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8	UNITED STAT	'ES DISTRICT COURT
9	NORTHERN DIS	TRICT OF CALIFORNIA
10		
11	IN RE: MCKINSEY & CO., INC. NATIONAL PRESCRIPTION OPIATE	Case No. 21-md-02996-CRB (SK)
12 13	CONSULTANT LITIGATION This Document Relates to:	CONSOLIDATED CLASS ACTION COMPLAINT (THIRD PARTY PAYORS)
15 14	ALL THIRD PARTY PAYOR ACTIONS	REDACTED
15	ALL THIRD FARTT FATOR ACTIONS	JURY TRIAL DEMANDED
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I.

PREAMBLE

The undersigned counsel of record for Third Party Payor ("TPP") Plaintiffs submit this 2 Consolidated Class Action Complaint (Third Party Payors). This is a consolidated class action 3 complaint that supersedes any underlying complaints filed by the TPP Plaintiffs whose claims are 4 incorporated in this Complaint. This consolidated Complaint is filed directly in this District for all 5 purposes including pretrial proceedings and trial and does not have any transferor or transferee 6 court for the purposes of 28 U.S.C. § 1407. 7

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II.

INTRODUCTION

1. For more than two decades, the opioid crisis has raged across this country. An 9 opioid-related public health emergency was declared by the President in 2017. Last year was the 10 worst on record, with drug overdoses soaring nearly 30%.¹ Today, there are increasingly few 11 Americans whose lives have not been affected by the consequences of opioid dependency, 12 addiction, and overdoses. 13

2. McKinsey is a management consulting firm with operations across the globe. It 14 played a central role in the unfolding, propagation, and exploitation of the opioid crisis by 15 advising multiple opioid manufacturers and other industry participants how to sell as many 16 opioids as conceivably possible. Knowing that its clients' products were highly addictive, 17 ineffective, and unsafe for the treatment of long-term chronic pain, non-acute pain, and non-18 cancer pain, McKinsey developed a singular focus on increasing opioid sales, no matter the 19 resultant cost to society. McKinsey did this for well over a decade, despite knowing full well the 20 risk to public health and safety and the widespread economic harm from developing and 21 implementing the transformation of strictly-controlled substances into top-selling blockbuster 22 drugs. 23

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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 25 make as much money as possible. They all did. This relentless drive to increase sales and create 26

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¹ Betsy McKay, "U.S. Drug-Overdose Deaths Soared Nearly 30% in 2020, Driven by Synthetic Opioids," Wall Street 28 Journal, July 14, 2021, available at: https://www.wsj.com/articles/u-s-drug-overdose-deaths-soared-nearly-30-in-2020-11626271200.

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1 2 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.

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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. 9 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 10 keystone of American corporate culture," and is "credited with taking a fledgling industry and 11 setting its course not only as to the kinds of services it could sell but also the standards it must 12 uphold for its work to be respected."³ A lawyer by trade, Bower stressed that management 13 consulting should be seen as an emergent profession, akin to the law or accounting, with 14 15 obligations to clients and to the broader society that extend beyond the mere commercial. 6. Bower instilled an ethos at McKinsey that has been reinforced throughout the 16 17 decades as a core value of the firm: "Deliver the bad news if you must, but deliver it properly."⁴ 18 Bower's principles, and the values he imparted within McKinsey, are said to guide the firm to the 19 present day. "In many ways, certainly in spirit and soul, Marvin continued to lead it after he 20 retired, and he leads it still," eulogized Rajat Gupta, McKinsey's then-global managing partner, at

- 21 Bower's funeral in 2003.⁵
- 22

23 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.

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

²⁵ 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 26 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 27 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 28 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.

1	7. This case is, in large part, about the firm's failure to adhere to Bower's simple,
2	foundational tenet. It arises instead from the firm's steadfast and continual work to maximize
3	opioid sales in partnership with numerous clients during the pendency of the worst man-made
4	epidemic in modern medical history. It is about McKinsey never delivering the "bad news" of
5	opioids' devastating impact on Plaintiffs and the public, properly or otherwise, and instead
6	looking the other way for money.
7	8. When it came to opioids, McKinsey did far more than just give advice. Not only
8	did it suggest courses of action that its clients should adopt, the firm remained in place and
9	worked collaboratively alongside its clients to actually implement McKinsey's recommendations
10	to achieve objectives jointly identified by the clients and McKinsey. McKinsey stood alongside
11	its clients in the arena doing the deeds.
12	9. The deceptive marketing strategies that McKinsey and its clients invented,
13	developed, deployed, and continually refined for years to expand the market for opioids are
14	foundational to the epidemic.
15	10. McKinsey worked hand-in-hand with major opioid manufacturers, including
16	Purdue Pharma L.P., Endo Pharmaceuticals, ⁶ Johnson & Johnson, ⁷ and Mallinckrodt ⁸ for years.
17	At the same time, McKinsey advised other participants in the opioid supply chain, including
18	distributors, pharmacies, and even regulators.
19	11. In particular, McKinsey advised the Sackler family and their company, Purdue, for
20	years while Purdue aggressively marketed OxyContin, widely viewed as the taproot of the opioid
21	
22	Consistent with Gupta's efforts to monetize McKinsey's consulting business in ways previous firm
23	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." <i>Id.</i> at 266.
24	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 <i>reputation</i> by historically advising <i>only</i> "blue chip" companies "at the top of the
25	corporate pyramid." <i>Id.</i> 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
26	its <i>imprimatur</i> , in addition to its services, for money. McKinsey's work with opioid manufacturers began under Gupta's leadership.
27	⁶ "Endo Pharmaceuticals" or "Endo" refers to Endo Health Solutions Inc., Endo International plc, and Endo Pharmaceuticals Inc., collectively.
28	 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.
	Mannickrout refers to Mannickrout LLC and Mannickrout pic, together.

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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.

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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.

11 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
representatives spent in the field increasing opioid sales and prioritizing OxyContin in incentive
compensation targets.⁹

18 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
20 no longer bound by its constraints. Within months, the Sacklers tasked McKinsey with
21 transforming Purdue's approach to OxyContin sales in order to extract as much money as
22 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
- 26
- 27 ⁹ PPLPC012000437346

^{28 &}lt;sup>10</sup> OxyContin, like any branded pharmaceutical, is subject to eventual patent expiration and competition from generic opioid manufacturers.

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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
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
¹¹ See Michael Forsythe and Walt Bogdanich, <i>McKinsey Advised Purdue Pharma How to 'Turbocharge' Opioid</i> Selag Languit Sang N.Y. Timog Feb. 1, 2010, available at https://www.putimog.com/2010/02/01/husingge/avardue
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 <i>Citizenship in a Republic</i> , a speech delivered by Theodore Roosevelt at the <i>Sorbonne</i> 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
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
<i>in a Republic</i> 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. <i>See</i> Dominic Barton <i>In the</i>
<i>Arena: Leadership in an Age of Disruption,</i> October 17, 2017, <i>available at:</i> 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.

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

3

3 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 4 efforts to increase opioid sales for years. It continued this work unabated and with alacrity despite 5 6 events as stunning as Purdue's 2007 guilty plea for misbranding OxyContin, Purdue's 2015 7 settlement with the State of Kentucky, and numerous other enforcement actions related to opioid 8 sales and marketing by McKinsey clients. Through it all, McKinsey remained steadfast in its 9 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 10 11 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 12

13

III. JURISDICTION AND VENUE

20. This Court has federal question subject matter jurisdiction arising out of Plaintiffs' RICO claims pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1961, et seq. and has supplemental jurisdiction over the Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367. This Court also has jurisdiction over this action pursuant to 28 U.S.C. §1332(d) because this is a class action in which the aggregate amount in controversy exceeds \$5,000,000 (exclusive of interest and costs), the number of the members of the class exceeds 100, and at least one member of the putative class is a citizen of a state different from that of one of the Defendants.

21 22 21. This Court has personal jurisdiction over McKinsey because it conducts business in the State of California, purposefully directs or directed its actions toward California, and/or has the requisite minimum contacts with California necessary to permit the Court to exercise

24 25

 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").

jurisdiction. This Court also has personal jurisdiction over McKinsey because Plaintiffs' claims 1 2 arise out of, or relate to, McKinsey's contacts with the State of California. 3 22. At all times relevant hereto, McKinsey engaged in the business of researching, designing, and implementing marketing and promoting strategies for various opioid 4 manufacturers, including Purdue, that were intended to be, and were, implemented in, or whose 5 6 implementation had a substantial and intended effect in California. 7 23. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2). 8 IV. PARTIES 9 Α. **Third Party Payor Individual and Representative Plaintiffs** 24. Plaintiff Teamsters Local 404 Health Services and Insurance Plan ("Teamsters 10 11 Local 404 HSIP") is a health and welfare benefit fund with its principal place of business at 115 Progress Avenue, Springfield, Massachusetts, 01104, and is involved in the business of providing 12 13 health benefits for covered lives. Teamsters Local 404 HSIP is a multi-employee employee welfare benefit plan, within the meaning of the Employee Retirement Income Security Act, 29 14 15 U.S.C. § 1001(2), and § 1002(37). Teamsters Local 404 HSIP paid or incurred costs for prescription opioid drugs manufactured, marketed, sold, or distributed by Purdue and other 16 17 Opioid Marketing Enterprise Defendants (defined in the RICO claim), for purposes other than 18 resale (intended for consumption by its covered participants, their dependents, and covered 19 retirees), and incurred costs for treatment related to the misuse, addiction and/or overdose of 20 opioid drugs during the Class period. Given its participants' history of opioid purchases and need for medical care resulting from opioid abuse or addiction, Teamsters Local 404 HSIP anticipates 21 22 that it will continue to purchase and/or provide reimbursement for opioids and/or incur costs for 23 opioid-related treatment in the foreseeable future. 25. Plaintiff District Council 37 Benefits Fund Trust ("DC 37") is a non-profit health, 24 25 self-funded welfare benefit plan that funds prescription drugs to its covered public sector

employees, retirees and their families (all referred to as Members in this Complaint) through its
subordinate trust, District Council 37 Health & Security Plan Trust, which administers DC 37's

28 prescription drug plan. Its principal place of business is in New York, New York at 55 Water

Street, 22nd Floor. DC 37 is New York City's largest public employee union. DC 37's health and 1 2 welfare benefit plan covers approximately 150,000 active union members as well as over 50,000 3 retirees and their families— totaling over 300,000 lives. DC 37 includes 51 local unions, 4 representing public sector employees serving in thousands of unique jobs from Accountants to 5 Zoo Keepers. Members covered by DC 37's benefit plan work in almost every agency in New 6 York City including but not limited to the City's police and fire departments, hospitals, schools, 7 libraries, social service centers, water treatment facilities, and city colleges. DC 37 provides 8 supplemental health benefits, including a prescription drug benefit to its members, retirees, and 9 their families. During the class Period and throughout the United States, DC 37 indirectly purchased, paid, and reimbursed for prescription opioid drugs manufactured, marketed, sold, or 10 11 distributed by Purdue and other Opioid Marketing Enterprise Defendants intended for consumption by its members, retirees, and their families and for substance abuse treatment. Given 12 13 its plan members' past purchases of opioids, DC 37 anticipates that it will continue to purchase 14 and/or provide reimbursement for opioids and for substance abuse treatment in the future. 15 26. Plaintiff Cleveland Bakers and Teamsters Health & Welfare Fund ("Cleveland Fund") is a multi-employer trust fund established to provide health and welfare benefits to 16 17 collectively bargained members represented by Bakers' Union Local No. 19 and Teamsters Local 18 No. 507. Cleveland Fund's principal place of business is located at 9665 Rockside Road, Valley 19 View, Ohio 44125. Cleveland Fund paid or incurred costs for prescription opioid drugs 20 manufactured, marketed, sold, or distributed by Purdue and the other Opioid Marketing 21 Enterprise Defendants, for purposes other than resale (intended for consumption by its covered 22 participants, their dependents, and covered retirees), and incurred costs for treatment related to 23 the misuse, addiction and/or overdose of opioid drugs during the class period. Given its participants' history of opioid purchases and need for medical care resulting from opioid abuse or 24 25 addiction, Cleveland Fund anticipates that it will continue to purchase and/or provide reimbursement for opioids and/or incur costs for opioid-related treatment in the foreseeable 26 future. 27

27. Plaintiff International Union of Operating Engineers Stationary Engineers Local 1 2 39 Health and Welfare Trust Fund ("Local 39") is a health and welfare benefit fund with its 3 principal place of business at 337 Valencia Street, San Francisco, California, 94103, and is 4 involved in the business of providing health benefits for covered lives. Local 39 is a multi-5 employer employee welfare benefit plan, within the meaning of the Employee Retirement Income 6 Security Act, 29 U.S.C. § 1001(2), and § 1002(37). Local 39 paid or incurred costs for 7 prescription opioid drugs manufactured, marketed, sold, or distributed by Purdue and other 8 Opioid Marketing Enterprise Defendants, for purposes other than resale (intended for 9 consumption by its covered participants, their dependents, and covered retirees), and incurred 10 costs for treatment related to the misuse, addiction and/or overdose of opioid drugs during the 11 Class period. Given its participants' history of opioid purchases and need for medical care resulting from opioid abuse or addiction, Local 39 anticipates that it will continue to purchase 12 13 and/or provide reimbursement for opioids and/or incur costs for opioid-related treatment in the foreseeable future. 14

15

B. <u>Defendants</u>

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

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

23 Wilmington, DE 19808

30. 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

1	31. Defendant McKinsey & Company, Inc. Washington D.C. is a Delaware
2	corporation with its principal place of business is located at 711 Third Avenue, New York, NY
3	10017. It may be served with process via its registered agent, Corporation Service Company, 251
4	Little Falls Drive, Wilmington, DE 19808.

32. 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."

- 33. McKinsey a is global management consultancy with offices in over 130 cities in 12 13 65 countries, including the following United States cities: Atlanta, GA; Austin, TX; Houston, TX; 14 Dallas, TX; San Francisco, CA; Los Angeles, CA; Redwood City, CA; Boston, MA; Charlotte, 15 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, 16 17 WA; St. Louis, MO; Stamford, CT; Waltham, MA; and Washington, D.C. 18 34. McKinsey is registered to do business in all fifty states.
- 19

20

V. FACTUAL ALLEGATIONS APPLICABLE TO ALL CLAIMS

A. <u>The Opioid Crisis</u>

35. 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.

36. 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.

3 37. In 1827, the pharmaceutical company Merck began large-scale production and 4 commercial marketing of morphine. During the American Civil War, field medics commonly 5 used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left 6 with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the 7 United States, and many doctors prescribed opioids solely to prevent their patients from suffering 8 withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in 9 1911: "The habit has this nation in its grip to an astonishing extent Our prisons and our 10 hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and 11 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." 12

38. 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.

39. 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.

40. 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.

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- 41. Throughout the twentieth century, pharmaceutical companies continued to develop 2 prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally 3 produced in combination with other drugs, with relatively low opioid content.
- 4 42. 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: 5 6 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin 7 delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen 8 times that.

9 43. 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 10 11 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 12 13 Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic 14 pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid 15 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 16 17 breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The 18 opioid manufacturers promoted the idea that pain should be treated by taking long-acting opioids 19 continuously and supplementing them by also taking short-acting, rapid-onset opioids for 20 episodic or "breakthrough" pain.

44. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As 21 22 tolerance increases, a patient typically requires progressively higher doses in order to obtain the 23 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 24 25 respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term 26 opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

27 45. Discontinuing opioids after more than just a few weeks of therapy will cause most 28 patients to experience withdrawal symptoms. These withdrawal symptoms include severe anxiety,

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1	nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and
2	other serious symptoms, which may persist for months after a complete withdrawal from opioids,
3	depending on how long the opioids were used.
4	46. As one doctor put it, the widespread long-term use of opioids "was an experiment
5	on the population of the United States. It wasn't randomized, it wasn't controlled, and no data
6	was collected until they started gathering death statistics."
7	47. The results were devastating, and the nation continues to reach ever grimmer
8	milestones. In 2020, drug-overdose deaths in the United States soared nearly 30%, reaching all-
9	time highs. ¹⁵
10	B. <u>Marketing and the Origins of the Opioid Crisis</u>
11	48. OxyContin, manufactured by Purdue Pharma L.P., was introduced to the market in
12	1996. Within six years of its introduction, the increasingly widespread misuse and abuse of
13	OxyContin and similar opioids had drawn the attention of the United States Senate.
14	49. Two decades ago, Dr. Art Van Zee traveled from the rural coal town of St.
15	Charles, in the southwestern corner of Virginia, to Washington D.C. to provide testimony to the
16	United States Senate Committee on Health, Education, Labor and Pensions. On February 12,
17	2002, that Committee held a hearing entitled "Examining the Effects of the Painkiller OxyContin,
18	Focusing on Federal, State, and Local Efforts to Decrease Abuse and Misuse of this Product
19	While Assuring Availability for Patients Who Suffer Daily from Chronic Moderate to Severe
20	Pain." ¹⁶
21	50. Today, OxyContin—and the methods used to sell it—is widely seen as a principal
22	taproot of the opioid crisis. In those early days of the unfolding opioid epidemic, Dr. Van Zee's
23	medical practice in St. Charles put him in a position to offer informed, first-hand observations of
24	the toll that the pharmaceutical industry's efforts to market opioids was exacting from his
25	community. He testified:
26	¹⁵ Betsy McKay, "U.S. Drug-Overdose Deaths Soared Nearly 30% in 2020, Driven by Synthetic Opioids," <i>Wall</i>
27	Street Journal, July 14, 2020, available at: https://www.wsj.com/articles/u-s-drug-overdose-deaths-soared-nearly-30-

in-2020-11626271200.
 ¹⁶ A transcript of the hearing is *available at*: https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/ CHRG-107shrg77770.htm

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2	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
3	epidemic of drug abuse and addiction that we have seen the last 3 years with
4	OxyContin. Contrary to what is sometimes portrayed in the media as long-term addicts switching to the drug <i>du jour</i> , what we have seen for the most part is
5	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. ¹⁷
6	51. Further, Dr. Van Zee identified the sales and marketing practices of the
7	pharmaceutical industry when selling controlled substances as a primary cause of the problem:
8	
9	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
10	with physician misprescribing and overprescribing of this drug. Second, this epidemic has been a vicious indicator of the alarming degree of prescription drug
11	abuse in our society. Third and perhaps the one closest to this committee and the
12	FDA is that the promotion and marketing of OxyContin by Purdue Pharma has played a major role in this problem. ¹⁸
13	52. Five years after Dr. Van Zee's testimony and eighty miles from his hometown of
14	St. Charles, United States Attorney John Brownlee announced in Abingdon, Virginia, the guilty
15	plea of the Purdue Frederick Company, the parent of Purdue Pharma, L.P., relating to the
16	misbranding of OxyContin. Brownlee stated, "Even in the face of warnings from health care
17	professionals, the media, and members of its own sales force that OxyContin was being widely
18	abused and causing harm to our citizens, Purdue, under the leadership of its top executives,
19	continued to push a fraudulent marketing campaign that promoted OxyContin as less addictive,
20	less subject to abuse, and less likely to cause withdrawal. In the process, scores died as a result of
21	OxyContin abuse and an even greater number of people became addicted to OxyContin; a drug
22	that Purdue led many to believe was safer, less subject to abuse, and less addictive than other pain
23	medications on the market."
24	53. Two years later, in 2009, Dr. Van Zee published <i>The Promotion and Marketing of</i>
25	OxyContin: Commercial Triumph, Public Health Tragedy in the American Journal of Public
26	Health.
27	
28	¹⁷ See https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm

^{28 &}lt;sup>17</sup> See https://www.govinfo.gov/content/pkg/CHRG-107shrg7770/html/CHRG-107shrg77770.html ¹⁸ Id. (emphasis added).

1 54. In his paper, Dr. Van Zee stated the matter plainly: "Compared with noncontrolled 2 drugs, controlled drugs, with their potential for abuse and diversion, pose different public health risks when they are overpromoted and highly prescribed."¹⁹ In one sense, Dr. Van Zee's 3 observation is not particularly novel. Indeed, it approaches tautology: controlled substances are 4 5 *controlled* precisely because they should not be sold to maximize volume and profits. This did not 6 prevent McKinsey and Purdue from marketing Purdue's opioids full hilt, however. By 2004, 7 "OxyContin had become the most prevalent prescription opioid in the United States."²⁰

8 55. Dr. Van Zee identified the three principal marketing tactics Purdue employed as a 9 source of OxyContin misuse and abuse-the exact tactics McKinsey identified and promoted-10 and suggested that regulation may be appropriate to curtail its use. The first was the use of 11 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 12 13 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 14 the physicians who were the highest prescribers for opioids across the country."²¹ 15

56. The second tactic was the use of incentive compensation structures to encourage 16 17 the salesforce to sell ever more prescriptions of OxyContin. Bonuses at Purdue were "uncapped," 18 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 19 20 more you make. "A lucrative bonus system encouraged sales representatives to increase sales of 21 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."²² 22

salesforce placed to prescribers. "From 1996 to 2000, Purdue increased its internal sales force

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26 ¹⁹ 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/ 27 PMC2622774/pdf/221.pdf

- 20 *Id*. 28
 - 21 *Id*. ²² Id.

57.

The third tactic was to increase the overall number of individual calls that the

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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."²³

58. 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."²⁴

59. 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.

11 60. 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 12 13 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 14 15 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 16 17 opioid industry participants to maximize the return on investment in sales and marketing efforts 18 for numerous opioid products, and did so contemporaneously. Despite the fact that the Schedule 19 II controlled substances were designed for a small, narrowly defined group—patients with acute, 20 terminal, or cancer-related pain-McKinsey's goal, in all instances, was to sell as many pills as 21 conceivably possible.

22

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

61. 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.

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- $\begin{array}{c|c} 28 & 23 Id. \\ & 24 Id. \end{array}$

62. 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."²⁵

5 63. Broadly speaking, there are two schools of management consulting. "Strategy" 6 consulting provides big-picture advice to clients about how they approach their business: how the 7 business is structured, which markets to compete in, potential new business lines, and mergers 8 and acquisitions. The strategy consultant provides a plan to the client that the client may choose 9 to adopt or not.

64. "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.

15 65. In his 1982 *Harvard Business Review* article entitled "Consulting is More Than
16 Giving Advice," Professor Arthur Turner of the Harvard Business School described the then17 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.²⁶

- 23 24
- 66. Although McKinsey has historically been regarded as a "strategy" consulting firm,
- 25 by the time it was working with Purdue, implementation services were a core component of the
- ²⁶ suite of services that McKinsey provided within the "transformational relationship" it developed

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 ²⁷ arthur Turner, *Consulting is More Than Giving Advice*, Harvard Business Review, September 1982, *available at:* 28 https://hbr.org/1982/09/consulting-is-more-than-giving-advice
 ²⁶ Id.

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1 with its clients.²⁷ Indeed, writing in 2013, Harvard Business School Professor Clayton 2 Christensen observed the decline in "pure" strategy work performed by consultants, as the 3 industry sought to diversify its income streams by offering implementation and other services to 4 clients. "For example, at traditional strategy-consulting firms, the share of work that is classic 5 strategy has been steadily decreasing and is now about 20%, down from 60% of 70% some 30 6 years ago."28 7 67. When partnering with clients, a core component of the McKinsey relationship is 8 discretion. "The basis of any client relationship with the firm is trust. Companies share their most

9 competitive secrets with McKinsey with the understanding that confidentiality is paramount.
10 McKinsey consultants aren't even supposed to tell their own spouses about their client work."²⁹
11 McKinsey recognizes it must have its clients' trust and make confidentiality "paramount," as
12 "[c]ompanies share their most competitive secrets with McKinsey" for McKinsey to do its
13 work.³⁰

14 68. During the implementation phase, McKinsey essentially bonds with the client.
15 Describing McKinsey's approach to implementation, one McKinsey consultant stated, "In some
16 of the most successful engagements I've seen, you can't even tell the difference between a

17 McKinsey team member and one of our clients because we working that cohesively together."³¹

69. 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."³²

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 ²⁷ 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).
 ²⁸ Clayton Christensen, Dina Wang, and Derek van Bever, "Consulting on the Cusp of Disruption," *Harvard*

 ²⁸ 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
 ²⁹ McDonald, *The Firm*, Pg. 308.

³⁰ *Id.* at 308.

²⁸ \int_{32}^{31} McKinsey on Implementation, April 30, 2017, *available at* https://www.youtube.com/watch?v=rEQOGVpl9CY



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1

1. <u>McKinsey's Long-Term Partnership with the Pharmaceuticals</u> <u>Industry</u>

374. Today, McKinsey's website explains "How We Help Clients" in the4pharmaceuticals industry: "Helping clients maximize commercial value by assisting with product5launch, marketing, sales, and market access."6pharmaceutical industry, from manufacturers to distributors and pharmacies. It often does so7contemporaneously. For instance, McKinsey might advise multiple opioid manufacturers on the8sales and marketing of competing branded opioid products.

