick Company, the parent of Purdue Pharma, L.P., relating to the misbranding of OxyContin. Brownlee stated, "Even in the face of warnings from health care professionals, the media, and members of its own sales force that OxyContin was being widely abused and causing harm to our citizens, Purdue, under the leadership of its top executives, continued to push a fraudulent marketing campaign that promoted OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal. In the process, scores died as a result of OxyContin abuse and an even greater number of people became addicted to OxyContin; a drug that Purdue led many to believe was safer, less subject to abuse, and less addictive than other pain medications on the market."

56. Two years later, in 2009, Dr. Van Zee published *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy* in the American Journal of Public Health.

57. In his paper, Dr. Van Zee stated the matter plainly: "Compared with noncontrolled drugs, controlled drugs, with their potential for abuse and diversion, pose different public health risks when they are overpromoted and highly prescribed."[29] In one sense, Dr. Van Zee's observation is not particularly novel. Indeed, it approaches tautology: controlled substances are *controlled* precisely because they should not be sold to maximize volume and profits. This did not prevent McKinsey and Purdue from marketing Purdue's opioids full hilt, however. By 2004, "OxyContin had become the most prevalent prescription opioid in the United States."[30]

58. Dr. Van Zee identified the three principal marketing tactics Purdue employed as a source of OxyContin misuse and abuse—the exact tactics McKinsey identified and promoted—

[28] *Id*. (emphasis added).
[29] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, American Journal of Public Health, February 2009, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf
[30] *Id.*

and suggested that regulation may be appropriate to curtail its use. The first was the use of granular sales and marketing data to profile individual prescribers and identify those that already prescribe large amounts of opioids. "Through these profiles, a drug company can identify the highest and lowest prescribers of particular drugs on a single zip code, county, state, or the entire country. One of the critical foundations of Purdue's marketing plan for OxyContin was to target the physicians who were the highest prescribers for opioids across the country."[31]

59. The second tactic was the use of incentive compensation structures to encourage the salesforce to sell ever more prescriptions of OxyContin. Bonuses at Purdue were "uncapped," meaning there was no upper limit to what an OxyContin salesperson could earn. Rather, salesforce remuneration was a direct function of overall OxyContin sales—the more you sell, the more you make. "A lucrative bonus system encouraged sales representatives to increase sales of OxyContin in their territories, resulting in large numbers of visits to physicians with high rates of opioid prescriptions, as well as a multifaceted information campaign aimed at them."[32]

60. The third tactic was to increase the overall number of individual calls that the salesforce placed to prescribers. "From 1996 to 2000, Purdue increased its internal sales force from 318 sales representatives to 671, and its total physician call list from approximately 33,400 to 44,500 to approximately 70,500 to 94,000 physicians."[33]

61. When combined, these tactics produced the intended result. "The use of prescriber profiling data to target high-opioid prescribers—coupled with very lucrative incentives for sales representatives—would seem to fuel increased prescribing by some physicians—perhaps the most liberal prescribers of opioids and, in some cases, the least discriminate."[34]

62. Dr. Van Zee's observations regarding the direct link between OxyContin marketing and overall opioid overdose mortality would, in time, be confirmed by further academic work, including empirical research published by the National Bureau of Economic Research in 2019.

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[31] *Id.*
[32] *Id.*
[33] *Id.*
[34] *Id.*

63. McKinsey played a central role in the sales and marketing of these Schedule II controlled substances in the United States for many years. Throughout that time, the purpose of McKinsey's actions was singular: making the most money possible no matter the resultant cost to society. Indeed, no significant concern was given to the fact that greater availability of drugs correlates to opioid-related deaths, addiction, abuse, and misuse. Return on investment was McKinsey's guiding light. McKinsey partnered with numerous opioid manufacturers and other opioid industry participants to maximize the return on investment in sales and marketing efforts for numerous opioid products, and did so contemporaneously. Despite the fact that the Schedule II controlled substances were designed for a small, narrowly defined group—patients with acute, terminal, or cancer-related pain—McKinsey's goal, in all instances, was to sell as many pills as conceivably possible.

C. What McKinsey Does: "Consulting is more than giving advice."

64. McKinsey is a global consulting firm with many areas of expertise, including the pharmaceutical industry. As a management consulting firm, McKinsey provides plans to managers, directors, and owners on how to run their companies or other enterprises, and helps implement those plans.

65. Management consulting is the business of providing solutions to clients. Solutions take many forms, depending on the client's needs. "Management consulting includes a broad range of activities, and the many firms and their members often define these practices quite differently."[35]

66. Broadly speaking, there are two schools of management consulting. "Strategy" consulting provides big-picture advice to clients about how they approach their business: how the business is structured, which markets to compete in, potential new business lines, and mergers and acquisitions. The strategy consultant provides a plan to the client that the client may choose to adopt or not.

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[35] Arthur Turner, *Consulting is More Than Giving Advice*, Harvard Business Review, September 1982, *available at*: https://hbr.org/1982/09/consulting-is-more-than-giving-advice

67. "Implementation" consulting is what comes next. If strategy consulting is providing advice to a client, "implementation" work is what happens once the client has adopted the consultant's plan. After a client has adopted the strategy consultant's recommendations, the implementation consultant remains in place with the client to actually do the necessary work and execute on the plan.

68. In his 1982 *Harvard Business Review* article entitled "Consulting is More Than Giving Advice," Professor Arthur Turner of the Harvard Business School described the then-current state of the consulting industry's attitude toward implementation work:

> The consultant's proper role in implementation is a matter of considerable debate in the profession. Some argue that one who helps put recommendations into effect takes on the role of manager and thus exceeds consulting's legitimate bounds. Others believe that those who regard implementation solely as the client's responsibility lack a professional attitude, since recommendations that are not implemented (or implemented badly) are a waste of money and time. And just as the client may participate in diagnosis without diminishing the value of the consultant's role, so there are many ways in which the consultant may assist in implementation without usurping the manager's job.[36]

69. Although McKinsey has historically been regarded as a "strategy" consulting firm, by the time it was working with Purdue, implementation services were a core component of the suite of services that McKinsey provided within the "transformational relationship" it developed with its clients.[37] Indeed, writing in 2013, Harvard Business School Professor Clayton Christensen observed the decline in "pure" strategy work performed by consultants, as the industry sought to diversify its income streams by offering implementation and other services to clients. "For example, at traditional strategy-consulting firms, the share of work that is classic strategy has been steadily decreasing and is now about 20%, down from 60% of 70% some 30 years ago."[38]

70. When partnering with clients, a core component of the McKinsey relationship is discretion. "The basis of any client relationship with the firm is trust. Companies share their most

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[36] *Id.*

[37] For McKinsey's own description of its implementation services, *See https://www.mckinsey.com/business-functions/mckinsey-accelerate/how-we-help-clients/implementation* (last accessed October 19, 2020).

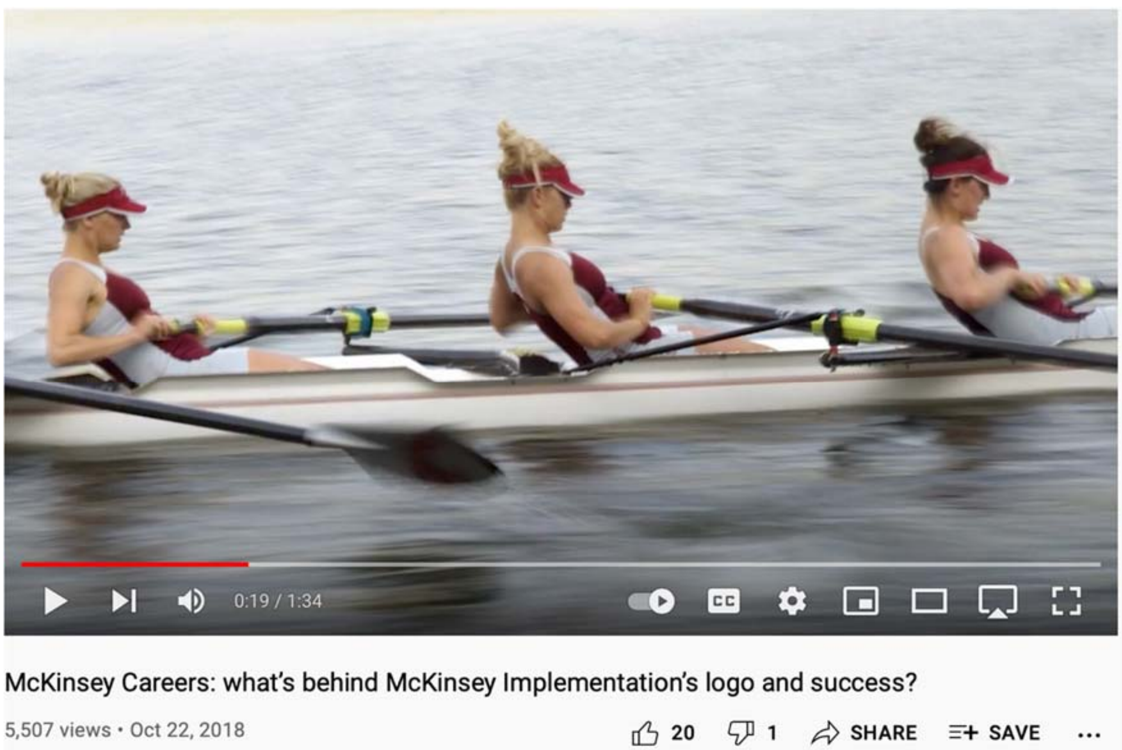
[38] Clayton Christensen, Dina Wang, and Derek van Bever, "Consulting on the Cusp of Disruption," *Harvard Business Review*, October 2013, *available at* https://hbr.org/2013/10/consulting-on-the-cusp-of-disruption

competitive secrets with McKinsey with the understanding that confidentiality is paramount. McKinsey consultants aren't even supposed to tell their own spouses about their client work."[39] McKinsey recognizes it must have its clients' trust and make confidentiality "paramount," as "[c]ompanies share their most competitive secrets with McKinsey" for McKinsey to do its work.[40]

71. During the implementation phase, McKinsey essentially bonds with the client. Describing McKinsey's approach to implementation, one McKinsey consultant stated, "In some of the most successful engagements I've seen, you can't even tell the difference between a McKinsey team member and one of our clients because we working that cohesively together."[41]

72. Another McKinsey Senior Implementation Coach described McKinsey's approach: "We're in there interacting with every element of that organization, from the welders or mechanics on the front line, all the way up to the board of directors."[42]

73. McKinsey's implementation team even has a symbol: a rowing team.



[39] McDonald, *The Firm*, Pg. 308.
[40] *Id.* at 308.
[41] McKinsey on Implementation, April 30, 2017, *available at* https://www.youtube.com/watch?v=rEQOGVpl9CY
[42] *Id.*

74. Jenny, a Practice Manager at McKinsey, explained its significance: "The rowers symbolized to us being in the boat with the clients, doing real work and being jointly responsible for the success."[43]

75. Eugene, a partner, further offered:

> The reason McKinsey implementation works is because clients love it. The fact that we are staying longer with them, the fact that we're getting in to the trenches, the fact that we are there to walk the emotional journey with them when they're going through the tough times and really changing their companies, is what makes McKinsey implementation truly distinctive.[44]

76. In the broadest of generalities, then, McKinsey's business model, as a provider of strategy and implementation consulting services, is to partner with clients to pursue business objectives identified by McKinsey. Once an objective is identified, the client and McKinsey then engage in concerted action as a seamless and cohesive unit in order to implement the necessary means to achieve it.

1. McKinsey's Long-Term Partnership with the Pharmaceuticals Industry

77. Today, McKinsey's website explains "How We Help Clients" in the pharmaceuticals industry: "Helping clients maximize commercial value by assisting with product launch, marketing, sales, and market access."[45] McKinsey helps numerous clients throughout the pharmaceutical industry, from manufacturers to distributors and pharmacies. It often does so contemporaneously. For instance, McKinsey might advise multiple opioid manufacturers on the sales and marketing of competing branded opioid products.

78. McKinsey's dominance of the consulting space in the pharmaceutical industry presents its own opportunity for further client service. Specifically, McKinsey also helps its clients by telling them what their competitors—who are also McKinsey clients—are doing.

[43] *See* "McKinsey Careers: what's behind McKinsey Implementation's logo and success?", October 22, 2018, *available at* https://web.archive.org/web/20200419140214/https://www.youtube.com/watch?v=3-Zx859VJtw
[44] *Id.*
[45] https://www.mckinsey.com/industries/life-sciences/how-we-help-clients/commercial

79. For example, McKinsey pitched its services to Purdue on the basis that it was able to "*bring examples from other successful companies*" and perform "detailed analytics."[46]

2. The McKinsey Pharmaceuticals and Medical Products Practice Group

80. Like most management consulting companies, McKinsey organizes itself into practice groups that specialize in a given industry.

81. McKinsey has long maintained a Pharmaceuticals and Medical Products ("PMP") industry practice group dedicated to working with pharmaceutical companies. In 2004, when McKinsey's relationship with Purdue began, the PMP group was led by Michael Pearson. Pearson worked for McKinsey for twenty-three years and was a member of the firm's shareholder council (McKinsey's equivalent of a board of directors) in addition to leading PMP before departing McKinsey in 2008 to helm Valeant Pharmaceuticals.[47]

82. Pearson stated: "At McKinsey pharmaceuticals was one of our biggest industry groups."[48] Pearson was "not the quintessential suave and intellectual McKinsey partner. He was loud and profane and was seen, in the words of one former colleague, as 'sharp-edged and sharp elbowed.'"[49]

83. Under his leadership, McKinsey's knowledge and expertise in the pharmaceutical industry was significant. By 2009, McKinsey described its capabilities: "We have an unparalleled depth of both functional and industry expertise as well as breadth of geographical reach. Our scale, scope, and knowledge allow us to address problems that no one else can. At heart, we are a network of people who are passionate about taking on immense challenges that matter to leading organizations, and often, to the world."

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[46] PPLPC021000601208 (emphasis added).

[47] John Gapper, *McKinsey's fingerprints are all over Valeant*, Financial Times, March 23, 2016, *available at:* https://www.ft.com/content/0bb37fd2-ef63-11e5-aff5-19b4e253664a

Notably, Rob Rosiello, a McKinsey partner who was a Director of Client Services (or "DCS") of the Purdue account alongside co-DCS'es Maria Gordian and Martin Elling , went on to join Pearson at Valeant in 2015 as Chief Financial Officer. The DCS is the partner in charge of the client account.

[48] Michael Peltz, *Mike Pearson's New Prescription for the Pharmaceuticals Industry*, Institutional Investor, September 3, 2014, *available at:* https://www.institutionalinvestor.com/article/b14zbjfm8nf1c4/mike-pearsons-new-prescription-for-the-pharmaceuticals-industry

[49] John Gapper, *McKinsey's fingerprints are all over Valeant*, Financial Times, March 23, 2016, *available at:* https://www.ft.com/content/0bb37fd2-ef63-11e5-aff5-19b4e253664a

84. In 2012, while advising Purdue, McKinsey described PMP and its health care capabilities thusly: “Indeed, there is a doctor in the house. We have more than 1,700 consultants with significant healthcare experience, including more than 150 physicians and 250 consultants with advanced degrees in genetics, immunology, biochemical engineering, neurobiology, and other life sciences. We also have 75 consultants with advanced degrees in public health, healthcare management, and related fields.”

85. That same year, the PMP group published a report entitled “Death of a Sales Model, or Not: Perspectives on the Evolution of Pharmaceutical Field Based Selling.”[50] In it, McKinsey partner Laura Moran co-authored a segment called “The Few, The Proud, The Super-Productive: How a ‘smart field force’ can better drive sales.” In the segment, Moran and her co-authors described various ways a pharmaceutical company could optimize its sales force. Moran worked on the Purdue account, where the strategies outlined in her article were incorporated into Project Turbocharge two years later.

86. With respect to pharmaceutical marketing, the PMP group states, “We support clients in creating high-impact strategies that maximize value, using customized tools. We also have detailed market data for all major geographic regions.”[51] PMP also works with pharma clients regarding their sales force: “Our efforts span the entire organization—we can help train and restructure sales forces, work directly in the field to provide coaching, maximize value from back-office services, develop strategies to accelerate short-term sales, and assist with company-wide commercial transformations.”[52]

87. McKinsey has long considered itself a “leadership factory” for good reason.[53] Nowhere is this more apparent than the pharmaceutical industry, where, thanks to PMP’s efforts under Pearson’s leadership, McKinsey continues to reign as the dominant management consultant.

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[50] “Death of a Sales Model, or Not,” Pharmaceutical and Medical Product Practice, McKinsey, *available at* https://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/pharma%20and%20medical%20products/pmp%20new/pdfs/2012%20death%20of%20a%20sales%20model%20or%20not.pdf

[51] *See* https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/how-we-help-clients/commercial

[52] *Id*.

[53] *See* Adam Jones, “Should business schools fear McKinsey’s leadership factory?,” *Financial Times*, May 22, 2016, *available at:* https://www.ft.com/content/0d17f670-1612-11e6-b197-a4af20d5575e

88. Consistent with PMP's ambition that McKinsey be the dominant consultant in the pharmaceutical industry, McKinsey has blanketed the entire pharmaceutical supply chain with alumni.

89. Rajiv de Silva, for instance, was appointed CEO of Endo Pharmaceutical in March 2013. Endo's two top-selling drugs were pain medications. Endo—and de Silva, individually—have been named in multiple lawsuits related to the ongoing opioid crisis. Previously, de Silva worked with Pearson in a leadership position within PMP at McKinsey before joining Rob Rosiello, a former McKinsey partner, and Pearson at Valeant.[54] McKinsey advised Endo on its opioid business.

90. Likewise, Frank Scholz was a partner at McKinsey and a leader in the PMP group for seventeen years prior to departing in 2013 to join Mallinckrodt, another opioid manufacturer presently in bankruptcy after being named in numerous lawsuits relating to the ongoing opioid crisis. In fact, Scholz was the President of the "Specialty Generics" division of Mallinckrodt (formerly SpecGX LLC), which is the division that sold generic opioids. McKinsey advised Mallinckrodt on its opioid business.

91. Teva Pharmaceuticals,[55] another opioid manufacturer named in numerous lawsuits for its role in the opioid crisis, is led by President and Chief Executive Officer and McKinsey alumnus, Kare Schultz. He joined the company in 2017, at which point he was also appointed to Teva's board of directors. Through an asset manager named Deerfield, McKinsey's in-house hedge fund held a financial stake in Teva Pharmaceuticals while McKinsey advised its numerous clients on how to maximize opioid sales.[56]

92. McKinsey's involvement with Teva has been long-term. In 2006, upon his retirement from McKinsey, Roger Abravanel joined Teva's board of directors the following

[54] David Sell, *"Endo CEO downplays Valeant link,"* Philadelphia Inquirer, November 5, 2015, *available at* https://www.inquirer.com/philly/business/20151106_Endo_CEO_downplays_Valeant_link.html

[55] "Teva Pharmaceuticals" or "Teva" refers to Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc., together.

[56] Gretchen Morgenson, "Consulting giant McKinsey allegedly fed the opioid crisis. Now an affiliate may profit from treating addicts.," *NBC News*, February 8, 2021, *available at* https://www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969
McKinsey's in-house hedge fund is discussed further, below.

year.[57] By 2011, Teva had acquired Cephalon, Inc., another manufacturer of opioids, as "a core part of [Teva's] strategy" of "growth through acquisitions."[58] Befitting the pattern, Cephalon had its own long-standing ties to McKinsey before being acquired by Teva. In 2008, when Cephalon's Executive Vice President, General Counsel, and Secretary John E. Osborn retired, he accepted a job as "an advisor on life sciences regulatory and compliance matters to the international consulting firm McKinsey & Company, Inc."[59]

93. McKinsey has ties to another notable opioid industry combination: the 2012 acquisition of Actavis, Inc.by Watson Pharmaceuticals, Inc. ("Watson") for €4.25 billion. In the aftermath of the acquisition of the large European pharmaceutical company, Watson created a "Global Integration Management Office" reporting directly to its CEO, Paul Bisaro, to focus "on planning and implementing the integration of Actavis."[60] In order to achieve this critical task, Watson hired Marc Lehnen: "We were very pleased to recruit Marc from McKinsey & Company, Inc. to lead the Integration Management Office. Marc has years of experience in the generic industry and knows our culture and way of operating."[61] Notably, the press release indicates that McKinsey was already advising Watson regarding the acquisition: "*Although Marc does not formally join our Company until July*, he will nevertheless be involved in the integration planning during this interim period."[62]

94. Allergan,[63] another opioid manufacturer and defendant in the nationwide opioid litigation, has also relied on McKinsey as a source of management candidates. McKinsey Senior Adviser Christopher J. Coughlin joined Allergan's board in 2014 and remains there today.

[57] Form 20-F dated December 31, 2012, Teva Pharmaceutical Industries Limited, *available at* https://www.sec.gov/Archives/edgar/data/818686/000119312513050510/d450498d20f.htm
[58] *Id.*
[59] "Cephalon General Counsel John E. Osborn to Resign Position," February 8, 2008, *available at* https://www.sec.gov/Archives/edgar/data/873364/000110465908008569/a08-5085_1ex99d1.htm
[60] "Watson Announces Formation of Global Integration Management Office to Support ending Actavis Acquisition," PR Newswire, May 9, 2012, *available at* https://www.prnewswire.com/news-releases/watson-announces-formation-of-global-integration-management-office-to-support-pending-actavis-acquisition-150755565.html
[61] *Id.*
[62] *Id*. (emphasis added).
[63] Allergan is part of the same corporate family as Actavis and Watson.

95. Abbott Labs, which partnered with Purdue in the early years of OxyContin to use Abbott's sales force to market Purdue's drug, has been led by CEO Miles White since 1998. White began his career at McKinsey around 1980.

96. As the preceding paragraphs make clear, McKinsey was in a truly unique position: given its dominance of pharmaceutical management consulting through PMP, practically all opioid industry participants were its clients. And those same clients routinely hire McKinsey consultants to leadership positions within their companies. While advising multiple industry participants regarding the sales of competing products, McKinsey was in a position to know confidential information and trade secrets of these clients "with the understanding that confidentiality is paramount."[64]

97. Because of its client relationships, McKinsey was, quite literally, the sole repository on Earth of this collective knowledge of industry-wide tactics regarding the sales and marketing of opioids, and the outcomes thereof. This unique collection of knowledge and expertise made McKinsey a hub: even if any two given industry participants did not know what each other was doing, McKinsey knew exactly what *both* were doing because both were clients.

98. McKinsey's relationships and influence carry far beyond the manufacturers. For instance, current McKinsey director Nancy Killefer has also been an independent director of Cardinal Health, Inc. ("Cardinal") —one of the "Big Three" Distributor Defendants in the ongoing nationwide opioid litigation—since 2015. Chunhui Moi, Cardinal's current Vice President of Corporate Strategy, was previously an associate principal at McKinsey, where he worked for nine years. Michele Holcomb, Cardinal's current Executive Vice President, Chief Strategy and Business Development Officer, was a partner in the Global Pharmaceutical Practice at McKinsey.

99. McKinsey populates the "strategy" positions at the other opioid distributors as well. At AmerisourceBergen, the "Director of Corporate Development and Strategy" was hired away from McKinsey, where she had previously been a senior associate. AmerisourceBergen's Executive Vice President and Chief Strategy Officer had previously been a partner at McKinsey.

[64] McDonald, *The Firm*, Pg. 308.

100. At McKesson Corporation ("McKesson"), another McKinsey client, the President of McKesson Specialty Health and, previously Vice President of Corporate Strategy, was Marc Owen. "Prior to joining McKesson, Owen was a senior partner at McKinsey, advising pharmaceutical manufacturers, healthcare providers, distributors and technology companies, *including McKesson*, for more than a decade."[65] After Owen was promoted in 2012, McKesson hired yet another Vice President of Corporate Strategy away from McKinsey.

101. In short, one way McKinsey adds value for a client is by knowing what all of its competitors are doing. It possesses a greater body of knowledge about any given industry in which it advises multiple participants than any individual participant does itself.

3. <u>The Transformational Relationship</u>

102. McKinsey has long touted the notion of a "transformational relationship." It is the goal of every client relationship McKinsey develops and, McKinsey argues, the best way to extract value from a client's use of McKinsey's services. McKinsey is not a one-off seller of advice for any given CEO's problem of the day. Rather, McKinsey argues that real value for the client derives from an ongoing "transformational" relationship with the firm.[66]

103. At its core, the "transformational relationship" is *long-term*. It is the antithesis of a one-off contract wherein McKinsey performs one discreet project for a client and then concludes its business. Rather, "once McKinsey is inside a client, its consultants are adept at artfully creating a feedback loop through their work that purports to ease executive anxiety but actually

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[65] "Marc Owen Appointed President of McKesson Specialty Health," McKesson, January 31, 2012, *available at* https://www.mckesson.com/about-mckesson/newsroom/press-releases/2012/marc-owen-appointed-president-of-mckesson-specialty-health/ (emphasis added)

[66] Duff McDonald, *The Firm*, Pg. 136-37 ("McKinsey no longer pitched itself as a project-to-project firm; from this point forth [the late 1970s], it sold itself to clients as an ongoing prodder of change, the kind a smart CEO would keep around indefinitely.").

creates more of it."[67] The long term result can be "dependence" on the McKinsey consultants. "We insinuate ourselves," Ron Daniel, McKinsey's then-managing partner, told *Forbes* in 1987.[68]

104. "They have follow-on work not just because they're good at what they do, but because they are trained in how to manage these kinds of client relationships. They understand that the core reality is the relationship and the conversation, and that any particular engagement is merely epiphenomenal," explained Alan Kantrow, formerly the editor of *McKinsey Quarterly*.[69]

105. This strategy of weaving itself into all aspects of its clients' business proved enormously successful for McKinsey over the years. It was a strategy McKinsey encouraged its consultants to take with clients to great effect:

> The sell worked: Once ensconced in the boardrooms of the biggest corporate players in the world, McKinsey rarely left, ensuring a steady and growing flow of billings for years if not decades. In 2002, for example, *BusinessWeek* noted that at that moment, the firm had served four hundred clients for fifteen years or more.[70]

106. Another aspect of the transformational relationship McKinsey develops with clients is the development and marketing of "leave-behind" products, such as software applications, that are sold to clients as tools that can be used by the business on an on-going and recurring basis, separate and apart from McKinsey's project-based consulting work. As described by Harvard Business School Professor Clayton Christensen, starting in 2007, "McKinsey & Company initiated a series of business model innovations that could reshape the way the global consulting firm engages with clients. One of the most intriguing of these is McKinsey Solutions, software and technology-based analytics and tools that can be embedded at a client, providing ongoing engagement outside the traditional project-based model."[71]

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[67] *Id.* at pg. 6. Purdue provides a fine example of this feedback loop in action. In 2008, when McKinsey was advising Purdue regarding Risk Evaluation and Mitigation Strategies ("REMS") for OxyContin required by the FDA, McKinsey partner Maria Gordian wrote to fellow partners Martin Elling and Rob Rosiello regarding progress in the "REMS work" as well as "Broader Strategy work." Regarding the latter, Gordian noted that Purdue board members Jonathan Sackler and Peter Boer "basically 'blessed' [Craig Landau] to do whatever he thinks is necessary to 'save the business.'. . . *I believe there is a good opportunity to get another project here.*" MCK-MAAG-0117875 (emphasis added). Indeed, after the REMS work was completed, McKinsey continued to work on "Broader Strategy work" for another decade.

[68] John Merwin, "We Don't Learn from Our Clients, We Learn from Each Other," *Forbes*, October 19, 1987.

[69] Duff McDonald, *The Firm*, Pg. 185.

[70] *Id.* at pg. 136.

[71] Clayton Christensen, Dina Wang, and Derek van Bever, "Consulting on the Cusp of Disruption," *Harvard Business Review*, October 2013, *available at* https://hbr.org/2013/10/consulting-on-the-cusp-of-disruption

107. McKinsey's relationship with Purdue provides an example of the deployment of these "leave-behind" products. One McKinsey Solution is a pharmaceutical sales and marketing workforce optimization tool called FieldGuide, a proprietary software application McKinsey sells to clients. "The FieldGuide tool optimizes salesforce deployment and territory design through advanced geospatial analysis that leverages both market-potential insights across device categories and advanced sales-response curve analysis."[72] McKinsey sold it to Purdue for the purpose of optimizing Purdue's OxyContin salesforce.

D. McKinsey and Purdue: A Case Study in Transformation

108. Indeed, McKinsey's work with Purdue is a prime example of the transformational relationship in action. McKinsey counted Purdue as a client at least as early as 2004, three years *before* Purdue's parent and officers first pleaded guilty to misbranding OxyContin in 2007. McKinsey was actively working with Purdue to increase OxyContin sales despite that guilty plea and continued to do so throughout the time period that Purdue and its advisors were bound by the terms of the Corporate Integrity Agreement entered in to alongside the guilty plea. McKinsey's work with Purdue continued through at least 2018.

109. McKinsey staffed at least forty known consultants to Purdue, from senior partners all the way down through engagement managers and entry-level associates. Throughout the unfolding of the nationwide opioid crisis that only continued to worsen after the 2007 guilty plea, McKinsey remained steadfast alongside the Sacklers and Purdue every step of the way. The *mea culpas* would come only later.

110. McKinsey partner Maria Gordian, in her March 26, 2009 "EY 2009 Impact Summary" internal report to McKinsey director Olivier Hamoir and McKinsey's Personnel Committee, recounted her accomplishments that year on the Purdue account. The document is an annual self-assessment produced by McKinsey partners. In it, Gordian described the state of firm's relationship for Purdue:

> With client work extending through the 3rd quarter, and several additional proposals in progress, we continue to expand the depth and breadth of our relationships at

[72] https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/how-we-help-clients/medtech/marketing-and-sales

> Purdue. We look forward to deepening our relationships with the Sackler family and serving them on key business development issues, and to expanding our relationship with [John] Stewart and other members of the senior management team.[73]

111. Gordian even described herself as a counselor to Richard Sackler in the same memorandum, in addition to being a "point of contact for the Board and Sackler family."[74]

112. The continued expansion of the depth and breadth of McKinsey's relationship with Purdue was an ever-present internal goal for McKinsey, as it was accompanied by recurring and ever-increasing client billings.

113. By 2014, both the breadth and depth of McKinsey's relationship with Purdue had expanded dramatically. During the 2009 to 2014 period in particular, Purdue relied extensively on McKinsey to develop and implement its sales and marketing strategy for OxyContin. But McKinsey's work for Purdue involved many other facets of Purdue's business beyond sales and marketing, including general and administrative consulting, review of product acquisition, evaluation of research and development, advising Purdue on the design of clinical studies, risk management, and interactions with regulators.

114. McKinsey's sales and marketing work for Purdue focused on creating and implementing strategies and tactics to bolster the sales of OxyContin, a Schedule II drug that is widely recognized as among the most frequently diverted and abused opioids. As Purdue faced growing scrutiny, McKinsey also helped the company protect its public image and profit from the market for illicit opioids, which McKinsey's industry-wide efforts helped to promote and maintain.

115. McKinsey understood the Sacklers' goals for Purdue and the work it would need to perform to maintain and grow Purdue's opioid profits amidst a growing epidemic of addiction and abuse. Part of McKinsey's work involved assessing the "underlying drivers" of OxyContin's (financial) performance. As described below, these drivers boil down to two things: (1) a widespread deceptive marketing campaign and (2) fueling an illicit market for non-medical use.

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[73] The Ad Hoc Group of Non-Consenting States' Statement in Support of the Official Committee of Unsecured Creditors' Motions to Compel Production of Purportedly Privileged Documents for *In Camera* Review, Doc. No. 2012, *In re Purdue Pharma, Inc.*, filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex 7, Pg. 48; MCK-MAAG 0118669.

[74] *Id.*

Purdue entered into guilty pleas arising out of both types of conduct in 2007 and 2020, respectively. McKinsey delved into the "granular" aspects of Purdue's sales and promotion. And, throughout the two companies' long-term relationship, McKinsey understood Purdue's business "both in terms of content and culture," as its own renewed consulting agreement assured in 2013.

1. 2004: McKinsey and Purdue Meet

116. On March 1, 2004, McKinsey entered into a Master Consulting Agreement with Purdue for services that would be defined from time to time.[75] The Agreement was signed on McKinsey's behalf by Rob Rosiello, then a senior partner in the PMP practice group. After a ruling that held patents on OxyContin unenforceable due to Purdue misleading the patent office, McKinsey stepped in to help Purdue.[76]

117. The Master Consulting Agreement [redacted]"[77] [redacted]"[78]

118. From 2004 through 2008, McKinsey advised Purdue on research and development, business development, and product licensing related to Purdue's opioid products.[79] Consistent with its business model, McKinsey leveraged these projects into growth of its "Broader Strategy work" also underway with Purdue.[80] Specifically, in October 2008, Purdue retained McKinsey for broad strategy work after two board members "blessed" Purdue executive Craig Landau with doing "whatever he thinks is necessary to 'save the business'" after the 2007 criminal plea and introduction of generic competition to the older OxyContin.[81]

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[75] PPLPC012000069192
[76] *Id.*
[77] *Id.*
[78] PPLPC020000034087
[79] PPLPC013000116218; PPLP004401340
[80] MCK-MAAG-0117875
[81] *Id.*

2. 2007: Purdue Pleads Guilty to Misbranding OxyContin and is Bound by a Corporate Integrity Agreement

119. On May 10, 2007, John Brownlee, United States Attorney for the Western District of Virginia, announced the guilty plea of the Purdue Frederick Company, the parent of Purdue Pharma, relating to the misbranding of OxyContin. Brownlee stated,

> Even in the face of warnings from health care professionals, the media, and members of its own sales force that OxyContin was being widely abused and causing harm to our citizens, Purdue, under the leadership of its top executives, continued to push a fraudulent marketing campaign that promoted OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal. In the process, scores died as a result of OxyContin abuse and an even greater number of people became addicted to OxyContin; a drug that Purdue led many to believe was safer, less subject to abuse, and less addictive than other pain medications on the market.

120. Purdue Frederick Company as well as three of Purdue's officers, pleaded guilty to the misbranding of OxyContin pursuant to various provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*

121. Purdue admitted that "supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications." Part of this deceptive messaging included highlighting OxyContin as a long-acting ("LA") or extended release ("ER") opioid and suggesting it created less chance for addiction than "immediate release" opioids because it had fewer "peak and trough" blood level effects or "did not cause a 'buzz' or euphoria" in the same manner as these other opioids.

122. Concurrent with its guilty plea, Purdue entered into a Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services on May 7, 2007. Purdue's compliance obligations under the Corporate Integrity Agreement ran for a period of five years, and ultimately terminated in January 2013.[82]

123. Pursuant to the Corporate Integrity Agreement, Purdue was obligated to implement written policies regarding its compliance program and compliance with federal health care program and Food and Drug Administration requirements, including:

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[82] *See* https://www.justice.gov/opa/press-release/file/1329576/download

a. "selling, marketing, promoting, advertising, and disseminating Materials or information about Purdue's products in compliance with all applicable FDA requirements, including requirements relating to the dissemination of information that is fair and accurate . . . including, but not limited to information concerning the withdrawal, drug tolerance, drug addiction or drug abuse of Purdue's products";

b. "compensation (including salaries and bonuses) for Relevant Covered Persons engaged in promoting and selling Purdue's products that are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion or sales of Purdue's products"; and

c. "the process by which and standards according to which Purdue sales representatives provide Materials or respond to requests from [health care providers] for information about Purdue's products, including information concerning withdrawal, drug tolerance, drug addiction, or drug abuse of Purdue's products," including "the form and content of Materials disseminated by sales representatives," and "the internal review process for the Materials and information disseminated by sales representatives."

124. Purdue was obligated to engage an Independent Review Organization to ensure its compliance with the strictures of the Corporate Integrity Agreement and to file compliance reports on an annual basis with the Inspector General.

125. In the wake of its accession to the Corporate Integrity Agreement, Purdue faced newly imposed constraints on its sales and marketing practices. The Corporate Integrity Agreement was a problem to solve. Despite the agreement's constraints (i.e., do not lie about OxyContin), Purdue and its controlling owners, the Sackler family, still intended to maximize OxyContin sales.

3. <u>The Sacklers React to the "Concentration of Risk" Posed to Them by the Opioid Business.</u>

126. The Sackler family has owned and controlled Purdue and its predecessors since 1952. At all times relevant to this Complaint, individual Sackler family members occupied either six or seven of the seats on Purdue's board of directors, and at all times held a majority of Board

seats. To advise the board of directors of Purdue Pharma was to advise the Sackler family. The interests of the Sackler family and the Purdue board of directors, and Purdue itself, as a privately held company, were all aligned. Practically, they were indistinguishable.[83]

127. As a result of the 2007 guilty plea, the Sacklers made the strategic decision to distance the family from Purdue, which was regarded, in the words of Richard Sackler, as an increasingly dangerous "concentration of risk" for Purdue's owners. Ten days after the guilty plea was announced, David Sackler wrote to his father, Richard Sackler, and uncle, Jonathan Sackler, describing precisely what that "risk" was: legal liability for selling OxyContin. In response to Jonathan stating that "there is no basis to sue 'the family,'" David replied:

Message

From: David Sackler [redacted]
Sent: 5/17/2007 11:08:08 PM
To: 'Sackler, Jonathan' [redacted] Sackler, Dr Richard [redacted]
CC: Ives, Stephen A. [redacted]
Subject: RE: Idea
Attachments: image001.jpg

Well I hope you're right, and under logical circumstances I'd agree with you, but we're living in America. This is the land of the free and the home of the blameless. We will be sued. Read the op-ed stuff in these local papers and ask yourself how long it will take these lawyers to figure out that we might settle with them if they can freeze our assets and threaten us.