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

12 76. For example, McKinsey pitched its services to Purdue on the basis that it was able
13 to "*bring examples from other successful companies*" and perform "detailed analytics."³⁶

14

2. The McKinsey Pharmaceuticals and Medical Products Practice Group

15 77. Like most management consulting companies, McKinsey organizes itself into16 practice groups that specialize in a given industry.

17 78. McKinsey has long maintained a Pharmaceuticals and Medical Products ("PMP")
18 industry practice group dedicated to working with pharmaceutical companies. In 2004, when
19 McKinsey's relationship with Purdue began, the PMP group was led by Michael Pearson. Pearson
20 worked for McKinsey for twenty-three years and was a member of the firm's shareholder council
21 (McKinsey's equivalent of a board of directors) in addition to leading PMP before departing
22 McKinsey in 2008 to helm Valeant Pharmaceuticals.³⁷

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- 24 25

 ³⁵ https://www.mckinsey.com/industries/life-sciences/how-we-help-clients/commercial
 ³⁶ PPLPC021000601208 (emphasis added).

 ³⁷ 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

²⁸ Notably, Rob Rosiello, a McKinsey partner who was a Director of Client Services (or "DCS") of the Purdue 28 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.

79. Pearson stated: "At McKinsey pharmaceuticals was one of our biggest industry
 groups."³⁸ 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."³⁹

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

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."

17 82. That same year, the PMP group published a report entitled "Death of a Sales
18 Model, or Not: Perspectives on the Evolution of Pharmaceutical Field Based Selling."⁴⁰ In it,
19 McKinsey partner Laura Moran co-authored a segment called "The Few, The Proud, The Super20 Productive: How a 'smart field force' can better drive sales." In the segment, Moran and her co21 authors described various ways a pharmaceutical company could optimize its sales force. Moran
22 worked on the Purdue account, where the strategies outlined in her article were incorporated into
23 Project Turbocharge two years later.

 ³⁸ 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

 ³⁹ 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

⁴⁰ "Death of a Sales Model, or Not," Pharmaceutical and Medical Product Practice, McKinsey, available at

²⁸ 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

83. 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."⁴¹ 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."⁴²

8 84. McKinsey has long considered itself a "leadership factory" for good reason.⁴³
9 Nowhere is this more apparent than the pharmaceutical industry, where, thanks to PMP's efforts
10 under Pearson's leadership, McKinsey continues to reign as the dominant management
11 consultant.

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

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 86.
 Rajiv de Silva, for instance, was appointed CEO of Endo Pharmaceutical in

16 March 2013. Endo's two top-selling drugs were pain medications. Endo—and de Silva,

17 individually—have been named in multiple lawsuits related to the ongoing opioid crisis.

18 Previously, de Silva worked with Pearson in a leadership position within PMP at McKinsey

19 before joining Rob Rosiello, a former McKinsey partner, and Pearson at Valeant.⁴⁴ McKinsey

20 advised Endo on its opioid business.

87. 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

^{26 &}lt;sup>41</sup> See https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/how-we-help-clients/commercial ⁴² Id.

⁴³ 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

^{28 &}lt;sup>44</sup> 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

(formerly SpecGX LLC), which is the division that sold generic opioids. McKinsey advised
 Mallinckrodt on its opioid business.

88. Teva Pharmaceuticals,⁴⁵ 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.⁴⁶

89. 9 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 10 year.⁴⁷ By 2011, Teva had acquired Cephalon, Inc., another manufacturer of opioids, as "a core 11 part of [Teva's] strategy" of "growth through acquisitions."⁴⁸ Befitting the pattern, Cephalon had 12 13 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 14 15 job as "an advisor on life sciences regulatory and compliance matters to the international consulting firm McKinsey & Company, Inc."49 16

17 90. McKinsey has ties to another notable opioid industry combination: the 2012
18 acquisition of Actavis, Inc.by Watson Pharmaceuticals, Inc. ("Watson") for €4.25 billion. In the
19 aftermath of the acquisition of the large European pharmaceutical company, Watson created a

- 20 "Global Integration Management Office" reporting directly to its CEO, Paul Bisaro, to focus "on
- 21 22
- ⁴⁵ "Teva Pharmaceuticals" or "Teva" refers to Teva Pharmaceutical Industries Ltd. and Teva
 Pharmaceuticals USA, Inc., together.
- ⁴⁶ 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
- 26 McKinsey's in-house hedge fund is discussed further, below.

⁴⁷ Form 20-F dated December 31, 2012, Teva Pharmaceutical Industries Limited, *available at* https://www.sec.gov/Archives/edgar/data/818686/000119312513050510/d450498d20f.htm

 48 *Id*.

^{28 &}lt;sup>49</sup> "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

planning and implementing the integration of Actavis."⁵⁰ In order to achieve this critical task, 1 2 Watson hired Marc Lehnen: "We were very pleased to recruit Marc from McKinsey & Company, 3 Inc. to lead the Integration Management Office. Marc has years of experience in the generic industry and knows our culture and way of operating."⁵¹ Notably, the press release indicates that 4 5 McKinsey was already advising Watson regarding the acquisition: "Although Marc does not 6 formally join our Company until July, he will nevertheless be involved in the integration planning 7 during this interim period."52

8

Allergan,⁵³ another opioid manufacturer and defendant in the nationwide opioid 91. 9 litigation, has also relied on McKinsey as a source of management candidates. McKinsey Senior 10 Adviser Christopher J. Coughlin joined Allergan's board in 2014 and remains there today.

92. 11 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. 12 13 White began his career at McKinsey around 1980.

93. As the preceding paragraphs make clear, McKinsey was in a truly unique position: 14 15 given its dominance of pharmaceutical management consulting through PMP, practically all opioid industry participants were its clients. And those same clients routinely hire McKinsey 16 17 consultants to leadership positions within their companies. While advising multiple industry 18 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 19 confidentiality is paramount."⁵⁴ 20

94. Because of its client relationships, McKinsey was, quite literally, the sole 21 repository on Earth of this collective knowledge of industry-wide tactics regarding the sales and 22 23 marketing of opioids, and the outcomes thereof. This unique collection of knowledge and

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⁵² Id. (emphasis added).

⁵⁰ "Watson Announces Formation of Global Integration Management Office to Support ending Actavis Acquisition," 26 PR Newswire, May 9, 2012, available at https://www.prnewswire.com/news-releases/watson-announces-formationof-global-integration-management-office-to-support-pending-actavis-acquisition-150755565.html 27 ⁵¹ *Id*.

²⁸ ⁵³ Allergan is part of the same corporate family as Actavis and Watson.

⁵⁴ McDonald, *The Firm*, Pg. 308.

1 expertise made McKinsey a hub: even if any two given industry participants did not know what 2 each other was doing, McKinsey knew exactly what *both* were doing because both were clients. 3 95. McKinsey's relationships and influence carry far beyond the manufacturers. For instance, current McKinsey director Nancy Killefer has also been an independent director of 4 5 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 6 7 President of Corporate Strategy, was previously an associate principal at McKinsey, where he 8 worked for nine years. Michele Holcomb, Cardinal's current Executive Vice President, Chief 9 Strategy and Business Development Officer, was a partner in the Global Pharmaceutical Practice at McKinsey. 10 96. McKinsey populates the "strategy" positions at the other opioid distributors as 11 well. At AmerisourceBergen, the "Director of Corporate Development and Strategy" was hired 12 13 away from McKinsey, where she had previously been a senior associate. AmerisourceBergen's 14 Executive Vice President and Chief Strategy Officer had previously been a partner at McKinsey. 97. 15 At McKesson Corporation ("McKesson"), another McKinsey client, the President of McKesson Specialty Health and, previously Vice President of Corporate Strategy, was Marc 16 17 Owen. "Prior to joining McKesson, Owen was a senior partner at McKinsey, advising 18 pharmaceutical manufacturers, healthcare providers, distributors and technology companies, including McKesson, for more than a decade."55 After Owen was promoted in 2012, McKesson 19 20 hired yet another Vice President of Corporate Strategy away from McKinsey. 98. In short, one way McKinsey adds value for a client is by knowing what all of its 21 22 competitors are doing. It possesses a greater body of knowledge about any given industry in 23 which it advises multiple participants than any individual participant does itself. 24 3. The Transformational Relationship 99. 25 McKinsey has long touted the notion of a "transformational relationship." It is the 26 goal of every client relationship McKinsey develops and, McKinsey argues, the best way to 27 ⁵⁵ "Marc Owen Appointed President of McKesson Specialty Health," McKesson, January 31, 2012, available at 28 https://www.mckesson.com/about-mckesson/newsroom/press-releases/2012/marc-owen-appointed-president-ofmckesson-specialty-health/ (emphasis added)

1 extract value from a client's use of McKinsey's services. McKinsey is not a one-off seller of 2 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.⁵⁶ 3 4 100. At its core, the "transformational relationship" is *long-term*. It is the antithesis of a 5 one-off contract wherein McKinsey performs one discreet project for a client and then concludes 6 its business. Rather, "once McKinsey is inside a client, its consultants are adept at artfully 7 creating a feedback loop through their work that purports to ease executive anxiety but actually creates more of it."⁵⁷ The long term result can be "dependence" on the McKinsey consultants. 8 "We insinuate ourselves," Ron Daniel, McKinsey's then-managing partner, told Forbes in 1987.58 9 101. "They have follow-on work not just because they're good at what they do, but 10 11 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 12 merely epiphenomenal," explained Alan Kantrow, formerly the editor of McKinsey Quarterly.⁵⁹ 13 This strategy of weaving itself into all aspects of its clients' business proved 14 102. enormously successful for McKinsey over the years. It was a strategy McKinsey encouraged its 15 consultants to take with clients to great effect: 16 17 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 18 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.⁶⁰ 19 20 21 22 ⁵⁶ 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 23 keep around indefinitely."). ⁵⁷ *Id.* at pg. 6. Purdue provides a fine example of this feedback loop in action. In 2008, when McKinsey was advising 24 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 25 "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 26 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 27 work" for another decade. ⁵⁸ John Merwin, "We Don't Learn from Our Clients, We Learn from Each Other," *Forbes*, October 19, 1987. 28 ⁵⁹ Duff McDonald, *The Firm*, Pg. 185. ⁶⁰ *Id.* at pg. 136.

1 103. Another aspect of the transformational relationship McKinsey develops with 2 clients is the development and marketing of "leave-behind" products, such as software 3 applications, that are sold to clients as tools that can be used by the business on an on-going and 4 recurring basis, separate and apart from McKinsey's project-based consulting work. As described 5 by Harvard Business School Professor Clayton Christensen, starting in 2007, "McKinsey & 6 Company initiated a series of business model innovations that could reshape the way the global 7 consulting firm engages with clients. One of the most intriguing of these is McKinsey Solutions, 8 software and technology-based analytics and tools that can be embedded at a client, providing ongoing engagement outside the traditional project-based model."⁶¹ 9

10 104. McKinsey's relationship with Purdue provides an example of the deployment of
11 these "leave-behind" products. One McKinsey Solution is a pharmaceutical sales and marketing
12 workforce optimization tool called FieldGuide, a proprietary software application McKinsey sells
13 to clients. "The FieldGuide tool optimizes salesforce deployment and territory design through
14 advanced geospatial analysis that leverages both market-potential insights across device
15 categories and advanced sales-response curve analysis."⁶² McKinsey sold it to Purdue for the
16 purpose of optimizing Purdue's OxyContin salesforce.

17

D. McKinsey and Purdue: A Case Study in Transformation

18 105. Indeed, McKinsey's work with Purdue is a prime example of the transformational
19 relationship in action. McKinsey counted Purdue as a client at least as early as 2004, three years
20 *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.

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 ⁶¹ 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
 ⁶² https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/how-we-help-

clients/medtech/marketing-and-sales

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1	106. McKinsey staffed at least forty known consultants to Purdue, from senior partners			
2	all the way down through engagement managers and entry-level associates. Throughout the			
3	unfolding of the nationwide opioid crisis that only continued to worsen after the 2007 guilty plea,			
4	McKinsey remained steadfast alongside the Sacklers and Purdue every step of the way. The mea			
5	culpas would come only later.			
6	107. McKinsey partner Maria Gordian, in her March 26, 2009 "EY 2009 Impact			
7	Summary" internal report to McKinsey director Olivier Hamoir and McKinsey's Personnel			
8	Committee, recounted her accomplishments that year on the Purdue account. The document is an			
9	annual self-assessment produced by McKinsey partners. In it, Gordian described the state of			
10	firm's relationship for Purdue:			
11	With client work extending through the 3 rd quarter, and several additional proposals			
12	in progress, we continue to expand the depth and breadth of our relationships at Purdue. We look forward to deepening our relationships with the Sackler family and			
13	serving them on key business development issues, and to expanding our relationship with [John] Stewart and other members of the senior management team. ⁶³			
14	with [John] Stewart and other members of the senior management team.			
15	108. Gordian even described herself as a counselor to Richard Sackler in the same			
16	memorandum, in addition to being a "point of contact for the Board and Sackler family." ⁶⁴			
17	109. The continued expansion of the depth and breadth of McKinsey's relationship with			
18	Purdue was an ever-present internal goal for McKinsey, as it was accompanied by recurring and			
19	ever-increasing client billings.			
20	110. By 2014, both the breadth and depth of McKinsey's relationship with Purdue had			
21	expanded dramatically. During the 2009 to 2014 period in particular, Purdue relied extensively on			
22	McKinsey to develop and implement its sales and marketing strategy for OxyContin. But			
23	McKinsey's work for Purdue involved many other facets of Purdue's business beyond sales and			
24	marketing, including general and administrative consulting, review of product acquisition,			
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27	⁶³ 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 <i>In Camera</i> Review, Doc. No. 2012, In no Purplue Rharman, Inc., filed Neuropher 18, 2020, Case No. 10, 22640 (S. D. N.Y.), Ex. 7, Ba. 48: MCK			
28	2012, <i>In re Purdue Pharma, Inc.</i> , filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex 7, Pg. 48; MCK-MAAG 0118669. ⁶⁴ <i>Id</i> .			
	1a.			

1 evaluation of research and development, advising Purdue on the design of clinical studies, risk 2 management, and interactions with regulators.

3 111. McKinsey's sales and marketing work for Purdue focused on creating and 4 implementing strategies and tactics to bolster the sales of OxyContin, a Schedule II drug that is 5 widely recognized as among the most frequently diverted and abused opioids. As Purdue faced 6 growing scrutiny, McKinsey also helped the company protect its public image and profit from the 7 market for illicit opioids, which McKinsey's industry-wide efforts helped to promote and 8 maintain.

9 112. 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 10 and abuse. Part of McKinsey's work involved assessing the "underlying drivers" of OxyContin's 11 12 (financial) performance. As described below, these drivers boil down to two things: (1) a 13 widespread deceptive marketing campaign and (2) fueling an illicit market for non-medical use. Purdue entered into guilty pleas arising out of both types of conduct in 2007 and 2020, 14 15 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 16 17 "both in terms of content and culture," as its own renewed consulting agreement assured in 2013. 18

2004: McKinsey and Purdue Meet 1.

113. On March 1, 2004, McKinsey entered into a Master Consulting Agreement with 19 Purdue for services that would be defined from time to time.⁶⁵ The Agreement was signed on 20 21 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, 22 McKinsey stepped in to help Purdue.⁶⁶ 23

24	114. The Master Consulting Agreement
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27	
28	⁶⁵ PPLPC012000069192 ⁶⁶ Id.

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5	115. From 2004 through 2008, McKinsey advised Purdue on research and development,
6	business development, and product licensing related to Purdue's opioid products. ⁶⁹ Consistent
7	with its business model, McKinsey leveraged these projects into growth of its "Broader Strategy
8	work" also underway with Purdue. ⁷⁰ Specifically, in October 2008, Purdue retained McKinsey for
9	broad strategy work after two board members "blessed" Purdue executive Craig Landau with
10	doing "whatever he thinks is necessary to 'save the business" after the 2007 criminal plea and
11	introduction of generic competition to the older OxyContin. ⁷¹
12	2. <u>2007: Purdue Pleads Guilty to Misbranding OxyContin and is Bound</u> by a Corporate Integrity Agreement
13	by a Corporate integrity Agreement
14	116. On May 10, 2007, John Brownlee, United States Attorney for the Western District
15	of Virginia, announced the guilty plea of the Purdue Frederick Company, the parent of Purdue
16	Pharma, relating to the misbranding of OxyContin. Brownlee stated,
17	Even in the face of warnings from health care professionals, the media, and members
18	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
19	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
20	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
21	abuse, and less addictive than other pain medications on the market.
22	117. Purdue Frederick Company as well as three of Purdue's officers, pleaded guilty to
23	the misbranding of OxyContin pursuant to various provisions of the Federal Food, Drug, and
24	Cosmetic Act, 21 U.S.C. §§ 301, et seq.
25	
26	⁶⁷ Id.
27	 ⁶⁸ PPLPC020000034087 ⁶⁹ PPLPC013000116218; PPLP004401340
28	⁷⁰ MCK-MAAG-0117875 ⁷¹ <i>Id.</i>
	CONSOLIDATED CLASS ACTION

1 118. 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.

8 119. Concurrent with its guilty plea, Purdue entered into a Corporate Integrity
9 Agreement with the Office of Inspector General of the United States Department of Health and
10 Human Services on May 7, 2007. Purdue's compliance obligations under the Corporate Integrity
11 Agreement ran for a period of five years, and ultimately terminated in January 2013.⁷²

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

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

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⁷² See https://www.justice.gov/opa/press-release/file/1329576/download

Materials disseminated by sales representatives," and "the internal review process for the
 Materials and information disseminated by sales representatives."

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

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

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

13 123. The Sackler family has owned and controlled Purdue and its predecessors since
14 1952. At all times relevant to this Complaint, individual Sackler family members occupied either
15 six or seven of the seats on Purdue's board of directors, and at all times held a majority of Board
16 seats. To advise the board of directors of Purdue Pharma was to advise the Sackler family. The
17 interests of the Sackler family and the Purdue board of directors, and Purdue itself, as a privately
18 held company, were all aligned. Practically, they were indistinguishable.⁷³

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

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 ⁷³ 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.
Case 3:21-md-02996-CRB Document 299 Filed 12/06/21 Page 37 of 171 Message 1 From: David Sackler 5/17/2007 11:08:08 PM Sent: 2 Sackler, Dr Richard To: 3 CC: Ives, Stephen A. Subject: RE: Idea 4 Attachments: image001.jpg 5 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 6 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. 7 125. Given concern over this "concentration of risk," the two sides of the Sackler 8 family spent considerable time and energy debating the best way to achieve distance from Purdue, 9 and collectively considered a variety of options for doing so. One option was to sell the company 10 to or merge the company with another pharmaceutical manufacturer. They discussed Shire as a 11 possible target, as were Cephalon, UCB, and Sepracor, Inc. The proceeds of such a transaction 12 13 could then be re-invested in diversified assets, thereby achieving the Sacklers' desired distance from opioids. 14 126. Mortimer D.A. Sackler advocated for a sale or merger in a February 21, 2008 15 email to Richard Sackler (a former president and co-chairman of Purdue) and several others, 16 17 writing, "The pharmaceutical industry has become far too volatile and risky for a family to hold 95% of its wealth in. It simply is not prudent for us to stay in the business given the future risks 18 we are sure to face and the impact they will have on the shareholder value of the business and 19 hence the family's wealth." The risk he referred to was, at least in significant part, further liability 20 related to OxyContin. 21 127. Another option was to have Purdue borrow money in order to assure Purdue had 22 adequate funds to continue operating while the Sacklers, as owners, began to make substantial 23 distributions of money from the company to themselves. Once again, the proceeds of the 24 distributions could then be re-invested in diversified assets, thereby achieving the Sacklers' 25 desired distance. 26 In order to pursue either of these options, the Sacklers needed to maximize opioid 27 128. sales in the short term so as to make Purdue-by then the subject of substantial public scrutiny-28

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1	appear either as an attractive acquisition target or merger partner to another pharmaceutical			
2	manufacturer or as a creditworthy borrower to a lender.			
3	129. In short, the Sacklers planned to engage in a final flurry of opioid pushing in order			
4	to rid themselves of their pharmaceutical company dependency for good.			
5	130. In fact, in the years after the 2007 guilty plea, Purdue would retain only the			
6	absolute minimum amount of money within it as possible: \$300 million. Purdue was required to			
7	retain that amount pursuant to a partnership agreement with separate company. Otherwise, all the			
8	money was distributed to its owners. ⁷⁴			
9	131. Given the complexity of the problem, the Sacklers and Purdue realized that they			
10	would need assistance in achieving these internally contradictory objectives. Purdue did not have			
11	the capabilities in-house to design and implement a sales strategy for OxyContin that would			
12	achieve the Sacklers' objectives. They turned to the global management consulting firm			
13	McKinsey, which had already been advising the Sacklers and Purdue for at least three years, for			
14	help with their new problem.			
15	132. Notably, under the terms of Paragraph II.C.1(b) of the Corporate Integrity			
16	Agreement, McKinsey, as a contractor to Purdue performing sales and marketing functions for			
17	the company, was itself a "Covered Person" subject to the strictures of the Agreement. ⁷⁵			
18	4. <u>Purdue Tasks McKinsey with Boosting Opioid Sales in Light of the</u>			
19	Guilty Plea and Corporate Integrity Agreement.			
20	133. The Sacklers faced a problem: the need to grow OxyContin sales as dramatically			
21	as possible so as to make Purdue an attractive acquisition target or borrower, while at the same			
22	time appearing to comply with the Corporate Integrity Agreement. As one Purdue executive			
23	stated of Purdue's attitude toward the Corporate Integrity Agreement: "They did not listen to their			
24				
25				
26	⁷⁴ See Jared S. Hopkins, At Purdue Pharma, Business Slumps as Opioid Lawsuits Mount, Wall Street Journal, June 20, 2010, gueilable at https://www.usi.com/articles/purdue.pharma_grapplas.with_internal_aballanges.as.opioid			
27	30, 2019, <i>available at:</i> https://www.wsj.com/articles/purdue-pharma-grapples-with-internal-challenges-as-opioid-lawsuits-mount-11561887120?mod=hp_lead_pos6			
28	⁷⁵ 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.			

1 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."⁷⁶ 2 3 134. Purdue and the Sacklers were well aware of the constraints posed by the 4 Agreement. Indeed, during a May 20, 2009 Executive Committee Meeting, the discussion led to 5 whether Purdue should have a single sales force marketing all Purdue products, including 6 OxyContin, or instead to "create a separate Sales Force for Intermezzo (a sleeping pill) that would 7 be comprised of approximately 300 representatives." John Stewart, Purdue's then-CEO, saw an 8 opportunity, and asked if the Corporate Integrity Agreement would apply if Purdue were to 9 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 10 Corporate Integrity Agreement, he asked?⁷⁷ 11 135. It would not, he was told by Bert Weinstein, Purdue's Vice President of 12 Compliance.⁷⁸ 13 Given the tension between compliance with the Corporate Integrity Agreement 14 136. and the desire to sell more OxyContin, Purdue needed help. 15 137. Ethan Rasiel, a former McKinsey consultant, has described the typical way 16 17 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."⁷⁹ 18 19 138. Such was the case with Purdue. Because it did not have the requisite expertise to 20 address the problems posed by the Corporate Integrity Agreement internally, Purdue expanded on 21 its already-existing relationship with McKinsey to devise a sales and marketing strategy to 22 increase opioid sales despite the Corporate Integrity Agreement and growing concern about the 23 "concentration of risk" that Purdue's business of selling opioids posed to its owners. 24 25 26 ⁷⁶ 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 27 ⁷⁷ PPLPC012000226606, Purdue Pharma Executive Committee Meeting Notes and Actions, May 20, 2009, Pg. 2. ⁷⁸ Id.

^{28 &}lt;sup>79</sup> *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

139. 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,
 turbocharging⁸⁰ the sales of a drug it knew fully well was addictive and deadly, while purporting
 to respect to the Corporate Integrity Agreement.

140. 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.

9 141. 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.

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

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

144. 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.⁸¹

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²⁸ \parallel ⁸⁰ If the description is overbearing, note that it is McKinsey's own, as described below. ⁸¹ PDD1712900096.

- 1 145. 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.
- 4 146. McKinsey would also work in granular detail with the Purdue sales and marketing
 5 staff, led during the relevant period by Russell Gasdia, Vice President of Sales and Marketing.
- 6 147. From as early as June 2009 and continuing at least through July 14, 2014, Purdue
 7 routinely relied upon McKinsey to orchestrate its sales and marketing strategy for OxyContin.
 8 The relationship was characterized by ongoing interactions between teams from McKinsey and
 9 Purdue regarding not only the *creation* of an OxyContin sales strategy, but also its
 10 *implementation*. McKinsey was a real presence at Purdue. "A team of McKinsey analysts went
- 11 in-house, camping out in a conference room at Purdue headquarters."⁸²
- 12

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

13 148. Purdue hired McKinsey not only to give advice, but to devise and then implement
14 a deceptive marketing strategy. For example, for one "major initiative" with Purdue, "McKinsey
15 forecast[ed] a potential incremental increase in sales in the \$200-400mm range" over a three-year
16 period, "[w]hen properly implemented."⁸³

17 149. McKinsey is not cheap, either. Indeed, hiring McKinsey is an expensive
18 proposition. A single junior consultant—typically a recent college or business school graduate—
19 runs clients millions of dollars annually.⁸⁴ McKinsey is a highly selective employer and

advertises that its employees join "for the opportunity to apply their talents to complex, important

- 21 challenges."⁸⁵ "Talent" is key to McKinsey's model; clients pay for the best and brightest.
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150. A client does not choose to pay McKinsey unless it expects to receive benefits it

- 23 could not have obtained within its own organization. McKinsey offers solutions to clients facing
- 24

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⁸² 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-26 shortlist

⁸³ PPLPC012000257444

⁸⁵ https://www.mckinsey.com/about-us/overview

 ⁸⁴ 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.

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.⁸⁶

151. 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.⁸⁷ 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.

11 152. When Purdue entered into a "Master Consulting Agreement" with McKinsey in
12 2004, Purdue explicitly recognized McKinsey "has a fine reputation as well as excellent
13 experience and relationships in our industry," which Purdue was counting on to boost its opioids
14 business.⁸⁸

15 153. Purdue explicitly recognized that McKinsey stepped in to help Purdue "protect
16 [its] sales and continue to *grow our business.*"⁸⁹

17 154. Furthermore, that the Sacklers, as board members of Purdue, relied on McKinsey
18 in their conduct of Purdue affairs is an admitted fact. In a public filing in the recent Purdue
19 bankruptcy proceedings, the one side of the Sackler family conceded that they did so: "McKinsey
20 is widely recognized as 'a leading management consulting firm' and the Former Directors were
21 statutorily entitled to rely on such expertise."⁹⁰

22

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

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

25

- 38 -

 ⁸⁶ Forbes, *McKinsey & Company* (retrieved September 9, 2021), https://www.forbes.com/companies/mckinsey company/?sh=1201a12624c1.

 ⁸⁷ 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
 ⁸⁸ PPLPC012000069192

^{28 &}lt;sup>89</sup> *Id.* (emphasis added).

⁹⁰ In re: Purdue Pharma, L.P., No. 19-23649, Doc. 3441-1, at ¶ 328 (Aug. 5, 2021).

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

156. 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.

157. 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.

9 158. 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.

159. 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
 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.

160. On January 20, 2009, McKinsey partner Maria Gordian wrote to partners Rob

19 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.⁹¹

161. Gordian's email to Rosiello and Elling forwarded encouraging words from

²⁴ 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

⁹¹ 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.

28 2012, *In re Purdue Pharma, Inc.*, filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex D, Pg. 25 (emphasis added).

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1	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. ⁹²			
2				
3	Marianna forwarded the well-wishes to Gordian and the team at McKinsey.			
4	162. In September 2009, Purdue made a presentation to the FDA advisory committee			
5	considering its application for its reformulated OxyContin and stated that the new formulation			
6	would deter abuse. According to metadata, the PowerPoint presentation was prepared by			
7	McKinsey.			
8	163. The FDA approved the reformulation of OxyContin in April 2010. ⁹³			
9	164. Having successfully navigated the approval process with McKinsey's chaperoning,			
10	Purdue then proceeded to market the ADF version of OxyContin as a solution to opioid abuse and			
11	as a reason that doctors could continue to safely prescribe their opioids.			
12	165. In 2020, two FDA advisory committees evaluating the impact of the reformulated			
13	OxyContin concluded that reformulated OxyContin did not, in fact, substantially reduce abuse.			
14	166. At the same time as it worked to rehabilitate Purdue's image with the FDA,			
15	McKinsey, in parallel, advised Purdue on how to limit FDA regulations aimed at mitigating the			
16	risks of opioid use. In 2008, shortly after Purdue's criminal plea, the FDA requested Purdue			
17	submit a proposed "Risk Evaluation and Mitigation Strategy" ("REMS") for OxyContin.			
18	McKinsey provided Purdue with drafts of the submission.94 Indeed, McKinsey was crucial in			
19	devising Purdue's response to the FDA's request for a REMS proposal from Purdue. Gordian			
20	informed Rosiello and Elling on October 23, 2008 that John Stewart, Purdue's CEO, "is aware of			
21	the critical role we are playing in pulling REMs together and is very appreciative." In the same			
22	email, she noted that "the family" was focused "on the response to the non-approval letter" from			
23	the FDA. ⁹⁵			
24				
25				
26	⁹² Id.			
27	 ⁹³ See https://www.fda.gov/media/126835/download ⁹⁴ PDD8901578031 			
28	⁹⁵ 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 <i>In Camera</i> Review, Doc. No. 2012. In no Purplus Pharma, Inc., filed Neurophar 18, 2020. Case No. 10, 23640 (S.D.N.X.), Ex.C. Bg, 22			

^{II} 2012, *In re Purdue Pharma, Inc.*, filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex C, Pg. 22.

1	167. In 2009, the FDA expanded its scope to a class-wide extended release/long-acting			
2	REMS program.			
3	168. Seeking to avoid a requirement that prescribers undergo mandatory training on			
4	OxyContin's risks or management or obtain certification before prescribing OxyContin, which			
5	would limit the numbers of available prescribers, Purdue turned to McKinsey. McKinsey found			
6	the cost to Purdue of a system to verify completion of prescriber education before prescriptions			
7	could be filled would be \$50 million—an estimate Purdue used to oppose efforts for more			
8	rigorous risk management strategies. ⁹⁶			
9				
10				
11				
12	169. Armed with McKinsey's analysis, Purdue's strategy on REMS was effective. The			
13	REMS program avoided verification and enrollment provisions that would harm Purdue's profits.			
14	170. Meanwhile, based on McKinsey's work on extended release opioid REMS,			
15	McKinsey was aware of warnings and adverse events included within the OxyContin medication			
16	guide and communications plans, including risks of overdose and adverse events including			
17	dizziness and lethargy.			
18	171. In June 2009, McKinsey helped Purdue prepare for an FDA advisory committee			
19	meeting.			
20				
21	172. McKinsey prepared for Purdue an "FDA Advisory Committee on Reformulated			
22	OxyContin: Question & Answer Book" in September 2009, with questions including "Why			
23	should we trust you?" In response, McKinsey recommended Purdue say "We acknowledge			
24	mistakes made in the past[;]" "We have x, y and z measures in place that did not exist before[;]"			
25				
26				
27	⁹⁶ PDD8901530124			
28	⁹⁷ PPLPC019000622253 ⁹⁸ PDD8901645845			

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and "[a]t all levels, Purdue's focus is on maintaining the highest ethical standards and meeting the
 needs of patients[.]"⁹⁹

3 173. Sometimes, McKinsey's work was as obfuscating as it was self-revealing. To the
4 question of "Who at Purdue takes personal responsibility for all these deaths?[,]" McKinsey
5 offered the following response:¹⁰⁰

5	
	Who at Purdue takes personal responsibility for all these deaths?
	We all feel responsible
	1
	12 MCK-MAAG-0152135
	b. The Granularity of Growth
	174. 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
	applicable to problems encountered by many businesses; they are conceptual frameworks that
	McKinsey deploys when tasked with solving a problem for a client.
	175. 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.
	176. 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
	 ⁹⁹ MCK-MAAG-0152135 ¹⁰⁰ 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 <i>In Camera</i> Review, Doc. No. 2012, <i>In re Purdue Pharma, Inc.</i>, filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex F, Pg. 39.

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1	matter: The Granularity of Growth: How to Identify the Sources of Growth and Drive Enduring			
2	Company Performance (Wiley, April 2008). "The key is to focus on granularity, to breakdown			
3	big-picture strategy into its smallest relevant components." ¹⁰¹			
4	177. Previously, in an article in <i>McKinsey Quarterly</i> (coincidentally published the same			
5	month that Purdue pled guilty), the authors explained:			
6 7 8 9	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. ¹⁰²			
10	178. Additionally, McKinsey encouraged a granular assessment of the geography of			
11	corporate growth. "The story gets more precise as we disaggregate the company's performance			
12	on the three growth drivers in 12 product categories for five geographic regions." ¹⁰³			
13	179. One can imagine this strategy applied to a seller of, say, cartons of milk. If			
14	McKinsey were to perform an analysis of the milk seller's sales and marketing and discover that			
15	the profit margin on milk cartons sold to university cafeterias in dairy-producing states is much			
16	greater than the margin on cartons sold at convenience stores in the southwest, and further that the			
17	milk seller has previously devoted equal amounts of time and resources selling to both university			
18	cafeterias and convenience stores, then McKinsey would likely advise the client to deploy			
19	additional resources towards selling milk to university cafeterias in dairy-producing states.			
20	McKinsey's "granular" approach to the milk seller's business channels has identified a way to			
21	increase higher margin sales, leading to newfound growth and profitability for the client.			
22	180. Rather than milk, McKinsey deployed this strategy on OxyContin, a controlled			
23	substance, after its manufacturer pled guilty to misrepresenting the addictive and deadly			
24	properties of the drug.			
25				
26				
27	¹⁰¹ 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			

¹⁰² 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 28

1	c. "Identifying Granular Growth Opportunities for OxyContin"
2	181. McKinsey's granular analysis of Purdue's OxyContin sales efforts led to the
3	implementation of a number of strategies to sell more pills.
4	182. By January 2010, McKinsey informed Purdue, in accordance with the lessons of
5	McKinsey's granular growth analysis, that Purdue could generate "\$200-400mm" in additional
6	annual sales of OxyContin by implementing McKinsey's strategies. ¹⁰⁴
7	183. In November 2010, a McKinsey report instructed sales reps to maximize profits by
8	"emphasizing [the] broad range of doses"-which meant pushing the doses that were highest and
9	most profitable. ¹⁰⁵
10	184. In 2012, John Stewart assigned McKinsey to "understand the significance of each
11	of the major factors affecting OxyContin's sales." ¹⁰⁶
12	185. This McKinsey did in excruciatingly granular detail, analyzing each sales channel
13	for Purdue's opioids to identify weaknesses, opportunities, and to suggest courses of action to
14	improve performance. Many core themes of McKinsey's work would be crystallized in a series of
15	presentations and updates made to the Sackler family and to Purdue's board of directors in the
16	summer of 2013 entitled "Identifying Granular Growth Opportunities for OxyContin."
17	i. Marketing – Countering Emotional Messages
18	186. From the outset of McKinsey's known work for Purdue, the work was grim. In
19	June 2009, McKinsey teamed with Purdue's then-Chief Medical Officer (and current CEO) Craig
20	Landau and his staff to discuss how best to "counter emotional messages from mothers with
21	teenagers that overdosed in [sic] OxyContin."
22	187. Months later, McKinsey advised Purdue to market OxyContin based on the false
23	and misleading notion that the drug can provide "freedom" and "peace of mind" for its users, give
24	patients "the best possible chance to live a full and active life," and concomitantly reduce stress
25	and isolation. ¹⁰⁷
26	
27	¹⁰⁴ PPLPC012000257443; PPLPC012000257446
28	¹⁰⁵ PPLPC018000346294 ¹⁰⁶ PPLPC020000587064
I	¹⁰⁷ PPLPC023000239858

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¹¹⁰ PPLPC019000329253

1	191. Claims that OxyContin improved function and quality of life were not supported
2	by substantial evidence and, in addition, failed to take into account risks of addiction. The FDA
3	and other federal agencies have, for years, made clear the lack of evidence for claims that the use
4	of opioids for chronic pain improves patients' function and quality of life. ¹¹¹ A Centers for
5	Disease Control and Prevention guideline, following a "systematic review of the best available
6	evidence," concluded that "[w]hile benefits for pain relief, function and quality of life with long-
7	term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are
8	clearer and significant." ¹¹² According to the CDC director, "for the vast majority of patients, the
9	known, serious, and too-often- fatal risks far outweigh the unproven and transient benefits [of
10	opioids for chronic pain]." ¹¹³
11	192. In addition to crafting carefully-tailored quality of life assurances designed to
12	avoid the pitfalls of the Corporate Integrity Agreement, McKinsey invented other misleading
13	marketing efforts for Purdue.
14	193. For instance, McKinsey urged Purdue to capitalize on OxyContin's extended-
15	release characteristics in another way: marketing OxyContin's twelve-hour dosing as though
16	users only need to take OxyContin twice a day, thus requiring fewer pills. OxyContin in fact was
17	well known to wear off after eight to ten hours in many patients, however. What McKinsey called
18	"convenient," would later be called "a [d]escription of Hell."
19	194. This misleading assurance of twelve-hour relief is especially pernicious, as end-of-
20	dose failure renders OxyContin even more dangerous because patients begin to experience
21	withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a
22	
23	¹¹¹ The FDA has warned other drug makers that claims of improved function and quality of life were misleading. <i>See</i> Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO,
24	Actavis Elizabeth LLC (Feb. 18, 2010) (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life.").
25	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.
26	(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
27	demonstrated by substantial evidence or substantial clinical experience."). ALLERGAN_CA_00161496. The FDA's warning letters were available to McKinsey on the FDA website.
• •	¹¹² CDC Guideline at 2, 18.

 ¹¹² CDC Guideline at 2, 18.
 ¹¹³ 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).

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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."¹¹⁴ 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
limitations, is misleading because it implies that the pain relief supplied by each dose lasts twelve
hours.

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

13 196. 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 lowerdose, immediate release opioids.¹¹⁵

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

20 21

ii. Targeting – Selling More OxyContin to Existing High Prescribers

198. 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

²⁷

 ¹¹⁴ 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/.
 ¹¹⁵ PDD8901645845

opioids was made with no notable concern about the parallel increase in opioid-related deaths,
 abuse, and misuse.

199. 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
that had historically been the highest prescribers.¹¹⁶ McKinsey then worked with Purdue's sales
and marketing staff to specifically target those prescribers with a marketing blitz to encourage
even further prescribing.

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

201. 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

13 OxyContin *before* the 2007 guilty plea and had already been subjected to Purdue's

14 misrepresentations regarding OxyContin that were the subject of that guilty plea.

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

18 203. McKinsey worked assiduously with Purdue over many years to continually refine 19 this approach and required ever-more granular data for its analysis. More than three years after 20 the initial introduction of the physician segmentation initiative, McKinsey requested, and Purdue 21 provided, "prescriber-level milligram dosing data" so that McKinsey could further analyze the 22 individual amounts of OxyContin prescribed by individual physicians.

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

- 27
- 28

¹¹⁶ PPLPC012000257446

205. 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."¹¹⁷

206. 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.¹¹⁸

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

208. 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.

17 209. Not only did McKinsey identify which doctors prescribed the most of Purdue's 18 opioids, McKinsey also recommended segmenting prescribers into "types" and tailoring messages and tactics to the different prescriber profiles. For prescribers dubbed "Early Adopting Experts" 19 20 and "Proactive Teachers," defined by a willingness to use extended release opioids, including in 21 opioid naïve patients (patients who were not already using opioids), McKinsey urged 22 emphasizing that its seven tablet strengths provide flexibility to "tailor the dose" to customer needs.¹¹⁹ Upon information and belief, this message aimed to encourage prescribers to initiate and 23 maintain patients on OxyContin long-term by reminding them they could increase the dose as 24 25 patients became tolerant with long-term use (rather than discontinue use when the drug lost its 26 effectiveness).

- 27
- 28 ¹¹⁷ PPLP004307354 ¹¹⁸ PPLP004409890
 - ¹¹⁸ PPLP004409890 ¹¹⁹ MCK-MDL2296-0126522

1 210. In its October 26, 2009 presentation, "OxyContin – driving growth through
 2 stronger brand loyalty,"¹²⁰ McKinsey proposed tactics to turnaround declining sales, "[e]nhance
 3 loyalty to OxyContin among loyalist prescribers," "[c]onvert[ing] 'fence sitters' into more loyal
 4 OxyContin prescribers," and "[p]rotect OxyContin's market share[.]"¹²¹ In other words,
 5 McKinsey proposed increasing sales by pushing both willing and reluctant physicians to prescribe
 6 more OxyContin.

211. 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.

14

iii. Titration – Selling Higher Doses of OxyContin

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

20 213. Consistent with its granular growth analysis, as early as October 26, 2009,
21 McKinsey advised the Sacklers and the Purdue board that Purdue should train its sales
22 representatives to "emphasiz[e] the broad range of doses," which would have the intended effect
23 of increasing the sales of the highest (and most profitable) doses of OxyContin.¹²²

24 214. McKinsey's work on increasing individual prescription dose strength continued
25 throughout the time period McKinsey worked with Purdue. The Sacklers were informed on July
26 23, 2013 that Purdue had identified weakness in prescribing rates among the higher doses of

- 27
- 28 121 *Id.* at 2.

 120 *Id*.

¹²² PPLPC018000346294

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.

4 215. Purdue implemented McKinsey's suggestions through adopting the marketing
5 slogan to "Individualize the Dose" and by 2013 encouraged its sales representatives to "practice
6 verbalizing the titration message" when selling Purdue's opioids to prescribers.¹²³

7 McKinsey would have known, however, that higher doses of opioids carry greater 216. 8 risk. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine 9 equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times 10 more likely to suffer overdose from opioid-related causes than those on low doses. As compared 11 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. 12 13 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.¹²⁴ 14

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

21	218.	Purdue adopted McKinsey's	proposal. ¹²⁵
22			
23			
24			
25			
• •	¹²³ PPLP003450		
26			escribing Opioids for Chronic Pain – United States,
27	²⁰¹⁶ . MNWR F ¹²⁵ PPLPC02300	Recomm Rep 2016;65(No. RR-1):1–49. DOI 0025122 <u>6</u> (); see also
	PPLPC0120002		
28); PPLPC012000246009 (; PPLPC021000265092 (
I)	

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2	126
3	219. The titration messaging worked. Nationwide, based on an analysis by the <i>Los</i>
4	Angeles Times, more than 52% of patients taking OxyContin longer than three months are on
5	doses greater than sixty milligrams per day, which converts to the ninety MED that the CDC
6	guideline urges prescribers to "avoid" or "carefully justify." ¹²⁷
7	iv. Covered Persons – Sales Quotas and Incentive Compensation
8	220. McKinsey urged the use of quotas and bonus payments to motivate Purdue's sales
9	force to sell as many OxyContin prescriptions as possible. As McKinsey described it, "[r]evision
10	to incentive comp could better align reps to Purdue's economics." ¹²⁸
11	221. Notably, this behavior was prohibited by the 2007 Corporate Integrity Agreement.
12	which required Purdue to implement written policies regarding "compensation (including salaries
13	and bonuses) for [sales representatives] engaged in promoting and selling Purdue's products that
14	are designed to ensure that financial incentives do not inappropriately motivate such individuals
15	to engage in the improper promotion or sales of Purdue's products." ¹²⁹
16	222. By 2010, Purdue had implemented a four-year plan, consistent with McKinsey's
17	strategy, to dramatically increase the quota of required annual sales visits by Purdue sales
18	representatives to prescribers. The quota was 545,000 visits in 2010, 712,000 visits in 2011,
19	752,000 in 2012, and 744,000 visits in 2013.
20	223. On August 15, 2013, as part of their "Identifying Granular Growth Opportunities
21	for OxyContin" presentation, McKinsey urged the Sacklers to "establish a revenue growth goal
22	(e.g., \$150M incremental stretch goal by July 2014) and set monthly progress reviews with CEO
23	and Board." ¹³⁰
24	224. In its "Identifying Granular Growth Opportunities for OxyContin" presentation to
25	the Purdue board in July 2013, McKinsey nonetheless urged Purdue, in addition to increasing the
26	¹²⁶ PKY183123435
27	¹²⁷ CDC Guideline at 16. ¹²⁸ PPLPC012000441016

¹²⁹ PDD1712900096 (emphasis added). 28 ¹³⁰ PPLP004409890

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- focus of the sales force on the top prescribers, to increase the overall quotas for sales visits for 1
- 2 individual sales representatives from 1,400 to 1,700 annually.
- 3

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225. 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

5 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		Potential new allocation	
Number of "on territory" days per year		Number of "on territory" days per year	
ltem	Days ¹	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	× 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: Pundue; team analysis

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By eliminating one third of the amount of time sales representatives were required 20226. 21 to be in training, McKinsey projected that Purdue could squeeze an additional 5% of physical 22 calls per day out of its newly less-trained sales force.

23 227. Additionally, McKinsey developed and advised Purdue on a new incentive 24 compensation structure for the sales representatives, who were Covered Persons pursuant to the 25 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 26 27 based on the number of OxyContin prescriptions the representative produced could be a powerful 28 driver of incremental OxyContin sales, without regard for patient safety.

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7. <u>Transformation: Purdue and McKinsey Adopt and Implement</u> <u>McKinsey's Strategies.</u>

228. 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.

8

9

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

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

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

18 232. This transformative collaboration would continue over the course of the19 relationship between Purdue and McKinsey.

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

25 234. Ms. Panara stated that the 2007 guilty plea was deliberately minimized by the
26 company in presentations to its sales staff: "They said, 'We were sued, they accused us of mis27 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."¹³¹ (Purdue and its
 executives paid \$634.5 million in fines.)

3	235. Consistent with McKinsey's mandate, McKinsey devised methods for sales staff to
4	sell OxyContin to doctors while at the same time maintaining technical compliance with the
5	Corporate Integrity Agreement. Ms. Panara stated that, though she was told she could not flatly
6	claim that OxyContin was better or safer than other opioids, "she was trained to talk about
7	product in ways that implied that it was safer." She might tout OxyContin's twelve-hour
8	formulation to a prescriber. "You could say that with a shorter-acting medication that wears off
9	after six hours, there was a greater chance the patient was going to jump their dosing schedule
10	and take an extra one a little earlier. We couldn't say [it was safer], but I remember we were told
11	that doctors are smart people, they're not stupid, they'll understand, they can read between the
12	lines." ¹³²
13	8. <u>Project Turbocharge</u>
14	236. The Corporate Integrity Agreement expired in January 2013. With this restriction
15	lifted, McKinsey devised additional marketing and sales strategies for Purdue to further increase
16	OxyContin sales.
17	237. On May 14, 2013, McKinsey entered into a "Statement of Services to the Master
18	Consulting Agreement" (the "2013 Agreement") with Purdue to "conduct a rapid assessment of
19	the underlying drivers of current OxyContin performance, identify key opportunities to increase
20	near-term OxyContin revenue and develop plans to capture priority opportunities."
21	
22	133
23	238. The 2013 Agreement stated, "We have a long history of partnership with Purdue,
24	and we would make best efforts to leverage our understanding of your business – both in terms of
25	content and culture." It was signed by then-principal Arnab Ghatak, who would "lead the team
26	
27 28	 ¹³¹ David Crow, <i>How Purdue's 'one-two' punch fuelled the market for opioids</i>, Financial Times, September 9, 2018, <i>available at</i>: https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c ¹³² Id.