128. Given concern over this "concentration of risk," the two sides of the Sackler family spent considerable time and energy debating the best way to achieve distance from Purdue, and collectively considered a variety of options for doing so. One option was to sell the company to or merge the company with another pharmaceutical manufacturer. They discussed Shire as a possible target, as were Cephalon, UCB, and Sepracor, Inc. The proceeds of such a transaction could then be re-invested in diversified assets, thereby achieving the Sacklers' desired distance from opioids.

129. Mortimer D.A. Sackler advocated for a sale or merger in a February 21, 2008 email to Richard Sackler (a former president and co-chairman of Purdue) and several others, writing, "The pharmaceutical industry has become far too volatile and risky for a family to hold

[83] Craig Landau, soon to become CEO of Purdue, acknowledged in May 2017 that Purdue operated with "the Board of Directors serving as the 'de facto' CEO." The future CEO of the company, in other words, understood that he would have little practical power despite his new title. The owners ran the business.

95% of its wealth in. It simply is not prudent for us to stay in the business given the future risks we are sure to face and the impact they will have on the shareholder value of the business and hence the family's wealth." The risk he referred to was, at least in significant part, further liability related to OxyContin.

130. Another option was to have Purdue borrow money in order to assure Purdue had adequate funds to continue operating while the Sacklers, as owners, began to make substantial distributions of money from the company to themselves. Once again, the proceeds of the distributions could then be re-invested in diversified assets, thereby achieving the Sacklers' desired distance.

131. In order to pursue either of these options, the Sacklers needed to maximize opioid sales in the short term so as to make Purdue==by then the subject of substantial public scrutiny—appear either as an attractive acquisition target or merger partner to another pharmaceutical manufacturer or as a creditworthy borrower to a lender.

132. In short, the Sacklers planned to engage in a final flurry of opioid pushing in order to rid themselves of their pharmaceutical company dependency for good.

133. In fact, in the years after the 2007 guilty plea, Purdue would retain only the absolute minimum amount of money within it as possible: $300 million. Purdue was required to retain that amount pursuant to a partnership agreement with separate company. Otherwise, all the money was distributed to its owners.[84]

134. Given the complexity of the problem, the Sacklers and Purdue realized that they would need assistance in achieving these internally contradictory objectives. Purdue did not have the capabilities in-house to design and implement a sales strategy for OxyContin that would achieve the Sacklers' objectives. They turned to the global management consulting firm McKinsey, which had already been advising the Sacklers and Purdue for at least three years, for help with their new problem.

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[84] *See* Jared S. Hopkins, *At Purdue Pharma, Business Slumps as Opioid Lawsuits Mount*, Wall Street Journal, June 30, 2019, *available at:* https://www.wsj.com/articles/purdue-pharma-grapples-with-internal-challenges-as-opioid-lawsuits-mount-11561887120?mod=hp_lead_pos6

135. Notably, under the terms of Paragraph II.C.1(b) of the Corporate Integrity Agreement, McKinsey, as a contractor to Purdue performing sales and marketing functions for the company, was itself a "Covered Person" subject to the strictures of the Agreement.[85]

4. Purdue Tasks McKinsey with Boosting Opioid Sales in Light of the Guilty Plea and Corporate Integrity Agreement.

136. The Sacklers faced a problem: the need to grow OxyContin sales as dramatically as possible so as to make Purdue an attractive acquisition target or borrower, while at the same time appearing to comply with the Corporate Integrity Agreement. As one Purdue executive stated of Purdue's attitude toward the Corporate Integrity Agreement: "They did not listen to their critics and insisted they had just a few isolated problems. After the settlement, they didn't change—the way the sales force was managed and incentivized, everything stayed the same."[86]

137. Purdue and the Sacklers were well aware of the constraints posed by the Agreement. Indeed, during a May 20, 2009 Executive Committee Meeting, the discussion led to whether Purdue should have a single sales force marketing all Purdue products, including OxyContin, or instead to "create a separate Sales Force for Intermezzo (a sleeping pill) that would be comprised of approximately 300 representatives." John Stewart, Purdue's then-CEO, saw an opportunity, and asked if the Corporate Integrity Agreement would apply if Purdue were to launch Intermezzo and another Purdue product, Ryzolt (a branded version of Tramadol, another narcotic painkiller), using the separate sales force. Might the new drug launch fall outside of the Corporate Integrity Agreement, he asked?[87]

138. It would not, he was told by Bert Weinstein, Purdue's Vice President of Compliance.[88]

139. Given the tension between compliance with the Corporate Integrity Agreement and the desire to sell more OxyContin, Purdue needed help.

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[85] The relevant language in the Corporate Integrity Agreement provides: "'Covered Persons' includes . . . all contractors, subcontractors, agents, and other persons who perform sales, marketing, promotional, pricing, government contract, or regulatory functions . . . on behalf of Purdue." PDD1712900096.

[86] David Crow, *How Purdue's 'one-two' punch fuelled the market for* opioids, Financial Times, September 9, 2018, *available at:* https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c

[87] PPLPC012000226606, Purdue Pharma Executive Committee Meeting Notes and Actions, May 20, 2009, Pg. 2.

[88] *Id.*

140. Ethan Rasiel, a former McKinsey consultant, has described the typical way McKinsey begins working with a client: “An organization has a problem that they cannot solve with their internal resources. That’s the most classic way that McKinsey is brought in.”[89]

141. Such was the case with Purdue. Because it did not have the requisite expertise to address the problems posed by the Corporate Integrity Agreement internally, Purdue expanded on its already-existing relationship with McKinsey to devise a sales and marketing strategy to increase opioid sales despite the Corporate Integrity Agreement and growing concern about the “concentration of risk” that Purdue’s business of selling opioids posed to its owners.

142. McKinsey’s task was to thread the needle: to increase OxyContin sales despite the strictures imposed by the five-year Corporate Integrity Agreement. This McKinsey did, turbocharging[90] the sales of a drug it knew fully well was addictive and deadly, while purporting to respect to the Corporate Integrity Agreement.

143. In short, Purdue would pay money to McKinsey in exchange for McKinsey enabling the company how to sell as much OxyContin as conceivably possible so that the Sacklers could obtain cash to diversify their investment holdings away from Purdue, and keep their money safe from the reach of court judgments, fines, and penalties they feared.

144. Consistent with their plan to dissociate themselves from the company, the Sacklers appointed Mr. Stewart as the CEO of Purdue in 2007. The Sacklers viewed Stewart as someone loyal to the family. He had previously worked for a division of Purdue in Canada. Stewart’s job was to assist the Sacklers with the divestiture or eventual orderly wind-down of Purdue. Stewart was paid more than $25 million for his services to Purdue from 2007 through 2013.

145. Purdue’s Executive Committee discussed Stewart’s concerns regarding the constraints posed by the Corporate Integrity Agreement on May 20, 2009. Within weeks, McKinsey was working with Purdue to devise and implement new marketing strategies for OxyContin.

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[89] *How McKinsey Became One of the Most Powerful Companies in the World*, CNBC, June 6, 2019 *available at:* https://www.youtube.com/watch?v=BBmmMj_maII

[90] If the description is overbearing, note that it is McKinsey’s own, as described below.

146. Stewart, as CEO, was in charge of the relationship with McKinsey. He controlled workflow to and from McKinsey and required his personal approval for any work orders with McKinsey.

147. In addition, Purdue's Vice President of Corporate Compliance, "responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in the [Corporate Integrity Agreement]," reported directly to Stewart.[91]

148. Throughout their relationship, McKinsey routinely obtained information from, advised, communicated with, and ultimately worked for the Purdue board of directors, controlled by the Sackler family.

149. McKinsey would also work in granular detail with the Purdue sales and marketing staff, led during the relevant period by Russell Gasdia, Vice President of Sales and Marketing.

150. From as early as June 2009 and continuing at least through July 14, 2014, Purdue routinely relied upon McKinsey to orchestrate its sales and marketing strategy for OxyContin. The relationship was characterized by ongoing interactions between teams from McKinsey and Purdue regarding not only the *creation* of an OxyContin sales strategy, but also its *implementation*. McKinsey was a real presence at Purdue. "A team of McKinsey analysts went in-house, camping out in a conference room at Purdue headquarters."[92]

5. **<u>Purdue Relies on McKinsey.</u>**

151. Purdue hired McKinsey not only to give advice, but to devise and then implement a deceptive marketing strategy. For example, for one "major initiative" with Purdue, "McKinsey forecast[ed] a potential incremental increase in sales in the $200-400mm range" over a three-year period, "[w]hen properly implemented."[93]

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[91] PDD1712900096.

[92] Patrick Radden Keefe, *Empire of Pain* 302 (2021). In September, McKinsey named Mr. Keefe's history of the Sackler family and Purdue and the opioid crisis to its 2021 shortlist for "Business Book of the Year." *See https://www.mckinsey.com/about-us/new-at-mckinsey-blog/for-your-reading-list-the-2021-business-book-of-the-year-shortlist*

[93] PPLPC012000257444

152. McKinsey is not cheap, either. Indeed, hiring McKinsey is an expensive proposition. A single junior consultant—typically a recent college or business school graduate—runs clients millions of dollars annually.[94] McKinsey is a highly selective employer and advertises that its employees join "for the opportunity to apply their talents to complex, important challenges."[95] "Talent" is key to McKinsey's model; clients pay for the best and brightest.

153. A client does not choose to pay McKinsey unless it expects to receive benefits it could not have obtained within its own organization. McKinsey offers solutions to clients facing challenges they feel they cannot adequately address on their own. This model has been a stunning success for McKinsey. In 2008, McKinsey's annual revenue was $6 billion. Today, the firm earn more than $10 billion in revenue each year.[96]

154. Clients pay these exorbitant rates for a reason: McKinsey's plans and partnership work. Even critics of the consulting industry recognize the unique efficacy of McKinsey's work. JPMorgan Chase CEO Jamie Dimon once derided consultants as "substituted management" and stated that "consultants can become a disease for corporations." Dimon made one exception to this rule: McKinsey.[97] Given unique levels of trust, respect, and access by major corporations across the United States and the world, McKinsey has unmatched power to affect how those corporations behave.

155. When Purdue entered into a "Master Consulting Agreement" with McKinsey in 2004, Purdue explicitly recognized McKinsey "has a fine reputation as well as excellent experience and relationships in our industry," which Purdue was counting on to boost its opioids business.[98]

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[94] Ian MacDougal, *How McKinsey is Making $100 Million (and Counting) Advising on the Government's Bumbling Coronavirus Response*, ProPublica (July 15, 2020), https://www.propublica.org/article/how-mckinsey-is-making-100-million-and-counting-advising-on-the-governments-bumbling-coronavirus-response.

[95] https://www.mckinsey.com/about-us/overview

[96] Forbes, *McKinsey & Company* (retrieved September 9, 2021), https://www.forbes.com/companies/mckinsey-company/?sh=1201a12624c1.

[97] Duff McDonald. *Behind the singular mystique of McKinsey & Co.* The Guest Blog. CNBC. Sept 25, 2013. Available at: https://www.cnbc.com/2013/09/25/behind-the-singular-mystique-of-mckinsey-co.html

[98] PPLPC012000069192

156. Purdue explicitly recognized that McKinsey stepped in to help Purdue "protect [its] sales and continue to *grow our business*."[99]

157. Furthermore, that the Sacklers, as board members of Purdue, relied on McKinsey in their conduct of Purdue affairs is an admitted fact. In a public filing in the recent Purdue bankruptcy proceedings, the one side of the Sackler family conceded that they did so: "McKinsey is widely recognized as 'a leading management consulting firm' and the Former Directors were statutorily entitled to rely on such expertise."[100]

6. <u>McKinsey Delivers.</u>

158. Purdue, as a monoline manufacturer of opioids, relied on McKinsey in practically all aspects of its business.

a. Courting the Regulators: "We All Feel Responsible."

159. One critical aspect of Purdue's operations, given its status as a producer of controlled substances, was regulatory compliance. McKinsey guided Purdue through practically all of its interactions with regulators whose efforts to protect the public might pose threats to Purdue's business.

160. McKinsey advised Purdue on how to approach the FDA in light of its criminal conviction and retain business in light of the reputational damage to the company and to OxyContin after the admissions in its guilty plea.

161. In 2008, Purdue submitted a New Drug Application for a reformulation of OxyContin, ostensibly to make it more difficult to abuse by extracting the active ingredient from it or otherwise defeating the time-release mechanism in OxyContin tablets—i.e., another product Purdue would later deceptively promote as safer than and less prone to abuse than it was.

162. Having advised Purdue on the design of tests of reformulated OxyContin as part of Purdue's FDA submission, McKinsey knew that reformulated OxyContin could still be abused. Purdue nonetheless touted its introduction of reformulated OxyContin and another ADF opioid as

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[99] *Id.* (emphasis added).
[100] *In re: Purdue Pharma, L.P.*, No. 19-23649, Doc. 3441-1, at ¶ 328 (Aug. 5, 2021).

evidence of its good corporate citizenship and commitment to protecting the public. McKinsey worked with the Sacklers to prepare for Purdue's meetings with the FDA.

163. On January 20, 2009, McKinsey partner Maria Gordian wrote to partners Rob Rosiello and Martin Elling to update them on these ongoing efforts with Purdue:

> We had a very good FDA rehearsal yesterday *with several family members present*. The team did an outstanding job on the study. [P]reparing the client and executing the mock meeting. We are off to DC today for the actually (sic) FDA meeting tomorrow.[101]

164. Gordian's email to Rosiello and Elling forwarded encouraging words from Richard Sackler. He wrote to his daughter, Marianna:

> I am writing to tell you how impressed I was by the preparation for the FDA meeting. Both the method and the process as well as the content was excellent and a major departure from efforts like this in the past. Please share with the team my views and best wishes for a successful interchange with the FDA.[102]

Marianna forwarded the well-wishes to Gordian and the team at McKinsey.

165. In September 2009, Purdue made a presentation to the FDA advisory committee considering its application for its reformulated OxyContin and stated that the new formulation would deter abuse. According to metadata, the PowerPoint presentation was prepared by McKinsey.

166. The FDA approved the reformulation of OxyContin in April 2010.[103]

167. Having successfully navigated the approval process with McKinsey's chaperoning, Purdue then proceeded to market the ADF version of OxyContin as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids.

168. In 2020, two FDA advisory committees evaluating the impact of the reformulated OxyContin concluded that reformulated OxyContin did not, in fact, substantially reduce abuse.

169. At the same time as it worked to rehabilitate Purdue's image with the FDA, McKinsey, in parallel, advised Purdue on how to limit FDA regulations aimed at mitigating the

[101] The Ad Hoc Group of Non-Consenting States' Statement in Support of the Official Committee of Unsecured Creditors' Motions to Compel Production of Purportedly Privileged Documents for *In Camera* Review, Doc. No. 2012, *In re Purdue Pharma, Inc.*, filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex D, Pg. 25 (emphasis added).

[102] *Id.*

[103] *See* https://www.fda.gov/media/126835/download

risks of opioid use. In 2008, shortly after Purdue's criminal plea, the FDA requested Purdue submit a proposed "Risk Evaluation and Mitigation Strategy" ("REMS") for OxyContin. McKinsey provided Purdue with drafts of the submission.[104] Indeed, McKinsey was crucial in devising Purdue's response to the FDA's request for a REMS proposal from Purdue. Gordian informed Rosiello and Elling on October 23, 2008 that John Stewart, Purdue's CEO, "is aware of the critical role we are playing in pulling REMs together and is very appreciative." In the same email, she noted that "the family" was focused "on the response to the non-approval letter" from the FDA.[105]

170. In 2009, the FDA expanded its scope to a class-wide extended release/long-acting REMS program.

171. Seeking to avoid a requirement that prescribers undergo mandatory training on OxyContin's risks or management or obtain certification before prescribing OxyContin, which would limit the numbers of available prescribers, Purdue turned to McKinsey. McKinsey found the cost to Purdue of a system to verify completion of prescriber education before prescriptions could be filled would be $50 million—an estimate Purdue used to oppose efforts for more rigorous risk management strategies.[106] [redacted]

172. Armed with McKinsey's analysis, Purdue's strategy on REMS was effective. The REMS program avoided verification and enrollment provisions that would harm Purdue's profits.

173. Meanwhile, based on McKinsey's work on extended release opioid REMS, McKinsey was aware of warnings and adverse events included within the OxyContin medication

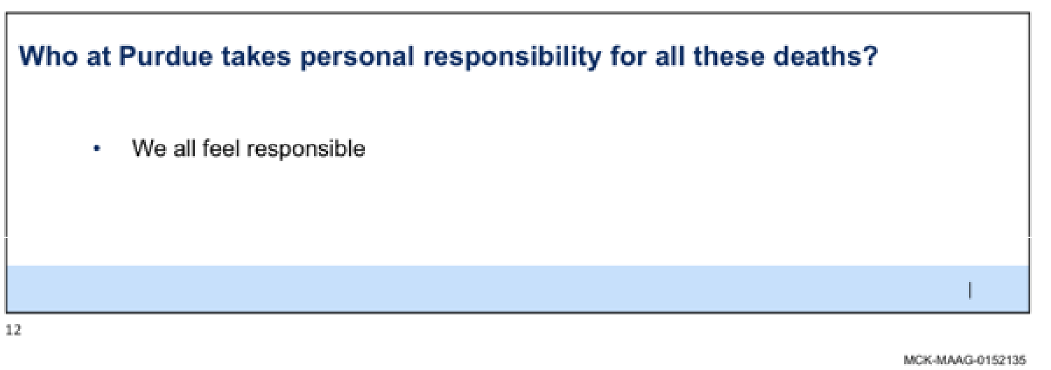
[104] PDD8901578031
[105] The Ad Hoc Group of Non-Consenting States' Statement in Support of the Official Committee of Unsecured Creditors' Motions to Compel Production of Purportedly Privileged Documents for *In Camera* Review, Doc. No. 2012, *In re Purdue Pharma, Inc.*, filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex C, Pg. 22.
[106] PDD8901530124
[107] PPLPC019000622253

guide and communications plans, including risks of overdose and adverse events including dizziness and lethargy.

174. In June 2009, McKinsey helped Purdue prepare for an FDA advisory committee meeting. [redacted]

175. McKinsey prepared for Purdue an "FDA Advisory Committee on Reformulated OxyContin: Question & Answer Book" in September 2009, with questions including "Why should we trust you?" In response, McKinsey recommended Purdue say "We acknowledge mistakes made in the past[;]" "We have x, y and z measures in place that did not exist before[;]" and "[a]t all levels, Purdue's focus is on maintaining the highest ethical standards and meeting the needs of patients[.]"[109]

176. Sometimes, McKinsey's work was as obfuscating as it was self-revealing. To the question of "Who at Purdue takes personal responsibility for all these deaths?[,]" McKinsey offered the following response:[110]



b. The Granularity of Growth

177. To this end, McKinsey prides itself on certain managerial techniques it professes to have detailed knowledge of and expertise in deploying. These techniques are generally

[108] PDD8901645845
[109] MCK-MAAG-0152135
[110] The Ad Hoc Group of Non-Consenting States' Statement in Support of the Official Committee of Unsecured Creditors' Motions to Compel Production of Purportedly Privileged Documents for *In Camera* Review, Doc. No. 2012, *In re Purdue Pharma, Inc.*, filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex F, Pg. 39.

applicable to problems encountered by many businesses; they are conceptual frameworks that McKinsey deploys when tasked with solving a problem for a client.

178. After Purdue's first guilty plea, the Sacklers desired dramatic, short-term growth of Purdue's opioid sales so as to increase the company's attractiveness as an acquisition target or borrower while allowing the Sacklers to take money out of the company. One service McKinsey offers to its clients is to tell them how to grow.

179. In order to identify growth opportunities for a client, McKinsey espouses a "granular" approach to identifying which subsets of the client's existing business are the sources of growth, and exploiting them for all they are worth. In August 2008, McKinsey directors Patrick Viguerie and Sven Smit, together with Mehrdad Baghai, published a treatise on the matter: *The Granularity of Growth: How to Identify the Sources of Growth and Drive Enduring Company Performance* (Wiley, April 2008). "The key is to focus on granularity, to breakdown big-picture strategy into its smallest relevant components."[111]

180. Previously, in an article in *McKinsey Quarterly* (coincidentally published the same month that Purdue pled guilty), the authors explained:

> Our research on revenue growth of large companies suggests that executives should "de-average" their view of markets and develop a granular perspective on trends, future growth rates, and market structures. Insights into subindustries, segments, categories, and micromarkets are the building blocks of portfolio choice. Companies will find this approach to growth indispensable in making the right decisions about where to compete.[112]

181. Additionally, McKinsey encouraged a granular assessment of the geography of corporate growth. "The story gets more precise as we disaggregate the company's performance on the three growth drivers in 12 product categories for five geographic regions."[113]

182. One can imagine this strategy applied to a seller of, say, cartons of milk. If McKinsey were to perform an analysis of the milk seller's sales and marketing and discover that the profit margin on milk cartons sold to university cafeterias in dairy-producing states is much

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[111] *The granularity of growth*, Book Excerpt, McKinsey & Company, March 1, 2008, *available at*: https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/the-granularity-of-growth
[112] Mehrdad Baghai *et. al.*, *The granularity of growth*, McKinsey Quarterly, May 2007, *available at:* https://www.mckinsey.com/featured-insights/employment-and-growth/the-granularity-of-growth
[113] *Id.*

greater than the margin on cartons sold at convenience stores in the southwest, and further that the milk seller has previously devoted equal amounts of time and resources selling to both university cafeterias and convenience stores, then McKinsey would likely advise the client to deploy additional resources towards selling milk to university cafeterias in dairy-producing states. McKinsey's "granular" approach to the milk seller's business channels has identified a way to increase higher margin sales, leading to newfound growth and profitability for the client.

183. Rather than milk, McKinsey deployed this strategy on OxyContin, a controlled substance, after its manufacturer pled guilty to misrepresenting the addictive and deadly properties of the drug.

c. "Identifying Granular Growth Opportunities for OxyContin"

184. McKinsey's granular analysis of Purdue's OxyContin sales efforts led to the implementation of a number of strategies to sell more pills.

185. By January 2010, McKinsey informed Purdue, in accordance with the lessons of McKinsey's granular growth analysis, that Purdue could generate "$200-400mm" in additional annual sales of OxyContin by implementing McKinsey's strategies.[114]

186. In November 2010, a McKinsey report instructed sales reps to maximize profits by "emphasizing [the] broad range of doses"—which meant pushing the doses that were highest and most profitable.[115]

187. In 2012, John Stewart assigned McKinsey to "understand the significance of each of the major factors affecting OxyContin's sales."[116]

188. This McKinsey did in excruciatingly granular detail, analyzing each sales channel for Purdue's opioids to identify weaknesses, opportunities, and to suggest courses of action to improve performance. Many core themes of McKinsey's work would be crystallized in a series of presentations and updates made to the Sackler family and to Purdue's board of directors in the summer of 2013 entitled "Identifying Granular Growth Opportunities for OxyContin."

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[114] PPLPC012000257443; PPLPC012000257446
[115] PPLPC018000346294
[116] PPLPC020000587064

i. Marketing – Countering Emotional Messages

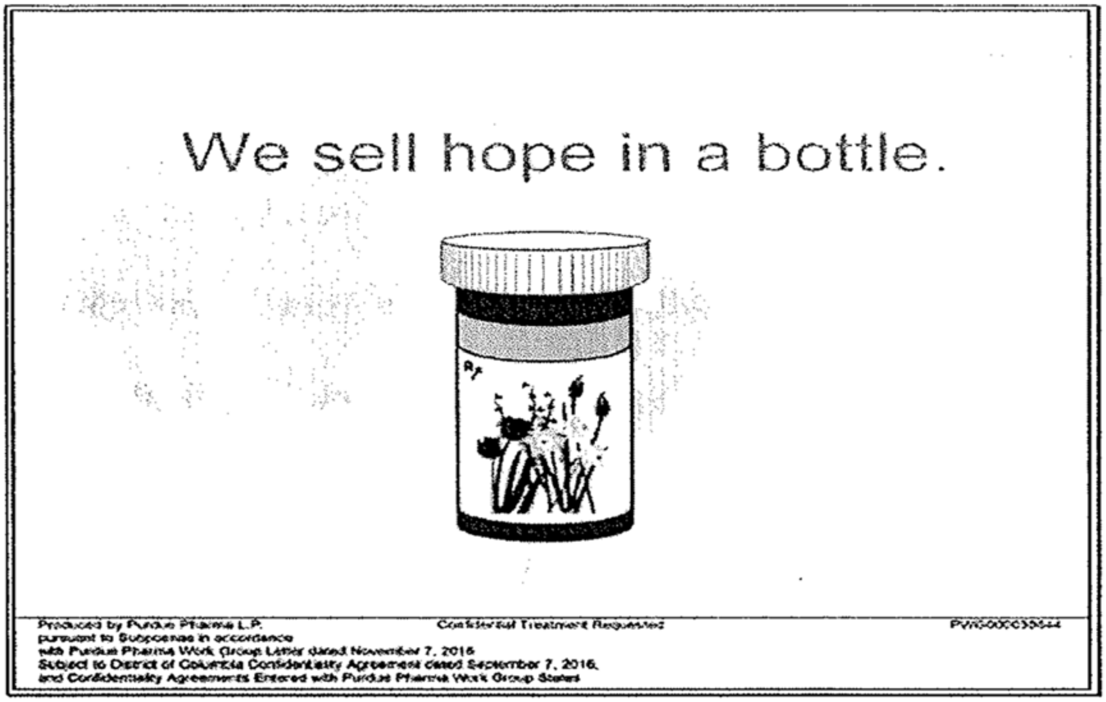
189. From the outset of McKinsey's known work for Purdue, the work was grim. In June 2009, McKinsey teamed with Purdue's then-Chief Medical Officer (and current CEO) Craig Landau and his staff to discuss how best to "counter emotional messages from mothers with teenagers that overdosed in [sic] OxyContin."

190. Months later, McKinsey advised Purdue to market OxyContin based on the false and misleading notion that the drug can provide "freedom" and "peace of mind" for its users, give patients "the best possible chance to live a full and active life," and concomitantly reduce stress and isolation.[117]

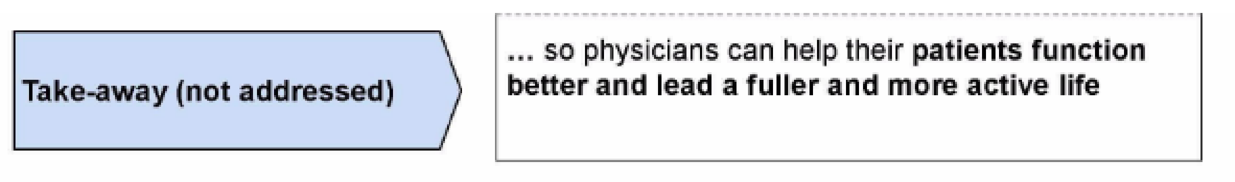
191. These marketing claims were tailored to avoid any pitfalls that the Corporate Integrity Agreement might hold. While false and misleading, these claims regarding "freedom" and "peace of mind" of OxyContin users were narrowly tailored in order to avoid representations regarding "the withdrawal, drug tolerance, drug addiction or drug abuse of Purdue's products," as specified in Section III.B.2.c of the Corporate Integrity Agreement.[118]

[117] PPLPC023000239858
[118] PDD1712900096

192. Purdue's marketing materials from that time period are illustrative of the approach:[119]



193. Likewise, McKinsey informed Purdue that by highlighting the ability to "tailor the dose" and treat a "broad range of appropriate patients," the prescriber-takeaway would be that "physicians can help their patients function better and lead a fuller and more active life," even though this conclusion was not to be explicitly addressed.[120]



194. Claims that OxyContin improved function and quality of life were not supported by substantial evidence and, in addition, failed to take into account risks of addiction. The FDA and other federal agencies have, for years, made clear the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[121] A Centers for

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[119] *Tennessee v. Purdue Pharma L.P.*, Case No. 1-173-18 (Compl. May 15, 2018) ¶ 24.
[120] PPLPC019000329253
[121] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010) (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact

Disease Control and Prevention guideline, following a "systematic review of the best available evidence," concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[122] According to the CDC director, "for the vast majority of patients, the known, serious, and too-often- fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[123]

195. In addition to crafting carefully-tailored quality of life assurances designed to avoid the pitfalls of the Corporate Integrity Agreement, McKinsey invented other misleading marketing efforts for Purdue.

196. For instance, McKinsey urged Purdue to capitalize on OxyContin's extended-release characteristics in another way: marketing OxyContin's twelve-hour dosing as though users only need to take OxyContin twice a day, thus requiring fewer pills. OxyContin in fact was well known to wear off after eight to ten hours in many patients, however. What McKinsey called "convenient," would later be called "a [d]escription of Hell."

197. This misleading assurance of twelve-hour relief is especially pernicious, as end-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, called OxyContin's twelve-hour dosing "the perfect recipe for addiction."[124] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking. Promotion of twelve-hour dosing, without disclosing its

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on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."). ALLERGAN_MDL_00387583; Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008) (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). ALLERGAN_CA_00161496. The FDA's warning letters were available to McKinsey on the FDA website.

[122] CDC Guideline at 2, 18.

[123] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

[124] Harriet Ryan, "'*'You Want a Description of Hell?' OxyContin's 12-Hour Problem*," Los Angeles Times, May 5, 2016, available at http://www.latimes.com/projects/oxycontin-part1/.

limitations, is misleading because it implies that the pain relief supplied by each dose lasts twelve hours.

198. In addition to designing misleading marketing messages, McKinsey even suggested encouraging a new channel through which those messages could be delivered to prescribers. McKinsey encouraged the tactic of "patient pushback," wherein McKinsey and Purdue would foment patients to directly lobby their doctors for OxyContin even when those physicians expressed reservations regarding the administration of Purdue's opioids.

199. The idea was that McKinsey and Purdue could spread their own message through pain patients who would be perceived as more credible sources suggesting a need for controlled or extended release opioid—even though the team devising this strategy would have known that extended release opioids did not substantially control pain or thwart addiction better than lower-dose, immediate release opioids.[125]

200. McKinsey also coached Purdue on building "trust" (which from its vantage point, McKinsey knew was misplaced) in Purdue following its criminal conviction.

ii. Targeting – Selling More OxyContin to Existing High Prescribers

201. Perhaps the key insight McKinsey provided was, using its granular approach, to identify historically large prescribers and target ever more sales and marketing resources on them, without any regard for, and indeed conscious disregard of, patient safety. Physician targeting proved effective. McKinsey advised Purdue that visiting high-prescribing doctors many times per year increased sales. This relentless drive to increase sales and create greater availability of opioids was made with no notable concern about the parallel increase in opioid-related deaths, abuse, and misuse.

202. On January 20, 2010, Purdue's board was informed of the ongoing work McKinsey was performing concerning a new "physician segmentation" initiative whereby McKinsey would analyze the opioid prescribing patterns of individual physicians to identify those

[125] PDD8901645845

that had historically been the highest prescribers.[126] McKinsey then worked with Purdue's sales and marketing staff to specifically target those prescribers with a marketing blitz to encourage even further prescribing.

203. Purdue trained its sales force in tactics to market to these high prescribers based on McKinsey's insights and designed in conjunction with McKinsey.

204. Many of the historically highest prescribers of OxyContin—those same individuals that McKinsey urged Purdue to target for ever more prescriptions—had prescribed Purdue's OxyContin *before* the 2007 guilty plea and had already been subjected to Purdue's misrepresentations regarding OxyContin that were the subject of that guilty plea.

205. McKinsey identified these physicians—those that had already been influenced by Purdue's misrepresentations and were thus already high prescribers—as optimal targets for a massive marketing push to sell more OxyContin.

206. McKinsey worked assiduously with Purdue over many years to continually refine this approach and required ever-more granular data for its analysis. More than three years after the initial introduction of the physician segmentation initiative, McKinsey requested, and Purdue provided, "prescriber-level milligram dosing data" so that McKinsey could further analyze the individual amounts of OxyContin prescribed by individual physicians.

207. At the same time it requested this "prescriber-level milligram dosing data" from Purdue, McKinsey urged the Sacklers to strictly manage the target lists of each sales representative to assure that the maximum amount of each sales representative's time was spent with the most attractive customers.

208. On July 23, 2013, Purdue's board discussed concerns about "the decline in higher strengths" of Purdue's opioids as well as an observed decline is "tablets per Rx." In order to assure that the threat to OxyContin sales growth be addressed, McKinsey was assigned "to actively monitor the number and size of opioid prescriptions written by individual doctors."[127]

[126] PPLPC012000257446
[127] PPLP004307354

209. In unveiling Project Turbocharge to Purdue and the Sacklers, McKinsey stated that the most prolific OxyContin prescribers wrote "25 times as many OxyContin scripts" as less prolific prescribers and urged Purdue and the Sacklers to "make a clear go-no go decision to 'Turbocharge the Sales Engine'" by devoting substantial capital toward McKinsey's plan.[128]

210. McKinsey also stated that increased numbers of visits by sales representatives to these prolific prescribers would increase the number of opioid prescriptions that they would write. This singular focus on increasing prescriptions was not coupled with colorable concern for the patient population.

211. By November 2013, McKinsey had obtained the physician-level data they had previously requested and continued to study ways to sell additional OxyContin prescriptions by refining and targeting the sales pitch to them. The Purdue board was kept apprised of McKinsey's progress.

212. Not only did McKinsey identify which doctors prescribed the most of Purdue's opioids, McKinsey also recommended segmenting prescribers into "types" and tailoring messages and tactics to the different prescriber profiles. For prescribers dubbed "Early Adopting Experts" and "Proactive Teachers," defined by a willingness to use extended release opioids, including in opioid naïve patients (patients who were not already using opioids), McKinsey urged emphasizing that its seven tablet strengths provide flexibility to "tailor the dose" to customer needs.[129] Upon information and belief, this message aimed to encourage prescribers to initiate and maintain patients on OxyContin long-term by reminding them they could increase the dose as patients became tolerant with long-term use (rather than discontinue use when the drug lost its effectiveness).

213. In its October 26, 2009 presentation, "OxyContin – driving growth through stronger brand loyalty,"[130] McKinsey proposed tactics to turnaround declining sales, "[e]nhance loyalty to OxyContin among loyalist prescribers," "[c]onvert[ing] 'fence sitters' into more loyal

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[128] PPLP004409890
[129] MCK-MDL2296-0126522
[130] *Id.*

OxyContin prescribers," and "[p]rotect OxyContin's market share[.]"[131] In other words, McKinsey proposed increasing sales by pushing both willing and reluctant physicians to prescribe more OxyContin.

214. McKinsey also recommended a strategy to target those prescribers who did not regularly prescribe OxyContin—so-called "Resigned Followers and ER Delayers" —encouraging them to "increase step-up" to extended release opioids. These were physicians with "low comfort with extended release opioids." McKinsey encouraged Purdue to emphasize to them the "range of appropriate patients." In other words, McKinsey's strategy recommended that Purdue encourage prescribers to use OxyContin earlier in a patient's treatment for a wider range of patients and for longer periods of time.

iii. Titration – Selling Higher Doses of OxyContin

215. McKinsey understood that the higher the dosage strength for any individual OxyContin prescription, the greater the profitability for Purdue. Of course, higher dosage strength, particularly for longer periods of use, also contributes to opioid dependency, addiction and abuse. Nonetheless, McKinsey advised Purdue to focus on selling higher strength dosages of OxyContin.

216. Consistent with its granular growth analysis, as early as October 26, 2009, McKinsey advised the Sacklers and the Purdue board that Purdue should train its sales representatives to "emphasiz[e] the broad range of doses," which would have the intended effect of increasing the sales of the highest (and most profitable) doses of OxyContin.[132]

217. McKinsey's work on increasing individual prescription dose strength continued throughout the time period McKinsey worked with Purdue. The Sacklers were informed on July 23, 2013 that Purdue had identified weakness in prescribing rates among the higher doses of OxyContin and reassured the Sacklers that "McKinsey would analyze the data down to the level of individual physicians" in order to study ways to maximize the sales of the highest-dose OxyContin pills.

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[131] *Id.* at 2.
[132] PPLPC018000346294

218. Purdue implemented McKinsey's suggestions through adopting the marketing slogan to "Individualize the Dose" and by 2013 encouraged its sales representatives to "practice verbalizing the titration message" when selling Purdue's opioids to prescribers.[133]

219. McKinsey would have known, however, that higher doses of opioids carry greater risk. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. The Centers for Disease Control and Prevention also recognize that higher doses of opioids tend to increase overdose risks relative to any potential patient benefit.[134]

220. Claims that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose, are deceptive and misleading. They were particularly important to promotional efforts, however, because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. Marketers needed to generate a comfort level among doctors to ensure the doctors maintained patients on the drugs even at the high doses that became necessary.

221. Purdue adopted McKinsey's [redacted] proposal.[135] [redacted][136]

222. The titration messaging worked. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on

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[133] PPLP003450924
[134] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1
[135] PPLPC023000251226 ([redacted]); see also PPLPC012000243668 ([redacted]); PPLPC012000245087 ([redacted]); PPLPC012000246009 ([redacted]; PPLPC021000265092 ([redacted])
[136] PKY183123435

doses greater than sixty milligrams per day, which converts to the ninety MED that the CDC guideline urges prescribers to "avoid" or "carefully justify."[137]

iv. Covered Persons – Sales Quotas and Incentive Compensation

223. McKinsey urged the use of quotas and bonus payments to motivate Purdue's sales force to sell as many OxyContin prescriptions as possible. As McKinsey described it, "[r]evision to incentive comp could better align reps to Purdue's economics."[138]

224. Notably, this behavior was prohibited by the 2007 Corporate Integrity Agreement, which required Purdue to implement written policies regarding "compensation (including salaries and bonuses) for [sales representatives] engaged in promoting and selling Purdue's products that are designed to ensure that financial incentives *do not inappropriately motivate such individuals to engage in the improper promotion or sales of Purdue's products*."[139]

225. By 2010, Purdue had implemented a four-year plan, consistent with McKinsey's strategy, to dramatically increase the quota of required annual sales visits by Purdue sales representatives to prescribers. The quota was 545,000 visits in 2010, 712,000 visits in 2011, 752,000 in 2012, and 744,000 visits in 2013.