¹³³ PPLPC030000770531

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1	with senior leadership from Rob Rosiello and Martin Elling." Elling was a leader of McKinsey's
2	PMP group. ¹³⁴
3	239. McKinsey was tasked with "Identifying Granular Growth Opportunities for
4	OxyContin," conducting an "assessment of the underlying drivers of current OxyContin
5	performance," identifying "key opportunities to drive near-term OxyContin performance," and
6	developing "plans to capture priority opportunities." ¹³⁵
7	240. For purposes of the project, McKinsey would need "[f]ull access to work done to
8	date and key data." ¹³⁶ And,
9	137
10	241. Staff told the Sacklers that McKinsey would study how to get doctors to prescribe
11	more OxyContin, ¹³⁸ how to use incentive compensation to push reps to generate more
12	prescriptions, how to use "patient pushback" to get doctors to prescribe more opioids, and how to
13	keep patients on opioids longer. ¹³⁹
14	242. The 2013 Agreement would lead to Project Turbocharge, McKinsey's successful
15	bid to transform Purdue's sales and marketing efforts for OxyContin now that Purdue was no
16	longer bound by the Corporate Integrity Agreement.
17	243. In the summer of 2013, McKinsey made multiple recommendations to Purdue's
18	board to increase OxyContin revenue, and urged the Sackler family to "make a clear go-no-go
19	decision to 'Turbocharge the Sales Engine."
20	244. Purdue, like McKinsey, recognized that the initiative was no small thing. An
21	internal Purdue email states that
22	140
23	245. The Sacklers were impressed. On August 15, 2013, Richard Sackler emailed
24	Mortimer D.A. Sackler, "[T]he discoveries of McKinsey are astonishing."
25	$\frac{1}{134}$ Id.
26	¹³⁵ PPLPC030000770531 / MCK-MAAG-0024283 ¹³⁶ <i>Id.</i>
27	¹³⁷ PPLPC012000431809 ¹³⁸ PPLPC012000431262
28	¹³⁹ <i>Id.</i> ; PPLPC012000431266 ¹⁴⁰ PPLPC012000437344
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1	246. Eight days later, on August 23, 2013, McKinsey partners met with the Sackler
2	family-not the Purdue board of directors-to pitch Project Turbocharge. Dr. Arnab Ghatak, one
3	of the McKinsey partners leading the Purdue account, recounted the meeting to fellow McKinsey
4	partner Martin Elling in an email exchange: "[T]he room was filled only with family, including
5	the elder statesman Dr. Raymond [Sackler] We went through exhibit by exhibit for about 2
6	hrs They were extremely supportive of the findings and our recommendations and
7	wanted to strongly endorse getting going on our recommendations." ¹⁴¹
8	247. Elling, a co-leader of the Purdue account, remarked in the same email
9	correspondence that McKinsey's "findings were crystal clear to" the Sacklers, and that the
10	Sacklers "gave a ringing endorsement of 'moving forward fast." ¹⁴²
11	248. As a result of the Sackler family endorsement of McKinsey's proposals, the
12	following month Purdue implemented Project Turbocharge based on McKinsey's
13	recommendations. In adopting "Project Turbocharge," Purdue acknowledged the improper
14	connotations of the name, and re-christened the initiative the decidedly more anodyne "E2E:
15	Evolve to Excellence. ¹⁴³
16	249. Evolve to Excellence ("E2E") was the theme of Purdue's 2014 National Sales
17	Meeting.
18	250. CEO John Stewart also told sales staff that board member Paolo Costa was a
19	"champion for our moving forward with a comprehensive 'turbocharge' process," referring to
20	McKinsey's plan.
21	251. After Purdue adopted McKinsey's recommendations, McKinsey continued to work
22	with Purdue sales and marketing staff reporting to Russell Gasdia during Purdue's
23	implementation of McKinsey's recommendations.
24	
25	
26	¹⁴¹ MCK-MDL2996-0403095 ¹⁴² Id.
27	¹⁴³ Regarding the name change, CEO John Stewart wrote to McKinsey partners Rob Rosiello and Arnab Ghatak on
28	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 – <i>though we do need to find a better and more permanently appropriate name.</i> " PPLPC012000436626 (emphasis added).
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1	order to increase profits, Purdue must again increase the number of sales visits to "high-value"
2	prescribers, i.e., those that prescribe the most OxyContin. ¹⁴⁴
3	257. Purdue and McKinsey worked together to implement "Turbocharging the Sales
4	Engine."
5	
6	145
7	258. McKinsey and Purdue also worked together on an "implementation plan" for E2E,
8	with McKinsey taking on the role of "executive oversight" of projects including the creation of
9	target lists, internal dashboards to track progress, and changes to Purdue's incentive
10	compensation plan consistent with E2E. ¹⁴⁶
11	a. Targeting High Subscribers
12	259. Project Turbocharge called for revising the existing process for targeting high-
13	prescribing physicians, with a shift from targeting solely on the basis of prescription deciles to
14	considering additional factors. Based on its analysis, McKinsey told Purdue that "[t]here is
15	significant opportunity to slow the decline of OxyContin by calling on more high-value
16	physicians" and that "[t]he revenue upside from sales re-targeting and adherence could be up to
17	\$250 million."
18	
19	
20	¹⁴⁴ 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
21	(emphasis added): Q: Are you familiar with McKinsey & Company?
22	A: I decline to answer on the ground that I may not be compelled to be a witness against myself in any proceeding.
23	Q: Did individuals at McKinsey <i>assist you in getting hired as the CEO</i> of Purdue? A: I decline to answer on the ground that I may not be compelled to be a witness against
24	myself in any proceeding. In fact, McKinsey appears to have played a substantial role in the succession of several Purdue CEO's.
25	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
26	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
27	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.
28	¹⁴⁵ PPLPC021000615265 ¹⁴⁶ MCK-MDL2996-0180338, at 0180340

260. 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."

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

McKinsey found that Purdue did not "focus on the highest potential docs," 11 262. measured both by the number of prescriptions and reimbursement considerations.¹⁴⁷ One 12 13 McKinsey analyst urged McKinsey to recommend Purdue target "[1]iterally, at least all" prescribers in the top 20% of prescribers, "minus another few percent who are no sees[.]"¹⁴⁸ 14 15 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."¹⁴⁹ ("No see" prescribers are prescribers 16 17 who do not accept visits from pharmaceutical sales representatives. Thus, McKinsey recognized 18 that most of the highest volume prescribers, or "high writers" of prescriptions, were willing to 19 entertain sales visits from sales representatives.)

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263. "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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¹⁴⁷ MCK-MDL2996-0364024

28 MCK-MDL2996-0364267

¹⁴⁹ Id.

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McKinsey concluded: "Given that there are 14,000 uncalled physicians in deciles 5-10, there is

2 significant opportunity to shift calls to higher potential prescribers."¹⁵⁰

264. McKinsey pointed to a "true physician example" in Wareham, Massachusetts, who wrote 167 more OxyContin prescriptions after Purdue sales reps visited him.¹⁵¹

	Specialty : Ane	sthesiology
n Sta	Location : Ware Market Decile : 8	eham, Massachusetts
4-71	12 months ending March 2012	12 months ending March 2013
Calls made on	0 P1	18 P1
	1 00	1 P2
physician	1 P2	172

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Graphic from McKinsey presentation recommending targeting high prescribers

16 265. To slow or reverse the decline in OxyContin sales, McKinsey recommended a shift 17 to "value deciles," which purported to weigh prescribers according to factors including overall 18 opioid prescriptions, including the number of branded versus generic prescriptions; prescriber 19 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.¹⁵² 20 21 The cumulative effect of the value rankings was to shift detailer emphasis onto the highest-22 volume prescribers. Further, McKinsey's analysis found that the highest-volume prescribers were 23 themselves most influenced by detail visits.

- 24 266. Purdue moved quickly to do as McKinsey advised. All sales representatives
 25 received a memo on December 23, 2013, identifying how to select "SuperCore" prescribers, or
- 26
- 27

28 ¹⁵⁰ MCK-MDL2996-0187168 / PPLP004409892 ¹⁵¹ PPLPC012000437356

¹⁵¹ PPLPC012000437356 ¹⁵² PPLPC022000646874

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1	the top ten targets, ¹⁵³ in their territory according to the E2E high prescribing principles and
2	required that each SuperCore prescriber be visited at least twice a month. ¹⁵⁴
3	
4	
5	¹⁵⁵ As part of these changes, McKinsey's plan involved <i>more</i> minimum sales calls
6	overall. ¹⁵⁶
7	267.
8	
9	who later plead guilty to criminal charges related to an opioid drug ring. The
10	prescriber also surrendered his license to practice after an Ohio Medical Board investigation
11	revealed that he prescribed excessive and dangerous combinations of opioids and muscle relaxers
12	and that he prescribed opioids to a patients who complained of headaches and others who showed
13	signs of addiction. ¹⁵⁷ The same prescriber received at least sixty visits from Purdue from mid-
14	2013 through 2016. ¹⁵⁸
15	268.
16	
17	The doctor, who worked at a family practice, was
18	charged with involuntary manslaughter, Medicaid fraud, drug trafficking, grand theft, and other
19	offenses.
20	269.
21	
22	¹⁵⁹ In 2018, the Drug Enforcement Administration issued an Order to Show Cause and
23	Immediate Suspension Order to Dr. Khan-Jaffrey over concerns that her DEA registration
24	
25	
23	¹⁵³ MCK-MDL2996-0316833
26	¹⁵⁴ PURCHI-000005915 ¹⁵⁵ PPLPC022000686986
	 ¹⁵⁴ PURCHI-000005915 ¹⁵⁵ PPLPC022000686986 ¹⁵⁶ MCK-MDL2996-0187168 ¹⁵⁷ https://www.cnhinews.com/article_91ffac58-1b32-11e8-b264-6b34793bf5c3.html
26	¹⁵⁴ PURCHI-000005915 ¹⁵⁵ PPLPC022000686986 ¹⁵⁶ MCK-MDL2996-0187168

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1	"constituted an imminent danger to the public health and safety," finding she prescribed opioids
2	without a legitimate medical purpose and disregarded urine screens indicating abuse and
3	diversion. ¹⁶⁰ Dr. Khan-Jaffrey's DEA registration was fully revoked on July 28, 2020. ¹⁶¹ Dr.
4	Louis Spagnoletti, of Marlton, New Jersey,
5	¹⁶² lost his state license to prescribe controlled substances in 2018. ¹⁶³
6	Similarly, Dr. Vivienne Matalon, a Decile 10 prescriber from Cherry Hill, New Jersey,
7	¹⁶⁴ went on to lose her license in 2018 as well, for
8	allegedly receiving kickbacks to prescribe the fentanyl drug Subsys to three patients, including
9	one that died. ¹⁶⁵
10	270. Another prescriber, Dr. Damon Cary of Wilmington, Delaware,
11	, ¹⁶⁶ received an
12	emergency suspension order in 2019 after prescribing controlled substances, including opioids, to
13	undercover officers without performing any medical examinations. ¹⁶⁷ Dr. Eva Dickinsson, of
14	Harrington, Delaware,
15	¹⁶⁸ was arrested on marijuana charges in 2016 and had her license suspended in
16	2017 for sharing drugs, including opioids, with her patients. ¹⁶⁹
17	271. Dr. Michael Cozzi of Fort Wayne, Indiana,
18	, had his medical license
19	suspended in 2016, where he had prescribed more controlled substances than any other Indiana
20	prescriber, with over two million doses of oxycodone, seeing ninety to100 patients a day. ¹⁷⁰ Dr.
21	
22	¹⁶⁰ https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order ¹⁶¹ <i>Id.</i>
23	 ¹⁶² PPLPC014000257127 ¹⁶³ https://patch.com/new-jersey/moorestown/state-suspends-doctor-accused-illegally-prescribing-opioids
24	 ¹⁶⁴ PPLPC014000257127 ¹⁶⁵ https://nj.gov/oag/newsreleases18/pr20180504d.html
25	 ¹⁶⁶ PPLPC014000257130 ¹⁶⁷ https://www.delawareonline.com/story/news/health/2019/08/05/doctor-prescribed-opioids-undercover-cops-
26	failed-follow-protocol/1920386001/ ¹⁶⁸ PPLPC014000257130
27	¹⁶⁹ https://www.delawareonline.com/story/news/health/2017/01/19/doctors-license-suspended-delaware- maryland/96779080/
28	¹⁷⁰ 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)
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1	Jamie Gurrero,
2	¹⁷¹ was sentenced to 100 months in prison in
3	2016 after pleading guilty to unlawful distribution or dispensing of controlled substances, health
4	care fraud, conspiracy, and money laundering. ¹⁷²
5	272.
6	Misrepresentations to these prescribers were especially
7	insidious because they were aimed at general practitioners who lack the time and expertise to
8	closely manage higher-risk patients on opioids.
9	273. McKinsey also urged, consistent with continually refining its granular approach,
10	that sales representatives devote two-thirds of their time to selling OxyContin and one-third of
11	their time selling Butrans, another Purdue opioid product. Previously, the split had been fifty-
12	fifty.
13	b. Circumventing Safeguards Against Abuse and Diversion
14	274. Project Turbocharge also involved a granular analysis of Purdue's individual sales
15	channels. In its August 8, 2013 report to the Purdue board, McKinsey also attributed the decline
16	in OxyContin sales to safeguards to limit suspicious opioid sales. McKinsey informed Purdue that
17	"[t]he retail channel, both pharmacies and distributors, is under intense scrutiny and direct risk."
18	"There are reports of wholesalers stopping shipments entirely to an increasing number of
19	pharmacies," "[m]any wholesalers are also imposing hard quantity limits on orders based on prior
20	purchase levels," and "[p]harmacy chains are implementing guidelines for which patients can fill
21	opioid prescriptions[.]" ¹⁷³
22	275. For instance, McKinsey recommended that Purdue circumvent pharmacies entirely
23	with a mail order program because enforcement by federal regulators was decreasing OxyContin
24	dispensing through Walgreens. McKinsey informed the Sacklers that "[d]eep examination of
25	Purdue's available pharmacy purchasing data shows that Walgreens has reduced its units by
26	
27	¹⁷¹ PPLPC014000257130 ¹⁷² https://www.justice.gov/usao-wdky/pr/kentuckiana-anesthesiologist-sentenced-100-months-unlawful-distribution-
28	controlled

28 controlled ¹⁷³ MCK-MAAG-0024297

1 18%." Further, "the Walgreens data also shows significant impact on higher OxyContin
 2 dosages."¹⁷⁴

276. 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.

9 277. McKinsey's initiative also included ways to circumvent these safeguards.
10 McKinsey recommended that the sales force distribute vouchers and "starter kits" for patients
11 who faced co-pays for OxyContin prescriptions.¹⁷⁵ In particular, McKinsey recommended
12 dispensing vouchers to outlets of a specific large national pharmacy chain where prescriptions
13 and OxyContin inventories were down.¹⁷⁶ This chain, as part of its own settlement with the Drug
14 Enforcement Administration, had removed pharmacist bonuses for dispensing opioids.¹⁷⁷

c. Incentivizing Opioid Sales

16	278. McKinsey's "turbocharging" plan also had other elements.
17	
18	
19	
20	179
21	9. <u>McKinsey's Efforts Triple OxyContin Sales</u>
22	279. In 2013, despite significant headwinds, with marketing activities turbocharged,
23	OxyContin sales peaked. The restrictions on Purdue's sales and marketing methods contained in
24	the Corporate Integrity Agreement should have resulted in fewer overall OxyContin sales; the
25	
26	¹⁷⁴ Id.
27	¹⁷⁵ MCK-MDL2996-0290827. ¹⁷⁶ MCK-MDL2996-0041646.
	¹⁷⁷ MCK-MDL2996-0104431; MCK-MDL2996-0041646.
28	 ¹⁷⁸ PPLPC012000437346. ¹⁷⁹ Id.

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

280. 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.¹⁸⁰

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

12 282. These distributions would not have been possible without the McKinsey's work13 dramatically increasing OxyContin sales.

14 283. The Sacklers were aware of the value McKinsey provided: on December 2, 2013,
15 CEO John Stewart informed Kathe Sackler and Vice President of Sales and Marketing Russell
16 Gasdia Project Turbocharge "was already increasing prescriptions and revenue." Crucially, these
17 results were already being realized *before* the strategy was fully deployed as the theme of the
18 2014 National Sales Meeting. Stewart elaborated to Sackler that "trends are more positive than
19 was the case a few months back, and when the E2E Project (the changes arising out of the
20 McKinsey analysis) is fully implemented there will certainly be additional increases."¹⁸¹

21

22

23

284. Later that month,

182

285. McKinsey's contributions to Purdue's growth after 2007 are remarkable.

24 OxyContin sales should have naturally declined; the Department of Justice identified OxyContin

25 sales that were illegitimate because of Purdue's conduct, and the Inspector General of the

 ¹⁸⁰ On February 10, 2018, Purdue announced that it is no longer marketing opioids, and disbanded its OxyContin sales force.
 ¹⁸¹ PPLPC012000454422

¹⁸² PPLPC012000457292

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1	Deserve of Health and Henry Consistent distance Compared Interview Association has been
1	Department of Health and Human Services entered into a Corporate Integrity Agreement whereby
2	Purdue was monitored to assure that those sales did not continue.
3	286. In 2007, the year of Purdue's guilty plea, net sales of OxyContin totaled
4	approximately \$1 billion. ¹⁸³
5	287. The guilty plea "did little to stem Purdue's blistering growth rate." In fact, by
6	2010, after McKinsey was advising Purdue on how to maximize sales, OxyContin sales exceeded
7	\$3 billion: a <i>tripling</i> of revenue from OxyContin sales. ¹⁸⁴
8	288. Under McKinsey's guidance, OxyContin sales would reach their all-time peak in
9	2013, the year McKinsey proposed, and Purdue adopted, Project Turbocharge. ¹⁸⁵ That OxyContin
10	sales peaked in 2013 is especially notable, given that overall opioid prescriptions had already
11	peaked three years earlier, in 2010. ¹⁸⁶ McKinsey's efforts added a final boost to OxyContin sales
12	before the eventual unraveling, and Purdue's decision, in the end, to cease marketing the drug.
13	289. Project Turbocharge was a continuing success.
14	¹⁸⁷ and Chief Financial Officer Edward
15	Mahoney reported to the Purdue board that the effort "has resulted in significant improvement."
16	
17	188
18	290. McKinsey was paid handsomely: it received more than for its work for
19	Purdue from 2008 to2013 alone. ¹⁸⁹ In pursuit of these profits, McKinsey continued to help Purdue
20	grow opioid sales even after Purdue reached a 2015 Assurance of Discontinuance with New York
21	arising out of an investigation concerning its Abuse and Diversion Detection program and media
22	
23	¹⁸³ See David Crow, How Purdue's 'one-two' punch fueled the market for opioids, Financial Times, September 9, 2018, multiple at https://www.ft.gom/content/%664cg0a.h122.1168.8d14.6f0/0006420a
24	2018, <i>available at</i> : https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c
25	¹⁸⁵ Phil McCausland and Tracy Connor, <i>OxyContin maker Purdue to stop promoting opioids in light of epidemic</i> , NBC News, February 10, 2018, <i>available at:</i> https://www.nbcnews.com/storyline/americas-heroin-epidemic/
26	oxycontin-maker-purdue-stop-promoting-opioids-light-epidemic-n846726 ¹⁸⁶ Gery P. Guy Jr, at al., Vital Signs: Changes in Opioid Prescribing Patterns in the United States, 2006-2015,
27	Centers for Disease Control and Prevention, July 7, 29017, <i>available at:</i> https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm
28	 ¹⁸⁷ PPLPC037000159028 ¹⁸⁸ PPLPC014000263961 ¹⁸⁹ PPLPC029000547371

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1	coverage highlighted its lack of attention to diversion control. McKinsey's own work elsewhere
2	identified "reducing prescribing" as among the efforts to combat the opioid epidemic and also
3	showed that opioid prescribers were frequently writing prescription for patients with known risks
4	of abuse. Still, McKinsey continued to work to help opioid manufacturers increase opioid sales,
5	including through Purdue's deceptive marketing campaign.
6	291. By 2014, according to Purdue, there were 5.4 million OxyContin prescriptions
7	written, 80% for twelve-hour dosing. Of those prescriptions, more than half were for doses
8	greater than sixty milligrams per day.
9	292. The Sackler family has withdrawn over \$10 billion from Purdue since 2008,
10	including \$1.7 billion in 2009 alone. These distributions were made possible by McKinsey's
11	services and came at the expense of a deepening national opioid crisis.
12	E. <u>McKinsey's Opioid-Related Work with Other Clients.</u>
13	293. Part of the unique value McKinsey provides is its deep knowledge of its clients'
14	competitors, often because it counts those same competitors as its clients. McKinsey generally
15	does not disclose to its clients its work for their competitors.
16	294. The opioid industry was no different. Indeed, McKinsey specifically worked to
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19	
20	1. <u>Endo</u>
21	295. While McKinsey was working for Purdue, McKinsey was also working for Endo
22	Pharmaceuticals. Arnab Ghatak was a principal McKinsey partner on both accounts at the same
23	time. ¹⁹¹ There was additional overlap between the McKinsey teams staffed to Purdue and Endo,
24	
25	¹⁹⁰ MCK-MDL2996-0041741. ¹⁹¹ Ghatak's familiarity with both Endo and Purdue is perhaps one reason why, on April 3, 2014, Ghatak was placed
26	in charge of analyzing a proposed <i>partnership</i> 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-
27	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
28	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.
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1 including McKinsey partners Nicholas Mills and Laura Moran. After all, these particular 2 consultants had granular expertise in the specific subject-matter relevant to these opioid 3 manufacturers. That subject-matter expertise is a compelling reason why McKinsey is hired in the 4 first place. McKinsey advised both Endo and Purdue how to maximize the sales or their branded 5 opioid products-Belbuca (Buprenorphine), Butrans (Buprenorphine), Opana (Oxymorphone), 6 and OxyContin (Oxycodone) —all at once. 7 New Blues a. 8 296. Like Purdue, Endo was historically a pharmaceutical manufacturer focused on the 9 pain market. Like Purdue, Endo relied on opioid sales for a significant portion of its business. As 10 a matter of fact, Endo's history with opioids predates the Sacklers' ownership of Purdue. In 1950, 11 Endo's predecessor, Intravenous Products of America, Inc., launched Percodan, an 12 Oxycodone/Aspirin tablet. In 1971, Endo, then owned by E.I. du Pont de Nemours and Company ("DuPont"), launched Percocet, another oxycodone-based tablet.¹⁹² 13 297. In 1997, Endo separated from DuPont to become a standalone private company 14 retaining Percodan and Percocet.¹⁹³ In 2000, as the result of an acquisition, the company became 15 public.¹⁹⁴ 16 17 298. In 2006, Endo launched its own branded oxymorphone products, Opana and Opana ER.¹⁹⁵ With the legacy assets of Percodan and Percocet, Endo's business had always been 18 focused on opioid sales. Oxymorphone is not a new opioid, and Opana was not Endo's first 19 20 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. 21 299. Numorphan was referred to as "blues," after the color of the 10mg pills. It 22 23 delivered a more euphoric high than heroin, according to some. In 1974, the National Institute on 24 Drug Abuse noted in its "Drugs and Addict Lifestyle" report that Numorphan was popular as an 25 26 27 ¹⁹² https://www.endo.com/about-us/history#fragment-25 ¹⁹³ https://www.endo.com/about-us/history#fragment-24 28 ¹⁹⁴ https://www.endo.com/about-us/history#fragment-21

¹⁹⁵ https://www.endo.com/about-us/history#fragment-15

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197

abused drug for its quick and sustained effect.¹⁹⁶ By 1979, Endo withdrew Numorphan from the

- 2 market. Upon information and belief,
- 3

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300. 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.¹⁹⁸ 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.¹⁹⁹

301. 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.

302. 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 reintroduced 27 years later. After 2006, Opana was on occasion referred to as "blue heaven," or,
more to the point, "new blues."²⁰⁰

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

304. In addition to its branded products, Endo, through subsidiaries Qualitest
Pharmaceuticals, Inc. and, after its acquisition in 2015, Par Pharmaceuticals, also manufactured
24

¹⁹⁶ John Fauber & Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015),
 available at: https://www.medpagetoday.com/psychiatry/addictions/51448
 ¹⁹⁷ EPI000443330 (

"); ENDO-OPIOID-MDL-06246554 (

27).
 28 ¹⁹⁸ See https://www.imdb.com/title/tt0097240/; https://www.bionity.com/en/encyclopedia/Oxymorphone.html
 28 ¹⁹⁹ Scene from Drugstore Cowboy, available at: https://www.youtube.com/watch?v=TksvZdrx9_A
 ²⁰⁰ https://www.deadiversion.usdoj.gov/drug_chem_info/oxymorphone.pdf

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1	generic versions of oxycodone, oxymorphone, hydromorphone, and hydrocodone. Over the
2	course of McKinsey's relationship with Endo, McKinsey would repeatedly advise Endo how to
3	maximize its generics business in addition to sales of Endo's branded opioids.
4	b. <u>Old Friends</u>
5	305. McKinsey's relationship with Endo began as early as in 2006, the same year as the
6	Opana launch.
7	306. McKinsey's earliest known work with Endo concerned the launch of Opana in
8	Europe, but its relationship with Endo would expand to encompass all aspects of Endo's business,
9	including corporate organization and resource allocation, the launch of a new branded
10	Buprenorphine product, and sales force optimization efforts for Endo's branded and generic
11	opioid products.
12	307. In 2007, McKinsey was shaping overall corporate strategy at Endo. In a
13	presentation to Endo's board of directors in May of that year
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15	
16	
17	.**201
18	308. McKinsey's partnership with Endo would last more than a decade, and, like its
19	relationship with Purdue, is an exemplary example of the transformational relationship in action.
20	309. In some ways, the McKinsey's relationship with Endo was even more tightknit and
21	companionable than with Purdue. For instance, no one at Purdue previously worked for
22	McKinsey. In early 2013, Rajiv de Silva, previously a leader of McKinsey's PMP group, was
23	appointed CEO of Endo. At Endo, McKinsey was now advising an old friend, one of its previous
24	senior partners. ²⁰²
25	
26	²⁰¹ ENDO-OPIOID_MDL-02899510.
27	²⁰² See "Rajiv De Silva Named President and CEO of Endo Health Solutions," Press Release dated February 25,
28	2013, <i>available at</i> : 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.")