226. On August 15, 2013, as part of their "Identifying Granular Growth Opportunities for OxyContin" presentation, McKinsey urged the Sacklers to "establish a revenue growth goal (*e.g.*, $150M incremental stretch goal by July 2014) and set monthly progress reviews with CEO and Board."[140]

227. In its "Identifying Granular Growth Opportunities for OxyContin" presentation to the Purdue board in July 2013, McKinsey nonetheless urged Purdue, in addition to increasing the focus of the sales force on the top prescribers, to increase the overall quotas for sales visits for individual sales representatives from 1,400 to 1,700 annually.

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[137] CDC Guideline at 16.
[138] PPLPC012000441016
[139] PDD1712900096 (emphasis added).
[140] PPLP004409890

228. In 2013, McKinsey identified one way that Purdue could squeeze more productivity out of its sales force: by slashing *one third* of the time that Purdue devoted to training its sales force (from 17.5 days per year to 11.5 days):

One possible way to attain benchmark ~1500 calls per year is to decrease training days by ~6 days and increase calls per day by 5%

One possible route to benchmark

Current call activity – Number of "on territory" days per year: Item	Days[1]	Potential new allocation – Number of "on territory" days per year: Item	Days[1]
Number of working days	260	Number of working days	260
Holidays	-11.3	Holidays	-11.3
Vacation and other time off	-27.2	Vacation and other time off	-27.2
Trainings and meetings	-17.5	Trainings and meetings	-11.5
Other company-related time off of field	-4.3	Other company-related time off of field	-4.3
Total days	199.7	**Total days**	205.7
Avg calls per day	x 7	**Avg calls per day**	x 7.35
Total calls per year	1398	**Total calls per year**	1512

1 Purdue 2012 Actual data was used for this analysis

SOURCE: Purdue; team analysis

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229. By eliminating one third of the amount of time sales representatives were required to be in training, McKinsey projected that Purdue could squeeze an additional 5% of physical calls per day out of its newly less-trained sales force.

230. Additionally, McKinsey developed and advised Purdue on a new incentive compensation structure for the sales representatives, who were Covered Persons pursuant to the Corporate Integrity Agreement. McKinsey knew that, combined with the strictures of sales quotas and less training for the sales force, bonus/incentive compensation to the sales representatives based on the number of OxyContin prescriptions the representative produced could be a powerful driver of incremental OxyContin sales, without regard for patient safety.

7. Transformation: Purdue and McKinsey Adopt and Implement McKinsey's Strategies.

231. As early as September 11, 2009, McKinsey determined and told Purdue that it could generate $200 million to $400 million in additional annual sales of OxyContin by implementing McKinsey's strategy based on the opportunities its granular growth analysis had identified. McKinsey reiterated its assurances regarding the hundreds of millions of dollars of additional OxyContin sales on January 20, 2010.

232. Purdue accepted and, with McKinsey's ongoing assistance, implemented McKinsey's strategies for selling and marketing OxyContin.

233. For instance, in January 2010, Purdue was training its sales and marketing force on the new sales tactics based on a "physician segmentation" initiative that McKinsey urged. The strategy developed as a result of McKinsey's granular analysis of OxyContin sales channels. The initiative sought to identify the most prolific OxyContin prescribers and then devote significant resources towards convincing those high prescribers to continue to prescribe ever more OxyContin, in higher doses, for longer times, to ever more patients.

234. On January 20, 2010, the Purdue board was informed of the progress in implementing McKinsey's "physician segmentation" initiative.

235. This transformative collaboration would continue over the course of the relationship between Purdue and McKinsey.

236. During the time that McKinsey was working with Purdue, Purdue deliberately minimized the importance of the Corporate Integrity Agreement. In 2008, Carol Panara joined the Purdue sales force from rival Novartis. She would stay with the company until 2013, during which time McKinsey was responsible for increasing OxyContin sales at Purdue, and culminating with the implementation of McKinsey's "Project Turbocharge," beginning September 2013.

237. Ms. Panara stated that the 2007 guilty plea was deliberately minimized by the company in presentations to its sales staff: "They said, 'We were sued, they accused us of mis-marketing, but that wasn't really the case. In order to settle it and get it behind us we paid a fine.'

You had the impression they were portraying it as a bit of a witch hunt."[141] (Purdue and its executives paid $634.5 million in fines.)

238. Consistent with McKinsey's mandate, McKinsey devised methods for sales staff to sell OxyContin to doctors while at the same time maintaining technical compliance with the Corporate Integrity Agreement. Ms. Panara stated that, though she was told she could not flatly claim that OxyContin was better or safer than other opioids, "she was trained to talk about product in ways that implied that it was safer." She might tout OxyContin's twelve-hour formulation to a prescriber. "You could say that with a shorter-acting medication that wears off after six hours, there was a greater chance the patient was going to jump their dosing schedule and take an extra one a little earlier. We couldn't say [it was safer], but I remember we were told that doctors are smart people, they're not stupid, they'll understand, they can read between the lines."[142]

8. <u>Project Turbocharge</u>

239. The Corporate Integrity Agreement expired in January 2013. With this restriction lifted, McKinsey devised additional marketing and sales strategies for Purdue to further increase OxyContin sales.

240. On May 14, 2013, McKinsey entered into a "Statement of Services to the Master Consulting Agreement" (the "2013 Agreement") with Purdue to "conduct a rapid assessment of the underlying drivers of current OxyContin performance, identify key opportunities to increase near-term OxyContin revenue and develop plans to capture priority opportunities." [redacted][143]

241. The 2013 Agreement stated, "We have a long history of partnership with Purdue, and we would make best efforts to leverage our understanding of your business – both in terms of content and culture." It was signed by then-principal Arnab Ghatak, who would "lead the team

[141] David Crow, *How Purdue's 'one-two' punch fuelled the market for opioids*, Financial Times, September 9, 2018, *available at*: https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c
[142] *Id.*
[143] PPLPC030000770531

with senior leadership from Rob Rosiello and Martin Elling." Elling was a leader of McKinsey's PMP group.[144]

242. McKinsey was tasked with "Identifying Granular Growth Opportunities for OxyContin," conducting an "assessment of the underlying drivers of current OxyContin performance," identifying "key opportunities to drive near-term OxyContin performance," and developing "plans to capture priority opportunities."[145]

243. For purposes of the project, McKinsey would need "[f]ull access to work done to date and key data."[146] And, [redacted][147]

244. Staff told the Sacklers that McKinsey would study how to get doctors to prescribe more OxyContin,[148] how to use incentive compensation to push reps to generate more prescriptions, how to use "patient pushback" to get doctors to prescribe more opioids, and how to keep patients on opioids longer.[149]

245. The 2013 Agreement would lead to Project Turbocharge, McKinsey's successful bid to transform Purdue's sales and marketing efforts for OxyContin now that Purdue was no longer bound by the Corporate Integrity Agreement.

246. In the summer of 2013, McKinsey made multiple recommendations to Purdue's board to increase OxyContin revenue, and urged the Sackler family to "make a clear go-no-go decision to 'Turbocharge the Sales Engine."

247. Purdue, like McKinsey, recognized that the initiative was no small thing. An internal Purdue email states that [redacted][150]

248. The Sacklers were impressed. On August 15, 2013, Richard Sackler emailed Mortimer D.A. Sackler, "[T]he discoveries of McKinsey are astonishing."

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[144] *Id.*
[145] PPLPC030000770531 / MCK-MAAG-0024283
[146] *Id.*
[147] PPLPC012000431809
[148] PPLPC012000431262
[149] *Id.*; PPLPC012000431266
[150] PPLPC012000437344

249. Eight days later, on August 23, 2013, McKinsey partners met with the Sackler family—not the Purdue board of directors—to pitch Project Turbocharge. Dr. Arnab Ghatak, one of the McKinsey partners leading the Purdue account, recounted the meeting to fellow McKinsey partner Martin Elling in an email exchange: "[T]he room was filled only with family, including the elder statesman Dr. Raymond [Sackler] . . . . We went through exhibit by exhibit for about 2 hrs . . . . They were extremely supportive of the findings and our recommendations . . . and wanted to strongly endorse getting going on our recommendations."[151]

250. Elling, a co-leader of the Purdue account, remarked in the same email correspondence that McKinsey's "findings were crystal clear to" the Sacklers, and that the Sacklers "gave a ringing endorsement of 'moving forward fast.'"[152]

251. As a result of the Sackler family endorsement of McKinsey's proposals, the following month Purdue implemented Project Turbocharge based on McKinsey's recommendations. In adopting "Project Turbocharge," Purdue acknowledged the improper connotations of the name, and re-christened the initiative the decidedly more anodyne "E2E: Evolve to Excellence."[153]

252. Evolve to Excellence ("E2E") was the theme of Purdue's 2014 National Sales Meeting.

253. CEO John Stewart also told sales staff that board member Paolo Costa was a "champion for our moving forward with a comprehensive 'turbocharge' process," referring to McKinsey's plan.

254. After Purdue adopted McKinsey's recommendations, McKinsey continued to work with Purdue sales and marketing staff reporting to Russell Gasdia during Purdue's implementation of McKinsey's recommendations.

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[151] MCK-MDL2996-0403095

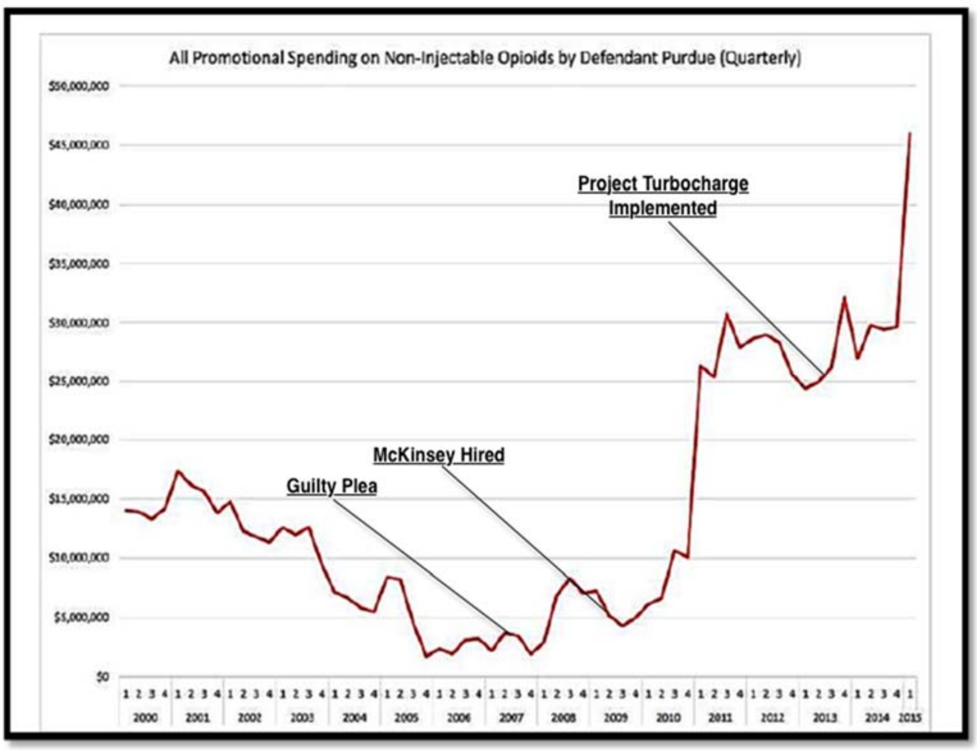
[152] *Id.*

[153] Regarding the name change, CEO John Stewart wrote to McKinsey partners Rob Rosiello and Arnab Ghatak on August 15, 2013: "Paolo Costa was especially engaged in the discussion and he (among others) will be a champion for our moving forward with a comprehensive 'turbocharge' process – *though we do need to find a better and more permanently appropriate name*." PPLPC012000436626 (emphasis added).

255. In fact, the entire E2E initiative was overseen by McKinsey and some Purdue executives, who together comprised the E2E Executive Oversight Team and Project Management Office.

256. At the same time, the Sacklers were kept informed of the implementation of McKinsey's OxyContin strategy. According to a September 13, 2013 board agenda, the board discussed with the Sacklers the ongoing implementation of McKinsey's sales tactics.

257. Evolve to Excellence called for a *doubling* of Purdue's sales budget. Under McKinsey's prior tutelage, Purdue's promotional spending had already skyrocketed. McKinsey's ongoing influence on Purdue's operations after the 2007 guilty plea is stark:



258. At the time of McKinsey's first known work for Purdue, Purdue spent approximately $5 million per quarter on sales and marketing. By the time McKinsey's Project Turbocharge was implemented, total quarterly sales and marketing spending at Purdue exceeded $45 million, an increase of *800%*.

259. Project Turbocharge continued despite the arrival of a new CEO at Purdue. On January 17, 2014, new CEO Mark Timney received reports from McKinsey emphasizing that, in

order to increase profits, Purdue must again increase the number of sales visits to "high-value" prescribers, i.e., those that prescribe the most OxyContin.[154]

260. Purdue and McKinsey worked together to implement "Turbocharging the Sales Engine." [redacted][155]

261. McKinsey and Purdue also worked together on an "implementation plan" for E2E, with McKinsey taking on the role of "executive oversight" of projects including the creation of target lists, internal dashboards to track progress, and changes to Purdue's incentive compensation plan consistent with E2E.[156]

a. Targeting High Subscribers

262. Project Turbocharge called for revising the existing process for targeting high-prescribing physicians, with a shift from targeting solely on the basis of prescription deciles to considering additional factors. Based on its analysis, McKinsey told Purdue that "[t]here is significant opportunity to slow the decline of OxyContin by calling on more high-value physicians" and that "[t]he revenue upside from sales re-targeting and adherence could be up to $250 million."

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[154] In fact, recent deposition testimony suggests McKinsey may have been responsible for the fact that Timney was given the CEO job at Purdue in the first place. On October 30, 2020, Timney provided the following testimony (emphasis added):

> Q: Are you familiar with McKinsey & Company?
> A: I decline to answer on the ground that I may not be compelled to be a witness against myself in any proceeding.
> Q: Did individuals at McKinsey *assist you in getting hired as the CEO* of Purdue?
> A: I decline to answer on the ground that I may not be compelled to be a witness against myself in any proceeding.

In fact, McKinsey appears to have played a substantial role in the succession of several Purdue CEO's. Martin Elling, in his 2018 annual self-assessment, provided the following example of "how I deliver impact:" "Actively managing CEO/CXO transitions: … from Michael Friedman to John Stewart (2007) to Mark Timney (2014) to Craig Landau (2017) at Purdue." MCK-MDL2996-0357931. "I drove our introduction of Purdue in 2004 and then, with Rob Rosiello, built it into a substantial and sustaining client… We have served across four CEOs and are now helping the new leadership team adapt to a world of headwinds for their core product OxyContin," he added. MCK-MDL2996-0357931.

[155] PPLPC021000615265

[156] MCK-MDL2996-0180338, at 0180340

263. The core objective of McKinsey's initiative was to ensure that Purdue was "making calls on the highest potential customers with the right frequency to maximize prescribing potential."

264. McKinsey determined and advised Purdue that the top half of prescribing physicians "write on average 25 times more scripts per prescriber" than the lower half. McKinsey advised that Purdue would see a greater return on its sales investment by focusing on these targets, including on prescribers with alarming prescribing patterns that raised red flags they were writing "prescriptions" for non-medical use. McKinsey's plan aimed at boosting sales of OxyContin by targeting the highest volume opioid prescribers, without addressing whether the expanded sales would be for an illicit market.

265. McKinsey found that Purdue did not "focus on the highest potential docs," measured both by the number of prescriptions and reimbursement considerations.[157] One McKinsey analyst urged McKinsey to recommend Purdue target "[l]iterally, at least all" prescribers in the top 20% of prescribers, "minus another few percent who are no sees[.]"[158] McKinsey team lead Arnab Ghatak replied that "they probably have 20% no see[], but i'd also assume there are not many high writers that are no see."[159] ("No see" prescribers are prescribers who do not accept visits from pharmaceutical sales representatives. Thus, McKinsey recognized that most of the highest volume prescribers, or "high writers" of prescriptions, were willing to entertain sales visits from sales representatives.)

266. "To put this in perspective," McKinsey stated,

> the average prescriber in decile 5-10 [the top half of prescribers by volume] writes 25 times as many OxyContin scripts as a prescriber in decile 0-4. In Q1 2013 the majority (52%) of OxyContin primary calls were made to decile 0-4 prescribers. Including the secondary calls, 57% of the primary detail equivalents (PDEs) were made to decile 0-4 prescribers. Best practice in the industry is over 80% of effort on higher value prescribers."

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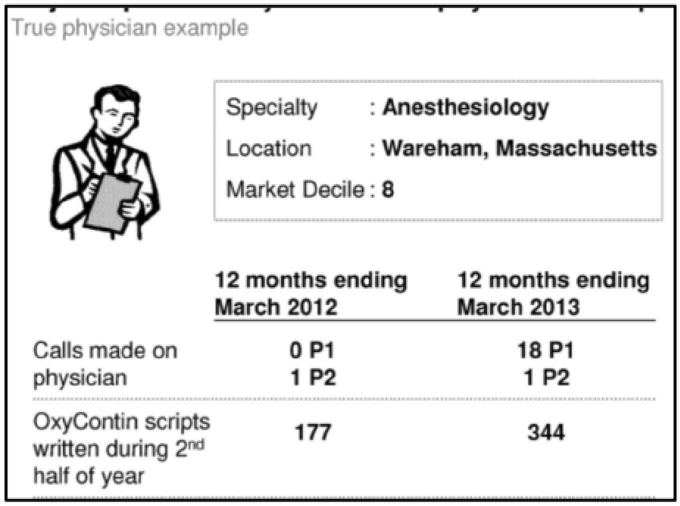
[157] MCK-MDL2996-0364024
[158] MCK-MDL2996-0364267
[159] *Id.*

McKinsey concluded: “Given that there are 14,000 uncalled physicians in deciles 5-10, there is significant opportunity to shift calls to higher potential prescribers.”[160]

267. McKinsey pointed to a “true physician example” in Wareham, Massachusetts, who wrote 167 more OxyContin prescriptions after Purdue sales reps visited him.[161]



Graphic from McKinsey presentation recommending targeting high prescribers

268. To slow or reverse the decline in OxyContin sales, McKinsey recommended a shift to “value deciles,” which purported to weigh prescribers according to factors including overall opioid prescriptions, including the number of branded versus generic prescriptions; prescriber rules in place limiting sales calls; managed care access; and the number of the prescribers new to brand prescriptions, including new opioid patients and switches from other opioid products.[162] The cumulative effect of the value rankings was to shift detailer emphasis onto the highest-volume prescribers. Further, McKinsey’s analysis found that the highest-volume prescribers were themselves most influenced by detail visits.

269. Purdue moved quickly to do as McKinsey advised. All sales representatives received a memo on December 23, 2013, identifying how to select “SuperCore” prescribers, or the top ten targets,[163] in their territory according to the E2E high prescribing principles and

[160] MCK-MDL2996-0187168 / PPLP004409892
[161] PPLPC012000437356
[162] PPLPC022000646874
[163] MCK-MDL2996-0316833

required that each SuperCore prescriber be visited at least twice a month.[164] [redacted][165] As part of these changes, McKinsey's plan involved *more* minimum sales calls overall.[166]

270. [redacted] who later plead guilty to criminal charges related to an opioid drug ring. The prescriber also surrendered his license to practice after an Ohio Medical Board investigation revealed that he prescribed excessive and dangerous combinations of opioids and muscle relaxers and that he prescribed opioids to a patients who complained of headaches and others who showed signs of addiction.[167] The same prescriber received at least sixty visits from Purdue from mid-2013 through 2016.[168]

271. [redacted] The doctor, who worked at a family practice, was charged with involuntary manslaughter, Medicaid fraud, drug trafficking, grand theft, and other offenses.

272. [redacted][169] In 2018, the Drug Enforcement Administration issued an Order to Show Cause and Immediate Suspension Order to Dr. Khan-Jaffrey over concerns that her DEA registration "constituted an imminent danger to the public health and safety," finding she prescribed opioids without a legitimate medical purpose and disregarded urine screens indicating abuse and

[164] PURCHI-000005915
[165] PPLPC022000686986
[166] MCK-MDL2996-0187168
[167] https://www.cnhinews.com/article_91ffac58-1b32-11e8-b264-6b34793bf5c3.html
[168] Public information about visits at which a payment was made is available for this time period through "Open Payments."
[169] PPLPC014000257127

diversion.[170] Dr. Khan-Jaffrey's DEA registration was fully revoked on July 28, 2020.[171] Dr. Louis Spagnoletti, of Marlton, New Jersey, [redacted][172] lost his state license to prescribe controlled substances in 2018.[173] Similarly, Dr. Vivienne Matalon, a Decile 10 prescriber from Cherry Hill, New Jersey, [redacted][174] went on to lose her license in 2018 as well, for allegedly receiving kickbacks to prescribe the fentanyl drug Subsys to three patients, including one that died.[175]

273. Another prescriber, Dr. Damon Cary of Wilmington, Delaware, [redacted],[176] received an emergency suspension order in 2019 after prescribing controlled substances, including opioids, to undercover officers without performing any medical examinations.[177] Dr. Eva Dickinsson, of Harrington, Delaware, [redacted][178] was arrested on marijuana charges in 2016 and had her license suspended in 2017 for sharing drugs, including opioids, with her patients.[179]

274. Dr. Michael Cozzi of Fort Wayne, Indiana, [redacted], had his medical license suspended in 2016, where he had prescribed more controlled substances than any other Indiana prescriber, with over two million doses of oxycodone, seeing ninety to100 patients a day.[180] Dr. Jamie Gurrero, [redacted][181] was sentenced to 100 months in prison in

[170] https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order
[171] *Id.*
[172] PPLPC014000257127
[173] https://patch.com/new-jersey/moorestown/state-suspends-doctor-accused-illegally-prescribing-opioids
[174] PPLPC014000257127
[175] https://nj.gov/oag/newsreleases18/pr20180504d.html
[176] PPLPC014000257130
[177] https://www.delawareonline.com/story/news/health/2019/08/05/doctor-prescribed-opioids-undercover-cops-failed-follow-protocol/1920386001/
[178] PPLPC014000257130
[179] https://www.delawareonline.com/story/news/health/2017/01/19/doctors-license-suspended-delaware-maryland/96779080/
[180] https://www.wane.com/news/fort-wayne-pain-doctors-medical-license-suspended/ (He later died in a tractor accident, https://www.journalgazette.net/news/local/police-fire/20180816/tractor-accident-kills-pain-doctor)
[181] PPLPC014000257130

2016 after pleading guilty to unlawful distribution or dispensing of controlled substances, health care fraud, conspiracy, and money laundering.[182]

275. [redacted] Misrepresentations to these prescribers were especially insidious because they were aimed at general practitioners who lack the time and expertise to closely manage higher-risk patients on opioids.

276. McKinsey also urged, consistent with continually refining its granular approach, that sales representatives devote two-thirds of their time to selling OxyContin and one-third of their time selling Butrans, another Purdue opioid product. Previously, the split had been fifty-fifty.

b. Circumventing Safeguards Against Abuse and Diversion

277. Project Turbocharge also involved a granular analysis of Purdue's individual sales channels. In its August 8, 2013 report to the Purdue board, McKinsey also attributed the decline in OxyContin sales to safeguards to limit suspicious opioid sales. McKinsey informed Purdue that "[t]he retail channel, both pharmacies and distributors, is under intense scrutiny and direct risk." "There are reports of wholesalers stopping shipments entirely to an increasing number of pharmacies," "[m]any wholesalers are also imposing hard quantity limits on orders based on prior purchase levels," and "[p]harmacy chains are implementing guidelines for which patients can fill opioid prescriptions[.]"[183]

278. For instance, McKinsey recommended that Purdue circumvent pharmacies entirely with a mail order program because enforcement by federal regulators was decreasing OxyContin dispensing through Walgreens. McKinsey informed the Sacklers that "[d]eep examination of Purdue's available pharmacy purchasing data shows that Walgreens has reduced its units by 18%." Further, "the Walgreens data also shows significant impact on higher OxyContin dosages."[184]

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[182] https://www.justice.gov/usao-wdky/pr/kentuckiana-anesthesiologist-sentenced-100-months-unlawful-distribution-controlled

[183] MCK-MAAG-0024297

[184] *Id.*

279. In order to counter these perceived problems, McKinsey suggested that Purdue's owners lobby Walgreens specifically to increase sales and circumvent the safeguarding sales limits. It also suggested the establishment of a direct-mail specialty pharmacy so that Purdue could circumvent Walgreens and sell directly to Walgreens' customers. Finally, McKinsey suggested the use of opioid savings cards distributed in neighborhoods with Walgreens locations to encourage the use of Purdue's opioids despite Walgreens actions.

280. McKinsey's initiative also included ways to circumvent these safeguards. McKinsey recommended that the sales force distribute vouchers and "starter kits" for patients who faced co-pays for OxyContin prescriptions.[185] In particular, McKinsey recommended dispensing vouchers to outlets of a specific large national pharmacy chain where prescriptions and OxyContin inventories were down.[186] This chain, as part of its own settlement with the Drug Enforcement Administration, had removed pharmacist bonuses for dispensing opioids.[187]

c. Incentivizing Opioid Sales

281. McKinsey's "turbocharging" plan also had other elements. [redacted][189]

9. <u>McKinsey's Efforts Triple OxyContin Sales</u>

282. In 2013, despite significant headwinds, with marketing activities turbocharged, OxyContin sales peaked. The restrictions on Purdue's sales and marketing methods contained in the Corporate Integrity Agreement should have resulted in fewer overall OxyContin sales; the guilty plea identified a specific segment of existing OxyContin sales that were illegitimate and should thus cease. All else being equal, OxyContin sales should have decreased to account for the

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185 MCK-MDL2996-0290827.
186 MCK-MDL2996-0041646.
187 MCK-MDL2996-0104431; MCK-MDL2996-0041646.
188 PPLPC012000437346.
189 *Id.*

successful elimination of improper sales. In fact, OxyContin sales did decrease in the immediate aftermath of the 2007 guilty plea.

283. And within five years, however, OxyContin sales would triple. McKinsey is responsible for the strategy that accomplished this. It presented specific plans to Purdue, which Purdue adopted and spent hundreds of millions of dollars implementing. The result: a final spasm of OxyContin sales before the inevitable decline of the drug.[190]

284. The Purdue McKinsey collaboration was a spectacular success. Between the 2008 and 2016, Purdue distributed in excess of $4 billion to the Sackler family, with $877 million distributed in 2010 alone.

285. These distributions would not have been possible without the McKinsey's work dramatically increasing OxyContin sales.

286. The Sacklers were aware of the value McKinsey provided: on December 2, 2013, CEO John Stewart informed Kathe Sackler and Vice President of Sales and Marketing Russell Gasdia Project Turbocharge "was already increasing prescriptions and revenue." Crucially, these results were already being realized *before* the strategy was fully deployed as the theme of the 2014 National Sales Meeting. Stewart elaborated to Sackler that "trends are more positive than was the case a few months back, and when the E2E Project (the changes arising out of the McKinsey analysis) is fully implemented there will certainly be additional increases."[191]

287. Later that month, [redacted][192]

288. McKinsey's contributions to Purdue's growth after 2007 are remarkable. OxyContin sales should have naturally declined; the Department of Justice identified OxyContin sales that were illegitimate because of Purdue's conduct, and the Inspector General of the Department of Health and Human Services entered into a Corporate Integrity Agreement whereby Purdue was monitored to assure that those sales did not continue.

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[190] On February 10, 2018, Purdue announced that it is no longer marketing opioids, and disbanded its OxyContin sales force.
[191] PPLPC012000454422
[192] PPLPC012000457292

289. In 2007, the year of Purdue's guilty plea, net sales of OxyContin totaled approximately $1 billion.[193]

290. The guilty plea "did little to stem Purdue's blistering growth rate." In fact, by 2010, after McKinsey was advising Purdue on how to maximize sales, OxyContin sales exceeded $3 billion: a *tripling* of revenue from OxyContin sales.[194]

291. Under McKinsey's guidance, OxyContin sales would reach their all-time peak in 2013, the year McKinsey proposed, and Purdue adopted, Project Turbocharge.[195] That OxyContin sales peaked in 2013 is especially notable, given that *overall* opioid prescriptions had *already peaked* three years earlier, in 2010.[196] McKinsey's efforts added a final boost to OxyContin sales before the eventual unraveling, and Purdue's decision, in the end, to cease marketing the drug.

292. Project Turbocharge was a continuing success. [redacted][197] and Chief Financial Officer Edward Mahoney reported to the Purdue board that the effort "has resulted in significant improvement." [redacted][198]

293. McKinsey was paid handsomely: it received more than [redacted] for its work for Purdue from 2008 to2013 alone.[199] In pursuit of these profits, McKinsey continued to help Purdue grow opioid sales even after Purdue reached a 2015 Assurance of Discontinuance with New York arising out of an investigation concerning its Abuse and Diversion Detection program and media coverage highlighted its lack of attention to diversion control. McKinsey's own work elsewhere identified "reducing prescribing" as among the efforts to combat the opioid epidemic and also

[193] *See* David Crow, *How Purdue's 'one-two' punch fueled the market for opioids*, Financial Times, September 9, 2018, *available at*: https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c
[194] *Id.*
[195] Phil McCausland and Tracy Connor, *OxyContin maker Purdue to stop promoting opioids in light of epidemic*, NBC News, February 10, 2018, *available at:* https://www.nbcnews.com/storyline/americas-heroin-epidemic/oxycontin-maker-purdue-stop-promoting-opioids-light-epidemic-n846726
[196] Gery P. Guy Jr, *at al.*, *Vital Signs: Changes in Opioid Prescribing Patterns in the United States, 2006-2015*, Centers for Disease Control and Prevention, July 7, 29017, *available at:* https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm
[197] PPLPC037000159028
[198] PPLPC014000263961
[199] PPLPC029000547371

showed that opioid prescribers were frequently writing prescription for patients with known risks of abuse. Still, McKinsey continued to work to help opioid manufacturers increase opioid sales, including through Purdue's deceptive marketing campaign.

294. By 2014, according to Purdue, there were 5.4 million OxyContin prescriptions written, 80% for twelve-hour dosing. Of those prescriptions, more than half were for doses greater than sixty milligrams per day.

295. The Sackler family has withdrawn over $10 billion from Purdue since 2008, including $1.7 billion in 2009 alone. These distributions were made possible by McKinsey's services and came at the expense of a deepening national opioid crisis.

E. <u>McKinsey's Opioid-Related Work with Other Clients.</u>

296. Part of the unique value McKinsey provides is its deep knowledge of its clients' competitors, often because it counts those same competitors as its clients. McKinsey generally does not disclose to its clients its work for their competitors.

297. The opioid industry was no different. Indeed, McKinsey specifically worked to [redacted]

1. <u>Endo</u>

298. While McKinsey was working for Purdue, McKinsey was also working for Endo Pharmaceuticals. Arnab Ghatak was a principal McKinsey partner on both accounts at the same time.[201] There was additional overlap between the McKinsey teams staffed to Purdue and Endo, including McKinsey partners Nicholas Mills and Laura Moran. After all, these particular consultants had granular expertise in the specific subject-matter relevant to these opioid

[200] MCK-MDL2996-0041741.

[201] Ghatak's familiarity with both Endo and Purdue is perhaps one reason why, on April 3, 2014, Ghatak was placed in charge of analyzing a proposed *partnership* between Purdue and Endo to sell opioids. Lauran Moran described the "partnership workstream" that McKinsey was then performing for Purdue to identify ways for Purdue to obtain near-term growth. She stated that Purdue and McKinsey "agreed the partnerships workstream should include the top 3 potential partners (Valeant, Endo and Pfizer for now). And for each what assets each partner would bring and what growth (most importantly) would the deal bring. Arnie [Ghatak] and Phil to work out Endo and Valeant, John G and Raul to do Pfizer tomo." MCK-MDL2996-0421790.

manufacturers. That subject-matter expertise is a compelling reason why McKinsey is hired in the first place. McKinsey advised both Endo and Purdue how to maximize the sales or their branded opioid products—Belbuca (Buprenorphine), Butrans (Buprenorphine), Opana (Oxymorphone), and OxyContin (Oxycodone) —all at once.

a. <u>New Blues</u>

299. Like Purdue, Endo was historically a pharmaceutical manufacturer focused on the pain market. Like Purdue, Endo relied on opioid sales for a significant portion of its business. As a matter of fact, Endo's history with opioids predates the Sacklers' ownership of Purdue. In 1950, Endo's predecessor, Intravenous Products of America, Inc., launched Percodan, an Oxycodone/Aspirin tablet. In 1971, Endo, then owned by E.I. du Pont de Nemours and Company ("DuPont"), launched Percocet, another oxycodone-based tablet.[202]

300. In 1997, Endo separated from DuPont to become a standalone private company retaining Percodan and Percocet.[203] In 2000, as the result of an acquisition, the company became public.[204]

301. In 2006, Endo launched its own branded oxymorphone products, Opana and Opana ER.[205] With the legacy assets of Percodan and Percocet, Endo's business had always been focused on opioid sales. Oxymorphone is not a new opioid, and Opana was not Endo's first oxymorphone product. It was first synthesized more than a century ago in Germany. Endo began selling it in the United States in 1959 under the name Numorphan.

302. Numorphan was referred to as "blues," after the color of the 10mg pills. It delivered a more euphoric high than heroin, according to some. In 1974, the National Institute on Drug Abuse noted in its "Drugs and Addict Lifestyle" report that Numorphan was popular as an abused drug for its quick and sustained effect.[206] By 1979, Endo withdrew Numorphan from the

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[202] https://www.endo.com/about-us/history#fragment-25
[203] https://www.endo.com/about-us/history#fragment-24
[204] https://www.endo.com/about-us/history#fragment-21
[205] https://www.endo.com/about-us/history#fragment-15
[206] John Fauber & Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015), *available at:* https://www.medpagetoday.com/psychiatry/addictions/51448

market. Upon information and belief, [redacted][207]

303. The memory of the 1970s Numorphan addiction crises did not fade quickly. In 1989, the film *Drugstore Cowboy* featured Matt Dillon as an addict in the 1970s who robs drug stores to obtain drugs to sell in order to finance his opioid dependency.[208] In one scene, an addict asks Dillon's character if he has any "blues." Dillon's character explains that "blues" are increasingly hard to find, and offers to sell morphine sulfate to an addict instead. The addict explained that he much preferred the Numorphan, but settled for the morphine.[209]

304. With the launch of Opana, Endo decided it was time for history to repeat itself. After Opana's approval in 2006, Endo solidified its position as a pain specialist among manufacturers. By 2012, opioid sales accounted for approximately $403 million of Endo's $3 billion in revenue, more than 10%. From 2010 to 2013, total Opana ER revenue alone exceeded $1.1 billion.

305. Opana and Numorphan were both oxymorphone. The brand name was the only thing that changed. What Endo removed from the market in 1979 due to abuse concerns, it re-introduced 27 years later. After 2006, Opana was on occasion referred to as "blue heaven," or, more to the point, "new blues."[210]

306. In 2017, Endo would once again remove its branded oxymorphone product from the market, and for the same reason. Endo's abuse-deterrent formulation of Opana was removed at the request of the FDA due to acute concerns about its abuse potential.

307. In addition to its branded products, Endo, through subsidiaries Qualitest Pharmaceuticals, Inc. and, after its acquisition in 2015, Par Pharmaceuticals, also manufactured generic versions of oxycodone, oxymorphone, hydromorphone, and hydrocodone. Over the

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[207] EPI000443330 ([redacted]"); ENDO-OPIOID-MDL-06246554 ([redacted]).
[208] *See* https://www.imdb.com/title/tt0097240/; https://www.bionity.com/en/encyclopedia/Oxymorphone.html
[209] Scene from Drugstore Cowboy, *available at*: https://www.youtube.com/watch?v=TksvZdrx9_A
[210] https://www.deadiversion.usdoj.gov/drug_chem_info/oxymorphone.pdf

course of McKinsey's relationship with Endo, McKinsey would repeatedly advise Endo how to maximize its generics business in addition to sales of Endo's branded opioids.

b. <u>Old Friends</u>

308. McKinsey's relationship with Endo began as early as in 2006, the same year as the Opana launch.

309. McKinsey's earliest known work with Endo concerned the launch of Opana in Europe, but its relationship with Endo would expand to encompass all aspects of Endo's business, including corporate organization and resource allocation, the launch of a new branded Buprenorphine product, and sales force optimization efforts for Endo's branded and generic opioid products.

310. In 2007, McKinsey was shaping overall corporate strategy at Endo. In a presentation to Endo's board of directors in May of that year [redacted]."[211]

311. McKinsey's partnership with Endo would last more than a decade, and, like its relationship with Purdue, is an exemplary example of the transformational relationship in action.

312. In some ways, the McKinsey's relationship with Endo was even more tightknit and companionable than with Purdue. For instance, no one at Purdue previously worked for McKinsey. In early 2013, Rajiv de Silva, previously a leader of McKinsey's PMP group, was appointed CEO of Endo. At Endo, McKinsey was now advising an old friend, one of its previous senior partners.[212]

313. As de Silva himself explained, "[redacted]

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[211] ENDO-OPIOID_MDL-02899510.