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1	310. As de Silva himself explained, "
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5	311. Under de Silva, Endo relied more heavily on McKinsey than ever before.
6	McKinsey consultants interacted directly and often exclusively with de Silva. McKinsey was so
7	close to the Endo CEO that it could intervene in direct reporting from one of de Silva's
8	deputies. ²⁰⁴ It is as if McKinsey had insinuated itself as a shadow layer of bureaucracy within
9	Endo.
10	312. McKinsey maintained weekly performance review meetings with de Silva and
11	senior Endo management. In these meetings, granular weekly sales data was reviewed for each of
12	Endo's branded products, including Opana. ²⁰⁵
13	313. McKinsey advised both Purdue and Endo contemporaneously for more than a
14	decade. With each client, the goal was the same: to maximize opioid sales. The work McKinsey
15	performed for each client was so similar that there was routinely confusion internally about
16	whether a specific project or task to perform was for Endo or Purdue. ²⁰⁶
17	314. Despite McKinsey's emphasis on confidentiality, the fact that McKinsey repeats
18	its work from one client to the next is well-known to the client. Indeed, it is part of the
19	justification in hiring McKinsey in the first place. McKinsey can tell you what everyone else is
20	doing.
21	
22	
23	
24	 ²⁰³ ENDO-OPIOID-DEPMAT-000047877 at pg. 320:22 – 321:3. ²⁰⁴ See MCK-MDL2996-0405502 (Email from Ghatak to de Silva, stating that it "would be great for you to push
25	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
26	help"). ²⁰⁵ MCK-MDL2996-0062712.
27	²⁰⁶ 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
28	<i>infra.</i>), McKinsey consultant Jeff Smith replied, "Craig – is this for Purdue or Endo? If for Endo, I am conflicted." MCK-MDL2996-0383805.
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1 new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."215 2

In 2013, an Endo training module directed key opinion leaders to instruct 3 323. 4 prescribers that OPANA ER with INTAC is the only oxymorphone designed to be "crush-5 resistant," and advised the key opinion leaders to state during their speeches that "[t]he only way 6 for your patients to receive oxymorphone ER in a formulation designed to be crush-resistant is to prescribe OPANA ER with INTAC."²¹⁶ The speakers were advised to stress that generic versions 7 8 of Oxymorphone "are not designed to be crush-resistant."

9 324. 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 10 11 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 12 13

,217

- using needles to inject the drug for the first time. As an internal Endo email put it,
- 15 325. 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 16 17 Humvee rolled over in 2008. After being prescribed opioids for his back pain, Jeff became 18 dependent, and began using Opana by snorting it. Endo then introduced the reformulated abusedeterrent version of Opana in 2012. "[A]nd then they reformulated them," he said, referring to the 19 20 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."²¹⁸21 Jeff and his companion Joy showed the journalist how the drug was used. "You 22 326.
- 23 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

24

14

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²¹⁷ END00010732.

²⁶ ²¹⁵ 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). 27 ²¹⁶ EPI000421543.

²⁸ ²¹⁸ 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

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1	hard, white coating just kind of floating off the piece of the pill. It looks like plastic," described			
2	the journalist witnessing the process. ²¹⁹			
3	327. Joy explained how the abuse-deterrent coating, once melted, was discarded by			
4	using the filter of a cigarette: "Now you see the coating of – all that mess laying there still?			
5	That's what the filter's for." ²²⁰ The journalist described what then took place:			
6	And Joy puts that cigarette filter into the liquid, and they Joy, Jeff and another guy			
7	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			
8	really, really quiet.			
9	328. Joy couldn't conceive of the position she was in. A nurse, she hurt her back at			
10	work and began taking prescription pain medication. She began taking the pills by mouth, and			
11	later began to snort them. Dependency began. But she told herself, "I'd never ever would use a			
12	needle, never. I'm never going to do that." ²²¹			
13	329. After Opana's reformulation, Joy began using it intravenously. "I started using the			
14	needle about – it was around the 6 th of February," she said. "I'm so ashamed I pack so much			
15	shame, and I'm going to cry I pack so much shame from it. I do."222			
16	330. Endo's 2012 reformulation of Opana caused outbreaks of HIV in populations of			
17	intravenous Opana users. In Austin, Indiana, where Jeff and Joy resided, Opana was linked to an			
18	outbreak of at least 200 HIV cases in a town with a population of 4,500. ²²³			
19	331. Intravenous use of reformulated Opana has also been associated with outbreaks of			
20	Hepatitis C and Thrombotic Thrombocytopenic Purpura ("TTP"). ²²⁴ The concerns even reached			
21	Wall Street, where an analyst asked Endo about a TPP outbreak in Tennessee associated with			
22	Opana ER. Endo assured the analyst that the outbreak was, like the outbreak in Indiana, in "a			
23	very, very distinct area of the country."			
24				
25	²¹⁹ Id.			
26	220 Id. 221 Id. 221 Id.			
27	²²² Id. ²²³ Id.			
28	²²⁴ "Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012," <i>Morbidity and Mortality Weekly Report</i> (Jan. 11, 2013).			

Case 3:21-md-02996-CRB Document 299 Filed 12/06/21 Page 81 of 171 332. Endo was well aware of these problems. 1 2 3 4 ,,225 5 In June of 2013, McKinsey 6 333. 7 8 9 10 11 12 13 226 14 334. McKinsey indicated 15 16 17 18 19 ,228 20 21 335. 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 22 nasally—i.e., by snorting the drug.²²⁹ The relevant concern for Opana's reformulated version was 23 *injection*, not insufflation. 24 25 26 ²²⁵ ENDO00260151. ²²⁶ EPI002107711. ²²⁷ Id. 27 ²²⁸ Id. (emphasis added). 28 ²²⁹ 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:

1	336. But the insufflation study worked for Purdue. Going forward, McKinsey suggested
2	.230
3	337. As the preceding paragraphs make clear, Endo and McKinsey were laser-focused
4	on maximizing overall sales of Endo products, and decidedly not on concerns over their actual
5	abuse potential or the appropriate <i>size</i> of the market for these products, given evident,
6	longstanding, and ever-present concerns about their abuse. To the point, McKinsey regarded
7	concerns about opioid abuse only as a means by which its clients could introduce differentiated
8	products (i.e., those with purported abuse-deterrent or tamper-resistant features) to continually
9	perpetuate overall opioids sales for their clients. In all instances, the parties desired for the size of
10	that overall opioids market to grow in line with the introduction of "differentiated" products like a
11	reformulated Opana.
12	338. Endo's purported concern about deterring abuse of its drugs was laid bare as farce
13	by a particularly striking decision: to continue to sell the old formulation of Opana despite touting
14	the notion that the old formulation was purportedly dangerous in ways that the new formulation
15	was not. Endo
	was not. Endo
16	
16 17	.231
16 17 18	. ²³¹ . 339. Endo not only continued to distribute original Opana for nine months after the
16 17 18 19	. ²³¹ . 339. 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
16 17 18 19 20	. ²³¹ . 339. 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. ²³² In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining
 16 17 18 19 20 21 	. ²³¹ . 339. 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. ²³² In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized." ²³³
 16 17 18 19 20 21 22 	. ²³¹ . 339. 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. ²³² In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized." ²³³
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 15 16 17 18 19 20 21 22 23 24 25 	231 339. 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. ²³² In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized." ²³³ 340. In June 2013, an Endo employee informed the McKinsey consultants of a
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1 234 2 3 d. **Belbuca: Endo's Answer to Butrans** 4 341. Buprenorphine is another differentiated product. Opioid manufacturers began to 5 introduce Buprenorphine products to the market after the introduction of OxyContin, Opana, and 6 other branded opioids long-known to have abuse and dependency problems. Buprenorphine 7 products were marketed as purportedly less dangerous than products such as OxyContin or 8 Opana. 342. 9 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 10 11 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. 12 13 343. For example, on August 13, 2015, McKinsey's Craig MacKenzie circulated a 14 discussion document to Endo and McKinsey staff entitled "Belbuca value proposition," which 15 laid out McKinsey's thoughts on how to differentiate Endo's buprenorphine product from other opioids in the marketplace.²³⁵ One point of differentiation McKinsey noted was that OxyContin 16 17 was commonly abused, while Endo's Belbuca hopefully would not be: ²³⁶ 18 19 Product strengths Comparative value propositions against Purdue products 20 * Hysingla ER OXYCONTIN C BELBUCA 21 Formulated with abuse deterrent Perceived due to inherent Commonly abused: reformulated properties in formulation and as "abuse deterrent" in 2010 properties 22 molecule Safety 23 Good tolerability after titration, low Average, can be associated with Lack of NSAID or tylenol decrease constipation nausea, vomiting, & constipation risk of adverse reaction 24 25 26 27 ²³⁴ ENDO-OR-CID-00400235 (emphasis added). 28 ²³⁵ MCK-MDL2996-0410742. ²³⁶ MCK-MDL2996-0006669, at 0006675.

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1	344. The cognitive dissonance was palpable. At the same time that MacKenzie sent his
2	email differentiating Belbuca, and as described supra, McKinsey was also maximizing
3	OxyContin sales for Purdue—the opioid it was describing to Endo as commonly abused.
4	345.
5	
6	Butrans was Purdue's buprenorphine product.
7	346. Once Butrans was launched at Purdue, McKinsey worked with Endo to create
8	another branded Buprenorphine product to compete with Butrans. These product planning and
9	launch processes are long-term affairs. McKinsey worked with Endo on this project for four years
10	before Endo's Belbuca obtained FDA approval.
11	347. McKinsey remained in place at Endo to implement the launch of Endo's
12	Buprenorphine product. The strategic goal of Belbuca-the key to its commercial success-was
13	to convert short acting opioid ("SAO") users to Belbuca. As McKinsey explained to CEO Rajiv
14	de Silva, "The fundamental question is whether Belbuca will take share from the short-acting
15	opioids." ²³⁷
16	348. Ultimately, Belbuca was not a large commercial success for Endo because it failed
17	to transition a sufficient number of short acting opioid users to the long-acting Belbuca. As the
18	drug underperformed, Endo felt ever more pressure to stimulate sales. John Harlow described one
19	meeting with de Silva on April 8, 2016: "We just got out of the review with Rajiv and clearly our
20	TRx trends are not good and are behind other recently launched pain products the request
21	from Rajiv was to do anything possible that could be implemented ASAP to stimulate RXs." ²³⁸
22	349. By July 6, 2016, McKinsey and Endo were increasingly focused on converting
23	short-acting opioid users.
24	
25	." ²³⁹ Notably, the goal was to increase <i>overall</i> buprenorphine
26	prescriptions, not only those of Belbuca. The discussion document identified an objective to
27	²³⁷ MCK-MDL2996-0210158.
28	 ²³⁸ MCK-MDL2996-0358973, at 0358975. ²³⁹ ENDO-OPIOID_MDL-07264539

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opioid users to long-acting opioids users of products *other than Buprenorphine*. McKinsey and
 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:²⁴⁴



353. 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.
 (Belbuca, in other words, was the result of Project X.) McKinsey described the "opioid
 dependence treatment pathway" as follows:²⁴⁵



1 2

e. **Turbocharging the Sales Force with a Blitz**

355. 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 3 Ghatak, McKinsey used the Purdue Pharma Project Turbocharge model from the previous year as 4 a template for the Endo proposal.²⁴⁷ Even the PowerPoint presentations used to create the 5 proposal to Endo were drafted off the Project Turbocharge slides. On June 28, 2015, Sherin Ijaz 6 of McKinsey emailed Ghatak, Nicholas Mills, and Laura Moran to circulate a draft proposal for 7 an "Endo sales force transformation" PowerPoint presentation. Ijaz explained, "Laura, I heavily 8 leveraged what you send (sic) from Purdue as it was all applicable."²⁴⁸ All three of the recipients 9 of Ijaz's email regarding the Endo proposal had been working on the Purdue account for years. 10

11	356. E	Endo			
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13					
14					,,249
15	357. E	Endo's Vice Pres	sident & Gen	eral Manager	of its Pain Business Unit, John Harlow,
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18			250		
19					
20				251	
21	358. 7	The Endo and Pu	urdue proposa	lls were essen	tially identical sales transformations.
22	The goals were	the same: to ma	ximize sales	of opioids. Me	erely the names were changed. While
23	McKinsey offer	ed to "turbochar	rge" Purdue's	sales force, N	AcKinsey proposed a "sales force blitz"
24	for Endo. ²⁵²				
25					
26	²⁴⁷ MCK-MDL299				
27	²⁴⁸ MCK-MDL299 ²⁴⁹ ENDO_AAC_0				
28	²⁵⁰ <i>Id.</i> ²⁵¹ <i>Id.</i> ²⁵² <i>E.g.</i> , MCK-MD	L2996-0130803; M	ICK-MDL2996	0132851.	
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3	362. Upon McKinsey's suggestion, Endo began reallocating sales force resources to
4	Opana from other Endo products such as Sumavel, a migraine medication, and Voltaren, an anti-
5	inflammatory. ²⁵⁴ Writing to the McKinsey team, Endo's Alicia Logan stated the joint mission, "I
6	agree that our main goal is to maximize the increased promotional efforts for [Opana ER] without
7	disrupting/sacrificing [Sumavel] or [Voltaren] TRx volume and it appears that we [can]
8	accomplish this with your recommendation of addition another 500 targets." ²⁵⁵
9	363. With the Sales Force Blitz underway, Endo received good news in New York.
10	Years prior, Endo had initiated patent litigation against generic manufacturers of Opana ER,
11	arguing that the generic versions of the drug infringed on Endo's patents. In part because of the
12	perceived impending loss of exclusivity, Endo had in recent years allocated its sales force
13	capacity away from Opana and to other Endo products.
14	364. On August 14, 2015, Endo received a favorable initial ruling declaring that the
15	generic versions of Opana violated Endo's patents, and enjoined their further sale. The ruling
16	provided additional patent exclusivity for Opana, and Endo was keen to exploit its advantage.
17	365. That afternoon,
18	
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21	256
22	366. The following week, Harlow wrote to the McKinsey team working for Endo to
23	focus their attention on Opana ER. "Now with our litigation victory from last week, plus our
24	UHC opportunity, there is an increased need to increase FF support to drive Sep-Dec
25	business With this win, I am now willing to go broader with OER targeting."257
26	
27	²⁵⁴ MCK-MDL2996-0409466. ²⁵⁵ MCK-MDL2996-0409436, at 0409437 (sic).
28	²⁵⁶ ENDO-OPIOID_MDL-02279530. ²⁵⁷ MCK-MDL2996-0358871, at 0358872; ENDO-OPIOID_MDL-02201117.

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

3

1

2

2. Johnson & Johnson

368. McKinsey also working with Johnson & Johnson, whose role overseeing and 4 5 contributing to the opioid crisis has been exhaustively detailed in other complaints. See, e.g., City 6 and County of San Francisco v. Purdue Pharma L.P., N.D. Cal. No. 18-2591, Doc. 128 (Mar. 13, 7 2020). Johnson & Johnson occupied multiple roles within the opioids industry. Through its 8 subsidiary, Janssen Pharmaceuticals ("Janssen"), it marketed and sold branded opioid products, 9 including Duragesic (a transdermal fentanyl patch) and Nucynta (tramadol tablets and oral solution). Through its Noramco and Tasmanian Alkaloids subsidiaries, Johnson & Johnson 10 11 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 12 13 to the other opioid manufacturers: Purdue, Endo, Mallinckrodt, and others. Johnson & Johnson 14 was the origin point in the entire opioids supply chain.

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

17 370. Just as Endo was led by former partner McKinsey partner Rajiv de Silva, Johnson 18 & Johnson similarly relied on McKinsey as a pipeline for its own management timber. As 19 described above, McKinsey alumni tend to move on to positions with McKinsey clients. 20 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 21 22 Sales and Marketing for Janssen Pharmaceuticals is currently a McKinsey partner. Moreover, Ian 23 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 24 25 McKinsey, "having served as Chairman and Worldwide Managing Director from 2003 until 2009."258 26

27 28

²⁵⁸ https://www.jnj.com/leadership/ian-e-l-davis

1	371. Kevin Sneader, until recently McKinsey's global managing partner, and one of
2	Davis' successors, described Davis as a "mentor" who was the managing partner of McKinsey's
3	London office when Sneader was working there and "worked on one of his teams." ²⁵⁹ Given
4	Frazier's presence on the board, Johnson & Johnson was obviously an important account for
5	McKinsey. At present, it is not known which McKinsey partner(s) was the Director(s) of Client
6	Services for the Johnson & Johnson account.
7	372. What is known, however, is that McKinsey
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10	^{,,260} On July 6,
11	2011, Ghatak attended an internal McKinsey call with the consultants working on the Johnson &
12	Johnson account to discuss the "J&J Nucynta sales force disruption." ²⁶¹ The same day, Laura
13	Moran, who like Ghatak worked both the Purdue and Endo accounts, also provided internal
14	advice regarding Nucynta to her McKinsey partner Gerti Pellumbi, who was leading Nucynta
15	sales efforts for the Johnson & Johnson account, and engagement manager Bryan Reinholt, who
16	was with Pellumbi on the Johnson & Johnson account. ²⁶² Martin Elling, one of the lead
17	McKinsey partners on the Purdue account alongside Ghatak, attended internal McKinsey calls on
18	March 25, 2010, ²⁶³ and again on May 27, 2011 to discuss McKinsey's work for Johnson &
19	Johnson's Nucynta. ²⁶⁴ Then, on December 13, 2011, Elling attended a meeting with Johnson &
20	Johnson personnel regarding "acceleration opportunities." ²⁶⁵ Aamir Malik attended the meeting
21	with Elling, and, naturally, also worked on the Endo account. ²⁶⁶ Malik and Ghatak had an internal
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23	
24	²⁵⁹ See Interview with Kevin Sneader, Harvard Project for Asian & International Relations, January 31, 2021,
25	<i>available at</i> https://www.youtube.com/watch?v=qed53EGG8kU ²⁶⁰ JAN-NH-00167575.
26	²⁶¹ MCK-MDL2996-0222833. ²⁶² MCK-MDL2996-0419348.
27	²⁶³ MCK-MDL-2996-0256186. ²⁶⁴ MCK-MDL-2996-0255907.
28	 ²⁶⁵ MCK-MDL-2996-0255926. ²⁶⁶ Id.; see also MCK-MDL-2996-0348536 (Example of Malik's work on Endo account).
	<i>Ia., see also</i> with Inde-2990-0546550 (Example of Mark's work on Endo account).

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1	McKinsey meeting amongst themselves regarding the "Nucynta Kickoff" at Johnson & Johnson
2	six months prior, on June 3, 2011. ²⁶⁷
3	a. Noramco
4	373. Janssen was not the only Johnson & Johnson unit
5	, and Janssen was not Johnson & Johnson's only division involved in the
6	narcotics trade.
7	374. Opioids—all of them—are derivatives of opium, which is derived from the poppy
8	plant. In order to sell opioids, someone needs to farm the opium poppy and process the harvest
9	into the raw materials necessary for opioid manufacturers—all of them—to make their products.
10	375. Johnson & Johnson was that farmer. It owned Noramco and Tasmanian Alkaloids,
11	which grew poppies in New Zealand and sold the raw ingredients for opioids to practically all
12	manufacturers.
13	376. On August 19, 2009, McKinsey's
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15	.268
15 16	. ²⁶⁸ 377.
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16 17 18 19	377.
16 17 18 19 20	377. 269
 16 17 18 19 20 21 	377. 269 378. Seven years later, in 2016, Johnson & Johnson exited the business by selling
 16 17 18 19 20 21 22 	377. 377. 269 378. 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
 16 17 18 19 20 21 22 23 	377. 377. 269 378. 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
 16 17 18 19 20 21 22 23 24 	377. 377. 269 378. 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. ²⁷⁰
 16 17 18 19 20 21 22 23 24 25 	377. 269 378. 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. ²⁷⁰

1 Not only was McKinsey's advice 2 invaluable to Johnson & Johnson, the perspective McKinsey gained of the overall opioid market 3 from advising the principal upstream supplier to the entire industry would be invaluable in to its 4 own work with its other opioid manufacturer clients. 5 b. Duragesic 379. Fentanyl was first synthesized by Paul Janssen and his pharmaceutical company 6 7 Janssen Pharmaceuticals in 1959. In the 1990s, the company (by then owned by Johnson & 8 Johnson) developed Duragesic, which is a transdermal patch that administers fentanyl to the 9 patient wearing it. "Duragesic proved to be one of the most successful analgesic pharmaceutical 10 380. 11 products ever developed, with sales in 2004 (its last year of patent life) exceeding \$2.4 billion. 12 The success of the fentanyl patch caused many generic companies to produce equivalents once it went off patent."271 13 McKinsey was an integral part of fentanyl's success. As early as 2002, McKinsey 14 381. 15 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 16 17 Janssen regarding how to market their opioid Duragesic. Incredibly, one of the recommendations 18 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.²⁷² 19 20 382. 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 21 22 OxyContin, specifically, that it was able to recommend to *a competitor of Purdue* that it boost its 23 own opioid sales by following in the footsteps of Purdue. 24 25 26 ²⁷¹ Theodore Stanley, "The Fentanyl Story," The Journal of Pain, Vol. 15, No. 12 (December), 2014, pg. 1220, 27 available at: https://www.jpain.org/article/S1526-5900(14)00905-5/pdf ²⁷² Chris McGreal, Johnson & Johnson faces multibillion opioids lawsuit that could upend big pharma, The 28 Guardian, June 23, 2019, available at: https://www.theguardian.com/us-news/2019/jun/22/johnson-and-johnson-

opioids-crisis-lawsuit-latest-trial



386. 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."

387. 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?"²⁷⁸ These same factors drove McKinsey's later work
turbocharging OxyContin.

15	388. Along the way, McKinsey
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18	279
19	389. Despite this ambivalence about tamper-resistance, in a status update on June 23,
20	2011, McKinsey informed Janssen that its "initial physician interview findings" indicate Nucynta
21	ER has "lower addictive/abuse potential and side-effect profile as key differentiators vs.
22	Oxycontin ER. ²⁸⁰
23	390. As part of the turbocharge process,
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27	278
28	 ²⁷⁸ MCK-MDL-2996-0135636. ²⁷⁹ JAN-MS-00322271. ²⁸⁰ MCK-MDL-2996-0009526, at 0009529.





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1	4. <u>McKinsey's Work with Opioid Distributors</u>
2	398. McKinsey worked with opioid distributor AmerisourceBergen
3	.292
4	399. McKinsey worked with opioid distributor McKesson on the company's
5	. 293
6	5. <u>McKinsey's Work with the FDA</u>
7	400. As described above, McKinsey assisted Purdue and others to confront FDA
8	regulations that posed threats to their clients' ability to maximize revenues from their opioid
9	products. McKinsey's role in shepherding its clients through regulatory interactions takes on a
10	different hew when considered in light of one of McKinsey's other clients: the Food and Drug
11	Administration itself.
12	401. Indeed, the FDA has proved a massive client for McKinsey, who since 2000 has
13	endeavored to expand its public sector practice under the direction and leadership of Nancy
14	Killefer, a now-retired senior partner and director of the firm. ²⁹⁴ Since 2008, the FDA has paid
15	McKinsey more than \$140 million. ²⁹⁵ A significant portion of that work for the FDA related to
16	the FDA's Center for Drug Evaluation and Research ("CDER"). The CDER is the principal
17	division tasked with approving, among other classes of drugs, opioids. Since 2008, McKinsey has
18	been awarded at least 17 contracts worth at least \$48 million for CDER work. ²⁹⁶
19	402. The REMS protocols, discussed above, that McKinsey assisted Purdue and others
20	in surmounting beginning in 2008 and culminating in 2012, were overseen by CDER. ²⁹⁷
21	403. Meanwhile, in 2010, McKinsey advised the FDA on building a monitoring system
22	called "track and trace" to assist in the identification of potentially improper distribution of
23	harmful prescription drugs, such as opioids. "The 'track and trace' system deeply impacted
24	
25	²⁹² ABDCMDL12135609, slide 5.
26	 ²⁹³ MCKSTCT00753097; MCKSTCT00753098. ²⁹⁴ Duff McDonald, <i>The Firm</i>. Killefer is also a director of Cardinal Health, one of the distributor defendants in the
27	ongoing nationwide opioid litigation, and a company subject to FDA regulations. ²⁹⁵ Letter to Dr. Janet Woodcock from Senator Margaret Hassan et al, August 23, 2021, <i>available at</i> :
28	https://www.hassan.senate.gov/imo/media/doc/fda-mckinsey_letter-final-210823.pdf ("Hassan Letter") ²⁹⁶ Id. ²⁹⁷ Id.

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1	McKinsey clients, including the nation's three largest drug distributors-McKesson,
2	AmerisourceBergen, and Cardinal Health [where Killefer has been a director since 2015]."298
3	404. Under one contract, McKinsey developed a roadmap and implemented plans to
4	modernize CDER's new drug regulatory program. Under another, McKinsey developed a
5	framework to increase information technology project delivery across CDER. ²⁹⁹
6	405. In 2007, Congress passed the Food and Drug Administration Amendments Act
7	("FDAAA"), which placed new restrictions on the use of certain high risk prescription drugs,
8	including opioids. The new law mandated that FDA require manufacturers of certain drugs to
9	create REMS.
10	406. The FDAAA also required the Secretary of Health and Human Services "to
11	develop standards and identify and validate effective technologies for the purpose of securing the
12	drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded,
13	or expired drugs." 21 U.S.C. § 355e(a).
14	407. In 2010 and 2011, under the FDAAA, the FDA awarded McKinsey contracts to
15	design a "track and trace" system to monitor prescription drugs, including opioids, throughout the
16	supply chain and to streamline the drug approval process. The track and trace system had the
17	greatest effect on drug distributors, including McKinsey clients McKesson, AmerisourceBergen,
18	and Cardinal Health. ³⁰⁰
19	408. Under these contracts, McKinsey was required to consult with "supply chain
20	stakeholders," which likely included these three McKinsey clients as well as pharmaceutical
21	manufacturers. ³⁰¹
22	409. In 2011, McKinsey also won a \$1.8 million contract with CDER's Office of
23	Surveillance and Epidemiology ("OSE"), which monitors and evaluates the safety profiles of
24	drugs available to American consumers. ³⁰² OSE "evaluates more than 2 million adverse event
25	
26	 ²⁹⁸ See http://cg.cardinalhealth.com/board-of-directors/default.aspx; Hassan Letter. ²⁹⁹ Letter to Senator Chuck Grassley from Andrew Tantillo, Oct. 22, 2021, available at:
27	https://www.grassley.senate.gov/imo/media/doc/fda_to_grassleymckinsey_conflicts_of_interest.pdf ³⁰⁰ Hassan Letter.
28	³⁰¹ <i>Id.</i> ³⁰² https://www.documentcloud.org/documents/21071060-mckinsey-ose-contract

1	reports submitted every year to FDA's MedWatch program" and provides "risk management
2	expertise on development and implementation of programs and initiatives to support [CDER's]
3	policies related to [REMS] authorities. ³⁰³
4	410. The OSE contract tasked McKinsey with a widespread mission of understanding
5	how OSE functions within the context of a broader system of drug safety in CDER and ultimately
6	developing and implementing a new operating model. In other words, McKinsey helped to
7	restructure a key body that has oversight over the opioid supply chain.
8	411. The 2012 Food and Drug Administration Safety and Innovation Act required the
9	FDA to modernize Sentinel, a system meant to monitor the safety of drugs once they are on the
10	market. ³⁰⁴ According to the FDA, "Sentinel generates <i>real-world evidence</i> to support regulatory
11	actions aimed at protecting the public's health," which in turn "inform[s] healthcare provider
12	decision-making for patients." ³⁰⁵
13	412. A 2014 contract with the FDA charged McKinsey with assessing the "strengths,
14	limitations and appropriate use" of Sentinel. Like the track and trace contract, the Sentinel project
15	required McKinsey to interview "external stakeholders," including "industry organizations" and
16	"drug and device industry leaders." ³⁰⁶ McKinsey also evaluated how the FDA employees used
17	Sentinel to inform regulatory decision making. ³⁰⁷
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23	303 https://www.fds.com/about.fds/aceton.demo.com/aboutien.ond.messarch.adas/adas.affice.com/aillence.and
24	³⁰³ https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-office-surveillance-and- epidemiology ³⁰⁴ https://www.documentaleud.gov/documenta/21071047 n_centical_concentrate_
25	³⁰⁴ https://www.documentcloud.org/documents/21071047-r_sentinel_assessment_award_contract_sow-redacted-pr ³⁰⁵ https://www.fda.gov/files/about%20fda/published/Sentinel-System-Overview—-Presentation.pdf;
26	https://www.healthaffairs.org/do/10.1377/hpb20150604.936915/full/ ³⁰⁶ Ian MacDougall, "McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency," Par Parkling (Opt. 4, 2021), angilable at https://www.agencyllics.org/article/washingen-
27	the Agency," <i>ProPublica</i> (Oct. 4, 2021), <i>available at</i> https://www.propublica.org/article/mckinsey-never-told-the- fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency
28	³⁰⁷ 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

1	413. McKinsey performed similar work for the FDA as recently as 2019, ³⁰⁸ when it
2	signed a contract extension with the agency for work relating to the FDA's efforts to modernize
3	the process by which it regulates new drugs. ³⁰⁹
4	414. The FDA's drug tracking programs have been panned as failures. ³¹⁰
5	415. A theme was emerging: as new legislation and regulatory systems were enacted
6	that could have hampered the opioid supply chain, McKinsey stepped in as a key consultant for
7	the FDA. Each time, the new system failed to reign in the out-of-control opioid market. While the
8	FDA was not solely responsible for regulating the opioid industry and McKinsey was not wholly
9	responsible for the FDA's inaction, tools like Sentinel and track and trace could have been
10	implemented in a way to provide new information to combat the country's growing opioid crisis.
11	416. At the same time it was consulting for the FDA, McKinsey was working with its
12	opioid industry clients on how skirt the FDA's regulatory systems.
13	417. For example, McKinsey advised Purdue on how to soften the FDA's proposed
14	REMS and on coordinating with other opioid manufacturers to advocate against strict
15	oversight. ³¹¹ The finalized REMS for opioid products was largely devoid of the restrictions that
16	FDA had initially proposed. ³¹²
17	418. McKinsey's work with the FDA was a key factor in why pharmaceutical industry
18	clients tapped McKinsey for FDA-related work. For example, in endorsing McKinsey's proposed
19	strategy of banding together with other opioid manufacturers, Purdue CEO John Stewart
20	suggested that the consultant itself facilitate the pharmaceutical group's approach to FDA. He
21	wrote: "Perhaps a consultant such as McKinsey who did similar work in the industry and FDA on
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23	³⁰⁸ Ian MacDougall, "McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for
24	the Agency," <i>ProPublica</i> (Oct. 4, 2021), <i>available at</i> https://www.propublica.org/article/mckinsey-never-told-the- fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency
25	³⁰⁹ Letter to Bob Sternfels from Representative Carolyn B. Maloney, Nov. 5, 2021, <i>available at:</i> https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-11-05.CBM%20to%20Sternfels-
26	McKinsey%20re%20Document%20and%20Information%20Request%20%28001%29.pdf ³¹⁰ Sabrina Tavernise, "F.D.A. Faulted for Problems With Drug Tracking" <i>The New York Times</i> , Jan. 14, 2016,
27	<i>available at</i> 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
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^{28 &}lt;sup>311</sup> Hassan Letter. ³¹² Hassan Letter; Maloney Letter.

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1	some aspects of clinical trials or a healthcare-related group that would be interested in playing an
2	active role in the program's development and delivery would be a good choice." ³¹³
3	419. McKinsey performed work for the FDA without disclosing its potential conflicts
4	of interest to the FDA in violation of the contracts between the company and the agency.
5	420. The FDA typically includes conflict of interest clauses in its contracts and relies on
6	contractors to assess and report any conflicts. McKinsey's contracts with the FDA related to
7	CDER processes contained such provisions. One contract required McKinsey to "make an
8	immediate and full disclosure, in writing, of any potential or actual organizational conflict of
9	interest or the existence of any facts that may cause a reasonably prudent person to question the
10	contractor's impartiality because of the appearance or existence of bias." ³¹⁴
11	421. But McKinsey never disclosed its work on behalf of opioid supply clients to the
12	FDA despite having a hand in developing some of the FDA's most important regulatory
13	processes. ³¹⁵
14	422. Disclosing its conflicts might have turned off the lucrative tap to not only FDA
15	contracts but also to pharmaceutical industry clients, given the clear value such clients placed on
16	McKinsey's work for the FDA.
17	423. McKinsey's manipulation of regulatory requirements—whether to skirt its own
18	contractual requirements or to bend processes that regulate its clients—is nothing new. McKinsey
19	has come under fire from the Office of Inspector General for the General Services Administration
20	for contract procurement violations ³¹⁶ and from the Justice Department related to violation of
21	Chapter 11 bankruptcy rules. ³¹⁷ Most recently, six senators have begun to investigate the
22	
23	³¹³ Purdue Bankruptcy, Doc. 2166-5, at 58-59.
24	³¹⁴ Ian MacDougall, McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency, <i>ProPublica</i> (Oct. 4, 2021), available at https://www.propublica.org/article/mckinsey-never-told-the-fda-it-
25	was-working-for-opioid-makers-while-also-working-for-the-agency ³¹⁵ <i>Id.</i> ; Letter to Senator Chuck Grassley from Andrew Tantillo, Oct. 22, 2021, <i>available at</i> :
26	https://www.grassley.senate.gov/imo/media/doc/fda_to_grassleymckinsey_conflicts_of_interest.pdf ³¹⁶ Ian MacDougall, How McKinsey Makes Its Own Rules, <i>ProPublica</i> (Dec. 14, 2019), available at
27	https://www.propublica.org/article/how-mckinsey-makes-its-own-rules

³¹⁷ 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-28 investigation-bankruptcy.html

1	relationship between McKinsey and the FDA ³¹⁸ the House Committee on Oversight and Reform
2	is exploring its abusive conduct in connection with the opioid industry. ³¹⁹
3	424. As one commentator noted, McKinsey's conduct suggests that it "behaves as if it
4	believes the rules should bend to its way of doing things, not the other way around." ³²⁰
5	F. <u>McKinsey's Efforts to Increase the Overall Size of the Opioid Market: the</u> Larger the Pie, the Larger the Slice
6	
7	425. McKinsey advised multiple opioid manufacturers regarding how to grow opioid
8	sales. In order to benefit all its clients, McKinsey engaged in efforts to grow the entire opioid
9	market, and not only each individual client's share of it. The theory, basically, is that a rising tide
10	lifts all boats.
11	426. For example, Purdue incentivized its sales staff "to increase not just sales of
12	OxyContin but also generic versions of extended release oxycodone." Typically, one would not
13	wish to encourage the sales of generic competitors that offer a similar product to one's own. If,
14	however, the goal is to position a company so as to look like an attractive acquisition target, the
15	growth of the overall opioid market is just as important as one's own market share: "Whereas
16	pharma salespeople are usually compensated based on their ability to grow sales of a particular
17	medicine, part of the bonus for Purdue's staff was calculated in relation to the size of the overall
18	market." ³²¹ McKinsey designed that plan. ³²²
19	
20	³¹⁸ Hassan Letter. ³¹⁹ Maloney Letter.
21	³²⁰ Ian MacDougall, How McKinsey Makes Its Own Rules, <i>ProPublica</i> (Dec. 14, 2019), available at
22	https://www.propublica.org/article/how-mckinsey-makes-its-own-rules ³²¹ See David Crow, How Purdue's 'one-two' punch fuelled the market for opioids, Financial Times, September 9,
23	2018, <i>available at</i> : https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c ³²² Worth noting is that this strategy of increasing overall opioid sales directly benefitted the Sacklers through their
24	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. <i>See, e.g.</i> , MCK-
25	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,
26	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
27	oligarchic position." Michelle Celarier, <i>The Story McKinsey Didn't Want Written</i> , Institutional Investor, July 8, 2019, <i>available at:</i> https://www.institutionalinvestor.com/article/b1g5zjdcr97k2y/The-Story-McKinsey-Didn-t-Want-
28	 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

1 427. This notion that the size of a company's market share is not as important as the 2 size of the *overall* market in which it competes is a core insight of McKinsey's granular approach 3 to identifying corporate growth opportunities. Describing their authors' conclusions in The 4 Granularity of Growth, McKinsey stated, "One of their most surprising conclusions is that 5 increased market-share is seldom a driver of growth. They contend, instead, that growth is driven 6 by where a company chooses to compete: which market segments it participates in . . . the key is 7 to focus on granularity, to breakdown big-picture strategy into its smallest relevant components."³²³ 8

In other words, "Purdue's marketing force was indirectly supporting sales of 9 428. millions of pills marketed by rival companies."³²⁴ "It's the equivalent of asking a McDonald's 10 store manager to grow sales of Burger King and KFC," stated a government official with the 11 Department of Health and Human Services.³²⁵ 12

13

G. McKinsey's Work Kills People.

429. The deceptive marketing strategies McKinsey developed and helped to implement 14 were successful. Its granular growth tactics, myopically focused on increased revenues for its 15 clients, substantially contributed to an explosion in the use of opioids across the country. 16 17 Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the 18 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.³²⁶ 19 430. In 2009, Dr. Van Zee identified the *precise tactics* that McKinsey deployed for all 20 of its opioid clients, including Purdue, as a source of OxyContin misuse and abuse, and suggested 21 22 that regulation may be appropriate to curtail the use of the McKinsey's tactics: "The use of 23 prescriber profiling data to target high-opioid prescribers—coupled with very lucrative incentives 24

³²³ The granularity of growth, Book Excerpt, McKinsey & Company, March 1, 2008, available at:

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suggests Purdue should reassess the roles of MSL and HECON Groups - and further drive the salesforce to be more 25 responsive to formulary coverage changes." (emphasis added).

²⁶ https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/the-granularity-of-growth ³²⁴ See David Crow, How Purdue's 'one-two' punch fueled the market for opioids, Financial Times, September 9,

²⁷ 2018, available at: https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c 325 Id.

²⁸ ³²⁶ 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

1 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."³²⁷ 2

3 431. In time, additional evidence mounted supporting the conclusion that McKinsey's tactics were demonstrably exacerbating the nationwide opioid crisis. One way of demonstrating 4 5 the link between aggressive sales and marketing of opioids and worsened mortality outcomes 6 arose out of a quirk of Purdue's own marketing tactics.

7 In 1996, when OxyContin was introduced, five states maintained "triplicate" 432. 8 programs that required prescribers of Schedule II controlled substances to fill out prescriptions in triplicate.³²⁸ One of the triplicate copies would then be filed with the state agency in charge of 9 maintaining a prescription database intended to monitor diversion and other potential issues 10 11 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 12 13 focus its marketing efforts in other states that did not impose these constraints.

This resource-allocation decision by Purdue to focus more marketing efforts in 14 433. states with fewer regulations regarding the prescribing of controlled substances provided a way to 15 test whether *marketing* of OxyContin, by itself, was a cause of not only increased overdose rates 16 17 for OxyContin, but of *all* opioid-related overdoses, *including* those involving illicit opioids such 18 as heroin and fentanyl.

19 434. 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 20 21 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.³²⁹ 22 435. The economists found that "OxyContin distribution was about 50% lower in

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'triplicate states' in the years after the launch. While triplicate states had higher rates of overdose

³²⁹ Abby E. Alpert, William N. Evans, Ethan M.J. Lieber, and David Powell, Origins of the Opioid Crisis and its 28 Enduring Impacts, NBER Working Paper No. 26500, November 2019, available at: https://www.nber.org/papers/

²⁶ ³²⁷ 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. 27 ³²⁸ Patrick Radden Keefe, *Empire of Pain*, Pg. 407.

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deaths prior to 1996, this relationship flipped shortly after the launch [of OxyContin] and 2 triplicate states saw substantially slower growth in overdose deaths, continuing even twenty years 3 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."³³⁰ 4

5 A 2017 Journal of American Medical Association study found that physicians 436. 6 ordered fewer promoted brand-name medications and prescribed more cost-effective generic 7 versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.³³¹ The changes in prescribing behavior 8 9 appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices which 10 11 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 12 13 drug utilization. An additional study found that doctor meetings with sales representatives are 14 related to changes in doctor prescribing practices and requests by physicians to add the drugs to 15 hospitals' formularies.

A more recent Journal of American Medical Association study analyzed the 16 437. 17 Centers for Medicare and Medicaid Services' Open Payments database regarding pharmaceutical 18 company marketing efforts towards doctors, as well as CDC data on prescription opioid overdose 19 deaths and prescribing rates, in order to assess whether pharmaceutical marketing of opioids to 20 physicians affected the rate of prescription opioid overdose deaths. Notably, the study analyzed these marketing practices beginning August 1, 2013 and ending December 31, 2015.³³² 21 22 438. Those dates are significant, as the study captures the same timeframe that

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McKinsey's Project Turbocharge, re-christened E2E, was implemented.

²⁶ ³³⁰ *Id.* (emphasis added). ³³¹ Ian Larkin et al., Association Between Academic Medical Center Pharmaceutical Detailing Policies and 27 Physician Prescribing, 317 J. Am. Med. Ass'n 1785 (2017).

³³² Scott E. Hadland et. al., Association of Pharmaceutical Industry Marketing of Opioid Products with Mortality

²⁸ from Opioid-Related Overdoses, JAMA Network, January 18, 2019, available at: https://jamanetwork.com/journals/ jamanetworkopen/fullarticle/2720914.

1 439. The study noted "physician prescribers are the most frequent source of prescription opioids for individuals who use opioids nonmedically."³³³ 2 3 440. The study found that "increased county-level opioid marketing was associated 4 with elevated overdose mortality 1 year later, an association mediated by opioid prescribing rates; 5 per capita, the number of marketing interactions with physicians demonstrated a stronger 6 association with mortality than the dollar value of marketing."³³⁴ 7 441. Referring to the sales and marketing tactics McKinsey specialized in 8 implementing, the authors concluded, "amid a worsening opioid crisis, our results suggest that 9 industry marketing to physicians may run counter to current efforts to curb excessive opioid prescribing."335 10 The authors' proposed solution was plain and simple, and echoed Dr. Van Zee's 11 442. congressional testimony from 2002: "Pharmaceutical companies might also consider, as one 12 manufacturer recently did, voluntarily ceasing marketing opioid products directly to 13 physicians."336 14 15 443. 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 16 17 control and restraint in their use was internally understood, as was the likelihood of large-scale 18 opioid addiction, abuse, overdoses, illness, and early death resulting from sharply increased use. 19 444. McKinsey also performed its own research in evaluating the anticipated effects of 20 Project Turbocharge. An April 2014 implementation update observed an increase in sales calls, as 21 well as that "OxyContin [health care providers] with increased calls consistently outperform HCPs with decreasing or no change in call frequency." 22 23 445. 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 24 therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."337 25 26 ³³³ Id. 27 ³³⁴ *Id.* (emphasis added) ³³⁵ Id. 28 ³³⁶ *Id.* (emphasis added).

³³⁷ Theodore J Cicero et al., Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural,
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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."³³⁸

5 446. There is a "parallel relationship between the availability of prescription opioid
6 analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and
7 associated adverse outcomes."³³⁹ The opioid epidemic is "directly related to the increasingly
8 widespread misuse of powerful opioid pain medications."³⁴⁰

9 447. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has
10 quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving
11 opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the
12 CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to
13 reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."³⁴¹

448. 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.

449. 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.

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28 ³⁴¹ 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.

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²⁵ *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.

^{26 &}lt;sup>338</sup> https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-actionto-combat-the-opioid-epidemic

 ³³⁹ 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).

³⁴⁰ Califf, MD, et al., A Proactive Response to Prescription Opioid Abuse, New Engl. J. Med. (Apr. 14, 2016).

450. As McKinsey itself has recognized in citing a study reaching this conclusion,
 roughly 80% of heroin users previously used prescription opioids.³⁴² 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.

451. 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
prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into
Plaintiffs' communities.

452. 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.

453. 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.

454. 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.

455. 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

^{28 &}lt;sup>342</sup> https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic

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. <u>McKinsey Knew that OxyContin Was Highly Abusable, Addictive, and</u> Dangerous, and that Its Marketing Strategies Increased Those Harms.

5 McKinsey continued working with Purdue long after the severity of the opioid 456. 6 crisis was well known. McKinsey knew that high dose OyxContin prescriptions carried a serious 7 risk of overdose. In 2017, over half of Purdue's opioids prescriptions exceeded the ninety mg 8 morphine equivalence threshold a day—the recommended maximal dose per the 2016 CDC 9 Guideline for Prescribing Opioids for Chronic Pain. Purdue's 2007 guilty plea put McKinsey on notice of Purdue's misconduct. By 10 457. 11 that time, McKinsey had access to public information indicating that OxyContin and other 12 opioids pose significant risk of addiction and misuse. 13 458. 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 14 the regulatory submissions for reformulated OxyContin.³⁴³ 15 459. The first bullet point of Purdue's 2007 "Observations and Activities Requiring an 16 [Abuse, Diversion, and Detection] Report" was "[a]n apparent pattern of an excessive number of 17 patients for the practice type[.]"³⁴⁴ Thus, McKinsey knew or should have known that there was a 18 higher risk of abuse and diversion among high-volume prescribers. 19 20 460. What is more, on September 13, 2013 McKinsey briefed Purdue on the ongoing concerns regarding OxyContin addiction and diversion among prescribers: 21 22 23 24 25 26 27 ³⁴³ McKinsey PPLPC0390000347612 28); McK-MAAG-0118819 (email chain).

³⁴⁴ PPLPC010000033944.

CONSOLIDATED CLASS ACTION COMPLAINT (THIRD PARTY PAYORS) 21-MD-02996-CRB (SK)

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1	
2	Findings on messaging and positioning
3	Opioids overall are still viewed as effective and necessary class of painkillers,
4	Key themes from prescriber interviews on abuse deterrents include:
5	Prescriber awareness of abuse deterrence and label change is mixed Opinions on impact/efficacy of abuse deterrence vary Most prescribers are concerned about abuse, but attempt to establish measures to
6	protect themselves Concerns remain that technology does not address oral abuse Less informed prescribers ask for additional information and education around
7	Easi indicated prevalues day for additional information and education dropid abuse deterrent formulations Existing market research suggests that most physicians do not feel that
8	reformulation positively impacts their prescribing behavior, and that diversion, abuse and regulatory concerns continue to weigh on prescribers
9	
10	
11	
12	McKinsay & Company 27
13	461. In a PowerPoint slide entitled "Findings on messaging and positioning," part of a
14	presentation to Purdue entitled "OxyContin growth opportunities: Phase 1 Final Report:
15	Diagnostic," McKinsey noted that "most prescribers are concerned about abuse," and that "most
16	physicians do not feel that [OxyContin] reformulation positively impacts their prescribing
17	behavior, and that diversion, abuse and regulatory concerns continue to weigh on prescribers."
18	462. In an August 2017 presentation, McKinsey recognized that the opioid epidemic
19	was "triggered, in large part, by a massive increase in prescribed opioids in the early 2000's."
20	463. McKinsey's presentations to Purdue included extensive discussion of doctors'
21	concerns about opioid misuse and side effects, demonstrating McKinsey's awareness of the
22	dangers of opioids. Rather than working to limit these disastrous effects, McKinsey treated
23	doctors' misgivings as obstacles to confront with new messaging.
24	464. Indeed, one reason that <i>Purdue</i> had knowledge that their own products were
25	addictive and dangerous is because McKinsey told them.
26	465. If McKinsey was not aware of the adverse consequences of OxyContin, the drug it
27	was paid to sell, such ignorance could not survive the granular reality of its relationship with
28	

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1	Purdue. For example, in June 2009, McKinsey worked to "counter the emotional messages from
2	mothers with teenagers that overdosed on OxyContin." ³⁴⁵
3	466. Within a few years of countering these emotional messages, McKinsey even
4	developed a method to identify geographic hot spots of OxyContin abuse and diversion. Once
5	developed, however, McKinsey simply never used it to decrease these harms.
6	467. Paul Coplan
7	
8	.346
9	468. In deposition testimony in prior opioid-related litigation, Coplan was asked,
10	"While you were at Purdue, did Purdue make an effort to identify hot spots for opioid abuse and
11	addiction or not?" ³⁴⁷
12	469. "
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14	**348
15	.349
16	470.
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20	" 350 ————————————————————————————————————
21	471. Instead, McKinsey focused on increasing opioid sales for its clients, despite
22	knowing the harmful consequences of doing so. In yet another indication that OxyContin sales
23	should not be turbocharged: during McKinsey's work for Purdue, Purdue was unable to purchase
24	product liability insurance to cover its practice of selling OxyContin.
25	
26	 ³⁴⁵ PDD8901645845. ³⁴⁶ Paul M. Coplan 1/18/19 Dep. Tr. At 16:18 -17:17.
27	³⁴⁷ <i>Id.</i> at 355:10. ³⁴⁸ <i>Id.</i> at 355:14–356:11.
28	³⁴⁹ <i>Id.</i> at 357:8-16. ³⁵⁰ <i>Id.</i> at 357:22–358:6.
	CONSOLIDATED CLASS ACTION

I

1	472. The basic premise of McKinsey's work put it on notice of the harmful
2	consequences that would ensure. It was tasked with advising a monoline manufacturer of opioids
3	about sales and marketing practices for its addictive products while that manufacturer was bound
4	by a five-year Corporate Integrity Agreement covering the very same opioid sales and marketing
5	practices. In 2012, OxyContin accounted for 94% of Purdue's revenue. ³⁵¹ As late as 2018, it
6	remained 84% of Purdue's revenue. ³⁵² According to the U.S. Department of Justice, "[f]rom 2010
7	to 2018, Purdue's profits were almost entirely driven by its success in selling OxyContin." ³⁵³ In
8	2015 alone, it obtained \$3 billion in annual opioid sales—a four-fold increase from its 2006 sales
9	of \$800 million.
10	473. McKinsey's mandate was to increase Purdue's opioid sales during a time when
11	Purdue was obligated to restrict its previous marketing strategies because those strategies had
12	caused the overprescribing of opioids and the inevitable consequences thereof. McKinsey's job
13	was to counter the intended results of the Corporate Integrity Agreement; to devise strategies to
14	sell as many pills as conceivably possible. Under McKinsey's tutelage, Purdue's growth
15	continued its upward trajectory unabated, the Corporate Integrity Agreement notwithstanding.
16	I. <u>McKinsey Portrays Itself as Part of a Solution to a Problem It was Integral in</u>
17	<u>Creating</u> .
18	474. McKinsey's work on the other side of the aisle—helping clients address opioid
19	abuse and addiction-further proves that it was well aware of the risks of OxyContin, and thus
20	the risks of pushing OxyContin sales and high dose sales, and targeting the highest-volume
21	prescribers. McKinsey advised Purdue on "Project Tango," a 2014 plan to enter the addiction
22	drug market. ³⁵⁴ McKinsey noted the
23	,,355
24	
25	³⁵¹ Gerald Posner, <i>Pharma</i> , pg. 524 (Simon & Schuster 2020).
26	 ³⁵² Id. ³⁵³ https://www.justice.gov/opa/press-release/file/1329571/download
27	 ³⁵⁴ 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-
28	lawsuit-anti-addiction-market. 355 PPLPC023000714734.