[212] *See* "Rajiv De Silva Named President and CEO of Endo Health Solutions," Press Release dated February 25, 2013, *available at*: https://investor.endo.com/news-releases/news-release-details/rajiv-de-silva-named-president-and-ceo-endo-health-solutions ("Earlier in his career, he was a Principal at McKinsey & Company, where he served as a member of the partnership group that led the global Pharmaceuticals and Medical Products practice.")

[redacted]"[213]

314. Under de Silva, Endo relied more heavily on McKinsey than ever before. McKinsey consultants interacted directly and often *exclusively* with de Silva. McKinsey was so close to the Endo CEO that it could intervene in direct reporting from one of de Silva's deputies.[214] It is as if McKinsey had insinuated itself as a shadow layer of bureaucracy within Endo.

315. McKinsey maintained weekly performance review meetings with de Silva and senior Endo management. In these meetings, granular weekly sales data was reviewed for each of Endo's branded products, including Opana.[215]

316. McKinsey advised both Purdue and Endo contemporaneously for more than a decade. With each client, the goal was the same: to maximize opioid sales. The work McKinsey performed for each client was so similar that there was routinely confusion internally about whether a specific project or task to perform was for Endo or Purdue.[216]

317. Despite McKinsey's emphasis on confidentiality, the fact that McKinsey repeats its work from one client to the next is well-known to the client. Indeed, it is part of the justification in hiring McKinsey in the first place. McKinsey can tell you what everyone else is doing. [redacted]"[217]

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[213] ENDO-OPIOID-DEPMAT-000047877 at pg. 320:22 – 321:3.

[214] *See* MCK-MDL2996-0405502 (Email from Ghatak to de Silva, stating that it "would be great for you to push Blaine and Bob [both Endo employees] on why there are no slides showing the metrics on field call attainment . . . there was an explicit agreement to track them. Setting the expectation that you want them included would really help").

[215] MCK-MDL2996-0062712.

[216] In response to an internal email from Craig MacKenzie to other McKinsey consultants seeking "expert input on labels for abuse deterrent formulations" in conjunction with McKinsey's work on the Belbuca launch (discussed *infra*.), McKinsey consultant Jeff Smith replied, "Craig – is this for Purdue or Endo? If for Endo, I am conflicted." MCK-MDL2996-0383805.

[217] ENDO-OPIOID-MDL-07619243.

c. **Opana**

318. McKinsey's earliest known work with Endo [redacted]. In a November 22, 2006 presentation[218] entitled "[redacted]," McKinsey advised [redacted]"[219]

319. McKinsey noted, [redacted].[220]

320. McKinsey also [redacted]"[221]

321. McKinsey advised [redacted][222]

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[218] The McKinsey presentation was [redacted]" ENDO-OPIOID_MDL-02936031. By 2007, McKinsey had [redacted]" ENDO-OPIOPID_MDL-06078889. Endo acquired Penwest in 2010. "Endo Pharmaceuticals Agrees to Acquire Penwest Pharmaceuticals," Fierce Biotech, August 10, 2010, *available at*: https://www.fiercebiotech.com/biotech/endo-pharmaceuticals-agrees-to-acquire-penwest-pharmaceuticals

[219] ENDO-OPIOID_MDL-02936031.

[220] *Id.*

[221] *Id.*

[222] *Id.*

322. McKinsey [redacted]"[223]

323. Within a few years of its introduction in the United States, abuse of the drug became widespread. Endo then sought to introduce a reformulated version of Opana that it could market as abuse-deterrent by introducing a tamper-resistant coating to the pill.

324. In December 2011, Endo obtained FDA approval for a new formulation of Opana ER with the coating that Endo claimed was crush-resistant. The following month, however, the FDA told Endo that it could not market Opana ER, even after the reformulation, as abuse-deterrent.

325. Endo "did not submit any new clinical safety or efficacy data" as part of its application, but rather relied entirely on the "bioequivalence" of the new and old formulations of Opana. Obtaining approval of reformulated Opana ER on this basis allowed Endo to rely on the safety and efficacy of the original version of the drug as the basis for approval of the reformulated version.[224] The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. In December 2011, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."[225]

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[223] *Id.*

[224] Intervenor Impax Laboratories, Inc.'s (1) Cross-Motion to Dismiss; or, in the Alternative, (2) Opposition to Plaintiff's Motion for a Preliminary Injunction, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.* ("Impax Br."), No. 1:12-cv-01936 Doc. 18 at 7 (D.D.C. Dec.9, 2012); *see also* FDA Summary Review for Regulatory Action, NDA 201655 (Dec. 9, 2011) (stating that "[n]o new safety data were included in this submission" and "[n]o efficacy studies were submitted in this application.").

[225] Endo Dec. 12, 2011 News Release; Ex. A to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 Doc. 18-2 (D.D.C. Dec. 9, 2012).

326. In 2013, an Endo training module directed key opinion leaders to instruct prescribers that OPANA ER with INTAC is the only oxymorphone designed to be "crush-resistant," and advised the key opinion leaders to state during their speeches that "[t]he only way for your patients to receive oxymorphone ER in a formulation designed to be crush-resistant is to prescribe OPANA ER with INTAC."[226] The speakers were advised to stress that generic versions of Oxymorphone "are not designed to be crush-resistant."

327. These abuse-deterrent attributes of the reformulation—the very characteristics McKinsey and Endo touted as a reason to prescribe Opana—were a sham. The reformulation was designed to prevent the pill from being crushed and snorted through the nose. It did not prevent intravenous use, however. The result was that many users already dependent of Opana began using needles to inject the drug for the first time. As an internal Endo email put it, [redacted]"[227]

328. Jeff, a veteran of the war in Iraq, explained the process. Jeff first became dependent on Percocet and Opana after returning from Iraq, where his back was injured when his Humvee rolled over in 2008. After being prescribed opioids for his back pain, Jeff became dependent, and began using Opana by snorting it. Endo then introduced the reformulated abuse-deterrent version of Opana in 2012. "[A]nd then they reformulated them," he said, referring to the Opana pills. "And the only way you could really do them is inject them because if you actually swallow them, it – you – they really don't do nothing."[228]

329. Jeff and his companion Joy showed the journalist how the drug was used. "You want to see how to cook it?" Jeff asked. He and Joy then proceeded to place a portion of an Opana pill on piece of aluminum and heat it with a lighter. "Right away, I can start to see this hard, white coating just kind of floating off the piece of the pill. It looks like plastic," described the journalist witnessing the process.[229]

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[226] EPI000421543.
[227] END00010732.
[228] Kelly McEvers, "Opioid Epidemic Sparks HIV Outbreak in Tiny Indiana Town," NPR, March 31, 2016, *available at*: https://www.npr.org/2016/03/31/472577254/opioid-epidemic-sparks-hiv-outbreak-in-tiny-indiana-town
[229] *Id.*

330. Joy explained how the abuse-deterrent coating, once melted, was discarded by using the filter of a cigarette: "Now you see the coating of – all that mess laying there still? . . . That's what the filter's for."[230] The journalist described what then took place:

> And Joy puts that cigarette filter into the liquid, and they Joy, Jeff and another guy each take turns with their needles, sticking it into the filter and pulling the liquid through. Joy and Jeff turn their back to me while they inject. And then it just gets really, really quiet.

331. Joy couldn't conceive of the position she was in. A nurse, she hurt her back at work and began taking prescription pain medication. She began taking the pills by mouth, and later began to snort them. Dependency began. But she told herself, "I'd never ever would use a needle, never. I'm never going to do that."[231]

332. After Opana's reformulation, Joy began using it intravenously. "I started using the needle about – it was around the 6th of February," she said. "I'm so ashamed . . . . I pack so much shame, and I'm going to cry . . . . I pack so much shame from it. I do."[232]

333. Endo's 2012 reformulation of Opana caused outbreaks of HIV in populations of intravenous Opana users. In Austin, Indiana, where Jeff and Joy resided, Opana was linked to an outbreak of at least 200 HIV cases in a town with a population of 4,500.[233]

334. Intravenous use of reformulated Opana has also been associated with outbreaks of Hepatitis C and Thrombotic Thrombocytopenic Purpura ("TTP").[234] The concerns even reached Wall Street, where an analyst asked Endo about a TPP outbreak in Tennessee associated with Opana ER. Endo assured the analyst that the outbreak was, like the outbreak in Indiana, in "a very, very distinct area of the country."

335. Endo was well aware of these problems. [redacted]

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[230] *Id.*
[231] *Id.*
[232] *Id.*
[233] *Id.*
[234] "Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012," *Morbidity and Mortality Weekly Report* (Jan. 11, 2013).

[redacted]"[235]

336. In June of 2013, McKinsey [redacted].[236]

337. McKinsey indicated [redacted]"[238]

338. In addition to being neither feasible nor safe/ethical, the study was beside the point. An insufflation study is meant to determine the abuse characteristics of a drug when used nasally—i.e., by snorting the drug.[239] The relevant concern for Opana's reformulated version was *injection*, not insufflation.

339. But the insufflation study worked for Purdue. Going forward, McKinsey suggested [redacted].[240]

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[235] ENDO00260151.
[236] EPI002107711.
[237] *Id.*
[238] *Id.* (emphasis added).
[239] *See* General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products, FDA Center for Drug Evaluation and Research, November 2017, *available at*: https://www.fda.gov/files/drugs/published/General-Principles-for-Evaluating-the-Abuse-Deterrence-of-Generic-Solid-Oral-Opioid-Drug-Products-Guidance-for-Industry.pdf
[240] EPI002107711.

340. As the preceding paragraphs make clear, Endo and McKinsey were laser-focused on maximizing overall sales of Endo products, and decidedly *not* on concerns over their actual abuse potential or the appropriate *size* of the market for these products, given evident, longstanding, and ever-present concerns about their abuse. To the point, McKinsey regarded concerns about opioid abuse only as a means by which its clients could introduce *differentiated* products (i.e., those with purported abuse-deterrent or tamper-resistant features) to continually perpetuate overall opioids sales for their clients. In all instances, the parties desired for the size of that overall opioids market to grow in line with the introduction of "differentiated" products like a reformulated Opana.

341. Endo's purported concern about deterring abuse of its drugs was laid bare as farce by a particularly striking decision: to continue to sell the old formulation of Opana despite touting the notion that the old formulation was purportedly dangerous in ways that the new formulation was not. Endo [redacted].[241]

342. Endo not only continued to distribute original Opana for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers.[242] In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[243]

343. In June 2013, an Endo employee informed the McKinsey consultants of a [redacted][244]

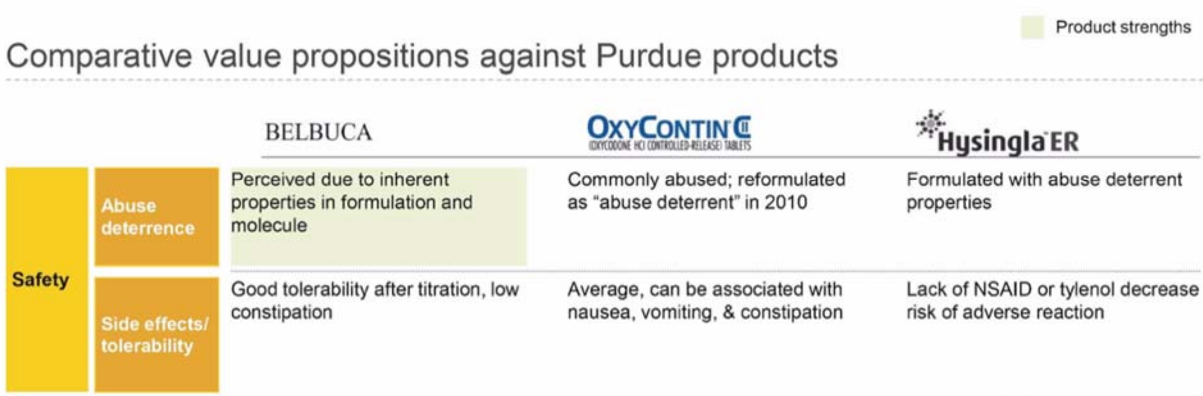
[241] ENDO-OPIOID-MDL-02324795.
[242] Impax Br. at 1.
[243] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).
[244] ENDO-OR-CID-00400235 (emphasis added).

d. Belbuca: Endo's Answer to Butrans

344. Buprenorphine is another differentiated product. Opioid manufacturers began to introduce Buprenorphine products to the market after the introduction of OxyContin, Opana, and other branded opioids long-known to have abuse and dependency problems. Buprenorphine products were marketed as purportedly less dangerous than products such as OxyContin or Opana.

345. Of course, Endo and Purdue continued to assiduously market and sell OxyContin and Opana alongside their Buprenorphine products, and McKinsey worked with each at every step of the way, despite the implicit contradiction in marketing two products at the same time whose point of differentiation is one being *less addictive and dangerous* than the other.

346. For example, on August 13, 2015, McKinsey's Craig MacKenzie circulated a discussion document to Endo and McKinsey staff entitled "Belbuca value proposition," which laid out McKinsey's thoughts on how to differentiate Endo's buprenorphine product from other opioids in the marketplace.[245] One point of differentiation McKinsey noted was that OxyContin was commonly abused, while Endo's Belbuca hopefully would not be: [246]



Comparative value propositions against Purdue products

Product strengths

		BELBUCA	OXYCONTIN (OXYCODONE HCl CONTROLLED-RELEASE TABLETS)	Hysingla ER
Safety	Abuse deterrence	Perceived due to inherent properties in formulation and molecule	Commonly abused; reformulated as "abuse deterrent" in 2010	Formulated with abuse deterrent properties
	Side effects/ tolerability	Good tolerability after titration, low constipation	Average, can be associated with nausea, vomiting, & constipation	Lack of NSAID or tylenol decrease risk of adverse reaction

347. The cognitive dissonance was palpable. At the same time that MacKenzie sent his email differentiating Belbuca, and as described *supra*, McKinsey was *also* maximizing OxyContin sales for Purdue—the opioid it was describing to Endo as commonly abused.

[245] MCK-MDL2996-0410742.

[246] MCK-MDL2996-0006669, at 0006675.

348. [redacted] Butrans was Purdue's buprenorphine product.

349. Once Butrans was launched at Purdue, McKinsey worked with Endo to create another branded Buprenorphine product to compete with Butrans. These product planning and launch processes are long-term affairs. McKinsey worked with Endo on this project for *four years* before Endo's Belbuca obtained FDA approval.

350. McKinsey remained in place at Endo to implement the launch of Endo's Buprenorphine product. The strategic goal of Belbuca—the key to its commercial success—was to convert short acting opioid ("SAO") users to Belbuca. As McKinsey explained to CEO Rajiv de Silva, "The fundamental question is whether Belbuca will take share from the short-acting opioids."[247]

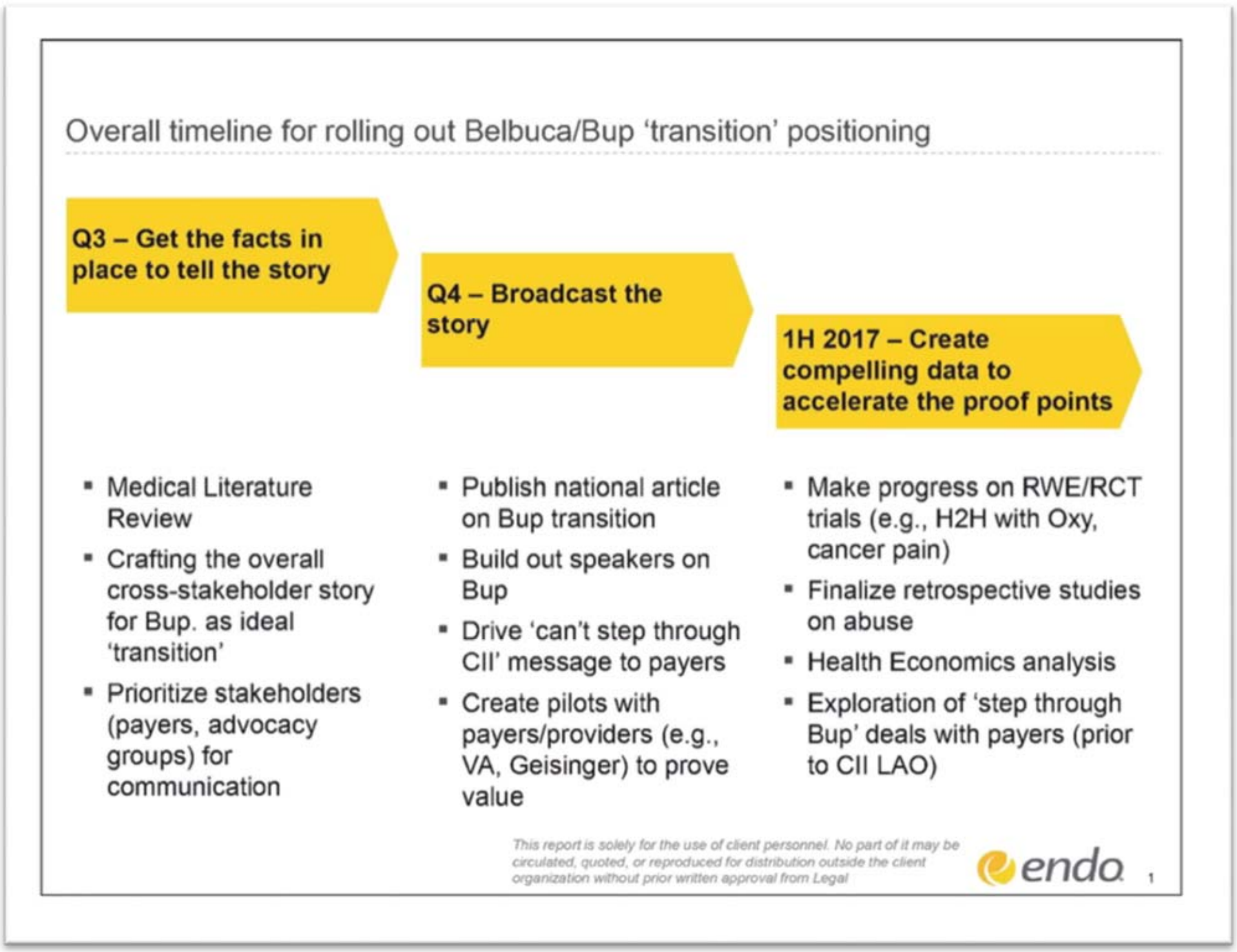
351. Ultimately, Belbuca was not a large commercial success for Endo because it failed to transition a sufficient number of short acting opioid users to the long-acting Belbuca. As the drug underperformed, Endo felt ever more pressure to stimulate sales. John Harlow described one meeting with de Silva on April 8, 2016: "We just got out of the review with Rajiv and clearly our TRx trends are not good and are behind other recently launched pain products . . . the request from Rajiv was to do anything possible that could be implemented ASAP to stimulate RXs."[248]

352. By July 6, 2016, McKinsey and Endo were increasingly focused on converting short-acting opioid users. [redacted]."[249] Notably, the goal was to increase *overall* buprenorphine prescriptions, not only those of Belbuca. The discussion document identified an objective to create "a new treatment paradigm for [Buprenorphine] and Belbuca at the transition between

[247] MCK-MDL2996-0210158.
[248] MCK-MDL2996-0358973, at 0358975.
[249] ENDO-OPIOID_MDL-07264539

SAO and LAO."[250] In order to do so, the discussion group needed to determine "what medical support we need to position Buprenorphine as the best transition from SAO to LAO."[251]

353. McKinsey provided a slide to Endo describing the way that narrative would first be *created* and then exploited for market positioning:[252]



354. McKinsey and Endo referred to this effort to revive Belbuca sales by promoting buprenorphine as a bridge to long-acting opioid use as a "moonshot."[253] One aspect of this "moonshot" would be that Belbuca (and Buprenorphine, generally) would convert short-acting opioid users to long-acting opioids users of products *other than Buprenorphine*. McKinsey and

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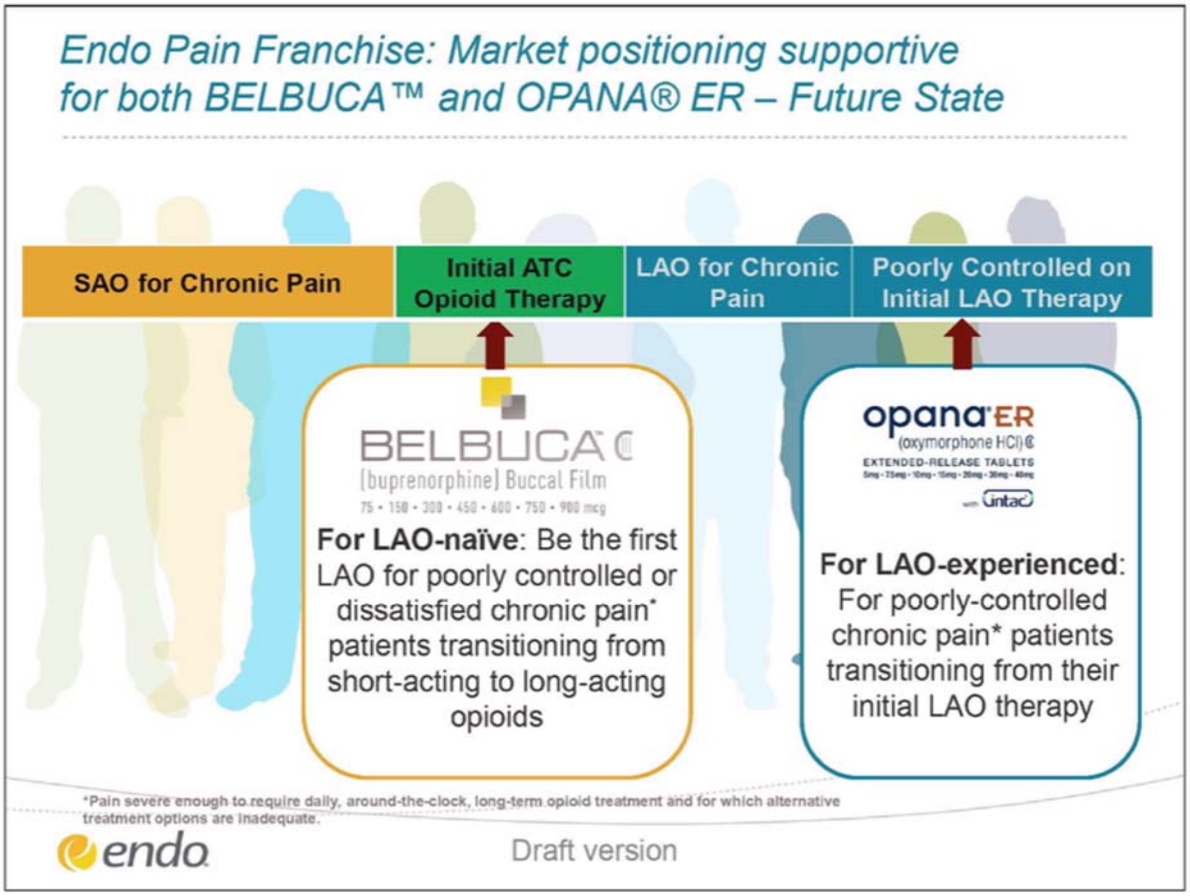
[250] *Id.*
[251] *Id.*
[252] MCK-MDL2996-0382731.
[253] MCK-MDL2996-0382412.

Endo instead conceived of Belbuca as an "*Initial* ATC Opioid Therapy." It was to be positioned as "the *first* LAO for poorly controlled or dissatisfied chronic pain patients transitioning from short-acting to long-acting opioids." Patients could eventually transition from Belbuca to other long-acting opioids, like Opana:[254]

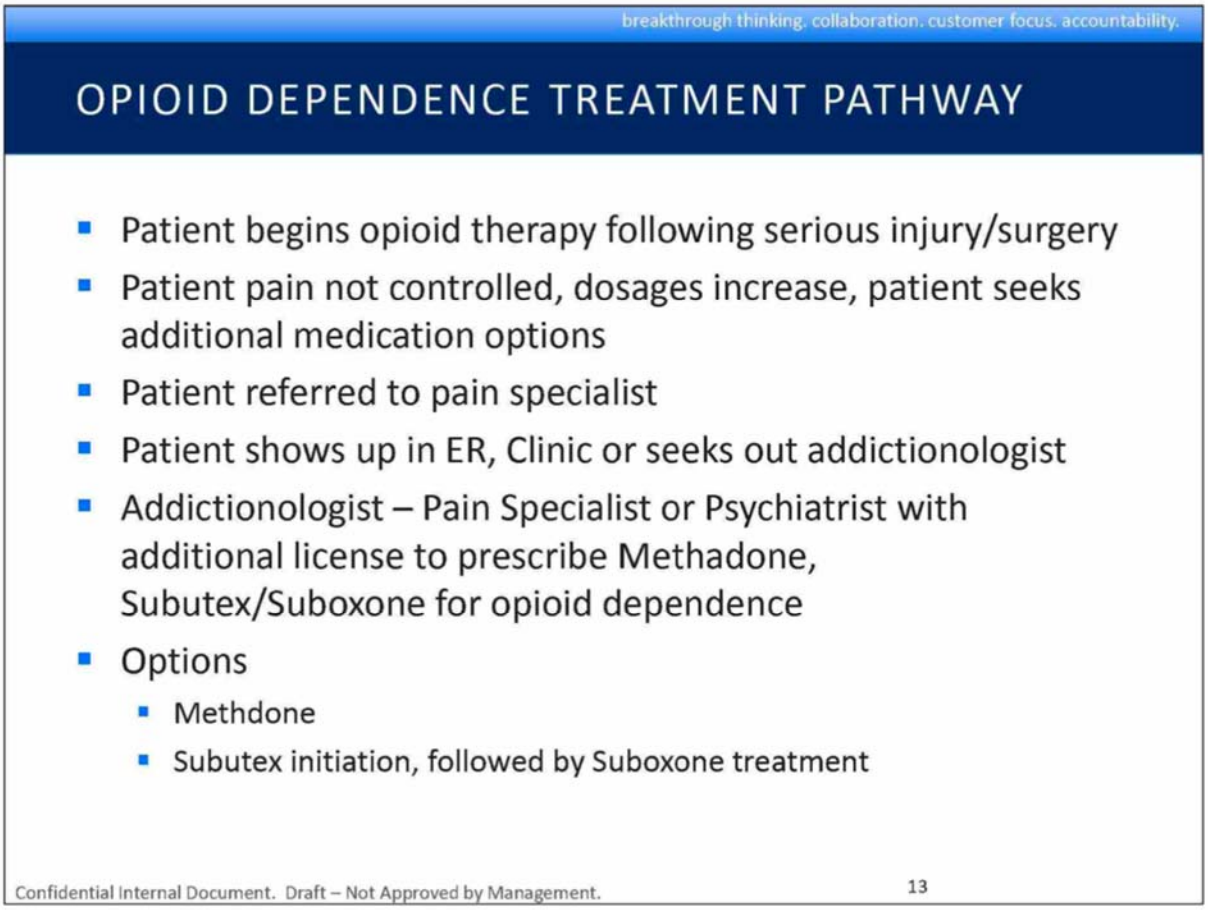


355. Thus, the overall marketing strategy McKinsey assisted Endo in designing and deploying for Belbuca was designed to transition ever more patients to long-acting opioids. Belbuca could find its market niche as a stepping stone as individuals proceed through the patient funnel from short acting opioid users to longer-term long-acting opioid users. The farther an individual proceeds through this funnel, the more the individual is worth.

356. McKinsey also knew that this same pathway that begins with opioid therapy after a serious injury also leads to opioid dependency and addiction. In 2011, McKinsey was working on "Project X." which was the project to develop a buprenorphine product to compete with Butrans.

[254] MCK-MDL2996-0404374, at 0404375.

(Belbuca, in other words, was the result of Project X.) McKinsey described the "opioid dependence treatment pathway" as follows:[255]



357. In the same presentation, McKinsey identified the key to a successful launch of a branded Buprenorphine product: "The challenge faced by Endo will not be to gain formulary approval, it will be to gain tier 2 status and *minimize restrictions on prescribing*."[256]

e. <u>Turbocharging the Sales Force with a Blitz</u>

358. In 2015, a McKinsey team led by Arnab Ghatak proposed to Endo a sales transformation to invigorate Endo's product sales, including its opioids. At the suggestion of Ghatak, McKinsey used the Purdue Pharma Project Turbocharge model from the previous year as a template for the Endo proposal.[257] Even the PowerPoint presentations used to create the proposal to Endo were drafted off the Project Turbocharge slides. On June 28, 2015, Sherin Ijaz

[255] MCK-MDL2996-0131500, at 0131512.
[256] MCK-MDL2996-0131500, 0131525 (emphasis added).
[257] MCK-MDL2996-0075895.

of McKinsey emailed Ghatak, Nicholas Mills, and Laura Moran to circulate a draft proposal for an "Endo sales force transformation" PowerPoint presentation. Ijaz explained, "Laura, I heavily leveraged what you send (sic) from Purdue as it was all applicable."[258] All three of the recipients of Ijaz's email regarding the Endo proposal had been working on the Purdue account for years.

359. Endo [redacted]"[259]

360. Endo's Vice President & General Manager of its Pain Business Unit, John Harlow, [redacted][260] [redacted][261]

361. The Endo and Purdue proposals were essentially identical sales transformations. The goals were the same: to maximize sales of opioids. Merely the names were changed. While McKinsey offered to "turbocharge" Purdue's sales force, McKinsey proposed a "sales force blitz" for Endo.[262]

362. In fact, the names weren't *entirely* changed. [redacted][263]

363. [redacted]

[258] MCK-MDL2996-0070237.
[259] ENDO_AAC_00363406.
[260] *Id.*
[261] *Id.*
[262] *E.g.*, MCK-MDL2996-0130803; MCK-MDL2996-0132851.
[263] MCK-MDL2996-0069747, at 0069749.

[redacted].

[redacted]

364. [redacted].

365. Upon McKinsey's suggestion, Endo began reallocating sales force resources to Opana from other Endo products such as Sumavel, a migraine medication, and Voltaren, an anti-inflammatory.[264] Writing to the McKinsey team, Endo's Alicia Logan stated the joint mission, "I agree that our main goal is to maximize the increased promotional efforts for [Opana ER] without

[264] MCK-MDL2996-0409466.

disrupting/sacrificing [Sumavel] or [Voltaren] TRx volume and it appears that we [can] accomplish this with your recommendation of addition another 500 targets."[265]

366. With the Sales Force Blitz underway, Endo received good news in New York. Years prior, Endo had initiated patent litigation against generic manufacturers of Opana ER, arguing that the generic versions of the drug infringed on Endo's patents. In part because of the perceived impending loss of exclusivity, Endo had in recent years allocated its sales force capacity away from Opana and to other Endo products.

367. On August 14, 2015, Endo received a favorable initial ruling declaring that the generic versions of Opana violated Endo's patents, and enjoined their further sale. The ruling provided additional patent exclusivity for Opana, and Endo was keen to exploit its advantage.

368. That afternoon, [redacted][266]

369. The following week, Harlow wrote to the McKinsey team working for Endo to focus their attention on Opana ER. "Now with our litigation victory from last week, plus our UHC opportunity, there is an increased need to increase FF support to drive Sep-Dec business. . . . With this win, I am now willing to go broader with OER targeting."[267]

370. McKinsey and Endo proceeded to design and implement retargeting strategies to boost Opana sales in late 2015.

2. <u>Johnson & Johnson</u>

371. McKinsey also working with Johnson & Johnson, whose role overseeing and contributing to the opioid crisis has been exhaustively detailed in other complaints. *See, e.g.*, *City and County of San Francisco v. Purdue Pharma L.P.*, N.D. Cal. No. 18-2591, Doc. 128 (Mar. 13, 2020). Johnson & Johnson occupied multiple roles within the opioids industry. Through its

[265] MCK-MDL2996-0409436, at 0409437 (sic).
[266] ENDO-OPIOID_MDL-02279530.
[267] MCK-MDL2996-0358871, at 0358872; ENDO-OPIOID_MDL-02201117 .

subsidiary, Janssen Pharmaceuticals ("Janssen"), it marketed and sold branded opioid products, including Duragesic (a transdermal fentanyl patch) and Nucynta (tramadol tablets and oral solution). Through its Noramco and Tasmanian Alkaloids subsidiaries, Johnson & Johnson farmed the poppy plant in New Zealand and created the precursor chemical and raw materials necessary to manufacture *all* opioids. Noramco and Tasmanian Alkaloids sold these raw materials to the other opioid manufacturers: Purdue, Endo, Mallinckrodt, and others. Johnson & Johnson was the origin point in the entire opioids supply chain.

372. Just like McKinsey's relationships with Purdue, Endo, and the others, McKinsey's opioid-related work for Johnson & Johnson spanned decades.

373. Just as Endo was led by former partner McKinsey partner Rajiv de Silva, Johnson & Johnson similarly relied on McKinsey as a pipeline for its own management timber. As described above, McKinsey alumni tend to move on to positions with McKinsey clients. Janssen's current Director of Customer Marketing & Value Based Care was hired from McKinsey's PMP group. The relationship flows both ways: Janssen's former Vice President of Sales and Marketing for Janssen Pharmaceuticals is currently a McKinsey partner. Moreover, Ian Davis has been an independent director since 2010 and currently sits on the Audit and Regulatory Compliance committees of Johnson & Johnson's board. Previously, he was a Senior Partner at McKinsey, "having served as Chairman and Worldwide Managing Director from 2003 until 2009."[268]

374. Kevin Sneader, until recently McKinsey's global managing partner, and one of Davis' successors, described Davis as a "mentor" who was the managing partner of McKinsey's London office when Sneader was working there and "worked on one of his teams."[269] Given Frazier's presence on the board, Johnson & Johnson was obviously an important account for McKinsey. At present, it is not known which McKinsey partner(s) was the Director(s) of Client Services for the Johnson & Johnson account.

[268] https://www.jnj.com/leadership/ian-e-l-davis
[269] *See* Interview with Kevin Sneader, Harvard Project for Asian & International Relations, January 31, 2021, *available at* https://www.youtube.com/watch?v=qed53EGG8kU

375. What is known, however, is that McKinsey [redacted]"[270] On July 6, 2011, Ghatak attended an internal McKinsey call with the consultants working on the Johnson & Johnson account to discuss the "J&J Nucynta sales force disruption."[271] The same day, Laura Moran, who like Ghatak worked both the Purdue and Endo accounts, also provided internal advice regarding Nucynta to her McKinsey partner Gerti Pellumbi, who was leading Nucynta sales efforts for the Johnson & Johnson account, and engagement manager Bryan Reinholt, who was with Pellumbi on the Johnson & Johnson account. [272] Martin Elling, one of the lead McKinsey partners on the Purdue account alongside Ghatak, attended internal McKinsey calls on March 25, 2010,[273] and again on May 27, 2011 to discuss McKinsey's work for Johnson & Johnson's Nucynta.[274] Then, on December 13, 2011, Elling attended a meeting with Johnson & Johnson personnel regarding "acceleration opportunities."[275] Aamir Malik attended the meeting with Elling, and, naturally, also worked on the Endo account.[276] Malik and Ghatak had an internal McKinsey meeting amongst themselves regarding the "Nucynta Kickoff" at Johnson & Johnson six months prior, on June 3, 2011.[277]

a. Noramco

376. Janssen was not the only Johnson & Johnson unit [redacted], and Janssen was not Johnson & Johnson's only division involved in the narcotics trade.

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[270] JAN-NH-00167575.
[271] MCK-MDL2996-0222833.
[272] MCK-MDL2996-0419348.
[273] MCK-MDL-2996-0256186.
[274] MCK-MDL-2996-0255907.
[275] MCK-MDL-2996-0255926.
[276] *Id.*; *see also* MCK-MDL-2996-0348536 (Example of Malik's work on Endo account).
[277] MCK-MDL-2996-0261694.

377. Opioids—all of them—are derivatives of opium, which is derived from the poppy plant. In order to sell opioids, someone needs to farm the opium poppy and process the harvest into the raw materials necessary for opioid manufacturers—all of them—to make their products.

378. Johnson & Johnson was that farmer. It owned Noramco and Tasmanian Alkaloids, which grew poppies in New Zealand and sold the raw ingredients for opioids to practically all manufacturers.

379. On August 19, 2009, McKinsey's [redacted].[278]

380. [redacted][279]

381. Seven years later, in 2016, Johnson & Johnson exited the business by selling Noramco and Tasmanian Alkaloids to SK Capital, a private equity firm focused on the pharmaceuticals business, for approximately $800 million.[280] [redacted] Not only was McKinsey's advice invaluable to Johnson & Johnson, the perspective McKinsey gained of the overall opioid market from advising the principal upstream supplier to the entire industry would be invaluable in to its own work with its other opioid manufacturer clients.

b. Duragesic

382. Fentanyl was first synthesized by Paul Janssen and his pharmaceutical company Janssen Pharmaceuticals in 1959. In the 1990s, the company (by then owned by Johnson &

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[278] NORAMCO_TX_01136410.
[279] NORAMCO_TX_01136411, slide 4.
[280] Gareth Macdonald, "US Investor buys J&J's opiate API business and announces restructuring," *Outsourcing Pharma*, July 20, 2016, *available at*: https://www.outsourcing-pharma.com/Article/2016/07/21/US-investor-buys-J-J-s-opiate-API-business-and-announces-restructuring

Johnson) developed Duragesic, which is a transdermal patch that administers fentanyl to the patient wearing it.

383. "Duragesic proved to be one of the most successful analgesic pharmaceutical products ever developed, with sales in 2004 (its last year of patent life) exceeding $2.4 billion. The success of the fentanyl patch caused many generic companies to produce equivalents once it went off patent."[281]

384. McKinsey was an integral part of fentanyl's success. As early as 2002, McKinsey was advising Johnson & Johnson regarding methods to boost sales of its opioids. For example, on March 14, 2002, McKinsey prepared a confidential report for Johnson & Johnson's subsidiary Janssen regarding how to market their opioid Duragesic. Incredibly, one of the recommendations McKinsey provided to Johnson & Johnson was that they concentrate their sales and marketing efforts on doctors that were *already* prescribing large amounts of Purdue's OxyContin.[282]

385. In other words, as early as 2002, McKinsey had such intricate knowledge of the sales and marketing practices of opioid manufacturers, generally, and Purdue's efforts with OxyContin, specifically, that it was able to recommend to *a competitor of Purdue* that it boost its own opioid sales by *following in the footsteps of Purdue*.

386. McKinsey also advised Johnson & Johnson to target Duragesic on "high abuse-risk patients (e.g., males under 40)." This targeting would take advantage of the marketing claim that Duragesic "was harder to abuse than other opioids on the market."[283]

387. McKinsey helped Janssen target its opioid marketing by identifying "priority growth opportunities" and growth strategies for Duragesic.[284] In 2002, McKinsey considered "[w]hat are settings of care for opioid high-prescribers and treaters of back pain," listing the

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[281] Theodore Stanley, "The Fentanyl Story," The Journal of Pain, Vol. 15, No. 12 (December), 2014, pg. 1220, *available at*: https://www.jpain.org/article/S1526-5900(14)00905-5/pdf

[282] Chris McGreal, *Johnson & Johnson faces multibillion opioids lawsuit that could upend big pharma*, The Guardian, June 23, 2019, *available at:* https://www.theguardian.com/us-news/2019/jun/22/johnson-and-johnson-opioids-crisis-lawsuit-latest-trial

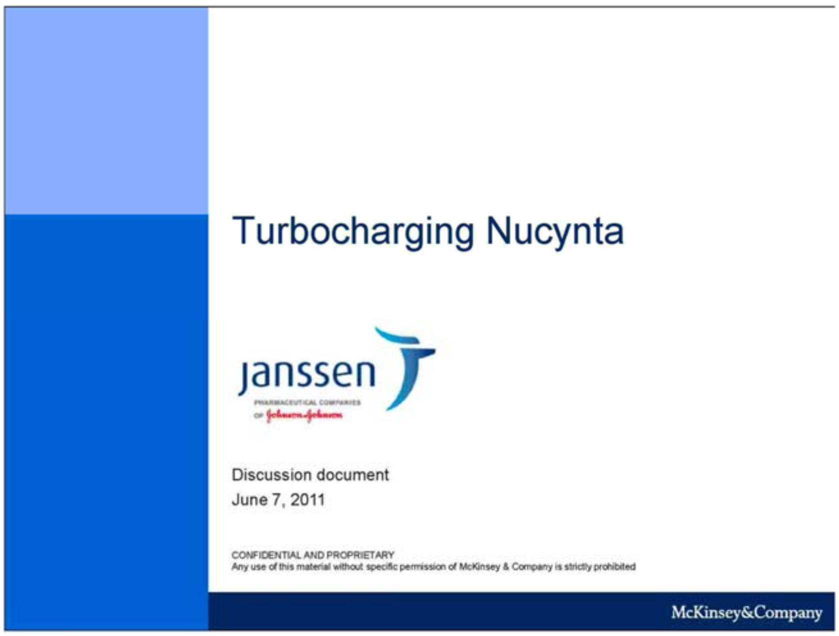
[283] Julia Lurie, *"Inside Johnson and Johnson's Quiet Domination of the Opioid Market,"* June 11, 2019, Mother Jones, *available at* https://www.motherjones.com/politics/2019/06/johnson-and-johnson-opioid-poppies-tasmania-oklahoma-lawsuit/

[284] *Oklahoma v. Johnson & Johnson*, Oklahoma Proposed Findings & Conclusions, citing 5/30/19pm Tr. & S-1253; *see also* JAN-MS-00481545 (Deem-Eshleman Ex 73).

"elderly" as an example;[285] [redacted].[286]

c. Turbocharging Nucynta

388. McKinsey's infamous Project Turbocharge to boost OxyContin sales at Purdue in 2013 and 2014—the same project detailed in Purdue's 2020 guilty plea with the Department of Justice—was not McKinsey's first experience turbocharging opioid sales. Before OxyContin, there was Nucynta:[287]



389. Nucynta was Janssen's branded tapentadol product. Tapentadol is generally regarded as a moderately strong opioid. Nucynta was first approved as a Schedule II controlled opioid agonist tablet and oral solution in 2008, and indicated for "relief of moderate to severe acute pain in patients 18 years of age or older." In 2011, Janssen obtained approval for a long-acting version Nucynta ER, which was indicated for "management of moderate to sever chronic pain in adults and neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults."

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[285] *Oklahoma v. Johnson & Johnson*, 5/30/19 Tr. At 46:1-15.
[286] JAN-MS-00481547 (Deem-Eshleman Ex 74) .
[287] MCK-MDL-2996-0135636.

390. McKinsey is a repeat opioid sales turbocharger. McKinsey's efforts to turbocharge Nucynta sales resembled those it later deployed in more robust form at Purdue a few years later. For example, "physician prescribing habits," and "switching behavior," were external factors McKinsey identified as key issues "impacting future Nucynta growth." Understanding these issues at a granular level would be crucial, including "What is physician/market awareness of Nucynta ER? By physician segment?"[288] These same factors drove McKinsey's later work turbocharging OxyContin.

391. Along the way, McKinsey [redacted][289]

392. Despite this ambivalence about tamper-resistance, in a status update on June 23, 2011, McKinsey informed Janssen that its "initial physician interview findings" indicate Nucynta ER has "lower addictive/abuse potential and side-effect profile as key differentiators vs. Oxycontin ER."[290]

393. As part of the turbocharge process, [redacted]"[291]

394. By 2014, Janssen was began exploring the sale of Nucynta, and McKinsey was involved in the process. Incredibly, [redacted][292] Purdue ultimately did not purchase Nucynta. Instead, in 2015, Johnson & Johnson's

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[288] MCK-MDL-2996-0135636.
[289] JAN-MS-00322271.
[290] MCK-MDL-2996-0009526, at 0009529.
[291] JAN-MS-02272779.
[292] PPLPC023000661013 [redacted]

Janssen unit sold its Nucynta rights to another manufacturer, Depomed Inc., for just over one billion dollars.[293]

395. The year prior, Nucynta accounted for $172 million in annual sales for Janssen. Janssen described the Nucynta sale to Depomed as "a strategic decision designed to focus efforts on growth efforts."[294] Depomed, for its part, saw the Nucynta acquisition as a transformational opportunity to position itself as "a pain and neurology-focused specialty pharmaceutical company."[295]

396. When Depomed bought Nucynta, [redacted]

[redacted] [296]

3. **Other Manufacturers**

397. McKinsey worked with numerous other manufacturers to promote the sale of opioids. To date, Plaintiffs have identified as McKinsey clients [redacted][297] and [redacted] [redacted].[298]

398. Coordination among these industry participants was a natural outgrowth of the fact that McKinsey had existing client relationships with each participant. For instance, on May 7, 2009, Richard Sackler's personal counselor, McKinsey partner Maria Gordian, [redacted]

[redacted]).

[293] *See* https://www.prnewswire.com/news-releases/depomed-announces-closing-of-acquisition-of-us-rights-to-nucynta-tapentadol-nucynta-er-tapentadol-extended-release-tablets-and-nucynta-tapentadol-oral-solution-from-janssen-pharmaceuticals-inc-for-105-billion-300060453.html

[294] Josh Beckerman, "DepoMed to Buy U.S. Rights to Nucynta From J&J Unit," *Wall Street Journal*, January 16, 2015, *available at*: https://www.wsj.com/articles/depomed-to-buy-u-s-rights-to-nucynta-from-j-j-unit-1421357503

[295] *Id.*

[296] DEPO-CDI-00071072 (emphasis added).

[297] MNK-MDL_001756041; MNK-T1_0000968026; MN-T1_0004715842; MNK-T1_0005985720.

[298] TEVA_CHI_00187019.

[redacted][299]

399. [redacted].[300]

400. [redacted].[301]

[redacted]

4. McKinsey's Work with Opioid Distributors

401. McKinsey worked with opioid distributor AmerisourceBergen [redacted].[302]

402. McKinsey worked with opioid distributor McKesson on the company's [redacted].[303]

5. McKinsey's Work with the FDA

403. As described above, McKinsey assisted Purdue and others to confront FDA regulations that posed threats to their clients' ability to maximize revenues from their opioid products. McKinsey's role in shepherding its clients through regulatory interactions takes on a

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[299] TEVA_CHI_00187019.
[300] TEVA_CHI_00187023.
[301] *See* ALLERGAN_MDL_00637407.
[302] ABDCMDL12135609, slide 5.
[303] MCKSTCT00753097; MCKSTCT00753098.

different hew when considered in light of one of McKinsey's other clients: the Food and Drug Administration itself.

404. Indeed, the FDA has proved a massive client for McKinsey, who since 2000 has endeavored to expand its public sector practice under the direction and leadership of Nancy Killefer, a now-retired senior partner and director of the firm.[304] Since 2008, the FDA has paid McKinsey more than $140 million.[305] A significant portion of that work for the FDA related to the FDA's Center for Drug Evaluation and Research ("CDER"). The CDER is the principal division tasked with approving, among other classes of drugs, opioids. Since 2008, McKinsey has been awarded at least 17 contracts worth at least $48 million for CDER work.[306]

405. The REMS protocols, discussed above, that McKinsey assisted Purdue and others in surmounting beginning in 2008 and culminating in 2012, were overseen by CDER.[307]

406. Meanwhile, in 2010, McKinsey advised the FDA on building a monitoring system called "track and trace" to assist in the identification of potentially improper distribution of harmful prescription drugs, such as opioids. "The 'track and trace' system deeply impacted McKinsey clients, including the nation's three largest drug distributors—McKesson, AmerisourceBergen, and Cardinal Health [where Killefer has been a director since 2015]."[308]

407. Under one contract, McKinsey developed a roadmap and implemented plans to modernize CDER's new drug regulatory program. Under another, McKinsey developed a framework to increase information technology project delivery across CDER.[309]

408. In 2007, Congress passed the Food and Drug Administration Amendments Act ("FDAAA"), which placed new restrictions on the use of certain high risk prescription drugs, including opioids. The new law mandated that FDA require manufacturers of certain drugs to create REMS.

[304] Duff McDonald, *The Firm*. Killefer is also a director of Cardinal Health, one of the distributor defendants in the ongoing nationwide opioid litigation, and a company subject to FDA regulations.
[305] Letter to Dr. Janet Woodcock from Senator Margaret Hassan et al, August 23, 2021, *available at*: https://www.hassan.senate.gov/imo/media/doc/fda-mckinsey_letter-final-210823.pdf ("Hassan Letter")
[306] *Id*.
[307] *Id*.
[308] *See* http://cg.cardinalhealth.com/board-of-directors/default.aspx; Hassan Letter.
[309] Letter to Senator Chuck Grassley from Andrew Tantillo, Oct. 22, 2021, *available at*: https://www.grassley.senate.gov/imo/media/doc/fda_to_grassley_-_mckinsey_conflicts_of_interest.pdf

409. The FDAAA also required the Secretary of Health and Human Services "to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs." 21 U.S.C. § 355e(a).

410. In 2010 and 2011, under the FDAAA, the FDA awarded McKinsey contracts to design a "track and trace" system to monitor prescription drugs, including opioids, throughout the supply chain and to streamline the drug approval process. The track and trace system had the greatest effect on drug distributors, including McKinsey clients McKesson, AmerisourceBergen, and Cardinal Health.[310]

411. Under these contracts, McKinsey was required to consult with "supply chain stakeholders," which likely included these three McKinsey clients as well as pharmaceutical manufacturers.[311]

412. In 2011, McKinsey also won a $1.8 million contract with CDER's Office of Surveillance and Epidemiology ("OSE"), which monitors and evaluates the safety profiles of drugs available to American consumers.[312] OSE "evaluates more than 2 million adverse event reports submitted every year to FDA's MedWatch program" and provides "risk management expertise on development and implementation of programs and initiatives to support [CDER's] policies related to [REMS] authorities.[313]

413. The OSE contract tasked McKinsey with a widespread mission of understanding how OSE functions within the context of a broader system of drug safety in CDER and ultimately developing and implementing a new operating model. In other words, McKinsey helped to restructure a key body that has oversight over the opioid supply chain.

414. The 2012 Food and Drug Administration Safety and Innovation Act required the FDA to modernize Sentinel, a system meant to monitor the safety of drugs once they are on the

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[310] Hassan Letter.

[311] *Id.*

[312] https://www.documentcloud.org/documents/21071060-mckinsey-ose-contract

[313] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-office-surveillance-and-epidemiology

market.[314] According to the FDA, "Sentinel generates *real-world evidence* to support regulatory actions aimed at protecting the public's health," which in turn "inform[s] healthcare provider decision-making for patients."[315]

415. A 2014 contract with the FDA charged McKinsey with assessing the "strengths, limitations and appropriate use" of Sentinel. Like the track and trace contract, the Sentinel project required McKinsey to interview "external stakeholders," including "industry organizations" and "drug and device industry leaders."[316] McKinsey also evaluated how the FDA employees used Sentinel to inform regulatory decision making.[317]

416. McKinsey performed similar work for the FDA as recently as 2019,[318] when it signed a contract extension with the agency for work relating to the FDA's efforts to modernize the process by which it regulates new drugs.[319]

417. The FDA's drug tracking programs have been panned as failures.[320]

418. A theme was emerging: as new legislation and regulatory systems were enacted that could have hampered the opioid supply chain, McKinsey stepped in as a key consultant for the FDA. Each time, the new system failed to reign in the out-of-control opioid market. While the FDA was not solely responsible for regulating the opioid industry and McKinsey was not wholly responsible for the FDA's inaction, tools like Sentinel and track and trace could have been implemented in a way to provide new information to combat the country's growing opioid crisis.

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[314] https://www.documentcloud.org/documents/21071047-r_sentinel_assessment_award_contract_sow-redacted-pr

[315] https://www.fda.gov/files/about%20fda/published/Sentinel-System-Overview-–-Presentation.pdf; https://www.healthaffairs.org/do/10.1377/hpb20150604.936915/full/

[316] Ian MacDougall, "McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency," *ProPublica* (Oct. 4, 2021), ***available at*** https://www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency

[317] Letter to Bob Sternfels from Representative Carolyn B. Maloney, Nov. 5, 2021, *available at*: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-11-05.CBM%20to%20Sternfels-McKinsey%20re%20Document%20and%20Information%20Request%20%28001%29.pdf

[318] Ian MacDougall, "McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency," *ProPublica* (Oct. 4, 2021), ***available at*** https://www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency

[319] Letter to Bob Sternfels from Representative Carolyn B. Maloney, Nov. 5, 2021, *available at*: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-11-05.CBM%20to%20Sternfels-McKinsey%20re%20Document%20and%20Information%20Request%20%28001%29.pdf

[320] Sabrina Tavernise, "F.D.A. Faulted for Problems With Drug Tracking" *The New York Times*, Jan. 14, 2016, *available at* https://www.nytimes.com/2016/01/15/health/fda-faulted-for-problems-with-drug-tracking.html; https://www.gao.gov/assets/gao-16-192.pdf

419. At the same time it was consulting for the FDA, McKinsey was working with its opioid industry clients on how skirt the FDA's regulatory systems.

420. For example, McKinsey advised Purdue on how to soften the FDA's proposed REMS and on coordinating with other opioid manufacturers to advocate against strict oversight.[321] The finalized REMS for opioid products was largely devoid of the restrictions that FDA had initially proposed.[322]

421. McKinsey's work with the FDA was a key factor in why pharmaceutical industry clients tapped McKinsey for FDA-related work. For example, in endorsing McKinsey's proposed strategy of banding together with other opioid manufacturers, Purdue CEO John Stewart suggested that the consultant itself facilitate the pharmaceutical group's approach to FDA. He wrote: "Perhaps a consultant such as McKinsey who did similar work in the industry and FDA on some aspects of clinical trials or a healthcare-related group that would be interested in playing an active role in the program's development and delivery would be a good choice."[323]

422. McKinsey performed work for the FDA without disclosing its potential conflicts of interest to the FDA in violation of the contracts between the company and the agency.

423. The FDA typically includes conflict of interest clauses in its contracts and relies on contractors to assess and report any conflicts. McKinsey's contracts with the FDA related to CDER processes contained such provisions. One contract required McKinsey to "make an immediate and full disclosure, in writing, . . . of any potential or actual organizational conflict of interest or the existence of any facts that may cause a reasonably prudent person to question the contractor's impartiality because of the appearance or existence of bias."[324]

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[321] Hassan Letter.
[322] Hassan Letter; Maloney Letter.
[323] Purdue Bankruptcy, Doc. 2166-5, at 58-59.
[324] Ian MacDougall, McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency, *ProPublica* (Oct. 4, 2021), available at https://www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency

424. But McKinsey never disclosed its work on behalf of opioid supply clients to the FDA despite having a hand in developing some of the FDA's most important regulatory processes.[325]

425. Disclosing its conflicts might have turned off the lucrative tap to not only FDA contracts but also to pharmaceutical industry clients, given the clear value such clients placed on McKinsey's work for the FDA.

426. McKinsey's manipulation of regulatory requirements—whether to skirt its own contractual requirements or to bend processes that regulate its clients—is nothing new. McKinsey has come under fire from the Office of Inspector General for the General Services Administration for contract procurement violations[326] and from the Justice Department related to violation of Chapter 11 bankruptcy rules.[327] Most recently, six senators have begun to investigate the relationship between McKinsey and the FDA[328] the House Committee on Oversight and Reform is exploring its abusive conduct in connection with the opioid industry.[329]

427. As one commentator noted, McKinsey's conduct suggests that it "behaves as if it believes the rules should bend to its way of doing things, not the other way around."[330]

F. **<u>McKinsey's Efforts to Increase the Overall Size of the Opioid Market: the Larger the Pie, the Larger the Slice</u>**

428. McKinsey advised multiple opioid manufacturers regarding how to grow opioid sales. In order to benefit all its clients, McKinsey engaged in efforts to grow the entire opioid market, and not only each individual client's share of it. The theory, basically, is that a rising tide lifts all boats.

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[325] *Id.*; Letter to Senator Chuck Grassley from Andrew Tantillo, Oct. 22, 2021, *available at*: https://www.grassley.senate.gov/imo/media/doc/fda_to_grassley_-_mckinsey_conflicts_of_interest.pdf

[326] Ian MacDougall, How McKinsey Makes Its Own Rules, *ProPublica* (Dec. 14, 2019), available at https://www.propublica.org/article/how-mckinsey-makes-its-own-rules

[327] Mary Williams Walsh and Emily Flitter, McKinsey Faces Criminal Inquiry Over Bankruptcy Case Conduct, *New York Times*, Nov. 8, 2019, *available at* https://www.nytimes.com/2019/11/08/business/mckinsey-criminal-investigation-bankruptcy.html

[328] Hassan Letter.

[329] Maloney Letter.

[330] Ian MacDougall, How McKinsey Makes Its Own Rules, *ProPublica* (Dec. 14, 2019), available at https://www.propublica.org/article/how-mckinsey-makes-its-own-rules

429. For example, Purdue incentivized its sales staff "to increase not just sales of OxyContin but also generic versions of extended release oxycodone." Typically, one would not wish to encourage the sales of generic competitors that offer a similar product to one's own. If, however, the goal is to position a company so as to look like an attractive acquisition target, the growth of the overall opioid market is just as important as one's own market share: "Whereas pharma salespeople are usually compensated based on their ability to grow sales of a particular medicine, part of the bonus for Purdue's staff was calculated in relation to the size of the overall market."[331] McKinsey designed that plan.[332]

430. This notion that the size of a company's market share is not as important as the size of the *overall* market in which it competes is a core insight of McKinsey's granular approach to identifying corporate growth opportunities. Describing their authors' conclusions in *The Granularity of Growth,* McKinsey stated, "One of their most surprising conclusions is that increased market-share is seldom a driver of growth. They contend, instead, that growth is driven by where a company chooses to compete: which market segments it participates in . . . the key is to focus on granularity, to breakdown big-picture strategy into its smallest relevant components."[333]

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[331] *See* David Crow, *How Purdue's 'one-two' punch fuelled the market for opioids*, Financial Times, September 9, 2018, *available at*: https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c

[332] Worth noting is that this strategy of increasing overall opioid sales directly benefitted the Sacklers through their ownership of Rhodes Pharma, a generic opioid manufacturer. Naturally, McKinsey worked with the Sacklers in connection with Rhodes as well, including proposing ideas for synergizing Purdue and Rhodes. *See, e.g.*, MCK-MDL2996-0324955; MCK-MDL2996-0285201. Especially worth noting is that this strategy also benefitted McKinsey's other opioid clients as well. As one observer wrote: "They have a huge amount of inside information, which raises serious conflict issues at multiple levels," stated a former consultant, referring to McKinsey's influential role as advisor to multiple participants in a given industry, such as opioid manufacturing. It "puts them in a kind of oligarchic position." Michelle Celarier, *The Story McKinsey Didn't Want Written*, Institutional Investor, July 8, 2019, *available at:* https://www.institutionalinvestor.com/article/b1g5zjdcr97k2y/The-Story-McKinsey-Didn-t-Want-Written.

For example, in an August 15, 2013 presentation to Purdue management entitled "Identifying OxyContin Growth Opportunities," McKinsey noted that "McKinsey's *knowledge of the ways other pharma companies operate* suggests Purdue should reassess the roles of MSL and HECON Groups – and further drive the salesforce to be more responsive to formulary coverage changes." (emphasis added).

[333] *The granularity of growth*, Book Excerpt, McKinsey & Company, March 1, 2008, *available at*: https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/the-granularity-of-growth

431. In other words, "Purdue's marketing force was indirectly supporting sales of millions of pills marketed by rival companies."[334] "It's the equivalent of asking a McDonald's store manager to grow sales of Burger King and KFC," stated a government official with the Department of Health and Human Services.[335]

G. McKinsey's Work Kills People.

432. The deceptive marketing strategies McKinsey developed and helped to implement were successful. Its granular growth tactics, myopically focused on increased revenues for its clients, substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and as of 2016, 20% of office visits for non-cancer pain included the prescription of an opioid.[336]

433. In 2009, Dr. Van Zee identified the *precise tactics* that McKinsey deployed for all of its opioid clients, including Purdue, as a source of OxyContin misuse and abuse, and suggested that regulation may be appropriate to curtail the use of the McKinsey's tactics: "The use of prescriber profiling data to target high-opioid prescribers—coupled with very lucrative incentives for sales representatives—would seem to fuel increased prescribing by some physicians—perhaps the most liberal prescribers of opioids and, in some cases, the least discriminate."[337]

434. In time, additional evidence mounted supporting the conclusion that McKinsey's tactics were demonstrably exacerbating the nationwide opioid crisis. One way of demonstrating the link between aggressive sales and marketing of opioids and worsened mortality outcomes arose out of a quirk of Purdue's own marketing tactics.

435. In 1996, when OxyContin was introduced, five states maintained "triplicate" programs that required prescribers of Schedule II controlled substances to fill out prescriptions in

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[334] *See* David Crow, *How Purdue's 'one-two' punch fueled the market for opioids*, Financial Times, September 9, 2018, *available at*: https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c
[335] *Id*.
[336] Deborah Dowell, Tamara M. Haegerich, and Roger Choi, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, CDC (March 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
[337] Art Van Zee, The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy, 99 AM. J. PUB. HEALTH 221, 221, 224 (Feb. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf.

triplicate.[338] One of the triplicate copies would then be filed with the state agency in charge of maintaining a prescription database intended to monitor diversion and other potential issues relating to the over-dissemination of Schedule II narcotics. Because Purdue viewed these triplicate requirements as an overly burdensome hindrance on prescribing, the company chose to focus its marketing efforts in other states that did not impose these constraints.

436. This resource-allocation decision by Purdue to focus more marketing efforts in states with fewer regulations regarding the prescribing of controlled substances provided a way to test whether *marketing* of OxyContin, by itself, was a cause of not only increased overdose rates for OxyContin, but of *all* opioid-related overdoses, *including* those involving illicit opioids such as heroin and fentanyl.

437. The results were stark. In 2019, economists from the University of Pennsylvania, Notre Dame, and the RAND Corporation analyzed the disparate outcomes in overall opioid overdose mortality experienced in the triplicate states where Purdue did not primarily focus its marketing efforts and non-triplicate states where Purdue did primarily focus those efforts.[339]

438. The economists found that "OxyContin distribution was about 50% lower in 'triplicate states' in the years after the launch. While triplicate states had higher rates of overdose deaths prior to 1996, this relationship flipped shortly after the launch [of OxyContin] and triplicate states saw substantially slower growth in overdose deaths, continuing even twenty years after OxyContin's introduction. *Our results show that the introduction and marketing of OxyContin explain a substantial share of overdose deaths over the last two decades.*"[340]

439. A 2017 *Journal of American Medical Association* study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.[341] The changes in prescribing behavior

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338 Patrick Radden Keefe, *Empire of Pain*, Pg. 407.

339 Abby E. Alpert, William N. Evans, Ethan M.J. Lieber, and David Powell, *Origins of the Opioid Crisis and its Enduring Impacts*, NBER Working Paper No. 26500, November 2019, *available at*: https://www.nber.org/papers/w26500

340 *Id*. (emphasis added).

341 Ian Larkin et al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 J. Am. Med. Ass'n 1785 (2017).

appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

440. A more recent *Journal of American Medical Association* study analyzed the Centers for Medicare and Medicaid Services' Open Payments database regarding pharmaceutical company marketing efforts towards doctors, as well as CDC data on prescription opioid overdose deaths and prescribing rates, in order to assess whether pharmaceutical marketing of opioids to physicians affected the rate of prescription opioid overdose deaths. Notably, the study analyzed these marketing practices beginning August 1, 2013 and ending December 31, 2015.[342]

441. Those dates are significant, as the study captures the same timeframe that McKinsey's Project Turbocharge, re-christened E2E, was implemented.

442. The study noted "physician prescribers are the most frequent source of prescription opioids for individuals who use opioids nonmedically."[343]

443. The study found that "increased county-level opioid marketing was associated with elevated overdose mortality 1 year later, an association mediated by opioid prescribing rates; per capita, *the number of marketing interactions with physicians demonstrated a stronger association with mortality* than the dollar value of marketing."[344]

444. Referring to the sales and marketing tactics McKinsey specialized in implementing, the authors concluded, "amid a worsening opioid crisis, our results suggest that

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[342] Scott E. Hadland *et. al.*, *Association of Pharmaceutical Industry Marketing of Opioid Products with Mortality from Opioid-Related* Overdoses, JAMA Network, January 18, 2019, *available at:* https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2720914.

[343] *Id.*

[344] *Id*. (emphasis added)

industry marketing to physicians may run counter to current efforts to curb excessive opioid prescribing."[345]

445. The authors' proposed solution was plain and simple, and echoed Dr. Van Zee's congressional testimony from 2002: "Pharmaceutical companies might also consider, as one manufacturer recently did, *voluntarily ceasing marketing opioid products directly to physicians*."[346]

446. The dangers of opioids were known to McKinsey at the time it engaged in the misconduct described in this Complaint. The addictive potential of opioids and the need for control and restraint in their use was internally understood, as was the likelihood of large-scale opioid addiction, abuse, overdoses, illness, and early death resulting from sharply increased use.

447. McKinsey also performed its own research in evaluating the anticipated effects of Project Turbocharge. An April 2014 implementation update observed an increase in sales calls, as well as that "OxyContin [health care providers] with increased calls consistently outperform HCPs with decreasing or no change in call frequency."

448. The evidence of a direct link between increased opioids marketing and sales and increased opioid abuse was everywhere. A 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[347] McKinsey evidently understands this. In a September 2016 online article, McKinsey asserts that "[t]here is no doubt that more consistent use of best practices – across geographic areas, institutions, and clinicians – would provide tremendous help in combating the crisis" and describes certain examples of such practices as "successful in reducing prescribing."[348]

449. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and

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[345] *Id.*
[346] *Id.* (emphasis added).
[347] Theodore J Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007), available at https://onlinelibrary.wiley.com/doi/10.1002/pds.1452.
[348] https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic

associated adverse outcomes."[349] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[350]

450. 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 opioid prescriptions 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."[351]

451. Compounding the harm from deceptive marketing, McKinsey worked with Purdue to continue and grow the opioid sales of prescribers that raised red flags of diversion, despite Purdue's legal obligations to report and halt supply. In doing so, it enabled an oversupply of opioids, which allows non-patients to become exposed to opioids, and facilitates access to opioids for both patients who could no longer access or afford prescription opioids and addicts struggling with relapse.

452. Most of the illicit use originates from prescribed opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

453. As McKinsey itself has recognized in citing a study reaching this conclusion, roughly 80% of heroin users previously used prescription opioids.[352] As many as one in four patients who receive prescription opioids long-term for chronic pain in primary care settings struggles with addiction. And, the link between prescription narcotic painkiller abuse and subsequent and/or simultaneous heroin abuse continues to grow.

454. In fact, people who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. A more recent, and even more deadly problem stemming from the prescription opioid epidemic involves fentanyl, a powerful opioid

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[349] Dart, MD, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, New Engl. J. Med., 372:241-248 (Jan. 15, 2015).
[350] Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse*, New Engl. J. Med. (Apr. 14, 2016).
[351] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *et al.* "Increases in drug and opioid overdose deaths – United States, 2000–2014." American Journal of Transplantation 16.4 (2016): 1323-1327.
[352] https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic

prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into Plaintiffs' communities.

455. Carfentanil, a powerful derivative of fentanyl, has increasingly been found in heroin and fentanyl sold illicitly. Carfentanil is so strong that it is typically used in veterinary medicine to sedate large wild animals such as elephants, and has been researched as a chemical weapon. A dose the size of a grain of salt can rapidly lead to deadly overdose in humans.

456. No demographic is untouched by this epidemic. Nationally, one in five deaths among younger adults in 2016 involved opioids, according to one study. And, deaths involving both prescription and illicit opioids have risen sharply, nearly doubling since 2009.

457. Opioids were involved in 42% of all fatal drug overdoses in 2015, and another 25% involved heroin. According to the CDC, between 1999 and 2015, more than 183,000 people died in the United States from prescription-related overdoses.

458. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses in other respects as well. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014 to 2016, and 25% of the smaller decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

H. McKinsey Knew that OxyContin Was Highly Abusable, Addictive, and Dangerous, and that Its Marketing Strategies Increased Those Harms.

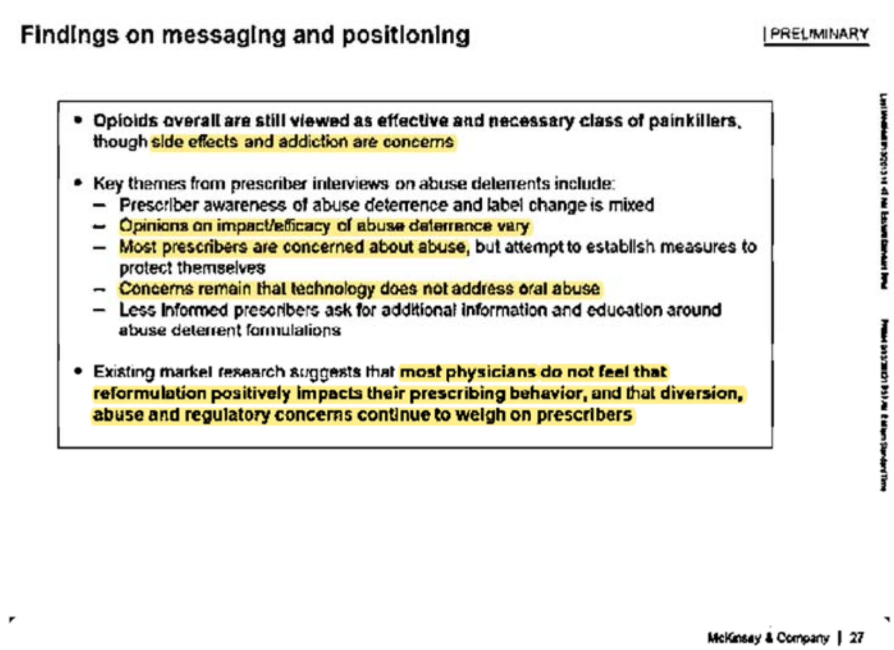
459. McKinsey continued working with Purdue long after the severity of the opioid crisis was well known. McKinsey knew that high dose OyxContin prescriptions carried a serious risk of overdose. In 2017, over half of Purdue's opioids prescriptions exceeded the ninety mg morphine equivalence threshold a day—the recommended maximal dose per the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain.

460. Purdue's 2007 guilty plea put McKinsey on notice of Purdue's misconduct. By that time, McKinsey had access to public information indicating that OxyContin and other opioids pose significant risk of addiction and misuse.

461. McKinsey was well aware of the risks of OxyContin based on its extensive experience in the pharmaceutical industry, close collaboration with Purdue, and participation in the regulatory submissions for reformulated OxyContin.[353]

462. The first bullet point of Purdue's 2007 "Observations and Activities Requiring an [Abuse, Diversion, and Detection] Report" was "[a]n apparent pattern of an excessive number of patients for the practice type[.]"[354] Thus, McKinsey knew or should have known that there was a higher risk of abuse and diversion among high-volume prescribers.

463. What is more, on September 13, 2013 McKinsey briefed Purdue on the ongoing concerns regarding OxyContin addiction and diversion among prescribers:



464. In a PowerPoint slide entitled "Findings on messaging and positioning," part of a presentation to Purdue entitled "OxyContin growth opportunities: Phase 1 Final Report:

[353] McKinsey [redacted] PPLPC0390000347612 ([redacted]); McK-MAAG-0118819 (email chain).

[354] PPLPC010000033944.

Diagnostic," McKinsey noted that "most prescribers are concerned about abuse," and that "most physicians do not feel that [OxyContin] reformulation positively impacts their prescribing behavior, and that diversion, abuse and regulatory concerns continue to weigh on prescribers."

465. In an August 2017 presentation, McKinsey recognized that the opioid epidemic was "triggered, in large part, by a massive increase in prescribed opioids in the early 2000's."

466. McKinsey's presentations to Purdue included extensive discussion of doctors' concerns about opioid misuse and side effects, demonstrating McKinsey's awareness of the dangers of opioids. Rather than working to limit these disastrous effects, McKinsey treated doctors' misgivings as obstacles to confront with new messaging.

467. Indeed, one reason that *Purdue* had knowledge that their own products were addictive and dangerous is because McKinsey told them.

468. If McKinsey was not aware of the adverse consequences of OxyContin, the drug it was paid to sell, such ignorance could not survive the granular reality of its relationship with Purdue. For example, in June 2009, McKinsey worked to "counter the emotional messages from mothers with teenagers that overdosed on OxyContin."[355]

469. Within a few years of countering these emotional messages, McKinsey even developed a method to identify geographic hot spots of OxyContin abuse and diversion. Once developed, however, McKinsey simply never used it to decrease these harms.

470. Paul Coplan [redacted].[356]

471. In deposition testimony in prior opioid-related litigation, Coplan was asked, "While you were at Purdue, did Purdue make an effort to identify hot spots for opioid abuse and addiction or not?"[357]

472. "[redacted]

[355] PDD8901645845.
[356] Paul M. Coplan 1/18/19 Dep. Tr. At 16:18 -17:17.
[357] *Id.* at 355:10.

[redacted]."[358] [redacted].[359]

473. [redacted]—[redacted]."[360]

474. Instead, McKinsey focused on increasing opioid sales for its clients, despite knowing the harmful consequences of doing so. In yet another indication that OxyContin sales should not be turbocharged: during McKinsey's work for Purdue, Purdue was unable to purchase product liability insurance to cover its practice of selling OxyContin.

475. The basic premise of McKinsey's work put it on notice of the harmful consequences that would ensure. It was tasked with advising a monoline manufacturer of opioids about sales and marketing practices for its addictive products while that manufacturer was bound by a five-year Corporate Integrity Agreement covering the very same opioid sales and marketing practices. In 2012, OxyContin accounted for 94% of Purdue's revenue.[361] As late as 2018, it remained 84% of Purdue's revenue.[362] According to the U.S. Department of Justice, "[f]rom 2010 to 2018, Purdue's profits were almost entirely driven by its success in selling OxyContin."[363] In 2015 alone, it obtained $3 billion in annual opioid sales—a four-fold increase from its 2006 sales of $800 million.

476. McKinsey's mandate was to increase Purdue's opioid sales during a time when Purdue was obligated to restrict its previous marketing strategies because those strategies had caused the *overprescribing of opioids* and the inevitable consequences thereof. McKinsey's job was to counter the intended results of the Corporate Integrity Agreement; to devise strategies to

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[358] *Id.* at 355:14–356:11.
[359] *Id.* at 357:8-16.
[360] *Id.* at 357:22–358:6.
[361] Gerald Posner, *Pharma*, pg. 524 (Simon & Schuster 2020).
[362] *Id.*
[363] https://www.justice.gov/opa/press-release/file/1329571/download

sell as many pills as conceivably possible. Under McKinsey's tutelage, Purdue's growth continued its upward trajectory unabated, the Corporate Integrity Agreement notwithstanding.