1	475. More than assisting specific clients with addressing the crisis itself, McKinsey saw
2	the ongoing opioid crisis as an opportunity to posture itself as contributing more broadly to
3	society. McKinsey likes to think of itself as a change agent capable of solving problems that truly
4	matter, and the opioid crisis is one McKinsey realizes matters. Dr. Sarun Charumilind, a
5	McKinsey partner in Philadelphia, "has led the firm's support to clients and society to combat the
6	opioid crisis. ³⁵⁶
7	476. In Detroit, partner Razili Lewis also helps "clients and <i>society</i> combat the opioids
8	crisis." She does so by providing "insights, expertise, analytics, and technology."357
9	477. Over in Cleveland, senior partner Tom Latkovic also "helps clients and <i>society</i>
10	combat the opioids crisis." ³⁵⁸
11	478. Kana Enomoto, a senior expert in Washington, D.C., is a "national leader in
12	mental health and substance-use policy," who acted as a "content director" on a study to "raise
13	awareness about opioid-use disorders." She also provided strategic guidance to the United States
14	Surgeon General regarding efforts to "combat the opioid epidemic" when she was his Chief of
15	Staff. ³⁵⁹
16	479. McKinsey consistently states that it takes its obligations to society seriously.
17	Indeed, the firm has established a center: ³⁶⁰
18	The Center for Societal Benefit through Healthcare was established to build on the
19	long-standing mission of McKinsey's Public & Social Sector and Healthcare Systems & Services Practices to improve healthcare. The Center's work is funded
20	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
21	healthcare expertise, advanced analytics, functional knowledge, technology assets,
22	network, and investment capacity.
23	The Center aspires to collaborate with other organizations to drive positive innovation to improve overall health and well-being and reduce healthcare
24	disparities.
25	
26	³⁵⁶ See https://www.mckinsey.com/our-people/sarun-charumilind
27	 ³⁵⁷ See https://www.mckinsey.com/our-people/razili-lewis ³⁵⁸ See https://www.mckinsey.com/our-people/tom-latkovic ³⁵⁹ See https://www.mckinsey.com/our-people/kana-enomoto
28	 See https://www.mckinsey.com/our-people/kana-enomoto ³⁶⁰ See https://www.mckinsey.com/industries/healthcare-systems-and-services/how-we-help-clients/center-for-societal-benefit-through-healthcare/overview

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1	
2	 RECENT CLIENT EXPERIENCE Designed and helped launch a health home program to expand resources and accountability for substance abuse treatment
3	Conducted a state wide assessment of opioid prescriber
4 5	Defined clinically relevant opioid quality measures for a portfolio
6	 Defined clinically relevant opioid quality measures for a Patient
7	 Centered Medical Home and Accountable Care Organizations Used predictive analytics to develop multi-faceted approach to access patient risk for enigid addiction
8	 assess patient risk for opioid addiction Used geo-spatial and social network analytics to assess intensity of opioid abuse and treatment needs
9	
10	Integrated claims and PDMP data to generate transparency on provider prescribing practices
11	>>> Developed a substance abuse episode of care focused on priority patient journeys
12	
13	486. In June 2018, Dr. Charumilind and Mr. Latkovic, along with fellow McKinsey
14 15	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
15	advising Purdue to sell more opioids and higher dose opioids, and target the highest volume
17	prescribers:
18	a. "Providers frequently prescribe opioids to patients with known or potential
19	risk factors for abuse[;]"
20	b. "Approximately 35% of the patients given opioid prescriptions in our
21	analysis had features that put them at increased risk for opioid abuse[;]"
22	c. "Most opioids are prescribed by providers other than the natural
23	'quarterback' of a patient's underlying complaint or condition This finding makes clear that
24	high-dose prescribers and multi-prescriber patterns are separate issues—and both are important to
25	address[;]" and
26 27	d. "A small portion of opioid use originates in emergency departments." ³⁶⁵
27 28	365 https://www.makingay.com/industries/healthcore.com/com/ and com/ins//www.makingay.com/insights/and the second second com/insights/and insights/and the second s
20	³⁶⁵ https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/ten-insights-on-the-us-opioid-crisis-from-claims-data-analysis

- 1 487. Two months later, the same authors, joined by Ms. Lewis, published "Why we need bolder action to combat the opioid epidemic."³⁶⁶ "Our research suggests that much broader – 2 and bolder – action is required," they announced. 367 3
 - J.

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Coda

5 488. Marvin Bower, the McKinsey legend who admonished, "Deliver bad news if you 6 must, but deliver it properly," died in 2003, one year before the firm began working with Purdue.

7 489. McKinsey's work with Purdue would have been unrecognizable to Bower, one of 8 the founders of modern management consulting. Instead of acknowledging the elephant in the 9 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, 10 11 McKinsey instead committed to partner with Purdue to maximize opioid sales without regard to the consequences. 12

13 490. On October 23, 2017, the president of the United States declared the ongoing 14 nationwide opioid epidemic a "public health emergency." Even at this late hour in the crisis, 15 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 16 17 rapidly address market access challenges."

18 491. Less than two months after the public health emergency declaration, McKinsey 19 proposed these high impact interventions to Purdue and its board. Among them was perhaps

20 McKinsey's most audacious gambit of the entire Purdue relationship: paying money—

"rebates"—to health insurers whenever someone overdosed on Purdue's drug. 21

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492. These payments for future OxyContin overdoses were christened "Event-Based contracts."368

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28 November 27, 2020, available at: https://www.nytimes.com/2020/11/27/business/mckinsey-purdue-oxycontinopioids.html

²⁵ ³⁶⁶ See https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolderaction-to-combat-the-opioid-epidemic ³⁶⁷ Id.

³⁶⁸ "Consultant-ese," when applied to work as grim as maximizing opioid sales in the face of a national disaster, led 27 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,

493. Helpfully, McKinsey provided estimates for the future costs of these "events."³⁶⁹
 McKinsey noted that, if Purdue were to start making overdose payments, it would "need to
 determine which payment amount is optimal."

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



495. 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.

496. 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

³⁶⁹ McKinsey defined an "event" as "first occurrence for overdose or opioid use disorder."

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1	customers. McKinsey "projected that in 2019, for example, 2,484 CVS customers would either
2	have an overdose or develop an opioid use disorder." ³⁷⁰
3	497. It is little surprise, then, that McKinsey was concerned with its legal liability for
4	this work. Within months of recommending "event-based contracts" to Purdue, Martin Elling
5	raised this concern with Arnab Ghatak and suggested corrective action: destroying evidence.
6	
7	Message
8 9 10	From:Martin Elling [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6B33C3264F744B04AF05FA59341271BE-MARTIN ELLI]Sent:7/4/2018 12:10:13 PMTo:A G [drarnabghatak@gmail.com]Subject:Re: [EXT]Re: Howdy
11	Have a great fourth. M
12	> On Jul 4, 2018, at 2:01 PM, A G <drarnabghatak@gmail.com> wrote:</drarnabghatak@gmail.com>
13	> Thanks for the heads up. Will do. > >> On Jul 4, 2018, at 7:57 AM, Martin Elling <martin_elling@mckinsey.com> wrote:</martin_elling@mckinsey.com>
14 15	>> >> 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
16 17	<pre>>> >> +=========+++++++++++++++++++++++</pre>
18	498. Elling's prediction that things would "get tougher" for Purdue would prove
19	prescient.
20	1. <u>Guilty Again - 2020</u>
21	499. On October 20, 2020, Purdue—McKinsey's co-conspirator—agreed with the
22	United States Department of Justice to plead guilty to improper marketing of OxyContin and
23	other opioids again (the "2020 Settlement Agreement"). This time the plea agreement concerned
24	conduct from 2010 to 2018. The agreement includes \$8.3 billion in penalties from Purdue and
25	\$225 million from the Sackler family.
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,	³⁷⁰ Walt Bogdanich and Michael Forsythe, McKinsey Proposed Paying Pharmacy Companies Rebates for OxyContin

 ³⁷⁰ 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

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1	500. Purdue pleaded guilty to a dual-object conspiracy to defraud the United States and
2	to violate the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331, 353, violating anti-kickback laws,
3	and "using aggressive marketing tactics to convince doctors to unnecessarily prescribe opioids-
4	frivolous prescriptions that experts say helped fuel a drug addiction crisis that has ravaged
5	America for decades."
6	501. The new plea agreement does not identify Purdue's co-conspirators, and
7	McKinsey is not identified by name in the agreement. Instead, McKinsey is referred to as the
8	"consulting company."
9	502. Purdue's new guilty plea concerns Covered Conduct (as defined in the plea
10	agreement) that directly implicates McKinsey in the conspiracy. It is the same conduct described
11	in this Complaint.
12	503. Indeed, the plea agreement signed by McKinsey's co-conspirator states bluntly:
13	"Purdue, in collaboration with [McKinsey], implemented many of [McKinsey's]
14	recommendations." (emphasis added).
15	504. Further, Purdue admitted that E2E "was overseen by [McKinsey] and some of
16	Purdue's top executives through the creation of the E2E Executive Oversight Team ('EOT') and
17	Project Management Office ('PMO')" (emphasis added).
18	2. <u>A Mea Culpa</u>
19	505. On December 5, 2020, six weeks after Purdue's second guilty plea, McKinsey
20	issued a rare public statement regarding its work with a specific client on its website. The client
21	was Purdue, and the statement was issued is response to Purdue's second guilty plea and recent
22	media reports regarding McKinsey's work selling OxyContin after 2007:
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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.

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

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

508. 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.³⁷¹ McKinsey has
long assisted the Sacklers in growing Mundipharma's opioids market.³⁷² 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

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³⁷¹ See Kinetz, Erika, *Fake doctors, pilfered medical records drive OxyChina sales*, Associated Press, November 19, 2019, *available at:* https://apnews.com/article/4122af46fdba42119ae3db30aa13537c

^{28 3&}lt;sup>72</sup> See, e.g., MCK-MDL2996-0256120; MCK-MDL2996-0327127; MCK-MDL2996-0183279; MCK-MDL2996-0286490.

was performing for the various Sackler interests, including "integrat[ing] the Mundipharma
 stuff." ³⁷³ 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.

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3. A Hedge Fund

509. 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.

510. 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.

15 511. Consultants don't typically have in-house hedge funds overseeing retirement
16 accounts and partners' personal investments. In fact, McKinsey is the only one. "Most large
17 companies, including all the major consulting firms, hire third-party firms . . . to oversee their
18 employees' retirement accounts."³⁷⁴ MIO manages approximately \$31 billion on behalf of
19 McKinsey partners, employees, and former partners.³⁷⁵

512. 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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³⁷³ MCK-MDL2996-0210149

 ³⁷⁴ 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

 ³⁷⁵ 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.



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"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.

5 518. In other words, for *at least 40*% of MIOs holdings, McKinsey partners are able to
6 know the specific investments held by the various MIO funds. "MIO has a ledger for every
7 security in their managed accounts."³⁷⁷ That comprises a pool of capital worth more than \$6
8 billion.

9 519. MIO is run for the benefit of McKinsey's partners and, to a separate extent, 10 McKinsey's employees. Those individuals (and, crucially, former McKinsey partners) invest their 11 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 12 13 ability to view the individual securities that account for approximately 40 to 50 percent." This is 14 approximately \$6 billion dollars of invested capital. What is more, MIO directly invests 15 approximately 10% of its assets. That is \$1.5 billion MIO directly invests in securities without the 16 use of any outside money manager. These numbers exclude leverage.

17 From a conflicts perspective, the fact that *former* partners may participate in MIO 520. 18 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 19 20 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 21 22 partner. Frank Scholz, President of opioid defendant SpecGX, a subsidiary of Mallinckrodt, is a 23 former McKinsey partner. Marc Owen, President of opioid defendant McKesson, is a former McKinsey partner. This list is merely illustrative; it is not exhaustive. 24

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521. 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

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 ³⁷⁷ 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).

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522. 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.

- 523. One is Deerfield Management Co., "a \$10 billion dollar health care investment
 firm based in New York."³⁷⁸ 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."³⁷⁹ 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.³⁸⁰
- 13 524. McKinsey is also invested in treatment, an inevitable growth industry sprouting 14 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 15 overdoses," and therefore "may also benefit from opioid settlement funds" paid by McKinsey as a 16 17 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).³⁸¹ Separately, Deerfield 18 invested \$331 million in Recovery Centers of America, an addiction treatment company that 19 operates facilities in states that McKinsey recently settled with.³⁸² 20
- 525. 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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- 27 ³⁷⁹ *Id*.
- ³⁸⁰ Id.
- $28 \qquad {}^{381}$ Id.

 ³⁷⁸ 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

³⁸² Id.

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VI. **TOLLING OF STATUTES OF LIMITATIONS**

At all times relevant to this Complaint, McKinsey and Purdue took active steps to 2 526. 3 conceal their unlawful activities, including through the conspiracy alleged herein. For example 4 and without limitation, McKinsey, Purdue, and other Opioid Marketing Enterprise Members 5 concealed their efforts to (i) circumvent the restrictions of the Corporate Integrity Agreement in 6 order to increase the sale of opioids; and (ii) further boost the sale of opioids after the expiration 7 of that Agreement, including through "Project Turbocharge" and "Evolve to Excellence." 8 McKinsey, Purdue, and other Opioid Marketing Enterprise Members further undertook active 9 efforts to deceive Plaintiffs, the class, and the general public, thus concealing their unlawful conduct, including by making unfair and/or deceptive representations about the use of opioids to 10 11 treat chronic and non-cancer pain, creating and implementing a deceptive opioid marketing strategy, omitting or concealing material facts, and failing to correct prior misrepresentations and 12 13 omissions about the purported benefits and risks of opioids.

Discovery Rule. McKinsey's consulting services were given confidentially, and 14 527. the content of those services was not public. Plaintiffs did not have knowledge of the scope, 15 magnitude, and unlawful nature of McKinsey's conduct until 2020, when documents produced in 16 the Purdue bankruptcy proceeding revealed details regarding McKinsey's role in advising Purdue 17 18 and working with Purdue to implement the unlawful conduct detailed in this Complaint. Information in the public domain was insufficient to place Plaintiffs and the Class on inquiry 19 20 notice of McKinsey's unlawful, unfair, and deceptive activities prior to 2020. For these reasons, any statutes of limitations applicable to the claims of Plaintiffs and the Class did not begin to run 21 and have been tolled until at least some point in 2020. 22

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528. Fraudulent Concealment. The statutes of limitation were further tolled by the doctrine of fraudulent concealment. McKinsey, Purdue, and other Opioid Marketing Enterprise 24 25 Members actively concealed the existence of their unlawful scheme, through false or misleading representations. Despite the requirements of the Corporate Integrity Agreement, which restrained 26 27 Purdue from making any deceptive or misleading claims about OxyContin, McKinsey devised a 28 strategy and worked with Purdue to implement the strategy to maximize the sale of opioids,

including deceptive and misleading claims regarding the risks, efficacy, and medical necessity of
opioids, generally, and Purdue's opioids, specifically. McKinsey knew these representations were
false, and made them recklessly without knowledge of the truth and/or had no reasonable ground
for believing such assertions, but devised and implemented a strategy to spread these deceptive
and misleading claims to health care providers, consumers, Plaintiffs, the Class, and the public in
order to boost sales of opioids, including Oxycontin, despite the public impression that Purdue
had corrected its conduct as a result of the Agreement.

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529. McKinsey and Purdue were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

530. McKinsey's fraudulent concealment prevented Plaintiffs and the Class from
discovering the scope, magnitude, and unlawful nature of McKinsey's conduct until 2020, when
documents produced in the Purdue bankruptcy proceeding revealed details regarding McKinsey's
role in advising Purdue and working with Purdue to implement the unlawful conduct detailed in
this Complaint.

16 531. Continuing Tort. McKinsey is estopped from relying on any statute of limitations
17 defense because its illegal, deceptive, and fraudulent practices as alleged herein, which were
18 continuing in nature, have created continuing and repeated injuries to Plaintiffs and the Class.

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VII. HARM CAUSED TO THIRD PARTY PAYOR PLAINTIFFS

532. By increasing opioid prescriptions and use, McKinsey fueled the opioid epidemic
alongside its clients. The deceptive marketing strategies McKinsey developed and helped to
implement worked, as described above. Deceptive marketing, including marketing McKinsey
worked to develop and implement, 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 20% of office visits now include the prescription of an opioid.

27 533. Compounding the harms from deceptive marketing, McKinsey's strategy and the
28 implementation of that strategy expanded Purdue's role in supplying opioids, even seeking to

increase the sales from prescribers who would have raised red flags of potential diversion, and
 profiting from Purdue's role in funneling opioids into communities, beyond what any legitimate
 market, even an expanded market for chronic pain, could bear.

- Scientific evidence demonstrates a close link between opioid prescriptions and
 opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic
 exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."³⁸³ 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 examples of
 such practices as "successful in reducing prescribing."³⁸⁴
- 535. 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
 associated adverse outcomes."³⁸⁵ The opioid epidemic is "directly related to the increasingly
 widespread misuse of powerful opioid pain medications."³⁸⁶
- 15 536. Compounding the harm from deceptive marketing, McKinsey worked with Purdue
 16 to continue and grow the opioid sales from prescribers that raised red flags of diversion, despite
 17 Purdue's legal obligations to report and halt supply. In doing so, it enabled an oversupply of
 18 opioids, which has allowed non-patients to become exposed to opioids, and facilitates access to
 19 opioids for both patients who could no longer access or afford prescription opioids and addicts
 20 struggling with relapse.
- 537. 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.
 This epidemic of opioid addiction, abuse, and use, has caused harm to Plaintiff Third Party
 Payors. The type of harm incurred by various Third Party Payor Plaintiffs is economic in nature
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 ³⁸³ 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).

 ³⁸⁴ https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic
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 ³⁸⁵ 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).

³⁸⁶ Califf, MD, et al., A Proactive Response to Prescription Opioid Abuse, New Engl. J. Med. (Apr. 14, 2016).

in that TPPs paid for more opioids than for other efficacious drugs that were available at cheaper 1 prices, and/or paid for more opioids due to addiction, and/or paid for treatment including 2 3 treatment for Opioid Use Disorders, drug addiction treatment, and emergency medical care 4 including the costs of opioid overdose reversal drugs, such as Naloxone Hydrochloride (Narcan), 5 as a result of the abuse, misuse, addiction and/or overdose of opioids. 6 VIII. CLASS ACTION ALLEGATIONS 7 538. Plaintiffs bring this suit as a class action pursuant to Rule 23(b)(3) and 23(c)(4) of the Federal Rules of Civil Procedure. 8 9 539. The class is defined as: 10 All health insurance companies, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and other health benefit 11 providers, in the United States of America and its territories, who have since June 1, 2009 (a) paid or incurred costs for prescription Opioid drugs manufactured, 12 marketed, sold, or distributed by the Opioid Marketing Enterprise Members, for purposes other than resale, and/or (b) paid or incurred costs for treatment related to 13 the misuse, addiction, and/or overdose of opioid drugs. 14 540. Excluded from the class are (1) the Opioid Marketing Enterprise Members and 15 their subsidiaries, affiliates, and controlled persons; (2) current or former officers, directors, 16 agents, servants, or employees of the Opioid Marketing Enterprise Members, and the immediate 17 family members of any such person; (3) all persons who make a timely election to be excluded 18 from the proposed class; (4) governmental entities; and (5) any judge to which this case is 19 assigned and his or her staff. 20 541. Plaintiffs reserve the right to amend or modify the class definition with greater 21 specificity, further division into subclasses, or limitation to particular issues. 22 542. The proposed class is sufficiently numerous, as thousands of members of the class 23 were induced to pay for opioid drugs and treatment due to the misuse, addiction and/or overdose 24 through the Opioid Marketing Enterprise Members scheme. The class members are so numerous 25 and dispersed throughout the United States that joinder of all members is impracticable. The class 26 is composed of thousands of third-party payors, and the disposition of their claims in a class 27 action will benefit both the parties and the Court. It is estimated that in 2007, at least half a 28

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1	million individuals nationwide received prescriptions for opioid drugs. The Opioid Marketing
2	Enterprise Members sell millions of doses of opioid drugs in the United States every year, and
3	thus the class is sufficiently numerous to make joinder impracticable, if not outright impossible.
4	543. Class members can be identified by, inter alia, records maintained by Opioid
5	Marketing Enterprise Members, class members, pharmacies, and pharmacy benefit managers.
6	544. Common questions of law and fact exist as to all members of the class and
7	predominate over any questions affecting solely individual members of the class. Among the
8	questions of law and fact common to the class members are:
9	a. Whether McKinsey engaged in the conduct alleged herein;
10	b. Whether McKinsey substantially caused or contributed to the opioid
11	epidemic;
12	c. Whether McKinsey's conduct in creating, proposing, and implementing
13	sales and marketing strategies for opioids before and after Purdue's first guilty plea in 2007
14	relating to misbranding of OxyContin contributed to the Class's injuries;
15	d. Whether McKinsey performed reasonable due diligence in ascertaining the
16	risks associated with Defendants' strategies for "turbocharging" sales of OxyContin and other
17	opioids;
18	e. Whether McKinsey's implementation of its own sales and marketing
19	strategies at its clients caused or contributed to an increase in opioid addiction;
20	f. Whether McKinsey engaged in a pattern of deceptive, fraudulent and/or
21	improper activity;
22	g. Whether McKinsey and the other Opioid Marketing Enterprise Members
23	formed the Opioid Marketing Enterprise for the purpose of effectuating their fraudulent schemes;
24	h. Whether the Opioid Marketing Enterprise used the U.S. mails and/or
25	interstate wire facilities to carry out its fraudulent scheme;
26	545. Whether the Opioid Marketing Enterprise engaged in a pattern of racketeering;
27	a. Whether McKinsey's conduct, in whole or in part, has substantially
28	affected interstate and intrastate commerce;

1 2 b. Whether McKinsey engaged in conduct that violated the federal racketeering laws as alleged herein;

3 c. Whether Plaintiffs and the other members of the class were injured by 4 McKinsey's conduct and, if so, the appropriate class-wide measure of damages; and 5 d. Whether McKinsey was unjustly enriched. 546. Plaintiffs' claims are typical of the claims of the members of the class because 6 7 Plaintiffs and the class sustained damages arising out of the Opioid Marketing Enterprise 8 Members' (including McKinsey's) wrongful conduct as detailed herein. Specifically, Plaintiffs, 9 having expended substantial sums for the purchase of opioids and treatment for their abuse, assert claims that are typical of the claims of the entire class, and will fairly and adequately represent 10 11 and protect the interest of the class. 547. Plaintiffs have no interests antagonistic to or in conflict with those of the class 12 13 members and therefore should be adequate as a representative for the class members. Plaintiffs have retained counsel with substantial experience in prosecuting complex litigation and class 14 15 actions. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the class members and have the financial resources to do so. Neither Plaintiffs nor counsel has 16 17 any interest adverse to those of other class members. 18 548. A class action is superior to other available methods for the fair and efficient 19 adjudication of this controversy since joinder of all members of the class is impracticable. 20 Furthermore, because the damages suffered by individual members of the class may in some 21 instances be relatively small, the expense and burden of individual litigation make it impossible 22 for such class members individually to redress the wrongs done to them. Also, the adjudication of 23 this controversy through a class action will avoid the possibility of inconsistent and possibly conflicting adjudications of the claims asserted herein. There will be no difficulty in the 24

25 management of this action as a class action.

26 549. Even if members of the class could afford individual litigation, the court system
27 could not. Individualized litigation creates a potential for inconsistent or contradictory judgments
28 and increases the delay and expense to all parties and the court system. By contrast, the class

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1 action device presents far fewer management difficulties and provides the benefits of single

2 adjudication, economies of scale, and comprehensive supervision by a single court.

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IX. <u>CLAIMS FOR RELIEF</u>

550. Plaintiffs realleage all of the foregoing allegations and incorporate them by reference as if fully set forth in their following Claims for Relief.

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A. Violation of RICO, 18 U.S.C. § 1961, et seq.

551. 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).

552. 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).

14 553. At all relevant times, McKinsey is and has been a "person" under 18 U.S.C. §
15 1961(3) because it is capable of holding, and does hold, "a legal or beneficial interest in
16 property."

17 554. Plaintiffs are each a "person," as the term is defined in 18 U.S.C. § 1961(3), and
18 have standing to sue under 18 U.S.C. § 1964(c) as they were and are injured in their business
19 and/or property "by reason of" the RICO Act violations described herein.