I. McKinsey Portrays Itself as Part of a Solution to a Problem It was Integral in Creating.

477. McKinsey's work on the other side of the aisle—helping clients address opioid abuse and addiction—further proves that it was well aware of the risks of OxyContin, and thus the risks of pushing OxyContin sales and high dose sales, and targeting the highest-volume prescribers. McKinsey advised Purdue on "Project Tango," a 2014 plan to enter the addiction drug market.[364] McKinsey noted the [redacted]"[365]

478. More than assisting specific clients with addressing the crisis itself, McKinsey saw the ongoing opioid crisis as an opportunity to posture itself as contributing more broadly to *society*. McKinsey likes to think of itself as a change agent capable of solving problems that truly matter, and the opioid crisis is one McKinsey realizes matters. Dr. Sarun Charumilind, a McKinsey partner in Philadelphia, "has led the firm's support to clients and *society* to combat the opioid crisis.[366]

479. In Detroit, partner Razili Lewis also helps "clients and *society* combat the opioids crisis." She does so by providing "insights, expertise, analytics, and technology."[367]

480. Over in Cleveland, senior partner Tom Latkovic also "helps clients and *society* combat the opioids crisis."[368]

481. Kana Enomoto, a senior expert in Washington, D.C., is a "national leader in mental health and substance-use policy," who acted as a "content director" on a study to "raise awareness about opioid-use disorders." She also provided strategic guidance to the United States

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[364] *See* David Armstrong, OxyContin Maker Explored Expansion Into "Attractive" Anti-Addiction Market, ProPublica (Jan. 30, 2019), *available at* https://www.propublica.org/article/oxycontin-purdue-pharma-massachusetts-lawsuit-anti-addiction-market.

[365] PPLPC023000714734.

[366] *See* https://www.mckinsey.com/our-people/sarun-charumilind

[367] *See* https://www.mckinsey.com/our-people/razili-lewis

[368] *See* https://www.mckinsey.com/our-people/tom-latkovic

Surgeon General regarding efforts to "combat the opioid epidemic" when she was his Chief of Staff.[369]

482. McKinsey consistently states that it takes its obligations to society seriously. Indeed, the firm has established a center:[370]

> The Center for Societal Benefit through Healthcare was established to build on the long-standing mission of McKinsey's Public & Social Sector and Healthcare Systems & Services Practices to improve healthcare. The Center's work is funded solely by McKinsey; it is not commissioned by any business, government, or other institution. The Center brings a range of capabilities to bear, including McKinsey's healthcare expertise, advanced analytics, functional knowledge, technology assets, network, and investment capacity.
>
> The Center aspires to collaborate with other organizations to drive positive innovation to improve overall health and well-being and reduce healthcare disparities.

483. The Center has focused on addressing the impacts of the opioid crisis on society. One of the metrics that McKinsey uses to track the opioid crisis *as a matter of public health* is the "opioid prescribing rate" per 100 people in every county in the United States.[371]

484. As McKinsey's data visualization makes clear, there is an association between areas with higher opioid prescribing rates and higher instances of opioid use disorder.

485. The Center's data visualization is also reminiscent of similar work McKinsey did for Purdue in 2013, although the analysis McKinsey did for Purdue was more granular, analyzing opioid prescribing patterns on the *zip-code* level in all 50 states, as opposed to the county level:[372]

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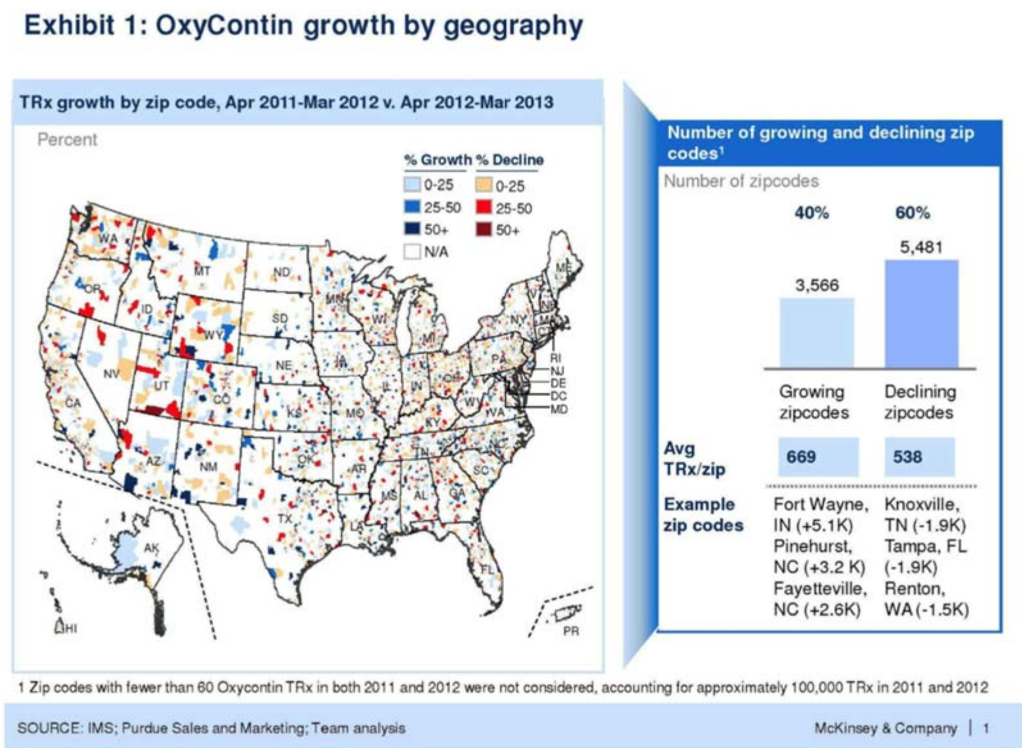
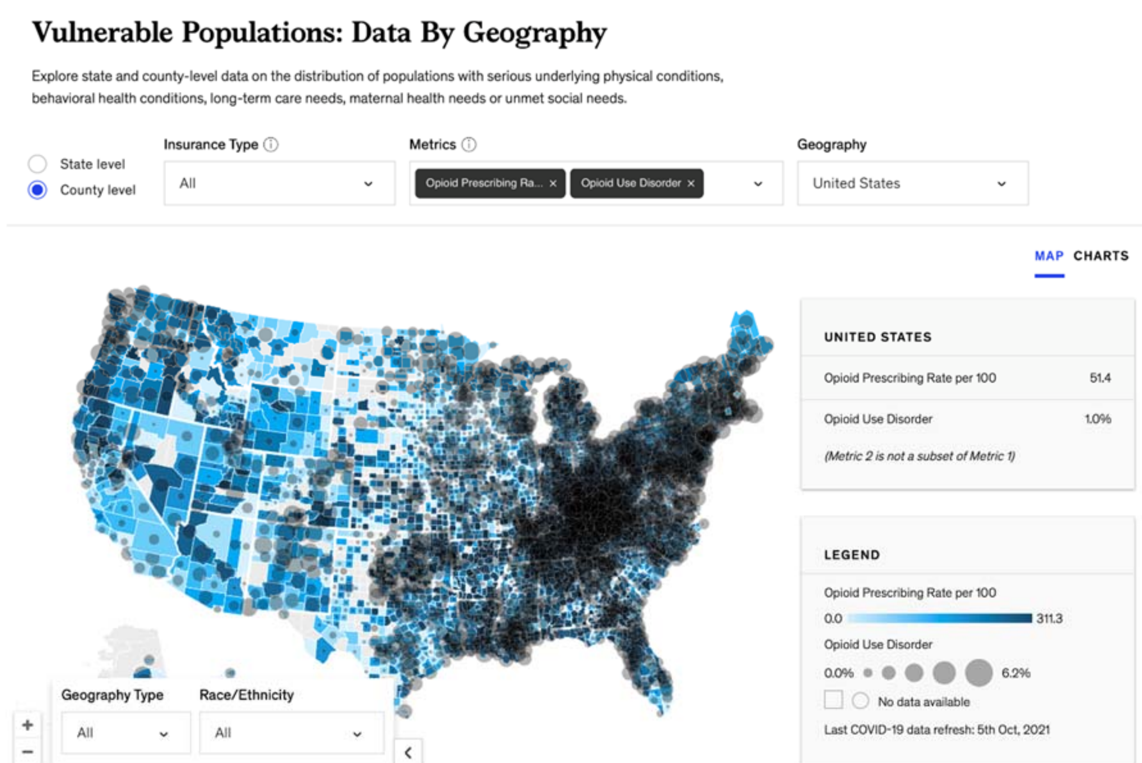
[369] *See* https://www.mckinsey.com/our-people/kana-enomoto
[370] *See* https://www.mckinsey.com/industries/healthcare-systems-and-services/how-we-help-clients/center-for-societal-benefit-through-healthcare/overview
[371] *See* https://csbh-dashboard.mckinsey.com/#/data-insights?chart=SC&geo=County&lob=All&metric1=opioid_rxrate&metric2=oud&tab=Map
[372] MCK-MAAG-0024283.

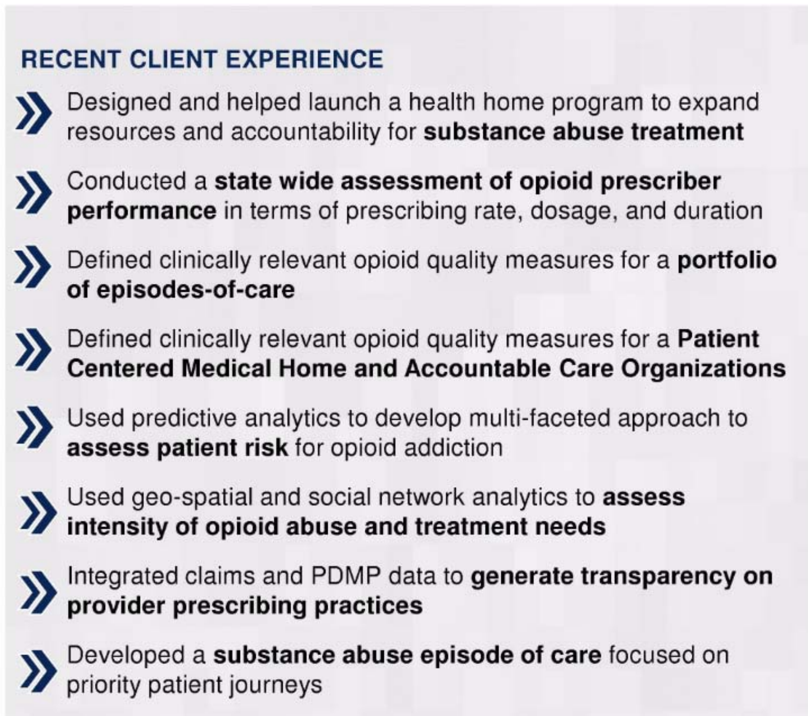


486. In other words, the "opioid prescribing rate" was a metric McKinsey worked with its client to boost for years. Now McKinsey measures the extent of the crisis by the same metric:



487. Meanwhile, McKinsey has partnered with Shatterproof, a national non-profit organization dedicated to reversing the addiction crisis in the United States, to prepare a report on overcoming stigma associated with opioid use disorder.[373] McKinsey touts the Shatterproof partnership on its webpage as an example of "our societal impact."[374]

488. In August 2017, McKinsey prepared a presentation entitled "Perspectives on Combatting the Opioid Crisis," which referenced its work on combatting opioid addiction for various other entities:



489. In June 2018, Dr. Charumilind and Mr. Latkovic, along with fellow McKinsey partner Elena Mendez-Escobar, published a public report, "Ten insights on the Opioid crisis from claims data analysis," stating information about the risks of opioids that McKinsey knew while advising Purdue to sell more opioids and higher dose opioids, and target the highest volume prescribers:

a. "Providers frequently prescribe opioids to patients with known or potential risk factors for abuse[;]"

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[373] *See* https://www.shatterproof.org/sites/default/files/2020-07/A-Movement-to-End-Addiction-Stigma.pdf
[374] *See* https://www.mckinsey.com/us/our-societal-impact

b. "Approximately 35% of the patients given opioid prescriptions in our analysis had features that put them at increased risk for opioid abuse[;]"

c. "Most opioids are prescribed by providers other than the natural 'quarterback' of a patient's underlying complaint or condition. . . . This finding makes clear that high-dose prescribers and multi-prescriber patterns are separate issues—and both are important to address[;]" and

d. "A small portion of opioid use originates in emergency departments."[375]

490. Two months later, the same authors, joined by Ms. Lewis, published "Why we need bolder action to combat the opioid epidemic."[376] "Our research suggests that much broader – and bolder – action is required," they announced.[377]

J. <u>Coda</u>

491. Marvin Bower, the McKinsey legend who admonished, "Deliver bad news if you must, but deliver it properly," died in 2003, one year before the firm began working with Purdue.

492. McKinsey's work with Purdue would have been unrecognizable to Bower, one of the founders of modern management consulting. Instead of acknowledging the elephant in the room—that Purdue's business was knowingly maximizing the amount of addictive and deadly opioids sold in the United States—and delivering that bad news promptly properly to the client, McKinsey instead committed to partner with Purdue to maximize opioid sales without regard to the consequences.

493. On October 23, 2017, the president of the United States declared the ongoing nationwide opioid epidemic a "public health emergency." Even at this late hour in the crisis, McKinsey continued to propose solutions to the Sacklers and Purdue to further boost opioid sales. These solutions were fashioned, in perfect McKinsey parlance, as "high impact interventions to rapidly address market access challenges."

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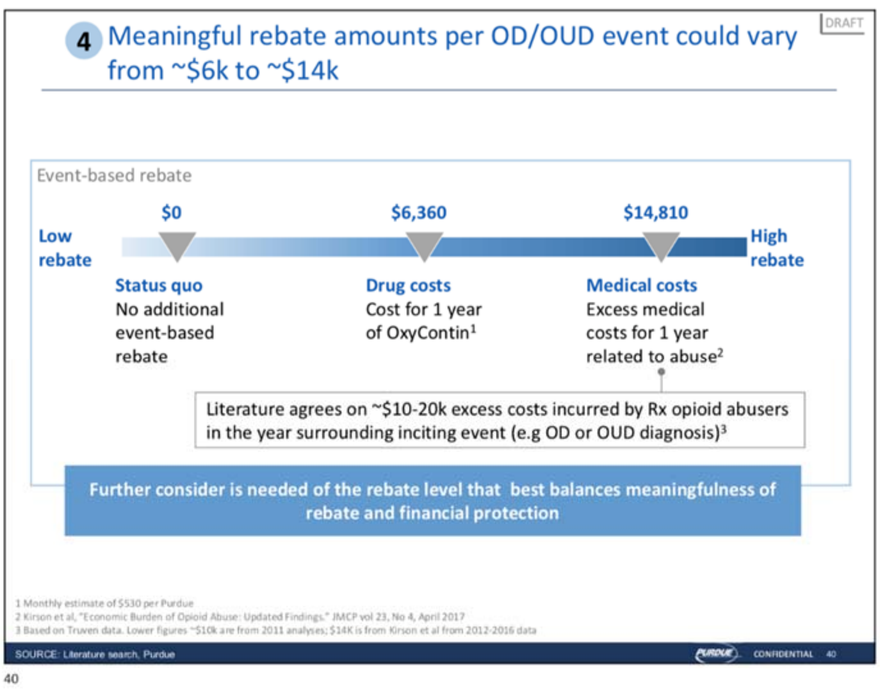
[375] https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/ten-insights-on-the-us-opioid-crisis-from-claims-data-analysis
[376] *See* https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic
[377] *Id.*

494. Less than two months after the public health emergency declaration, McKinsey proposed these high impact interventions to Purdue and its board. Among them was perhaps McKinsey's most audacious gambit of the entire Purdue relationship: paying money—"rebates"—to health insurers whenever someone overdosed on Purdue's drug.

495. These payments for future OxyContin overdoses were christened "Event-Based contracts."[378]

496. Helpfully, McKinsey provided estimates for the future costs of these "events."[379] McKinsey noted that, if Purdue were to start making overdose payments, it would "need to determine which payment amount is optimal."

497. A "meaningful" amount, according to McKinsey, would be somewhere between six and fifteen thousand dollars for each person who overdoses or develops opioid-use disorder as a result of Purdue's drugs:



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378 "Consultant-ese," when applied to work as grim as maximizing opioid sales in the face of a national disaster, led one former McKinsey consultant to state: "This is the banality of evil, M.B.A. edition." Walt Bogdanich and Michael Forsythe, *McKinsey Proposed Paying Pharmacy Companies Rebates for OxyContin Overdoses*, New York Times, November 27, 2020, *available at*: https://www.nytimes.com/2020/11/27/business/mckinsey-purdue-oxycontin-opioids.html

379 McKinsey defined an "event" as "first occurrence for overdose or opioid use disorder."

498. The money would be paid to health insurers for the increased costs of additional medical services that resulted from the fact that Purdue's medications caused opioid-use disorder and overdoses in people whose health care costs were the payors' obligation. The money McKinsey proposed Purdue pay out in these circumstances would not go to the individuals afflicted, nor the estates of the dead.

499. McKinsey's analysis also suggested that it could predict the number of people who would become addicted to opioids or overdose on pills sold through Purdue's downstream customers. McKinsey "projected that in 2019, for example, 2,484 CVS customers would either have an overdose or develop an opioid use disorder."[380]

500. It is little surprise, then, that McKinsey was concerned with its legal liability for this work. Within months of recommending "event-based contracts" to Purdue, Martin Elling raised this concern with Arnab Ghatak and suggested corrective action: destroying evidence.

Message

From: Martin Elling [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6B33C3264F744B04AF05FA59341271BE-MARTIN ELLI]
Sent: 7/4/2018 12:10:13 PM
To: A G [drarnabghatak@gmail.com]
Subject: Re: [EXT]Re: Howdy

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Have a great fourth.  M

> On Jul 4, 2018, at 2:01 PM, A G <drarnabghatak@gmail.com> wrote:
>
> Thanks for the heads up.  Will do.
>
>> On Jul 4, 2018, at 7:57 AM, Martin Elling <martin_elling@mckinsey.com> wrote:
>>
>> Just saw in the FT that Judy Lewent is being sued by states attorneys general for her role on the
Purdue Board.  It probably makes sense to have a quick conversation with the risk committee to see if we
should be doing anything other that eliminating all our documents and emails.  Suspect not but as things
get tougher there someone might turn to us.  M
>>
>> +=====================================================================+
>> This email is confidential and may be privileged. If you have received it
>> in error, please notify us immediately and then delete it.  Please do not
>> copy it, disclose its contents or use it for any purpose.
>> +=====================================================================+
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501. Elling's prediction that things would "get tougher" for Purdue would prove prescient.

[380] Walt Bogdanich and Michael Forsythe, *McKinsey Proposed Paying Pharmacy Companies Rebates for OxyContin Overdoses*, N.Y. Times (Nov. 27, 2020, updated Dec. 17, 2020), https://www.nytimes.com/2020/11/27/business/mckinsey-purdue-oxycontin-opioids.html

1. **Guilty Again - 2020**

502. On October 20, 2020, Purdue—McKinsey's co-conspirator—agreed with the United States Department of Justice to plead guilty to improper marketing of OxyContin and other opioids again (the "2020 Settlement Agreement"). This time the plea agreement concerned conduct from 2010 to 2018. The agreement includes $8.3 billion in penalties from Purdue and $225 million from the Sackler family.

503. Purdue pleaded guilty to a dual-object conspiracy to defraud the United States and to violate the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331, 353, violating anti-kickback laws, and "using aggressive marketing tactics to convince doctors to unnecessarily prescribe opioids—frivolous prescriptions that experts say helped fuel a drug addiction crisis that has ravaged America for decades."

504. The new plea agreement does not identify Purdue's co-conspirators, and McKinsey is not identified by name in the agreement. Instead, McKinsey is referred to as the "consulting company."

505. Purdue's new guilty plea concerns Covered Conduct (as defined in the plea agreement) that directly implicates McKinsey in the conspiracy. It is the same conduct described in this Complaint.

506. Indeed, the plea agreement signed by McKinsey's co-conspirator states bluntly: "Purdue, *in collaboration with [McKinsey]*, implemented many of [McKinsey's] recommendations." (emphasis added).

507. Further, Purdue admitted that E2E "*was overseen by [McKinsey]* and some of Purdue's top executives through the creation of the E2E Executive Oversight Team ('EOT') and Project Management Office ('PMO')" (emphasis added).

2. **A Mea Culpa**

508. On December 5, 2020, six weeks after Purdue's second guilty plea, McKinsey issued a rare public statement regarding its work with a specific client on its website. The client was Purdue, and the statement was issued is response to Purdue's second guilty plea and recent media reports regarding McKinsey's work selling OxyContin after 2007:

McKinsey statement on its past work with Purdue Pharma

December 5, 2020—As we look back at our client service during the opioid crisis, we recognize that we did not adequately acknowledge the epidemic unfolding in our communities or the terrible impact of opioid misuse and addiction on millions of families across the country. That is why last year we stopped doing any work on opioid-specific business, anywhere in the world.

Our work with Purdue was designed to support the legal prescription and use of opioids for patients with legitimate medical needs, and any suggestion that our work sought to increase overdoses or misuse and worsen a public health crisis is wrong. That said, we recognize that we have a responsibility to take into account the broader context and implications of the work that we do. Our work for Purdue fell short of that standard.

We have been undertaking a full review of the work in question, including into the 2018 email exchange which referenced potential deletion of documents. We continue to cooperate fully with the authorities investigating these matters.

509. As the statement indicates, McKinsey stopped doing work "anywhere in the world." Given that Purdue's operations addressed only the United States, the global reach of McKinsey's regret is noteworthy.

510. In August 2013, when the Sacklers adopted McKinsey's "Project Turbocharge" for Purdue, Tim Reiner, a long-time McKinsey consultant, joined Mundipharma. Mundipharma is a separate company—also owned by the Sacklers—that sells opioids internationally.

511. As late as 2019, Mundipharma has been asserting many of the same misleading claims about opioids that previously led to criminal liability in the United States.[381] McKinsey has long assisted the Sacklers in growing Mundipharma's opioids market.[382] By 2015, McKinsey's workload with Mundipharma was large enough to merit formal coordination and incorporation with the overall McKinsey team servicing the Purdue account. Around this time, McKinsey's Elling agreed to assume "a real operational DCS" role with respect to the work that McKinsey was performing for the various Sackler interests, including "integrat[ing] the Mundipharma

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[381] *See* Kinetz, Erika, *Fake doctors, pilfered medical records drive OxyChina sales*, Associated Press, November 19, 2019, *available at*: https://apnews.com/article/4122af46fdba42119ae3db30aa13537c

[382] *See, e.g.*, MCK-MDL2996-0256120; MCK-MDL2996-0327127; MCK-MDL2996-0183279; MCK-MDL2996-0238998; MCK-MDL2996-0286490.

stuff." [383] Even if the various components of the Sackler "family conglomerate" were nominally independent, McKinsey consolidated its own treatment of its work for all of these companies as serving just a single client.

3. A Hedge Fund

512. On February 4, 2021, forty-nine state attorneys general announced a multistate settlement with McKinsey related to its work for opioid manufacturers. McKinsey agreed to pay almost $600 million dollars. At the time of the announcement, most of the participating states each filed a complaint and consent decree finalizing the settlement.

513. Three days after the settlement, it came to light that McKinsey appears to have benefitted from its work promoting opioids not only through the fees paid to McKinsey by its clients, but also through investments in opioid-related business made by McKinsey's own hedge fund, the McKinsey Investment Office ("MIO"). MIO is the hedge fund referenced above, with respect to McKinsey's investment in Teva Pharmaceutical.

514. Consultants don't typically have in-house hedge funds overseeing retirement accounts and partners' personal investments. In fact, McKinsey is the only one. "Most large companies, including all the major consulting firms, hire third-party firms . . . to oversee their employees' retirement accounts."[384] MIO manages approximately $31 billion on behalf of McKinsey partners, employees, and former partners.[385]

515. Through MIO, McKinsey was heavily invested in the opioid industry, and stood to gain financially from the continuation of the opioid crisis. It even invested in opioid addiction treatment businesses—a growing industry, as McKinsey knew.

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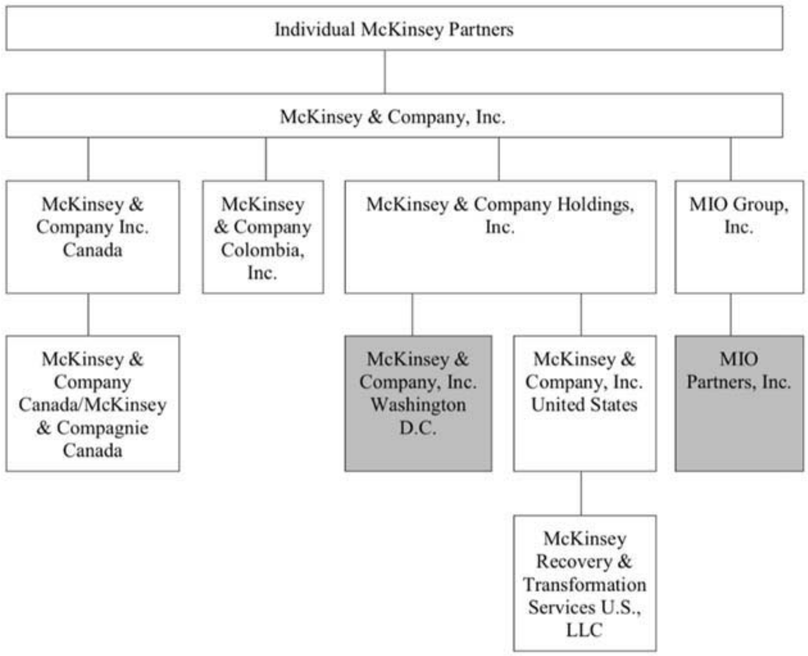
[383] MCK-MDL2996-0210149

[384] Gretchen Morgenson, "Consulting giant McKinsey allegedly fed the opioid crisis. Now an affiliate may profit from treating addicts.," *NBC News*, February 8, 2021, *available at* https://www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969

[385] SEC Order dated November 19, 20201 at Para. 5, available at*:* https://www.sec.gov/litigation/admin/2021/ia-5912.pdf. That $31 billion under management would make MIO Partners the thirteenth largest hedge fund on Earth. *See* https://www.pionline.com/interactive/largest-hedge-fund-managers-2021.

516. In short, "during the years McKinsey was helping opioid makers propel sales of the drugs, MIO Partners held stakes in companies that profited from increased usage."[386]

517. To understand MIO, an organizational chart of McKinsey is helpful:



518. MIO Group, Inc., and MIO Partners, Inc. are directly-owned subsidiaries of McKinsey & Company, Inc. Given that McKinsey advises countless large corporations, McKinsey's hedge fund inevitably invests in McKinsey's clients.

519. MIO manages money for pension plans sponsored by McKinsey in which current and former McKinsey employees participate, as well as privately-offered investment funds available to partners and former partners. Today, nine of MIO's eleven directors are current or former McKinsey partners. Prior to 2017, there were no outside directors at MIO.

520. MIO structures its investment activities in three principal ways: (1) approximately 50-60% of MIO's assets are managed by third-party money managers, who have sole discretion on what securities to buy with MIO's money, and where MIO may or may not have information regarding which securities the third-party money manager has purchased for MIO's benefit; (2)

[386] Gretchen Morgenson, "Consulting giant McKinsey allegedly fed the opioid crisis. Now an affiliate may profit from treating addicts.," *NBC News*, February 8, 2021, *available at* https://www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969

"separately managed accounts," comprising approximately 40% of MIO's holdings, are portfolios of securities managed by a third-party money manager, but where MIO "knows what securities are held through each account," and; (3) direct investments, where MIO invests its own money directly, which comprises approximately 10% of MIO's investments.

521. In other words, for *at least 40*% of MIOs holdings, McKinsey partners are able to know the specific investments held by the various MIO funds. "MIO has a ledger for every security in their managed accounts."[387] That comprises a pool of capital worth more than $6 billion.

522. MIO is run for the benefit of McKinsey's partners and, to a separate extent, McKinsey's employees. Those individuals (and, crucially, former McKinsey partners) invest their own money in MIO, and their access to those investment opportunities constitutes a meaningful and important component of those individuals' compensation. MIO has, "at a minimum, the ability to view the individual securities that account for approximately 40 to 50 percent." This is approximately $6 billion dollars of invested capital. What is more, MIO *directly invests* approximately 10% of its assets. That is $1.5 billion MIO directly invests in securities without the use of any outside money manager. These numbers exclude leverage.

523. From a conflicts perspective, the fact that *former* partners may participate in MIO investments merits consideration. With respect to McKinsey's opioid investments, it is notable to consider just who some of those "former partners" are. As noted above, Rajiv de Silva, Chief Executive Officer of opioid defendant Endo Pharmaceuticals, is a former McKinsey partner. Kare Shultz, Chief Executive Officer of opioid defendant Teva Pharmaceutical, is a former McKinsey partner. Frank Scholz, President of opioid defendant SpecGX, a subsidiary of Mallinckrodt, is a former McKinsey partner. Marc Owen, President of opioid defendant McKesson, is a former McKinsey partner. This list is merely illustrative; it is not exhaustive.

524. The result is the prospect of individual executives at various opioid manufacturing and distribution companies obtaining financial gain from the ongoing propagation of the opioid

[387] Michelle Celarier, *McKinsey's Managed Accounts Come Under Scrutiny in Trial*, Institutional Investor, February 5, 2020, *available at*: https://www.institutionalinvestor.com/article/b1k6wnn251s472/McKinsey-s-Managed-Accounts-Come-Under-Scrutiny-in-Trial

crisis *not* via compensation from their employers, but via participating in investments alongside their *former* employer (and, in many cases, current consultant).

525. Three days after McKinsey and the state attorneys general announced their settlement, NBC News reported that MIO, McKinsey's hedge fund, owned opioid-related investments during the time that it advised its opioid clients.

526. One is Deerfield Management Co., "a $10 billion dollar health care investment firm based in New York."[388] As ever, "two top Deerfield executives previously worked at McKinsey." A retirement fund managed by MIO held a $108 million stake in funds managed by Deerfield and invested in opioid industry participants. "In 2017, for example, Deerfield was a 6 percent shareholder in Mallinckrodt, a major opioid maker."[389] From 2011 through 2016, Deerfield held a stake of up to $90 million in Teva. Deerfield also took stakes in the distributors described above, including McKesson and Cardinal Health.[390]

527. McKinsey is also invested in treatment, an inevitable growth industry sprouting from the over-selling of opioids. Separate from its investments with Deerfield, MIO is also invested in Adamis Pharmaceuticals, "a company that develops products to treat opioid overdoses," and therefore "may also benefit from opioid settlement funds" paid by McKinsey as a result of its settlement with the states. As of 2020, MIO owned 26% of the Adamis' preferred shares through another outside investment manager (not Deerfield).[391] Separately, Deerfield invested $331 million in Recovery Centers of America, an addiction treatment company that operates facilities in states that McKinsey recently settled with.[392]

528. These relationships and investments give a glimpse into the myriad means McKinsey deploys to make money. Consulting is more than giving advice. Indeed, On November 19, 2021, MIO Partners agreed to pay an $18 million fine to the SEC due to MIO's possession of material nonpublic information related to its holdings, information obtained through consulting.

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[388] Gretchen Morgenson, "Consulting giant McKinsey allegedly fed the opioid crisis. Now an affiliate may profit from treating addicts.," *NBC News*, February 8, 2021, *available at* https://www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969
[389] *Id.*
[390] *Id.*
[391] *Id.*
[392] *Id.*

VI. TOLLING OF STATUTES OF LIMITATIONS

529. McKinsey is equitably estopped from relying upon a statute of limitations defense. Alongside its clients, McKinsey undertook active efforts to deceive the Plaintiffs and to purposefully conceal its unlawful conduct and fraudulently assure the public, including Plaintiffs, that opioids were non-addictive, effective, and safe for the treatment of long-term chronic pain and non-acute, non-cancer pain with the goal of increased sales, greater availability and access to opioids, and maximizing profits.

530. McKinsey and its clients were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing of opioids. This deceptive marketing—which included the above falsehoods that opioids were safer, less subject to abuse, and less addictive than other pain medications—was a substantial factor in the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

531. McKinsey deliberately advised its clients on marketing strategies and tactics to bolster their opioid products as non-addictive, safe, and efficacious without reliable scientific evidence to support same. McKinsey's consulting services were given confidentially, and both McKinsey and its clients concealed the content of those services from the public. In doing so, McKinsey concealed its role in shaping, editing, and providing the content of the false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers, and the public at large, including Plaintiffs.

532. McKinsey also concealed from Plaintiffs the existence of the Plaintiffs' claims by hiding it and its client's lack of cooperation with law enforcement. For example, in May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction and entered into a Corporate Integrity Agreement explained above. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science. Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty

and agreed to pay $8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.

533. Nevertheless, even after the guilty pleas, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. Purdue also assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly $900 million dollars on lobbying and political contributions—eight times what the gun lobby spent during that period. McKinsey participated extensively in these actions and provided Purdue with strategies and assistance to maximize sales as described in this Complaint. McKinsey knew that the actions it took with Purdue were unlawful, and yet deliberately proceeded in order to increase Purdue's sales and profits, and in turn to serve McKinsey's financial interests.

534. McKinsey affirmatively sought to convince the public that its clients' legal duties to report suspicious sales of opioids had been satisfied through public assurances that they were working to curb the opioid epidemic. For example, after the 2007 Purdue guilty plea described above, McKinsey provided services to protect the company's public image and sales, aiding in the concealment of the addictive nature and dangers associated with opioid use and denying blame for the epidemic, attributing it instead solely to abuse and inappropriate prescribing. At the guidance and advice of McKinsey, Purdue and other McKinsey clients publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways, insisting they were good corporate citizens. Instead, McKinsey assisted Purdue, for example, with marketing campaigns and messaging that continued business as usual, indiscriminately targeting high prescribers and promoting opioids as safe but avoiding the pitfalls of the Corporate Integrity Agreement. These repeated misrepresentations misled regulators, prescribers, and the public, including the Plaintiffs, and deprived Plaintiffs of actual or implied knowledge of facts sufficient to put the Plaintiffs on notice of potential claims.

535. Plaintiffs did not discover the nature, scope, and magnitude of McKinsey's misconduct, and its full impact on Plaintiffs, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

536. Prior to the applicable limitations period, Plaintiffs did not suspect, and had no reason to suspect, that McKinsey's conduct caused their injuries, including the consumption of Plaintiffs' resources as the opioid epidemic remains unabated.

537. McKinsey intended that its actions and omissions made with its clients would be relied upon, including by the Plaintiffs. The Plaintiffs did not know and did not have the means to know the truth due to McKinsey and its clients' actions and omissions.

538. The Plaintiffs reasonably relied on the affirmative statements developed by McKinsey and made by its clients regarding their purported compliance with their obligations under the law and consent orders, which were false and only intended to save the clients' public image.

539. McKinsey's fraudulent concealment has tolled the running of any statute of limitations. Through it and its clients' affirmative misrepresentations and omissions, McKinsey actively concealed from Plaintiffs the risks associated with opioids that led to the opioids crisis. The wrongdoing, misrepresentations, and omissions by McKinsey has not ceased because the public nuisance remains unabated.

VII. <u>HARM TO SCHOOL DISTRICTS AND STATE CLASSES</u>

540. McKinsey's intentional and/or unlawful conduct, as described herein, resulted in direct and foreseeable, past and continuing, economic damages, which Plaintiffs and the State Classes have incurred and continue to incur, including: (1) costs associated with special education means, including, but not limited to, special programs for children with opioid-related learning disabilities, or for children in need of psychological counseling or other supports due to opioid-related family crisis; (2) costs associated with providing care and support for children whose family members suffer from opioid-related disability or incapacitation and/or opioid use disorder; (3) costs associated with increased school security in all facilities of the school board district; (4) costs for providing medical care, additional therapeutic and prescription drug purchases, and

other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (5) costs associated with increased healthcare and healthcare insurance; (6) costs regarding disability payments; (7) loss of tax revenue; and (8) treble damages, and for which Plaintiff seeks relief as to all claims and counts, as alleged herein. Plaintiff also seeks the means to abate the epidemic (created by McKinsey's wrongful and/or unlawful conduct), including but not limited to, economic damages from McKinsey as reimbursement for the costs associated with past, present, and future efforts to address, pay for and/or eliminate the aforementioned hazards to public health and safety.

541. Plaintiffs, and similarly situated school districts in their states, have had to increase resources or divert resources away from other essential functions because of McKinsey's schemes to increase opioid sales. The costs to schools have included increased disability evaluations, increased numbers of students qualifying for educational disability, increased classroom therapies and services, increased administrative expenses, and resources increasingly diverted from classroom instruction to address behavioral disruptions caused by students whose ability to self-regulate has been compromised by prenatal opioid exposure or their families' addiction to opioids.

542. A significantly higher proportion of children with a history of NOWS are diagnosed with educational disabilities, including developmental delay or speech or language impairment. They are more likely to have severe intellectual disabilities, autism spectrum disorders, or Attention Deficit Disorder. They are also more likely to fail to meet grade level norms. These differences, individually and in combination make children with a history of NOWS significantly and disproportionately more likely to qualify for and receive mandated special education services.[393]

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[393] Mary-Margaret A. Fill et al., *Educational Disabilities Among Children Born With Neonatal Abstinence Syndrome*, 142 Pediatrics e20180562 (2018); *see also* Oei JL, Melhuish E, Uebel H, et al. *Neonatal Abstinence Syndrome and High School Performance*, 139 Pediatrics 2 (2017); Sirnes, Eivind, et al. "Brain morphology in school-aged children with prenatal opioid exposure: a structural MRI study." *Early human development* 106 (2017): 33-39. In addition, eighty percent of children with ADHD receive school-based services, at some point, via federally mandated Individual Education Plans (IEPs) or services pursuant to Section 504 of the Rehabilitation Act. Danielson, Melissa L., et al. "A national description of treatment among United States children and adolescents with attention-deficit/hyperactivity disorder." *The Journal of pediatrics* 192 (2018): 240-246.

543. In every one of the states where Plaintiffs are located, McKinsey conspired with and aided and abetted Purdue and other opioid manufacturers to flood those states with prescription opioids, causing an increase in babies born with NOWS in those states and an increase in enrollment by students with NOWS histories in Plaintiffs' school districts.

544. The states in which the school districts bringing this Complaint are located have been especially hard hit.

a. **West Virginia** has the highest rate of opioid-related overdose deaths in the country. In 2017, there were 833 drug overdose deaths involving opioids in the state, a rate of 49.6 deaths per 100,000 persons. West Virginia was specifically targeted with aggressive opioid marketing to doctors and pharmacists with over 780 million doses of prescription painkillers transported into the state over the course of six years.[394] McKinsey identified particular counties and towns in West Virginia, and even particular prescribers and pharmacies, to target for excessive opioid sales. Kermit, West Virginia, a town with a population of 392, received nearly 9 million hydrocodone pills over the course of two years.[395] One pharmacy in Oceana, West Virginia received nearly 600 times as many oxycodone pills as a nearby Rite Aid.[396] Between 2007 and 2013, the incidence of Neonatal Opioid Withdrawal Syndrome increased from 7.74 per 1000 live births per year to 31.56 per 1000 live births per year in West Voirginia.[397] Researchers examined a 15-month period from October 1, 2016 to December 31, 2017, and found Neonatal Opioid Withdrawal Syndrome in 52.6 per 1000 live births among West Virginia residents.[398]

b. In **Kentucky**, McKinsey identified particular counties and towns, and even particular pharmacies, in Kentucky to flood with opioids. From August 1, 2014 until July 31, 2015, there were 1,234 NOWS births reported to the Kentucky Department of Public Health—

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[394] Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*, Charleston Gazette-Mail (Dec. 17, 2016), https://www.wvgazettemail.com/news/health/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_78963590-b050-11e7-8186-f7e8c8a1b804.html
[395] *Id.*
[396] *Id.*
[397] Umer, Amna, et al. "Capturing the statewide incidence of neonatal abstinence syndrome in real time: the West Virginia experience" *Pediatric research* 85.5 (2019): 607-611.
[398] *Id.*

translating to about 100 newborns per month. In 2018, providers wrote 79.5 opioid prescriptions for every 100 persons in the state.[399]

VIII. CLASS ACTION ALLEGATIONS

545. Plaintiffs bring this case on behalf of themselves and as statewide class actions under Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) and, alternatively, 23(c)(4) on behalf of all independent public school districts in their respective states ("the State Classes"). All class members bear the steadily rising costs of providing special education and related supports and services and diversion of resources to their states to provide for (1) children exposed to opioids *in utero*, which makes those children about twice as likely to exhibit learning and developmental disabilities than children who were not exposed,[400] and (2) children presenting emotional and behavioral challenges in schools because of their family members' use of opioids.

546. Plaintiffs and the State Classes will continue to incur significant costs in the years to come as the current and future cohorts of adversely impacted children come of school age and move from lower school to high school with special needs all along the way.

547. Plaintiffs' State Classes are defined as follows:

a. **West Virginia Class**: All independent public school districts in the State of West Virginia.

b. **Kentucky Class**: All independent public school districts in the State of Kentucky.

548. Plaintiffs reserve the right to amend or modify the class definitions with greater specificity or further division into subclasses or limitation to particular issues.

549. Numerosity. The potential members of the State Classes as defined are so numerous that joinder of all members is unfeasible and not practicable. There are 55 public school districts in West Virginia[401] and 171 in Kentucky.[402]

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[399] Centers for Disease Control and Prevention. U.S. Opioid Prescribing Rate Maps. (2019, October 3). Retrieved from https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.

[400] Paul Morgan and Yangyang Wang, *The Opioid Epidemic, Neonatal Abstinence Syndrome, and Estimated Costs for Special Education Services*, 25 American Journal of Managed Care 13 (2019).

[401] https://www.greatschools.org/schools/districts/West_Virginia/WV/

[402] Kentucky Department of Education, https://education.ky.gov/comm/schdist/Pages/default.aspx

550. Commonality and Predominance. There are questions of law and fact common to the State Classes, which predominate over any questions affecting only individual State Class members. These common questions of law and fact include, without limitation:

a. McKinsey's conduct in creating, urging, and implementing marketing, promotion, distribution, and sales strategies for opioids after Purdue's first guilty plea in 2007;

b. Whether McKinsey disregarded the risks associated with its strategies for "turbocharging" opioid sales in 2013 and later;

c. Whether McKinsey's developing, urging, and implementing its opioid strategies with Purdue and other opioid manufacturers it worked with caused or contributed to an increase in opioid addiction and abuse and the effects alleged;

d. Whether McKinsey's conduct with respect to developing, urging, and implementing nationwide opioid sales, including in each State Class's state, was negligent, grossly negligent, reckless, or intentional;

e. Whether McKinsey's conduct with respect to developing, urging, and implementing nationwide opioid sales, including in each State Class's state, caused or contributed to causing a public nuisance;

f. Whether McKinsey's conduct with respect to developing, urging, and implementing nationwide opioid strategies resulted in false misrepresentations to prescribers, including those in each State Class's state, regarding opioids;

g. Whether McKinsey aided and abetted and/or conspired with Purdue, Rhodes, the Sacklers, and other opioid manufacturers it worked with in developing, urging, and implementing its opioid strategies;

h. Whether McKinsey's actions, as set out in this Complaint, caused an increase in the number of children born with *in utero* opioid exposure;

i. Whether children affected by opioid usage *in utero* require special education services and other supports in public schools; and

j. Whether opioid addiction or use disorder in the family home increases the risk that a student will present emotional and behavioral difficulties in school in school.

551. Typicality. The claims of the named Plaintiffs are typical of the claims of each of their State Classes. Plaintiffs and the State Classes sustained damages as aforesaid arising out of and caused by McKinsey's unlawful conduct as alleged in this Complaint.

552. Adequacy of Representation. Plaintiffs will fairly and adequately represent and protect the interests of the members of their State Class. Counsel representing Plaintiffs are competent and experienced in litigating class actions.

553. Superiority of Class Action. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since joinder of all the members of the State Classes is impracticable. Furthermore, the adjudication of this controversy through a class action will avoid the possibility of inconsistent and potentially conflicting adjudication of the claims asserted herein. A class action would provide a superior vehicle for resolving the issues for all similarly affected and situated. There will be no difficulty in the management of this action as a class action.

IX. CLAIMS FOR RELIEF

554. All cases of action are brought on behalf of both Plaintiffs and State Classes.

A. Violation of RICO, 18 U.S.C. § 1961, *et seq.*

555. Plaintiffs realleage all of the foregoing allegations and incorporate them by reference.

556. This claim is brought by Plaintiffs against McKinsey for actual damages, treble damages, and available injunctive and/or equitable relief under 18. U.S.C. § 1964, for violations of 18 U.S.C. § 1961, *et seq.*, specifically, 18 U.S.C. § 1962(c) and (d).

557. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . . ." 18 U.S.C. § 1962(c).

558. At all relevant times, McKinsey is and has been a "person" under 18 U.S.C. § 1961(3) because it is capable of holding, and does hold, "a legal or beneficial interest in property."

559. Plaintiffs are each a "person," as the term is defined in 18 U.S.C. § 1961(3), and have standing to sue under 18 U.S.C. § 1964(c) as they were and are injured in their business and/or property "by reason of" the RICO Act violations described herein.

560. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

561. McKinsey conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c) and § 1962(d).

Description of the Enterprise

562. Section 1961(4) defines an enterprise as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4).

563. Under 18 U.S.C. § 1961(4), a RICO "enterprise" may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose. *See Boyle v. United States*, 556 U.S. 938, 946 (2009).

564. Opioid manufacturers, including Purdue, Johnson & Johnson, Janssen, Cephalon, Endo, and Mallinckrodt (collectively the "Opioid Manufacturers"), together with McKinsey, which participated in the marketing and sale of opioids as described in this Complaint, (collectively, the "Opioid Marketing Enterprise Members" or the "Enterprise Members") engaged in a scheme to unlawfully increase sales of opioids—and grow their share of the prescription painkiller market and the market as a whole—through repeated and systematic misrepresentations, concealments, and omissions of material fact about the safety and efficacy of opioids for treating long-term chronic pain, together with other deceptive and fraudulent acts and practices, as described in the Factual Allegations section of this Complaint.

565. In order to unlawfully increase the demand for opioids and thereby increase their own profits despite their knowledge of the harmful effects that would follow, the Opioid Marketing Enterprise Members formed an association-in-fact enterprise (the "Opioid Marketing Enterprise" or the "Enterprise"). The Opioids Manufacturers worked together to accomplish their

aims, with McKinsey serving as a go-between that held all of the companies together and helped coordinate the deceptive marketing and sales strategies. Through McKinsey and their own personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose: lying to prescribers and Plaintiffs in order to increase sales of addictive and dangerous drugs and line the enterprise members' pockets. The Opioid Marketing Enterprise Members' substantial financial contributions to the Opioid Marketing Enterprise and the advancement of opioids-friendly messaging fueled the U.S. opioid epidemic.

566. In the alternative, the association-in-fact Opioid Marketing Enterprise existed just between McKinsey and Purdue, who worked together to unlawfully increase sales of opioids—and grow Purdue's share of the prescription painkiller market—through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain. McKinsey knew Purdue was marketing its opioids illegally and fueling an opioid epidemic, but using the knowledge it gained from its work with other opioid manufacturers, McKinsey joined forces with Purdue to turbocharge the opioids market in order to profit from this crisis.

567. The Controlled Substances Act (the "CSA") and its implementing regulations require that "[e]very person who manufactures, distributes, dispenses, imports, or exports any controlled substance," including opioids, become a "registrant." *See* 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.11(a). These registrants, including opioid manufacturer and distributors, must maintain a system to identify and report suspicious orders, including orders of unusual size or frequency, or orders deviating from a normal pattern, and maintain effective controls against diversion of controlled substances. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

568. Despite these duties, McKinsey and the other Enterprise Members engaged in a scheme with the overarching purpose of materially expanding prescription opioid use by altering the medical community's opioid prescribing practices through repeated fraudulent statements and misrepresentations. The Opioid Marketing Enterprise's scheme was sophisticated, well-developed, and fraudulent and was designed to increase the prescription rate for opioid medications the Enterprise Members knew where dangerous and highly addictive. At all relevant

times, McKinsey was aware of the conduct of the Enterprise, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of payments from other Enterprise Members as a reward for work done to increase sales and distribution of prescription opioids.

The Common Purpose and Scheme of the Opioid Marketing Enterprise.

569. The Opioid Marketing Enterprise Members, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and Plaintiffs and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. These misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition, which the Opioid Marketing Enterprise Members named “pseudoaddiction”; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

570. The scheme devised, implemented, and conducted by the Opioid Marketing Enterprise Members was a common course of conduct designed to ensure that the Opioid Marketing Enterprise Members unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the Opioid Manufacturers’ drugs. The Opioid Marketing Enterprise Members acted together for a common purpose and perpetuated the Opioid Marketing Enterprise’s scheme.

571. There was regular communication between the Opioid Marketing Enterprise Members in which information was shared, misrepresentations were coordinated, and payments were exchanged. The Opioid Marketing Enterprise Members functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise’s scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

572. As public scrutiny and media coverage focused on how opioids ravaged communities throughout the United States, McKinsey did not challenge Purdue or other manufacturers' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence. Instead, despite its knowledge of the ongoing fraud and the danger it posed, McKinsey continued to participate in the Opioid Marketing Enterprise for financial gain.

573. The impact of the Opioid Marketing Enterprise's scheme is still in place—i.e., the opioids continue to be prescribed and used for chronic pain throughout the United States, and the epidemic continues to injure Plaintiffs and consume the resources of Plaintiffs.

574. The evidence shows that the Opioid Marketing Enterprise Members, including McKinsey, were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

The Conduct of the Opioid Marketing Enterprise Violated Civil RICO.

575. From at least 2004 to the present, each of the Opioid Marketing Enterprise Members played some part in directing the affairs of the Opioid Marketing Enterprise and participated in the operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. Creating and providing a body of deceptive, misleading, and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

b. Creating and providing a body of deceptive, misleading, and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

c. Creating and providing a body of deceptive, misleading, and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

d. Devising and implementing marketing schemes that included targeting and misleading physicians, unlawfully incentivizing sales representatives to maximize prescriptions and dosages, and evading regulatory constraints; and

e. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications.

576. The scheme devised and implemented by the Opioid Marketing Enterprise Members amounted to a common course of conduct intended to enrich themselves by increasing sales of prescription opioids by convincing doctors to prescribe and patients to use opioids, including for long-term chronic pain, despite the Opioid Marketing Enterprise Members' knowledge of the addictions and deaths that would occur as a result. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

The Opioid Marketing Enterprise Members Conducted or Participated, Directly or Indirectly, in the Conduct of the Enterprise's Affairs.

577. "[T]o conduct or participate, directly or indirectly, in the conduct" of an enterprise, "one must participate in the operation or management of the enterprise itself." *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993).

578. As described herein, the Opioid Marketing Enterprise Members participated in the conduct of the Enterprise through a pattern of racketeering activity, and McKinsey was the mastermind of marketing schemes deployed by the Enterprise members to defraud prescribers and Plaintiffs by using the mail and wires in furtherance of plans that were designed with specific intent to defraud.

579. The Opioid Marketing Enterprise Members conducted an association-in-fact enterprise and/or participated in the conduct of an enterprise through a pattern of illegal activities

(the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the Opioid Marketing Enterprise, i.e., to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term, chronic pain. Through the racketeering activities of the Opioid Marketing Enterprise, the Opioid Marketing Enterprise Members sought to further the common purpose of the Enterprise through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use. In so doing, each of the Opioid Marketing Enterprise Members knowingly conducted and participated in the conduct of the Enterprise by engaging in mail and wire fraud, in violation of 18 U.S.C. §§ 1962(c) and (d).

580. The Opioid Marketing Enterprise is an association-in-fact enterprise that consists of the Opioid Marketing Enterprise Members.

581. Each of the Opioid Marketing Enterprise Members conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the Enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order to increase the market for prescription opioids by changing prescriber habits and public perceptions.

582. Specifically, the Opioid Marketing Enterprise Members each worked together to coordinate the Enterprise's goals and conceal their role, and the Enterprise's existence, from prescribers and Plaintiffs by, among other things, (i) funding, editing, and distributing publications that supported and advanced their false messages; (ii) funding key opinion leaders ("KOLs") to further promote their false messages; and (iii) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians.

583. Further, each of the Opioid Marketing Enterprise Members had systematic links to, and personal relationships with, each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities. The systematic links and personal relationships that were formed and developed allowed the Opioid Marketing Enterprise Members the opportunity to form the common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of

the Opioid Marketing Enterprise Members coordinated their efforts through the same KOLs and front groups, based on their agreement and understanding that the front groups and KOLs were industry friendly and would work together with the Opioid Marketing Enterprise Members to advance the common purpose of the Opioid Marketing Enterprise; and each of the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

584. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each Opioid Manufacturer and its members; (b) was separate and distinct from the pattern of racketeering in which the Opioid Marketing Enterprise Members engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the Opioid Marketing Enterprise Members; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise; and (e) had sufficient longevity for the Enterprise to pursue its purpose and functioned as a continuing unit.

585. The Opioid Marketing Enterprise Members conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids and expand the market for opioids.

586. The Opioid Marketing Enterprise Members each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the Opioid Marketing Enterprise Members committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Opioid Marketing Enterprise Members' regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise, the U.S. Mail,

and interstate wire facilities. The Opioid Marketing Enterprise Members participated in the scheme to defraud by using mail, telephones, and the internet to transmit communications and payments in interstate or foreign commerce.

The Conduct was More than a Typical Business Relationship.

587. There were strong relationships among those associated with the Opioid Enterprise and sufficient longevity among Enterprise associates to pursue the Enterprise's common purpose. The common purpose was to increase opioid revenues unlawfully by misrepresenting and lying about opioids in order to changing prescriber habits and the perception regarding the safety and efficacy of opioids for chronic pain and long-term use. The Enterprise's deceit was, in part, in its failure to disclose that increasing strength and dosing actually increased the risk of addiction and overdose and that patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief.

588. On March 1, 2004, McKinsey entered into a "Master Consulting Agreement" with Purdue for "services that would be defined from time to time."[403] The Master Consulting Agreement was signed by then-McKinsey director Rob Rosiello."[404]

589. From 2004 through 2008, McKinsey advised Purdue on research and development, business development, and product licensing related to Purdue's opioid products.[405] Consistent with its business model, McKinsey leveraged these projects into growth of its "Broader Strategy work" also underway with Purdue.[406] Specifically, in October 2008, Purdue retained McKinsey for broad strategy work after two board members "blessed" Purdue executive Craig Landau with doing "whatever he thinks is necessary to 'save the business'" after the 2007 criminal plea and introduction of generic competition to the older OxyContin.[407] Purdue relied heavily on McKinsey to help Purdue publicly portray itself as a good corporate citizen who could now be trusted and was even working on an "abuse-deterrent" or "ADF" form of OxyContin.

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[403] MCK-MDL2996-0085849; PPLPC012000069192
[404] MCK-MDL2996-0085849, at 0085880.
[405] PPLPC013000116218; PPLP004401340
[406] MCK-MAAG-0117875
[407] MCK-MAAG-0117875

590. Over their many years of working together, McKinsey and Richard Sackler developed a close relationship. Indeed, one McKinsey partner, Maria Gordian, describes herself as a counselor to Richard Sackler in an "Ey 2009 Impact Summary."[408]

591. The Opioid Marketing Enterprise was more than a typical business relationship. Rather, the members of the Enterprise knew that opioids were addictive and causing serious harm to people and communities but chose to work together to lie to prescribers and Plaintiffs about these drugs in order to increase their bottom lines. McKinsey worked closely with the Opioid Manufacturers to achieve these aims. McKinsey, as an advisor of multiple Opioid Manufacturers, also had access to information about multiple players and was able to coordinate the fraud occurring across the Enterprise. As discussed below, McKinsey was particularly embedded in Purdue's organizational structure and the relationship's longevity was sufficient to pursue the Enterprise's purposes. During the 2009-2014 period in particular, Purdue relied extensively on McKinsey to develop its sales and marketing strategy for OxyContin.

592. The intent to defraud is evident in the McKinsey's attempts to strengthen its relationship with Purdue and assist Purdue in selling opioids after Purdue's 2007 criminal guilty plea. As part of the guilty plea, Purdue admitted that its "supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medication."[409] But rather than be deterred by this, McKinsey dove in. In a March 2009 self-assessment, Ms. Gordian described McKinsey's progress in having "continue[d] to expand the depth and breadth of [its] relationships with Purdue" and plans to "deepen[]" McKinsey's "relationship with the Sackler family," including by "serving them on key business development issues" and "expanding" McKinsey's relationship with members of Purdue's senior management team.[410]

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[408] MCK-MAAG-0118669

[409] Information at pp. 5-6, *United States v. Purdue Frederick Co.*, No. 07-cr-29-JPJ (W.D. Va. May 10, 2007), Doc. 5.

[410] MCK-MAAG-0118669

593. By August 2009, Richard Sackler had convened a meeting of Purdue board members and staff to discuss efforts to "reverse the decline in the OxyContin tablets market."[411] During the 2009-2014 period in particular, Purdue relied extensively on McKinsey to develop its sales and marketing strategy for OxyContin. McKinsey worked closely with Purdue on both the creation and implementation of OxyContin sales strategy. McKinsey's work for Purdue included consulting, review of product acquisition, evaluation of research and development, advising Purdue on the design of clinical studies, risk management, and product marketing.[412]

594. On May 28, 2013, McKinsey entered into a "Statement of Services to the Master Consulting Agreement" (the "2013 Agreement") with Purdue to "conduct a rapid assessment of the underlying drivers of current OxyContin performance, identify key opportunities to increase near-term OxyContin revenue and develop plans to capture priority opportunities."[413] The 2013 Agreement stated, "We have a long history of partnership with Purdue, and we would make best efforts to leverage our understanding of your business—both in terms of content and culture." The 2013 Agreement was signed by then-principal Arnab Ghatak who would "lead the team with senior leadership from Rob Rosiello and Martin Elling."

595. [redacted].[414]

596. Thereby, even after the 2007 guilty plea, Purdue, with McKinsey's aid, saw growing profits from opioid sales. In 2015 alone, Purdue obtained $3 billion in annual opioid sales—a four-fold increase from its 2006 sales of $800 million.

597. McKinsey's relationship with Purdue went far beyond a typical business relationship. McKinsey worked closely with Purdue on both the creation and implementation of

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[411] PPLPC061000045395
[412] PPLPC029000547371
[413] Excerpt from U.S. Department of Justice Plea Agreement with Purdue Pharma L.P. October 20, 2020. 18, ¶88. https://www.justice.gov/opa/press-release/file/1329576/download.
[414] PPLPC018001462324 [redacted])

OxyContin sales strategy, a strategy McKinsey knew had been based on misleading and defrauding doctors and patients alike about a dangerous and highly addictive drug.

598. Further, McKinsey had access to detailed prescribing information enabling it to determine if there were suspicious or problematic prescribing patterns. Rather than using this information to help its clients prevent diversion of controlled substances, McKinsey and the Opioid Marketing Enterprise used this information in furtherance of their scheme to defraud prescribers and Plaintiffs, target and increase sales to prescribers who were overprescribing, and continue to fuel opioid addiction and the resulting epidemic.

The Fraudulent Schemes

599. As detailed above, the operation of the Opioid Marketing Enterprise, included several schemes to defraud that helped to further the goals its members—i.e., to expand the market and increase profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and to increase profits for the Enterprise Members via expanding the market for opioids.

Fraudulent Marketing Scheme: Deceptive Messaging Regarding Opioid Use

600. As described throughout, McKinsey sought to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term, chronic pain by changing prescriber habits and public perception regarding the safety and efficacy of opioids. McKinsey's fraud specifically targeted prescribers and set out to convince them that they should prescribe more and more opioids, overcoming what could otherwise be a check on opioid manufacturers ability to increase sales of addictive products.

601. Despite McKinsey knowing that reformulated OxyContin could still be abused, having advised Purdue on the design of tests of reformulated OxyContin as part of Purdue's FDA submission,[415] in furtherance of the scheme to defraud, McKinsey spread messages that prescribing opioids could provide "freedom" and "peace of mind" for its users and that physicians could "tailor the dose."

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[415] McK-MAAG-0118669

602. After Purdue's 2007 criminal plea for illegally marketing OxyContin, McKinsey created strategies to repair Purdue's reputation and boost OxyContin sales. In 2008, Purdue submitted a New Drug Application for a reformulation of OxyContin, ostensibly to make it more difficult to abuse by extracting the active ingredient from it or otherwise defeating the time-release mechanism in OxyContin tablets—i.e., another product Purdue would later deceptively promote as safer than and less prone to abuse than it was.

603. In June 2009, McKinsey helped Purdue prepare for an FDA advisory committee meeting. [redacted]

604. McKinsey prepared for Purdue an "FDA Advisory Committee on Reformulated OxyContin: Question & Answer Book" in September 2009, with questions including "Why should we trust you?" In response, McKinsey recommended Purdue say "We acknowledge mistakes made in the past[;]" "We have x, y and z measures in place that did not exist before[;]" and "[a]t all levels, Purdue's focus is on maintaining the highest ethical standards and meeting the needs of patients[.]"[418] To the question of "Who at Purdue takes personal responsibility for all these deaths?[,]" McKinsey recommended Purdue say, "We all feel responsible[.]"

605. McKinsey and the other Opioid Marketing Enterprise Members knew the changes Purdue made would not make opioids non-addictive or prevent them from being used to create and further substance abuse problems. For example, in 2009, the FDA noted in permitting ADF labeling that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." Similarly, in approving reformulated OxyContin, the FDA cautioned that the reformulation "is not completely tamper resistant and those intent on abusing this new formulation will likely find a means to do so. In addition, the product can still be

[416] PDD8901645845
[417] *Id.*
[418] MCK-MAAK-0152135

misused or abused and result in overdose by simply administering or ingesting larger than recommended oral doses."[419]

606. Despite this knowledge, the Opioid Marketing Enterprise pursued messaging and a strategy that was deceptive and was designed to deceive doctors in particular. Even after Purdue pleaded guilty to offenses related to its marketing and distribution of addictive opioids, McKinsey advised Purdue to market OxyContin to encourage more prescriptions (that it knew would lead to abuse and overdose events) into higher dose prescriptions by a smaller number of loyalist prescribers.

607. Far from the deception of doctors being an unforeseen consequence, McKinsey intentionally set out to target doctors as a cog in the Enterprise's scheme to defraud. Indeed, deceiving doctors was part of the marketing scheme, and doctors were utilized in furtherance of the marketing scheme. Medical providers were not a break in the causal chain of harm to Plaintiffs but were targeted players in the scheme to defraud and key links in the casual chain.

608. The marketing scheme involved using data to target high prescribers and training marketers to make misleading statements with the goal to increase high dose prescriptions which McKinsey and Opioid Marketing Enterprise Members knew were more likely to be abused. Enterprise Members knew that overdoses were expected and that such overdoses would lead to need for increased services.

609. Purdue's 2020 guilty plea acknowledged its role in using aggressive marketing to convince doctors to prescribe opioids unnecessarily, fueling the drug addiction crisis. McKinsey was the mastermind of marketing scheme following Purdue's 2007 guilty plea. McKinsey developed and helped implement these strategies.

610. In an October 26, 2009 presentation, "OxyContin – driving growth through stronger brand loyalty," McKinsey proposed tactics to turnaround declining sales, "[e]nhance loyalty to OxyContin among loyalist prescribers," "convert[ing] 'fence sitters' into more loyal OxyContin prescribers,"[420] and "protect OxyContin's market share[.]"[421] In other words,

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[419] FDA Summary Review, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000SumR.pdf
[420] MCK-MDL2996-0126522
[421] *Id.* at 2

McKinsey proposed increasing sales by pushing both willing and reluctant physicians to prescribe more OxyContin.

611. McKinsey recommended segmenting prescribers and tailoring messages and tactics to different segments. For prescribers dubbed "Early Adopting Experts" and "Proactive Teachers," defined by a willingness to use extended release opioids, including in patients who were not already using opioids, McKinsey urged emphasizing that its 7 tablet strengths provide flexibility to "tailor the dose" to customer needs.[422] Upon information and belief, this message aimed to encourage prescribers to initiate and maintain patients on OxyContin long-term by reminding them they could increase the dose as patients became tolerant with long-term use (rather than discontinue use when the drug lost its effectiveness).

612. Purdue adopted McKinsey's [redacted] proposal.[423] [redacted]

613. As detailed throughout, McKinsey and Opioid Marketing Enterprise Members were aware of the catastrophic injury inflected on the public by selling harmful, addictive opioid products. Yet when promoting opioids and engaging in doctor detailing, the Enterprise Members intentionally hid the potential for abuse and addiction by marketing OxyContin's 12-hour dosing as meaning that users only need to take OxyContin twice a day, thus requiring fewer pills.

614. It was foreseeable that this marketing strategy would lead to greater addiction because OxyContin wore off after 8 to 10 hours in many patients. Prescribing 12-hour dosing led to "end of dose failure," which led to a vicious cycle that became "the perfect recipe for

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[422] *Id.* at 12.
[423] PPLPC023000251226 ([redacted]); see also PPLPC012000243668 ([redacted]); PPLPC012000245087 ([redacted]); PPLPC012000246009 ([redacted]; PPLPC021000265092 ([redacted])
[424] PKY183123435

addiction."[425] As a result, what McKinsey marketed as "convenient" led to what was described as "a [d]escription of Hell."[426]

615. The marketing scheme worked. Nationwide, based on an analysis by the Los Angeles Times, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 morphine equivalent dose that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[427]

616. A key element of the marketing scheme that fueled the deadly epidemic of opioid abuse was doctor detailing using detailed prescriber data.

Data Scheme: Use of Prescriber Data for Intentional Targeting of High Opioid Prescribers-Not Diversion Prevention

617. McKinsey was an advisor to DEA registrants and Opioid Marketing Enterprise Members, who had a legal duty to guard against diversion and report suspicious orders of controlled substances. Rather than assisting in reporting suspicious orders, McKinsey used its position and access to detailed prescriber information to actually divert resources to target high volume prescribers to sell more opioids.

618. Distributors of controlled substances have a legal duty to report suspicious orders, and to report those that deviate substantially from a normal pattern and orders of unusual size and frequency. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b). These obligations included a legal duty to maintain effective controls and procedures to guard against diversion of controlled substances and a legal duty to maintain a system to identify and report suspicious orders of controlled substances. *See* 21 C.F.R. §§ 1301.7(a) (b); 1301.74(b). Rather than advising their registrant clients on how to comply with their legal duties to maintain effective controls to guard against diversion and how to operate a system to identify and report suspicious orders, in furtherance of the scheme, McKinsey and the Opioid Marketing Enterprise Members used detailed data to target prescribers to increase the opioid market.

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[425] Harriet Ryan, "'*You Want a Description of Hell?' OxyContin's 12-Hour Problem*," Los Angeles Times, May 5, 2016, available at http://www.latimes.com/projects/oxycontin-part1/.
[426] *Id.*
[427] CDC Guideline at 16.

619. Consistent with the Enterprise's purpose of increasing profit by deceptively marketing opioids, McKinsey was tasked with "Identifying Granular Growth Opportunities for OxyContin," conducting an "assessment of the underlying drivers of current OxyContin performance," identifying "key opportunities to drive near-term OxyContin performance," and developing "plans to capture priority opportunities."[428]

620. McKinsey received physician-level sales data to develop its marketing strategy to increase OxyContin performance after Purdue's 2007 guilty plea. Rather than using this access to the granular data to avoid diversion and to prevent Enterprise members from targeting prescribers with suspicious prescribing patterns, McKinsey used this information to help the Opioid Marketing Enterprise members push more opioids on high volume prescribers in furtherance of its schemes to defraud. The targets were chosen based on their history of prescribing high doses of opioids in large quantities.

621. One of the services the Enterprise used in furtherance of this scheme concerned the use of data to help Purdue meet its goals. McKinsey's analysis for the "Evolve to Excellence" proposal shows that it had detailed information from which it could discern, as could Purdue, whether a prescriber had problematic patterns suggesting operation as a "pill mill," including a shift to other opioids after OxyContin's reformulation. Yet, McKinsey urged Purdue to target, and seek to increase the prescribing of, all of these prescribers from whom it perceived Purdue could obtain greater profits.

622. McKinsey found that Purdue did not "focus on the highest potential docs," measured both by the number of prescriptions and reimbursement considerations.[429] A McKinsey analyst urged McKinsey to recommend Purdue target "[l]itefrally, at least all" prescribers in the top 20% of prescribers, "minus another few percent who are no sees[.]" McKinsey team lead Arnab Ghatak replied that "they probably have 20% no see[], but i'd also assume there are not many high writers that are no see."[430] ("No see" prescribers are prescribers who do not accept visits from pharmaceutical sales representatives. Thus, upon information and belief, McKinsey

[428] PPLPC030000770531
[429] MCK-MDL2996-0364024
[430] MCK-MDL2996-0364267

recognized that most of the highest volume prescribers, or "high writers" of prescriptions, were willing to entertain sales visits from sales representatives.)

623. The Opioid Marketing Enterprise used data for intentional targeting of high prescribers and not for diversion prevention. McKinsey advised Purdue to raise sales of Oxycontin by focusing on high dose sales and deceptively messaging to physicians that OxyContin would improve function and quality of life. McKinsey urged Purdue to maximize sales by dictating which prescribers its sales representatives would target. For example, McKinsey advised Purdue that it should take "specific actions" to increase sales of OxyContin, including "Prescriber Targeting" and "Turbocharg[ing] Purdue's Sales Engine."

624. McKinsey targeted not just doctors but also nurse practitioners and physician assistants, recommending Purdue "[d]ouble down on nurse practitioners and physician assistants . . . as they represent a growing market segmentation of prescribers."[431]

625. The Enterprise's scheme also explored ways to increase the amount of time sales representatives spent in the field increasing opioid sales, and prioritizing OxyContin in incentive compensation targets.[432]

626. By April 24, 2014, the plan was working and McKinsey reported that Purdue's "sales force is selecting an increasing percentage of high-value OxyContin prescribers as targets."[433]

627. McKinsey ensured Purdue would benefit from the lessons learned by other Enterprise members, stating that "its experience with other pharmaceutical companies suggests that such a comprehensive Sales transformation program takes nine months."[434] Likewise, McKinsey recommended physician targeting to other Enterprise members, including Endo and Janssen.[435]

628. By targeting physicians based on their prescribing patterns, the Opioid Marketing Enterprise was working toward the common purpose of deceptively convincing doctors to

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[431] MCK-MDL2996-0303399
[432] PPLPC012000437346
[433] MCK-MDL2996-0104840; PPLPC035000220406
[434] MCK-MDL2996-0187168
[435] MCK-MDL2996-0130803; MCK-MDL2996-0135713

prescribe more opioids and thereby increase their own profits. By developing "Evolve to Excellence," which was implemented as a plan to "turbocharge" opioid sales, McKinsey advised that Purdue would see a greater return on its sales investment by focusing its targets, including on prescribers with alarming prescribing patterns that raised red flags they were writing "prescriptions" for non-medical use. The plan aimed at boosting sales of OxyContin by targeting the highest volume opioid prescribers, which McKinsey and the other members of the Opioid Marketing Enterprise knew and/or should have known would result in the expansion of the illicit opioid market.

629. The Enterprise sought to grow opioid sales to prescribers who raised red flags of diversion and orders it knew or should have known were likely to be diverted or fuel an illegal market. Purdue had a legal obligation not to target these prescribers; rather, it was obligated to report their conduct to law enforcement. Yet the Enterprise used access to prescriber data not to report diversion but to enhance diversion.

Pattern of Racketeering Activity

630. McKinsey together with the other Opioid Marketing Enterprise Members engaged in a scheme to unlawfully increase sales of opioids—and grow their share of the prescription painkiller market—through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain. As a unique consulting entity with knowledge of both the addictive properties and abuse potential of opioids and with access to data regarding internal prescribing behaviors of its targets, McKinsey perpetrated a number of fraudulent schemes using the mails and wires, including advising Purdue to market more opioids, in higher doses, to high volume prescribers while helping Purdue avoid mandatory prescriber education regarding the risks of opioids. McKinsey fueled the epidemic alongside its clients. Through targeted marketing that McKinsey worked to develop, "turbocharge," and implement, McKinsey substantially contributed to an explosion in the use of opioids across the United States. McKinsey is an enterprise that is engaged in and affects interstate commerce because the company advised opioid manufacturers on the sale of opioid products across the United States, as alleged herein.

631. The Opioid Marketing Enterprise Members devised and knowingly carried out this illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute, and non-cancer pain. They knew that these representations deviated from the FDA-approved use of these drugs and were not supported by actual evidence. The Opioid Marketing Enterprise Members intended that their common purpose and scheme to defraud would, and did, deceive consumers, prescribers, regulators, Plaintiffs, and other intended victims and they used the U.S. Mail and interstate wire facilities with the specific intent to advance, and for the purpose of executing, their illegal scheme.

632. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain, the Opioid Marketing Enterprise Members engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

633. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the Opioid Marketing Enterprise Members hid from the consumers, prescribers, regulators, and Plaintiffs: (a) the fraudulent nature of the Opioid Marketing Enterprise Members' marketing scheme; (b) the fraudulent nature of statements made by the Opioid Marketing Enterprise Members regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

634. The Opioid Marketing Enterprise Members with knowledge and intent, to the overall objective of the Opioid Marketing Enterprise Members' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

635. Indeed, for the Opioid Marketing Enterprise Members' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This coordination was accomplished via their relationships with each other and via McKinsey's relationships and contacts with key opioids manufacturers.

636. The Opioid Marketing Enterprise Members' predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs, while simultaneously generating

billion-dollar revenues and profits for the Opioid Marketing Enterprise Members. The predicate acts were committed or caused to be committed by the Opioid Marketing Enterprise Members through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

637. The Opioid Marketing Enterprise Members' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity. McKinsey in particular used mail and wire transmission, directly or indirectly, in furtherance of this scheme by transmitting deliberately false and misleading statements to prescribers and the public.

638. McKinsey had a specific intent to deceive and defraud prescribers, regulators and Plaintiffs. For example, as alleged above, McKinsey made repeated and unequivocal statements through the mails and wires that were false and misleading. McKinsey advised Purdue to market OxyContin based on the false and misleading notion that the drug can provide "freedom" and "peace of mind" for its users, and concomitantly reduce stress and isolation.

639. Similarly, they caused to be transmitted through the mails and wires false and misleading statements regarding the addiction potential of opioids. Moreover, McKinsey had direct involvement in marketing statements and thus caused the statements to be made, notwithstanding that they knew they were false for the reasons detailed above.

640. The marketing scheme is especially egregious since the public relies on physicians as a position of trust and authority in the community regarding their health and well-being. McKinsey intentionally deceived physicians regarding the abuse potential of opioids. It intended prescribers and the public to rely on its false statements. McKinsey intended reliance on these false statements as it was their goal for doctors to prescribe more and higher quantities of these dangerous pills to the public. This scheme was therefore reasonably calculated to deceive not only persons of ordinary prudence and comprehension but also educated physicians in a place of high trust in the community.

Predicate Acts

641. To carry out, or attempt to carry out, the scheme, the Enterprise Members, each of whom is a person associated-in-fact with the Enterprise, did knowingly conduct or participate in, directly or indirectly, the affairs of the Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

642. Specifically, the Enterprise Members have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.

643. The multiple acts of racketeering activity which the Enterprises Members committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

644. The racketeering activity was made possible by the Enterprise's regular use of the facilities, services, distribution channels, and employees of the Enterprise Members.

645. The Opioid Marketing Enterprise Members participated in the schemes by using mail, telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.

646. The Enterprise Members used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their schemes through common misrepresentations, concealments, and material omissions.

647. In devising and executing the illegal schemes, the Opioid Marketing Enterprises Members devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiffs and prescribers and to obtain money by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

648. For the purpose of executing the illegal schemes, the Enterprise Members committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal schemes.

649. The Opioid Marketing Enterprise Members' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to the conduct described in the Factual Allegations section of this Complaint, and:

650. Mail Fraud: The Opioid Marketing Enterprise Members violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

651. Wire Fraud: The Opioid Marketing Enterprise Members violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

652. The Opioid Marketing Enterprise Members' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments, and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute, and non-cancer pain, with the goal of profiting from the increased sales of the Opioid Marketing Enterprise Members' drugs that occurred because consumers, prescribers, regulators, and Plaintiffs relied on the Opioid Marketing Enterprise Members' misrepresentations. These uses of the U.S. Mail or interstate wires included, inter alia:

653. Marketing materials about opioids and their risks and benefits, which the Opioid Marketing Enterprise Members sent to health care providers, transmitted through the internet and television, and published across the country, including in counties and cities and on Tribal Reservations and to Plaintiffs;

654. Written representations and telephone calls among the Opioid Marketing Enterprise Members and between the Opioid Marketing Enterprise Members regarding the

misrepresentations, marketing statements, and claims about opioids, including the non-addictive, safe use of opioids for chronic, long-term pain generally;

655. E-mails, telephone calls, and written communications among the Opioid Marketing Enterprise Members agreeing to or implementing the opioids marketing scheme;

656. Communications among the Opioid Marketing Enterprise Members and between the Opioid Marketing Enterprise Members and the media regarding the publication, drafting, and dissemination of treatment guidelines as part of the Opioid Marketing Enterprise;

657. Written and oral communications directed to prescribers, the public, and Plaintiffs that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

658. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

659. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities are not obtainable (e.g., each time a McKinsey trained marketer “calls” or reached out to a physician using the mails or wires in furtherance of the marketing scheme). Because the Opioid Marketing Enterprise Members disguised their participation in the Enterprise, and worked to keep the Enterprise’s existence secret, many of the precise dates of the Opioid Marketing Enterprise’s uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the Opioid Marketing Enterprise Members. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. Plaintiffs have, however, described the types of predicate acts of mail and/or wire fraud, including the specific types of fraudulent statements upon which, through the mail and wires, McKinsey engaged in fraudulent activity in furtherance of their scheme.

660. Below, Plaintiffs also describe examples of occasions on which the Opioid Marketing Enterprise Members disseminated misrepresentations and false statements to consumers, prescribers, regulators, and Plaintiffs, and how those acts were in furtherance of the scheme.

From	To	Date	Description
Purdue	Prescribers and Plaintiffs	2007	Statements that pain relief from opioids improves patients' function and quality of life in advertising and a book
Purdue	Prescribers	Continuous	Telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function
Purdue	FDA advisory committee	September 2009	Presentation prepared by McKinsey indicating that its reformulated OxyContin will deter abuse
Purdue	Prescribers and Plaintiffs	2010 onwards	Statements that the reformulated OxyContin will deter abuse and therefore doctors can continue to safely prescribe opioids
Purdue	Prescribers and Plaintiffs	2010-2020	Statements from Purdue at McKinsey's direction that opioids can provide "freedom," "peace of mind," and give patients "the best possible chance to live a full and active life"
Purdue	Prescribers and Plaintiffs	Advertising produced in 2016	Advertising from Purdue that "We sell hope in a bottle."
Purdue	Prescribers and Plaintiffs	2010 onwards	Statements that OxyContin's 12-hour dosing would allow patients to only need to take OxyContin twice a day, thus requiring fewer pills
Purdue	Prescribers and Plaintiffs	2013 onwards	Statements from Purdue at McKinsey's direction that OxyContin allowed physicians to "Individualize the Dose" and that the dose of OxyContin can safely be increased or tailored as the patients adapt to a certain dose
Endo	Prescribers and Plaintiffs	2009	Statements made on an Endo-sponsored website, PainKnowledge.com, indicating that patients who take opioids as prescribed usually do not become addicted
Endo	Prescribers and Plaintiffs	2009	Statements made on another Endo-sponsored website, PainAction.com, indicating that most chronic pain patients do not become addicted to opioid medications
Endo	Prescribers and Plaintiffs	Various	Statements in pamphlets and publications described by Endo indicating that most people who take opioids for pain relief do not develop an addiction
Endo	Prescribers and Plaintiffs	Various	Statements made on the Endo-run website, Opana.com, indicating that opioid use does not result in addiction
Endo	Prescribers and Plaintiffs	Various	Statements made on the Endo-run website, Opana.com, indicating that opioid dependence can be addressed by dosing methods such as tapering
Endo	Prescribers and Plaintiffs	Various	Statements made on its website, PainKnowledge.com, that opioid dosages could be increased indefinitely
Endo	Prescribers and Plaintiffs	Various	Statements made in a publication entitled "Understanding Your Pain: Taking Oral Opioid Analgesics" suggesting that opioid doses can be increased indefinitely
Endo	Prescribers	Various	Electronic and telephonic communications to its sales representatives indicating that the formula for its medicines is "crush resistant"

Endo	Prescribers and Plaintiffs	2007	Statements that pain relief from opioids improves patients' function and quality of life in advertising and a book
Endo	Prescribers	Various	Telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function
Janssen	Prescribers and Plaintiffs	Various	Statements on its website, PrescribeResponsibly.com, indicating that concerns about opioid addiction are overestimated
Janssen	Prescribers and Plaintiffs	2009	Statements in a 2009 patient education guide claiming that opioids are rarely addictive when used properly
Janssen	Prescribers and Plaintiffs	2009	Statements included on a 2009 Janssen-sponsored website promoting the concept of opioid pseudoaddiction
Janssen	Prescribers and Plaintiffs	Various	Statements on its website, PrescribeResponsibly.com, advocating the concept of opioid pseudoaddiction
Janssen	Prescribers and Plaintiffs	Various	Statements on its website, PrescribeResponsibly.com, indicating that opioid addiction can be managed
Janssen	Prescribers and Plaintiffs	2009	Statements in its patient education guide indicating the risks associated with limiting the dosages of pain medicines
McKinsey	Purdue (with prescribers as the planned target)	July 18, 2013	Discussion of McKinsey plan to increase calls to doctors' offices to fraudulently promote OxyContin, including via "phone, video and even Google like proprietary tools" [436]
McKinsey	Purdue (with prescribers as the planned target)	April 24, 2017	Plan to promote OxyContin to "no-see" physicians through "remote interactions" including presenting "brand interaction and materials" "over the phone/internet"[437]
McKinsey	McKinsey	July 14, 2013	Internal emails interpreting "the Purdue situation" and discussing OxyContin sales strategy including sales benchmarks and "focus on the highest potential docs"[438]
McKinsey	Purdue (with prescribers as the planned target)	September 23, 2013	Evolve 2 Excellence PowerPoint planning execution of the scheme and discussing targeted performance metrics including "sales management calls per day, calls per year and adhering to target list"[439]
McKinsey	Purdue	July 30, 2013	Presentation showing "Scope of potential OxyContin growth opportunities" with proposed process including "Generate

[436] MCK-MDL2996-0104431, at 0104442
[437] MCK-MDL2996-0104840
[438] MCK-MDL2996-0364024
[439] MCK-MDL2996-0316833, at 0316834

			target list" and using "Reps/DMs [to] perform call planning (including refining target list)"[440]

661. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the Opioid Marketing Enterprise Members defrauded and intended to defraud consumers, prescribers, regulators, Plaintiffs, and other intended victims.

662. These were not isolated incidents. Instead, the Opioid Marketing Enterprise Members engaged in a pattern of racketeering activity by committing thousands of predicate acts in a five-year period, in the form of mail and wire fraud, and there remains a threat that such conduct will continue in the future.

663. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers, prescribers, regulators, and Plaintiffs. The Opioid Marketing Enterprise Members calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In designing and implementing the scheme, the Opioid Marketing Enterprise Members understood and intended that those in the opioid distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the Opioid Marketing Enterprise Members' products.

664. Opioid Marketing Enterprise Members' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the Opioid Marketing Enterprise Members are distinct from the Opioid Marketing Enterprise.

665. The racketeering activities conducted by the Opioid Marketing Enterprise Members amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive consumers, prescribers, regulators, and Plaintiffs. Each separate use of the U.S. Mail and/or interstate wire facilities employed by the Opioid Marketing Enterprise was related, had similar intended purposes, involved similar participants and methods of execution, and had the

[440] MCK-MDL2996-0303399

same results affecting the same victims, including consumers, prescribers, regulators, and Plaintiffs. The Opioid Marketing Enterprise Members have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

666. Each of the Opioid Marketing Enterprise Members aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

667. As described herein, the Opioid Marketing Enterprise Members engaged in a pattern of related and continuous predicate acts for many years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

668. The Opioid Marketing Enterprise Members' violations of law and pattern of racketeering activity directly and proximately caused Plaintiffs injury in their business and property. The Opioid Marketing Enterprise Members' pattern of racketeering activity logically, substantially, and foreseeably caused an opioid epidemic. The injuries of Plaintiff, as described herein, were not unexpected, unforeseen, or independent. Rather, as Plaintiffs allege, the Opioid Marketing Enterprise Members as a whole and McKinsey in particular knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the Opioid Marketing Enterprise Members engaged in a scheme of deception that utilized the mail and wires in order to carry out the Opioid Marketing Enterprise's fraudulent scheme, thereby increasing sales of their opioid products.

669. It was foreseeable and expected that the Opioid Marketing Enterprise Members creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry out their fraudulent scheme would lead to a nationwide opioid

epidemic, including increased opioid addiction and overdose and the injuries that occurred as a result.

<u>The Enterprise Was Well Aware of Risks of Abuse Before It "Turbocharged" its Marketing Scheme.</u>

670. These devastating results were eminently foreseeable by the Opioid Marketing Enterprise Members.

671. When Purdue pleaded guilty in 2007, it was evident that Purdue's behavior and excessive prescribing was directly linked to a drug addiction crisis that caused severe and extensive damage to America. Purdue's methods included "using aggressive marketing tactics to convince doctors to unnecessarily prescribe opioids – frivolous prescriptions that experts say helped fuel a drug addiction crisis that has ravaged America for decades."[441]

672. McKinsey cannot deny knowledge regarding Purdue's 2007 guilty plea. At that point, McKinsey knew that opioids were addictive. McKinsey knew that OxyContin was being widely abused and causing harm to people and entities like Plaintiffs. And McKinsey knew that Purdue had been fraudulently marketing OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal. And yet, years later, in 2013, McKinsey orchestrated a scheme to continue to aggressively promote opioids despite knowledge that people were still dying from overdoses.

673. Thus, McKinsey continued to add fuel to this fire by persisting in aggressively marketing to physicians and continuing to fuel the opioid crisis after Purdue's guilty plea. It was foreseeable that continuing to do so would devastate American communities.

[redacted]

[441] Jan Hoffman & Katie Benner, *Purdue Pharma Pleads Guilty to Criminal Charges for Opioid Sales*, N.Y. Times (updated Dec. 17, 2020), <u>https://www.nytimes.com/2020/10/21/health/purdue-opioids-criminal-charges.html</u>.

[442] MCK-MDL2996-0070516, at 0070517

[redacted]

[redacted]

675. [redacted]:

[redacted]

676. Similarly, news stories across the nation reported additional consequences of wide scale opioid addiction: needles littered around public property, posing costs to the governments and danger to residents.[443]

677. The foreseeability of the abuse and need for additional services that would be required following the misleading marketing and increased prescribing and use of high dose opioids is also evidenced by McKinsey's attempt to put a price tag on overdoses. McKinsey suggested payment amounts for event-based contracts: $6,000 to $15,000 (paid to health insurers for increased medical services). Indeed, McKinsey was well aware that increased prescriptions would lead to overdoses and to an additional financial burden for social and health services.

678. McKinsey is liable for its successful efforts to increase OxyContin sales after Purdue's 2007 guilty plea for misbranding the drug. Indeed, McKinsey's focus on increasing opioid sales after Purdue's guilty was incendiary to escalating and perpetuating the opioid epidemic by: (a) using data to specifically target high volume prescribers; (b) persuading sales of higher doses of opioids; (c) tailoring marketing messages to conceal their addictive principles; and (d) by reducing the training of sales representatives.

679. In 2012, when the consent decree expired (which obligated Purdue to submit annual compliance reports regarding its marketing), McKinsey helped Purdue reengage in its nefarious conduct of targeting and deceiving doctors about the abuse potential of opioids.

680. After Purdue's guilty plea, McKinsey identified physicians—that had already been influenced by Purdue's misrepresentations and were thus already high prescribers—as optimal targets for a massive marketing push to sell more OxyContin. McKinsey monitored the prescription behaviors of individual doctors and utilized the prescriber-level data and urged Purdue to allocate its time and resources to high prescribing physicians.

681. By November 2013, McKinsey had obtained the physician-level data it had previously requested and continued to study ways to sell additional OxyContin prescriptions by refining and targeting the sales pitch to them.

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[443] *See, e.g.*, https://www.bostonglobe.com/metro/regionals/south/2014/10/25/hypodermic-needles-litter-landscape-south-boston/pzgmgbyjYFCD967TePDyiM/story.html

682. In 2013, Project Turbocharge began. McKinsey proposed Project Turbocharge, a marketing strategy to increase opioids sales by hundreds of millions of dollars annually. With McKinsey's assistance, Purdue trained its sales representatives to operate using McKinsey's strategy for selling OxyContin. It is not coincidental to the Enterprise scheme that as soon as the constraints associated with its guilty plea and consent agreement ended, McKinsey assisted Purdue in turbocharging sales.

683. While McKinsey was pushing hard to turbocharge and promote the sale of opioids, it anticipated and expected that people would die from opioid overdoses. It acknowledged this when in 2017, it proposed that Purdue pay health insurers or other entities in the distribution chain rebates "for every OxyContin overdose attributable to pills they sold."[444]

684. McKinsey cannot deny that it was not aware of the abuse and overdose potential of opioids when it provided estimates for the future costs of overdose or opioid use disorder events.

685. McKinsey and the other Opioid Marketing Enterprise Members marketed a product, through intentionally deceptive means, that it knew would result in consumer deaths and harm to Plaintiffs. This is not an attenuated causal chain. Rather, aggressively marketing to high prescribing individuals, and training to not fully disclose the risk of abuse, were integral parts of the marketing scheme. Deceptive messaging to targeted prescribers who were likely to prescribe more pills in a dose with an anticipated abuse potential was part and parcel of the scheme to defraud.

686. As a result, Plaintiffs have shouldered the burden of these anticipated increased services and harm to business and property that are inherently tied to opioid abuse and misuse, and both the increased services and harms were reasonably and actually expected from increased prescribing.

687. The Enterprise's goal was to increase opioid prescribing, and the Enterprise Members knew that doing so would also result in the need for increased medical services. It was

[444] Walt Bogdanich & Michael Forsythe, *McKinsey Proposed Paying Pharmacy Companies Rebates for OxyContin Overdoses*, N.Y. Times (updated Nov. 5, 2021), https://www.nytimes.com/2020/11/27/business/mckinsey-purdue-oxycontin-opioids.html

also foreseeable that increased prescriptions would also result in increased costs to Plaintiffs and communities throughout the United States.

688. But for the increase in prescribed opioids, Plaintiffs would not have to expend additional resources or suffered other harm to business and property as a result of harms associated with opioid addiction. The Enterprise persisted in targeting prescribers to prescribe high doses of opioids and knew that doing so would result in adverse health and social outcomes, including overdoses, neo-natal complications, harm to communities like Plaintiffs, hazardous waste in Plaintiff communities, as well as and increased expenditures on services to combat such ill effects.

Plaintiffs' Business and Property Have Been Damaged by the Enterprise's RICO Violations.

689. The Opioid Marketing Enterprise's misleading marketing and failure to prevent prescription opioid diversion damaged public school district plaintiffs. The Opioid Marketing Enterprise's misconduct has contributed to a precipitous rise in babies born addicted to opioids and diagnosed with Neonatal Opioid Withdrawal Syndrome. Babies born with NOWS have a significantly increased risk of developing severe intellectual disabilities that qualify them for, and necessitate, special education and related services in school.

690. Plaintiffs have experienced vast harm to business and property directly, proximately, and foreseeably caused by the racketeering enterprise. Plaintiffs are required by federal law to provide special education services, and thereby incur the increased costs and diversion of resources associated with providing these services to children who were born with NOWS. Plaintiffs have also diverted resources to provide additional support to children presenting emotional and behavioral challenges in school due to opioid addiction or opioid-related death in their families.

691. The Opioid Marketing Enterprise Members' creation of, and then participation in, the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme has injured Plaintiffs in the form of substantial losses of money and property

that logically, directly, and foreseeably arise from the opioid epidemic. The injuries to Plaintiff, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Costs associated with providing special education and related services to students who were exposed to opioids in utero and students born with NOWS;

b. Costs of providing mental-health services, treatment, counseling, rehabilitation services, and social services to students with family members who are struggling with opioid use disorder;

c. Costs associated with providing care for children whose parents suffer from opioid-related disability, death or incapacitation; and

d. Losses caused by diverting revenue and resources that otherwise would have been used to provide other educational services to other students and, because of the conduct of the Opioid Marketing Enterprise must instead be used to support students whose families are struggling with opioid use disorder and provide special education and related services to students who were exposed to opioids in utero and students born with NOWS.

692. These injuries to Plaintiffs were directly and proximately caused by the Opioid Marketing Enterprise Members' racketeering activities, which were the logical, substantial, and foreseeable cause of the injuries to Plaintiff. But for the opioid-addiction epidemic the Opioid Marketing Enterprise Members created through their Opioid Marketing Enterprise, Plaintiffs would not have lost money or property.

693. Plaintiffs have been injured by the Enterprise's conduct, and such injury would not have occurred but for the predicate acts which also constitute acts taken in furtherance of the conspiracy pursuant to Section 1962(d). By working to expand the opioid market, fraudulently concealing the abuse potential of opioids, targeting high volume prescribers, and deceiving prescribers and the public in order to allow opioids to continue to remain on the market, the Enterprise caused the expansion of opioid prescribing and caused a large number of people across the United States, and in Plaintiffs' communities to become addicted to opioids. This forced Plaintiffs to expend, time, money, and resources to provide special education and related services to students born with in utero opioid exposure and NOWS and social, emotional, and behavioral

supports to students whose families have been negatively impacted by opioid addiction. Indeed, McKinsey intentionally deceived doctors and public health workers in order to continue to grow the opioid market. The repeated fraudulent misstatements by the Defendants contributed to an explosion in the use of opioids across the country.

694. Plaintiffs were direct victims of McKinsey's misconduct. The Enterprise displayed a wanton disregard for public health and safety by intentionally deceiving doctors about the addiction potential of opioids and by marketing higher doses to physicians. This in turn caused an increase in opioid addiction among women, and an increase in children born with in utero opioid exposure and NOWS. The harm created by McKinsey required Plaintiffs to expend financial and other resources to support and educate students born with such afflictions and support students whose families struggled with opioid addiction. The expansion of this market was the goal of the Enterprise and was critical to its success. Therefore, the harm suffered by Plaintiffs to its property and because it was forced to expend resources beyond ordinary costs of services to combat the opioid epidemic, was directly foreseeable, and in fact, and intentional result of Defendant's misconduct. In fact, McKinsey anticipated overdose events and actually estimated price premiums on these expected overdose events. McKinsey knew that the products it was marketing were highly addictive and could lead to deadly overdoses yet continued to "turbocharge" sales by fraudulently pushing the product on doctors through its deceptive marketing scheme.

695. The creation and implementation of the marketing scheme that McKinsey developed and deployed through its Enterprise, directly harmed Plaintiffs by imposing costs on their businesses and properties. Plaintiffs' injuries are not solely the result of routine government expenses. Instead, as a result of Defendant's misconduct, Plaintiffs have been and will be forced to go far beyond what a public school district might ordinarily be expected to pay to educate and support students. This includes providing special education and related services to students born with in utero opioid exposure and Neonatal Opioid Withdrawal Syndrome and social, emotional, and behavioral supports to students whose families are negatively impacted by opioids. As a result of the conduct of the Enterprise, Plaintiffs have incurred and will continue to incur costs that far exceed the norm.

696. The injuries to Plaintiffs were directly and proximately caused by these racketeering activities. These activities were the logical, substantial, and foreseeable cause of the injuries to Plaintiffs. But for the opioid epidemic the Opioid Marketing Enterprise Members created through their Opioid Marketing Enterprise, Plaintiffs would not have lost money or property, and the health and welfare of residents in Plaintiffs' jurisdictions would not have been harmed. Moreover, McKinsey's internal documents show that it actually did foresee many of the harms that resulted from its conduct.

697. There are no intervening acts or parties that could interrupt the causal chain between Defendant's mail and wire fraud and Plaintiffs' injuries. McKinsey, in furtherance of the Enterprise's common purpose, caused to be made false and misleading statements directly to the doctors (who consumers rely on to provide health advice) and the public. Doctors are not a break in the causal chain. Instead, the Enterprise members as a whole and McKinsey in particular intentionally targeted doctors and sought to device them. That were the doctors were then deceived and behaved as the Enterprise wanted, prescribing more and more opioids, was the purpose of the scheme, not an intervening cause.

B. <u>Common Law Public Nuisance</u>

698. Plaintiffs re-allege and incorporate by reference the foregoing allegations as if they were fully set out herein.

699. McKinsey's conduct has created a foreseeable, ongoing, significant, unlawful, and unreasonable interference with rights common to the general public, including the public health, welfare, safety, peace, comfort, and convenience of the Plaintiffs' and their State Classes' communities through its work in marketing, promoting, distributing, and selling massive doses of opioids throughout the states where Plaintiffs and their State Classes are located, fueling an opioid epidemic in those communities.

700. By its conduct, McKinsey has knowingly exacerbated an opioid epidemic that affects entire communities, municipalities, towns, school districts, and states, including in Plaintiffs' and their State Classes' communities. McKinsey knew, or reasonably should have

known, that opioids would be used, possessed and/or diverted unlawfully nationwide, including in and around Plaintiffs' and their State Classes' school district communities.

701. McKinsey's nuisance-creating conduct has been intentional and unreasonable and/or violated statutes imposing specific legal requirements for the protection of others.

702. As a direct and proximate result of McKinsey's intentional, unreasonable, and unlawful conduct, the Plaintiffs and their State Classes have suffered damages, including, but not limited to, expenditures to provide special education and other supports and services because of learning disabilities after children's damaging exposure in utero to opioids and direct costs to Plaintiffs and their State Classes for health care, disability benefits and workers' compensation.

703. By incurring pecuniary losses as a result of the increase in children born with NOWS who qualify for special education services due in part to McKinsey's conduct, the Plaintiffs and their State Classes have suffered harm that is different in kind to the harm suffered by the general public in their respective states.

704. In marketing of and efforts to boost sales of opioids in Plaintiffs' and their State Classes' communities, McKinsey violated federal law, including, but not limited to 18 U.S.C. § 2 and 21 U.S.C. § 846 with respect to Purdue's violation of 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.74.

705. McKinsey's conduct, if unabated, will continue to threaten the health, safety, and welfare of the students and staff and taxpayers of the schools of the Plaintiffs and their State Classes. The Plaintiffs and their State Classes have a clearly ascertainable right to abate this nuisance and its effects and seek relief from it.

C. <u>Negligence</u>

706. Plaintiffs re-allege and incorporate by reference the foregoing allegations as if they were fully set out herein.

707. McKinsey owed a duty of care to Plaintiffs, under which it was required to exercise reasonable not to cause or encourage the over-marketing, excessive distribution, over-prescribing, or sale of controlled substances, such as opioids, which were known at the time to be addictive and known at the time to be a threat to public health.

708. McKinsey breached its duty to exercise reasonable care by the conduct alleged in this Complaint.

709. McKinsey's conduct in breach of its duty caused loss and damage to Plaintiffs and the State Classes as alleged in this Complaint.

710. McKinsey's conduct as alleged was reckless and consciously indifferent to the consequences of its actions and inactions and caused loss and damage to Plaintiffs and the State Classes as alleged above.

711. As a direct and proximate result of its negligent conduct, McKinsey injured Plaintiffs and the State Classes, causing them damages.

D. Negligence: Failure to Warn

712. Plaintiffs re-allege and incorporate by reference the foregoing allegations as if they were fully set out herein.

713. McKinsey had a duty to exercise reasonable care in the marketing, promotion, distribution, and sale of opioids manufactured by Purdue, Rhodes and other opioid manufacturers that were marketed, promoted, distributed, and sold pursuant to McKinsey's plans. McKinsey had an ongoing relationship with each as alleged above as it assisted each in implementing its plans. McKinsey's duty to exercise reasonable care included the duty to warn adequately of the potential dangers associated with the use of Purdue's, Rhodes' and other opioid manufacturers' opioids as alleged above.

714. McKinsey knew, or in the exercise of reasonable care should have known, that opioids were highly addictive and inappropriate and unsafe for the treatment of chronic pain, and McKinsey knew, or in the exercise of reasonable care, should have known, the dangers associated with the use of opioids manufactured by Purdue, Rhode and the other opioid manufacturer it worked with.

715. McKinsey further knew, or in the exercise of reasonable care should have known, that widespread opioid addiction and abuse were harmful to men and women, including pregnant women, consuming opioids, their children, their friends, families and communities, and those, like Plaintiffs and the State Classes, which are responsible for paying for federally mandated

special education related services for children exposed to opioids in utero, as well as for health care costs associated with opioid addiction and abuse among their insureds.

716. Nonetheless, McKinsey unreasonably persisted in spreading misinformation and burying the truth about the safety and efficacy of opioids. McKinsey breached its duty and failed to take reasonable precautions to warn of the dangers of opioids in presenting opioids to the public in conjunction with Purdue, Rhodes, and other opioid manufacturers it worked with. Further, McKinsey was reckless and consciously indifferent to the consequences of its actions and inactions.

717. By failing to adequately warn the public, including prescribing doctors, Plaintiffs, and the State Classes of the dangers of opioids, McKinsey's conduct directly injured Plaintiffs and the State Classes. Because of McKinsey's misinformation campaign and failure to warn, Plaintiffs and the State Classes became obligated and have paid for federally mandated special education related services for children exposed to opioids in utero, will do so in the future, and has paid for or otherwise reimbursed the cost of unnecessary and/or inappropriate opioid prescriptions, as well as the health care costs associated, disability benefits, and workers' compensation for its employees.

718. As a consequence of McKinsey's breach of its duty to warn, which was a continuing duty, Plaintiffs and the State Classes have and will continue to suffer damages as alleged above.

719. McKinsey, Purdue, and other opioid manufacturers acted as a joint enterprise with the common purpose of deliberately failing to warn about the dangerous nature of prescription opioids for the purpose of increasing widespread distribution of opioids across the United States and increasing levels of addiction among millions of Americans.

720. McKinsey, Purdue, and other opioid manufacturers each had express or implied authority to act for all with respect to the means of creating and executing said marketing strategy to sell more prescription opioids by failing to warn of their dangerousness, thereby increasing the market share of prescription opioids and increase levels of addiction among Americans.

721. McKinsey, Purdue, and the other opioid manufacturers with whom McKinsey contracted each had an equal right of control over the direction of the joint enterprise to create and execute said marketing strategy.

722. As a result of McKinsey, Purdue, and other opioid manufacturers' conduct through a joint enterprise to create and executive a marketing strategy meant to flood the market with prescription opioids, Plaintiffs and the State Classes were injured and sustained damages.

E. Negligence: Violation of Statutory Duties

723. Plaintiffs re-allege and incorporate by reference the foregoing allegations as if they were fully set out herein.

724. Reasonably prudent prescription opioid manufacturers, and companies working with them, that had accepted the responsibilities to plan and implement marketing, promoting, distributing, and sales programs would not have misrepresented the risks of prescription opioids, nor overstated their benefits, and would have implemented basic controls—required under federal law—to prevent opioid diversion in the supply chain.

725. Instead, McKinsey planned and implemented the Purdue and Rhodes programs for the marketing, promotion, distributing, and selling of opioids that enabled Purdue and Rhodes to systematically violate statutory duties related to marketing opioids. These duties required Purdue and Rhodes to maintain effective controls against the diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders and to notify the DEA of suspicious orders. McKinsey thus enabled Purdue's and Rhodes' failure to meet the standard of care established by statute by promoting the flow of excessive quantities of prescription opioids into the communities in which Plaintiffs and the State Classes provide public education to the children of their states and employ residents of their states. *See, e.g.*, the Controlled Substances Act, 21 U.S.C. § 801 *et seq*; 21 C.F.R. § 1301.74(b).

726. Every registrant—including Purdue, Rhodes, and other opioid manufacturers—is charged to be vigilant in deciding whether a customer, be it a pharmacy, wholesaler, or end customer, can be trusted to deliver or use controlled prescription narcotics only for lawful purposes. Specifically, drug manufacturers and distributors are required to maintain "effective

control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."

727. McKinsey, in the ways alleged above, enabled Purdue, Rhodes, and other opioid manufacturers to breach their duties to exercise due care in the business of manufacturing, marketing, and wholesale distribution of prescription opioids by filling unreasonably suspect orders over and over again, without imposing proper controls to monitor, identify, investigate, limit, and report suspicious orders for opioids. The very purpose of these duties was to prevent the harms that have directly followed, including the diversion of highly addictive drugs for illegal and/or non-approved purposes. Thus, the McKinsey-designed-and-implemented marketing, promotion, distribution, and sales strategies enabled Purdue, Rhodes, and other opioid manufacturers to accomplish those violations and caused the ensuing harm.

728. Accordingly, McKinsey enabled Purdue, Rhodes, and other opioid manufacturers to breach their statutory and regulatory established duties of care that were designed specifically to prevent harms from the overuse, abuse, and misuse of controlled substances, including opioids, by failing to use reasonable care, to the significant harm of Plaintiffs and the State Classes. McKinsey was reckless and acted with conscious indifference to the consequences of its actions and inactions as alleged herein.

F. Civil Conspiracy

729. Plaintiffs re-allege and incorporate by reference the foregoing allegations as if they were fully set out herein.

730. McKinsey, Purdue, and other opioid manufacturers engaged in a civil conspiracy in their unlawful marketing of opioids and/or efforts to boost the sale of opioids into Plaintiffs' and the State Classes' school district's communities. McKinsey entered into an agreement with Purdue and other opioid manufacturers to increase the sales of OxyContin by unfair, deceptive, and unconscionable means, in violation of federal consumer protection and controlled-substances laws and the state laws of Plaintiffs' respective states.[445]

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[445] The state laws that McKinsey engaged in conspiracy to violate include but are not limited to: Kentucky Controlled Substances Act, Ky. Rev. Stat. Ch. 218A; West Virginia Uniform Controlled Substances Act, W.Va. Code § 60A-3-308; W.Va. Code §§ 60A-4-401 through 403; and W.Va. Code § 60A-8-1 *et seq.*;

731. McKinsey, Purdue, and other opioid manufacturers, engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful marketing of opioids and/or distribution of opioids into Plaintiffs' and the State Classes' communities.

732. McKinsey aided Purdue and other opioid manufacturers in unlawfully failing to act to prevent diversion and failing to monitor for, report, and prevent suspicious orders of opioids.

733. McKinsey aided Purdue and other opioid manufacturers in unlawfully marketing opioids in Plaintiffs' and the State Classes' communities in furtherance of that conspiracy.

734. McKinsey aided Purdue and other opioid manufacturers in unlawfully creating a public nuisance in Plaintiffs' and the State Classes' communities.

735. McKinsey's conspiracy and acts in furtherance thereof are alleged in detail in this Complaint, including, without limitation, in the public nuisance count and are specifically incorporated herein.

736. McKinsey's overt acts in furtherance of this conspiracy include, but are not limited to, designing and implementing marketing messages that:

a. Comprised untrue, false, unsubstantiated, and misleading marketing, directly and with and through third parties, in violation of 21 C.F.R. § 202.1(e), thereby causing opioid drugs to be misbranded;

b. Promoted other purported advantages of OxyContin and other prescription opioids, including but not limited to improved function and quality of life in violation of FDA regulations, including 21 C.F.R. § 202.1(e);

c. Promoted higher sales, higher dose sales, and targeted the highest volume prescribers of a highly abusable, addictive and dangerous drug;

d. Promoted higher dose OxyContin prescriptions, known to pose greater risks; and

e. Targeted the highest prescribing physicians, without addressing whether those prescribers may be engaged in abuse and diversion and should not be targeted, to induce them to increase prescriptions of OxyContin further.

737. The conspiracy was the product of an agreement with McKinsey, Purdue, and other opioid manufacturers operating in close collaboration. When McKinsey's role in the conspiracy threatened to be exposed, upon information and belief, it took efforts to conceal its participation by attempting to destroy inculpating emails and files.

738. McKinsey, Purdue, and other opioid manufacturers 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 caused the injuries alleged herein.

739. McKinsey, Purdue, and other opioid manufacturers acted with malice, purposely, intentionally, unlawfully and without a reasonable or lawful excuse.

740. McKinsey's conduct in furtherance of the conspiracy described herein was not mere parallel conduct. McKinsey encouraged Purdue, and other opioid manufacturers to act directly against their commercial interests in not reporting the unlawful practices of competitors to the authorities and in seeking to avoid "strict" regulation.

741. McKinsey's conspiracy as well as its actions and omissions in furtherance thereof caused the direct and foreseeable losses alleged herein.

742. McKinsey's actions demonstrated both malice and aggravated and egregious fraud. McKinsey engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. McKinsey's fraudulent wrongdoing was done with a particularly gross and conscious disregard.

743. McKinsey's misconduct alleged in this case was ongoing and persistent for many years.

744. McKinsey's misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a school district would reasonably expect to occur and is not part of the normal and expected costs of a public school district's existence.

G. <u>Aiding and Abetting</u>

745. Plaintiffs re-allege and incorporate by reference the foregoing allegations as if they were fully set out herein.

746. The pleading of a separate claim for aiding and abetting in certain states does not waive any claim for vicarious liability under aiding and abetting principles under the laws of any state. Plaintiffs and the State Classes reserve the right to establish joint and several liability under aiding and abetting principles.

747. McKinsey gave substantial assistance and/or encouragement to Purdue, Rhodes, the Sacklers, and other opioid manufacturers regarding conduct McKinsey knew to be tortious and/or in violation of a duty owed by Purdue, Rhodes, the Sacklers, and other opioid manufacturers to third persons, including Plaintiffs and the State Classes. McKinsey assisted and encouraged Purdue over many years to commit unlawful acts relating to the sales and marketing of Purdue's opioid products that McKinsey knew to be misleading and in violation of a reasonable standard of care. McKinsey gave substantial assistance and/or encouragement to Purdue to use unlawful means to commit lawful acts as part of these marketing efforts and sales.

748. Further, McKinsey gave substantial assistance and/or encouragement to Purdue to take actions that violated state laws, including but not limited to public nuisance and statutory prohibitions through McKinsey's misleading and predatory marketing campaign.

749. McKinsey and Purdue knowingly made or caused to be made false or misleading representations as to the characteristics, ingredients, uses, and benefits of opioids, generally, and Purdue's opioids, specifically, by downplaying the risks of addiction and abuse, overstating the efficacy, and misrepresenting the medical necessity of opioids, generally, and Purdue's opioids, specifically.

750. McKinsey and other opioid manufacturers it assisted knowingly made or caused to be made false or misleading representations as to the characteristics, ingredients, uses, and benefits of opioids, by downplaying the risks of addition and abuse, by overstating the efficacy, and by misrepresenting the medical necessity of opioids.

751. McKinsey acted with intent to facilitate the spread of misleading information by Purdue and other opioid manufacturers, specifically with regard to the misrepresentations about the addictiveness of opioids in its marketing and sales efforts.

752. McKinsey, Purdue, Rhodes, the Sacklers, and other opioid manufacturers acted jointly in furtherance of the conspiracy.

753. McKinsey, Purdue, and the Sacklers agreed to deploy unlawful sales and marketing tactics to achieve their shared objective of maximizing revenue of a closely held company.

754. McKinsey's support was a substantial factor in causing harm to third persons, including Plaintiffs and the State Classes.

X. PRAYER FOR RELIEF

Plaintiffs, individually and on behalf of the State Classes they seek to represent, respectfully pray for the following relief:

1. An order certifying the State Classes as defined above, appointing Plaintiffs as the representatives of their State Classes, and appointing their counsel as Class Counsel;

2. An award of all economic, monetary, actual, consequential, compensatory, and punitive damages available under the law, including trebling of economic injury;

3. An award of all equitable relief requested herein;

4. Injunctive/equitable relief;

5. An award of reasonable litigation expenses and attorneys' fees;

6. An award of pre- and post-judgment interest, to the extent allowable; and

7. Such other further relief that the Court deems reasonable and just.

XI. JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

Dated: December 6, 2021

Respectfully submitted,

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