20 555. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section
21 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

22 556. McKinsey conducted the affairs of an enterprise through a pattern of racketeering
23 activity, in violation of 18 U.S.C. § 1962(c) and § 1962(d).

24 **Description of the Enterprise**

557. 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).

558. Under 18 U.S.C. § 1961(4), a RICO "enterprise" may be an association-in-fact 1 2 that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among 3 those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's 4 purpose. See Boyle v. United States, 556 U.S. 938, 946 (2009). 5 559. Opioid manufacturers, including Purdue, Johnson & Johnson, Janssen, Cephalon, Endo, and Mallinckrodt (collectively the "Opioid Manufacturers"), together with McKinsey, 6 7 which participated in the marketing and sale of opioids as described in this Complaint, 8 (collectively, the "Opioid Marketing Enterprise Members" or the "Enterprise Members") engaged 9 in a scheme to unlawfully increase sales of opioids—and grow their share of the prescription 10 painkiller market and the market as a whole—through repeated and systematic 11 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 12 13 practices, as described in the Factual Allegations section of this Complaint. 14 560. 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 15 16 Marketing Enterprise Members formed an association-in-fact enterprise (the "Opioid Marketing 17 Enterprise" or the "Enterprise"). The Opioids Manufacturers worked together to accomplish their 18 aims, with McKinsey serving as a go-between that held all of the companies together and helped 19 coordinate the deceptive marketing and sales strategies. Through McKinsey and their own 20 personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to 21 form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose: lying 22 to prescribers and Plaintiffs in order to increase sales of addictive and dangerous drugs and line 23 the enterprise members' pockets. The Opioid Marketing Enterprise Members' substantial 24 financial contributions to the Opioid Marketing Enterprise and the advancement of opioids-25 friendly messaging fueled the U.S. opioid epidemic. In the alternative, the association-in-fact Opioid Marketing Enterprise existed just 26 561. 27 between McKinsey and Purdue, who worked together to unlawfully increase sales of opioidsmisrepresentations 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.

5 562. The Controlled Substances Act (the "CSA") and its implementing regulations
6 require that "[e]very person who manufactures, distributes, dispenses, imports, or exports any
7 controlled substance," including opioids, become a "registrant." *See* 21 U.S.C. § 823(a)-(b); 21
8 C.F.R. § 1301.11(a). These registrants, including opioid manufacturer and distributors, must
9 maintain a system to identify and report suspicious orders, including orders of unusual size or
10 frequency, or orders deviating from a normal pattern, and maintain effective controls against
11 diversion of controlled substances. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

Despite these duties, McKinsey and the other Enterprise Members engaged in a 12 563. 13 scheme with the overarching purpose of materially expanding prescription opioid use by altering 14 the medical community's opioid prescribing practices through repeated fraudulent statements and 15 misrepresentations. The Opioid Marketing Enterprise's scheme was sophisticated, welldeveloped, and fraudulent and was designed to increase the prescription rate for opioid 16 17 medications the Enterprise Members knew where dangerous and highly addictive. At all relevant 18 times, McKinsey was aware of the conduct of the Enterprise, was a knowing and willing 19 participant in that conduct, and reaped profits from that conduct in the form of payments from 20 other Enterprise Members as a reward for work done to increase sales and distribution of 21 prescription opioids.

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The Common Purpose and Scheme of the Opioid Marketing Enterprise.

564. 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

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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.

565. 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.

13 566. There was regular communication between the Opioid Marketing Enterprise
14 Members in which information was shared, misrepresentations were coordinated, and payments
15 were exchanged. The Opioid Marketing Enterprise Members functioned as a continuing unit for
16 the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose,
17 and each agreed and took actions to hide the scheme and continue its existence.

567. 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.

568. 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.

569. The evidence shows that the Opioid Marketing Enterprise Members, including 1 2 McKinsey, were each willing participants in the Opioid Marketing Enterprise, had a common 3 purpose and interest in the object of the scheme, and functioned within a structure designed to 4 effectuate the Enterprise's purpose. The Conduct of the Opioid Marketing Enterprise Violated Civil RICO. 5 570. From at least 2004 to the present, each of the Opioid Marketing Enterprise 6 7 Members played some part in directing the affairs of the Opioid Marketing Enterprise and 8 participated in the operation or management of the affairs of the Opioid Marketing Enterprise, 9 directly or indirectly, in the following ways: Creating and providing a body of deceptive, misleading, and unsupported medical 10 571. 11 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 12 13 more likely to be relied upon by physicians, patients, and payors; 14 572. Creating and providing a body of deceptive, misleading, and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the 15 benefits of long-term use; (ii) appeared to be the result of independent, objective research; and 16 17 (iii) was thus more likely to be relied upon by physicians, patients, and payors; 18 573. Creating and providing a body of deceptive, misleading, and unsupported sales and 19 promotional training materials about opioids that (i) understated the risks and overstated the 20 benefits of long-term use; (ii) appeared to be the result of independent, objective research; and 21 (iii) was thus more likely to be relied upon by physicians, patients, and payors; 22 574. Devising and implementing marketing schemes that included targeting and 23 misleading physicians, unlawfully incentivizing sales representatives to maximize prescriptions and dosages, and evading regulatory constraints; and 24 25 575. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications. 26 27 576. The scheme devised and implemented by the Opioid Marketing Enterprise 28 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

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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.

15 579. 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 16 17 (the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the 18 Opioid Marketing Enterprise, i.e., to unlawfully increase profits and revenues from the continued 19 prescription and use of opioids for long-term, chronic pain. Through the racketeering activities of 20 the Opioid Marketing Enterprise, the Opioid Marketing Enterprise Members sought to further the 21 common purpose of the Enterprise through a fraudulent scheme to change prescriber habits and 22 public perception about the safety and efficacy of opioid use. In so doing, each of the Opioid 23 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). 24

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

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Enterprise's common purpose of increasing profits and sales through the knowing and intentional 2 dissemination of false and misleading information about the safety and efficacy of long-term 3 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. 4

5 582. Specifically, the Opioid Marketing Enterprise Members each worked together to 6 coordinate the Enterprise's goals and conceal their role, and the Enterprise's existence, from 7 prescribers and Plaintiffs by, among other things, (i) funding, editing, and distributing 8 publications that supported and advanced their false messages; (ii) funding key opinion leaders 9 ("KOLs") to further promote their false messages; and (iii) tasking their own employees to direct 10 deceptive marketing materials and pitches directly at physicians.

11 583. 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 12 13 industry organizations, contractual relationships, and continuing coordination of activities. The 14 systematic links and personal relationships that were formed and developed allowed the Opioid 15 Marketing Enterprise Members the opportunity to form the common purpose and agree to 16 conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of 17 the Opioid Marketing Enterprise Members coordinated their efforts through the same KOLs and 18 front groups, based on their agreement and understanding that the front groups and KOLs were 19 industry friendly and would work together with the Opioid Marketing Enterprise Members to 20 advance the common purpose of the Opioid Marketing Enterprise; and each of the individuals and 21 entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and 22 fraudulent scheme of the Opioid Marketing Enterprise.

23 584. 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 24 25 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 26 27 legal entities, including each of the Opioid Marketing Enterprise Members; (d) was characterized 28 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.

9 The Opioid Marketing Enterprise Members each committed, conspired to commit, 586. 10 and/or aided and abetted in the commission of at least two predicate acts of racketeering activity 11 (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 12 13 abetted in the commission of, were related to each other, posed a threat of continued racketeering 14 activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity 15 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, 16 17 and interstate wire facilities. The Opioid Marketing Enterprise Members participated in the 18 scheme to defraud by using mail, telephones, and the internet to transmit communications and 19 payments in interstate or foreign commerce.

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The Conduct was More than a Typical Business Relationship.

587. 21 There were strong relationships among those associated with the Opioid Enterprise 22 and sufficient longevity among Enterprise associates to pursue the Enterprise's common purpose. 23 The common purpose was to increase opioid revenues unlawfully by misrepresenting and lying 24 about opioids in order to changing prescriber habits and the perception regarding the safety and 25 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 26 27 overdose and that patients on opioids for more than a brief period develop tolerance, requiring 28 increasingly high doses to achieve pain relief.

1 588. On March 1, 2004, McKinsey entered into a "Master Consulting Agreement" with Purdue for "services that would be defined from time to time."³⁸⁷ The Master Consulting 2 3 Agreement was signed by then-McKinsey director Rob Rosiello."³⁸⁸ From 2004 through 2008, McKinsey advised Purdue on research and development, 589. 4 business development, and product licensing related to Purdue's opioid products.³⁸⁹ Consistent 5 6 with its business model, McKinsey leveraged these projects into growth of its "Broader Strategy" work" also underway with Purdue.³⁹⁰ Specifically, in October 2008, Purdue retained McKinsey 7 for broad strategy work after two board members "blessed" Purdue executive Craig Landau with 8 doing "whatever he thinks is necessary to 'save the business" after the 2007 criminal plea and 9 introduction of generic competition to the older OxyContin.³⁹¹ Purdue relied heavily on 10 11 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. 12 13 590. Over their many years of working together, McKinsey and Richard Sackler developed a close relationship. Indeed, one McKinsey partner, Maria Gordian, describes herself 14 as a counselor to Richard Sackler in an "Ey 2009 Impact Summary."³⁹² 15 The Opioid Marketing Enterprise was more than a typical business relationship. 16 591. 17 Rather, the members of the Enterprise knew that opioids were addictive and causing serious harm 18 to people and communities but chose to work together to lie to prescribers and Plaintiffs about 19 these drugs in order to increase their bottom lines. McKinsey worked closely with the Opioid 20 Manufacturers to achieve these aims. McKinsey, as an advisor of multiple Opioid Manufacturers, 21 also had access to information about multiple players and was able to coordinate the fraud 22 occurring across the Enterprise. As discussed below, McKinsey was particularly embedded in 23 Purdue's organizational structure and the relationship's longevity was sufficient to pursue the

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- ³⁸⁷ MCK-MDL2996-0085849; PPLPC012000069192
 ³⁸⁸ MCK-MDL2996-0085849, at 0085880.
 ³⁸⁹ PPLPC013000116218; PPLP004401340
 ³⁹⁰ MCK-MAAG-0117875
 ³⁹¹ MCK-MAAG-0117875
 - ³⁹² MCK-MAAG-0118669

- Enterprise's purposes. During the 2009-2014 period in particular, Purdue relied extensively on
 McKinsey to develop its sales and marketing strategy for OxyContin.
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3 592. 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 4 5 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 6 7 abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medication."³⁹³ But rather than be deterred by this, McKinsey dove in. In a March 2009 self-8 9 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 10 11 "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 12 team.³⁹⁴ 13

14 593. By August 2009, Richard Sackler had convened a meeting of Purdue board
15 members and staff to discuss efforts to "reverse the decline in the OxyContin tablets market."³⁹⁵
16 During the 2009-2014 period in particular, Purdue relied extensively on McKinsey to develop its
17 sales and marketing strategy for OxyContin. McKinsey worked closely with Purdue on both the
18 creation and implementation of OxyContin sales strategy. McKinsey's work for Purdue included
19 consulting, review of product acquisition, evaluation of research and development, advising
20 Purdue on the design of clinical studies, risk management, and product marketing.³⁹⁶

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."³⁹⁷ The 2013

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³⁹³ Information at pp. 5-6, *United States v. Purdue Frederick Co.*, No. 07-cr-29-JPJ (W.D. Va. May 10, 2007), Doc.
5.

³⁹⁴ MCK-MAAG-0118669

^{27 &}lt;sup>395</sup> PPLPC061000045395

³⁹⁶ PPLPC029000547371

^{28 &}lt;sup>397</sup> 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.

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Agreement stated, "We have a long history of partnership with Purdue, and we would make best 1 2 efforts to leverage our understanding of your business—both in terms of content and culture." 3 The 2013 Agreement was signed by then-principal Arnab Ghatak who would "lead the team with 4 senior leadership from Rob Rosiello and Martin Elling." 5 595. 6 7 398 8 596. 9 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 10 sales—a four-fold increase from its 2006 sales of \$800 million. 11 597. McKinsey's relationship with Purdue went far beyond a typical business 12 13 relationship. McKinsey worked closely with Purdue on both the creation and implementation of 14 OxyContin sales strategy, a strategy McKinsey knew had been based on misleading and 15 defrauding doctors and patients alike about a dangerous and highly addictive drug. 598. Further, McKinsey had access to detailed prescribing information enabling it to 16 17 determine if there were suspicious or problematic prescribing patterns. Rather than using this 18 information to help its clients prevent diversion of controlled substances, McKinsey and the 19 Opioid Marketing Enterprise used this information in furtherance of their scheme to defraud 20 prescribers and Plaintiffs, target and increase sales to prescribers who were overprescribing, and 21 continue to fuel opioid addiction and the resulting epidemic. The Fraudulent Schemes 22 23 599. As detailed above, the operation of the Opioid Marketing Enterprise, included 24 several schemes to defraud that helped to further the goals its members—i.e., to expand the 25 market and increase profits and sales through the knowing and intentional dissemination of false 26 and misleading information about the safety and efficacy of long-term opioid use, and to increase 27 profits for the Enterprise Members via expanding the market for opioids. 28 ³⁹⁸ PPLPC018001462324 (
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Fraudulent Marketing Scheme: Deceptive Messaging Regarding Opioid Use

600. As described throughout, McKinsey sought to unlawfully increase profits and 2 3 revenues from the continued prescription and use of opioids for long-term, chronic pain by 4 changing prescriber habits and public perception regarding the safety and efficacy of opioids. 5 McKinsey's fraud specifically targeted prescribers and set out to convince them that they should 6 prescribe more and more opioids, overcoming what could otherwise be a check on opioid 7 manufacturers ability to increase sales of addictive products.

8 601. Despite McKinsey knowing that reformulated OxyContin could still be abused, 9 having advised Purdue on the design of tests of reformulated OxyContin as part of Purdue's FDA submission,³⁹⁹ in furtherance of the scheme to defraud, McKinsey spread messages that 10 prescribing opioids could provide "freedom" and "peace of mind" for its users and that physicians 11 12 could "tailor the dose."

13 602. 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 14 15 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-16 17 release mechanism in OxyContin tablets—i.e., another product Purdue would later deceptively 18 promote as safer than and less prone to abuse than it was.

19 603. In June 2009, McKinsey helped Purdue prepare for an FDA advisory committee 20 meeting. 21 22 23 24 McKinsey prepared for Purdue an "FDA Advisory Committee on Reformulated 604. OxyContin: Question & Answer Book" in September 2009, with questions including "Why 25 26 should we trust you?" In response, McKinsey recommended Purdue say "We acknowledge 27 ³⁹⁹ McK-MAAG-0118669 400 PDD8901645845 28

⁴⁰¹ *Id*.

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[.]"⁴⁰² To the question of "Who at Purdue takes personal responsibility for all
these deaths?[,]" McKinsey recommended Purdue say, "We all feel responsible[.]"

5 McKinsey and the other Opioid Marketing Enterprise Members knew the changes 605. 6 Purdue made would not make opioids non-addictive or prevent them from being used to create 7 and further substance abuse problems. For example, in 2009, the FDA noted in permitting ADF 8 labeling that "the tamper-resistant properties will have no effect on abuse by the oral route (the 9 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 10 11 this new formulation will likely find a means to do so. In addition, the product can still be misused or abused and result in overdose by simply administering or ingesting larger than 12 recommended oral doses."403 13

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.

20 Far from the deception of doctors being an unforeseen consequence, McKinsey 607. 21 intentionally set out to target doctors as a cog in the Enterprise's scheme to defraud. Indeed, 22 deceiving doctors was part of the marketing scheme, and doctors were utilized in furtherance of 23 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. 24 25 608. 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 26

^{28 &}lt;sup>402</sup> MCK-MAAK-0152135

⁴⁰³ FDA Summary Review, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000SumR.pdf

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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.

8 610. In an October 26, 2009 presentation, "OxyContin – driving growth through
9 stronger brand loyalty," McKinsey proposed tactics to turnaround declining sales, "[e]nhance
10 loyalty to OxyContin among loyalist prescribers," "convert[ing] 'fence sitters' into more loyal
11 OxyContin prescribers,"⁴⁰⁴ and "protect OxyContin's market share[.]"⁴⁰⁵ In other words,
12 McKinsey proposed increasing sales by pushing both willing and reluctant physicians to prescribe
13 more OxyContin.

McKinsey recommended segmenting prescribers and tailoring messages and 14 611. 15 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 16 17 were not already using opioids, McKinsey urged emphasizing that its 7 tablet strengths provide flexibility to "tailor the dose" to customer needs.⁴⁰⁶ Upon information and belief, this message 18 aimed to encourage prescribers to initiate and maintain patients on OxyContin long-term by 19 20 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). 21

22	612.	Purdue adopted	l McKinsey's	p	proposal. ⁴⁰⁷	
23						
24						
25	404 MCK-MDL2	2996-0126522				
26	405 <i>Id.</i> at 2 406 <i>Id.</i> at 12.	2770 0120322				
27	⁴⁰⁷ PPLPC02300 PPLPC0120002); PPLPC012000245087	7 (); see also	
28			2000246009 (LPC021000265092	
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2 3 613. As detailed throughout, McKinsey and Opioid Marketing Enterprise Members 4 were aware of the catastrophic injury inflected on the public by selling harmful, addictive opioid 5 products. Yet when promoting opioids and engaging in doctor detailing, the Enterprise Members 6 intentionally hid the potential for abuse and addiction by marketing OxyContin's 12-hour dosing 7 as meaning that users only need to take OxyContin twice a day, thus requiring fewer pills. 8 614. It was foreseeable that this marketing strategy would lead to greater addiction 9 because OxyContin wore off after 8 to 10 hours in many patients. Prescribing 12-hour dosing led 10 to "end of dose failure," which led to a vicious cycle that became "the perfect recipe for addiction."⁴⁰⁹ As a result, what McKinsey marketed as "convenient" led to what was described as 11 "a [d]escription of Hell."⁴¹⁰ 12 13 615. The marketing scheme worked. Nationwide, based on an analysis by the Los 14 Angeles Times, more than 52% of patients taking OxyContin longer than three months are on 15 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."⁴¹¹ 16 17 616. A key element of the marketing scheme that fueled the deadly epidemic of opioid 18 abuse was doctor detailing using detailed prescriber data. Data Scheme: Use of Prescriber Data for Intentional Targeting of High Opioid Prescribers-19 20 **Not Diversion Prevention** McKinsey was an advisor to DEA registrants and Opioid Marketing Enterprise 21 617. 22 Members, who had a legal duty to guard against diversion and report suspicious orders of 23 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 24 25 volume prescribers to sell more opioids. 26 408 PKY183123435 27 ⁴⁰⁹ Harriet Ryan, ""You Want a Description of Hell?" OxyContin's 12-Hour Problem," Los Angeles Times, May 5,

1

⁴¹¹ CDC Guideline at 16.

2016, available at http://www.latimes.com/projects/oxycontin-part1/.

618. Distributors of controlled substances have a legal duty to report suspicious orders, 1 2 and to report those that deviate substantially from a normal pattern and orders of unusual size and 3 frequency. See 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b). These obligations included a legal duty 4 to maintain effective controls and procedures to guard against diversion of controlled substances 5 and a legal duty to maintain a system to identify and report suspicious orders of controlled 6 substances. See 21 C.F.R. §§ 1301.7(a) (b); 1301.74(b). Rather than advising their registrant 7 clients on how to comply with their legal duties to maintain effective controls to guard against 8 diversion and how to operate a system to identify and report suspicious orders, in furtherance of 9 the scheme, McKinsey and the Opioid Marketing Enterprise Members used detailed data to target 10 prescribers to increase the opioid market.

11 619. Consistent with the Enterprise's purpose of increasing profit by deceptively marketing opioids, McKinsey was tasked with "Identifying Granular Growth Opportunities for 12 13 OxyContin," conducting an "assessment of the underlying drivers of current OxyContin performance," identifying "key opportunities to drive near-term OxyContin performance," and 14 developing "plans to capture priority opportunities."⁴¹² 15

McKinsey received physician-level sales data to develop its marketing strategy to 16 620. 17 increase OxyContin performance after Purdue's 2007 guilty plea. Rather than using this access to 18 the granular data to avoid diversion and to prevent Enterprise members from targeting prescribers 19 with suspicious prescribing patterns, McKinsey used this information to help the Opioid 20 Marketing Enterprise members push more opioids on high volume prescribers in furtherance of 21 its schemes to defraud. The targets were chosen based on their history of prescribing high doses 22 of opioids in large quantities.

23

621. One of the services the Enterprise used in furtherance of this scheme concerned the 24 use of data to help Purdue meet its goals. McKinsey's analysis for the "Evolve to Excellence" 25 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 26 27 shift to other opioids after OxyContin's reformulation. Yet, McKinsey urged Purdue to target, and

⁴¹² PPLPC030000770531

seek to increase the prescribing of, all of these prescribers from whom it perceived Purdue could
 obtain greater profits.

3 622. McKinsey found that Purdue did not "focus on the highest potential docs," measured both by the number of prescriptions and reimbursement considerations.⁴¹³ A McKinsey 4 5 analyst urged McKinsey to recommend Purdue target "[1]itefrally, at least all" prescribers in the 6 top 20% of prescribers, "minus another few percent who are no sees[.]" McKinsey team lead 7 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."⁴¹⁴ ("No see" prescribers are prescribers who do not accept 8 9 visits from pharmaceutical sales representatives. Thus, upon information and belief, McKinsey recognized that most of the highest volume prescribers, or "high writers" of prescriptions, were 10 11 willing to entertain sales visits from sales representatives.) 623. The Opioid Marketing Enterprise used data for intentional targeting of high 12 13 prescribers and not for diversion prevention. McKinsey advised Purdue to raise sales of 14 Oxycontin by focusing on high dose sales and deceptively messaging to physicians that 15 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, 16 17 McKinsey advised Purdue that it should take "specific actions" to increase sales of OxyContin, 18 including "Prescriber Targeting" and "Turbocharg[ing] Purdue's Sales Engine." 19 624. McKinsey targeted not just doctors but also nurse practitioners and physician 20 assistants, recommending Purdue "[d]ouble down on nurse practitioners and physician 21 assistants . . . as they represent a growing market segmentation of prescribers."⁴¹⁵ 22 625. The Enterprise's scheme also explored ways to increase the amount of time sales 23 representatives spent in the field increasing opioid sales, and prioritizing OxyContin in incentive compensation targets.⁴¹⁶ 24 25 26 27 413 MCK-MDL2996-0364024 ⁴¹⁴ MCK-MDL2996-0364267 28 ⁴¹⁵ MCK-MDL2996-0303399 ⁴¹⁶ PPLPC012000437346

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."⁴¹⁷

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."⁴¹⁸ Likewise,
McKinsey recommended physician targeting to other Enterprise members, including Endo and
Janssen.⁴¹⁹

9 628. By targeting physicians based on their prescribing patterns, the Opioid Marketing 10 Enterprise was working toward the common purpose of deceptively convincing doctors to 11 prescribe more opioids and thereby increase their own profits. By developing "Evolve to 12 Excellence," which was implemented as a plan to "turbocharge" opioid sales, McKinsey advised 13 that Purdue would see a greater return on its sales investment by focusing its targets, including on 14 prescribers with alarming prescribing patterns that raised red flags they were writing 15 "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 16 17 Marketing Enterprise knew and/or should have known would result in the expansion of the illicit 18 opioid market.

19 629. The Enterprise sought to grow opioid sales to prescribers who raised red flags of
20 diversion and orders it knew or should have known were likely to be diverted or fuel an illegal
21 market. Purdue had a legal obligation not to target these prescribers; rather, it was obligated to
22 report their conduct to law enforcement. Yet the Enterprise used access to prescriber data not to
23 report diversion but to enhance diversion.

24

27

Pattern of Racketeering Activity

25 630. McKinsey together with the other Opioid Marketing Enterprise Members engaged
26 in a scheme to unlawfully increase sales of opioids—and grow their share of the prescription

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⁴¹⁷ MCK-MDL2996-0104840; PPLPC035000220406

^{28 &}lt;sup>418</sup> MCK-MDL2996-0187168

⁴¹⁹ MCK-MDL2996-0130803; MCK-MDL2996-0135713

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painkiller market—through repeated and systematic misrepresentations about the safety and 1 2 efficacy of opioids for treating long-term chronic pain. As a unique consulting entity with 3 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 4 5 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 6 7 education regarding the risks of opioids. McKinsey fueled the epidemic alongside its clients. 8 Through targeted marketing that McKinsey worked to develop, "turbocharge," and implement, 9 McKinsey substantially contributed to an explosion in the use of opioids across the United States. 10 McKinsey is an enterprise that is engaged in and affects interstate commerce because the 11 company advised opioid manufacturers on the sale of opioid products across the United States, as alleged herein. 12

13 631. The Opioid Marketing Enterprise Members devised and knowingly carried out this 14 illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, 15 representations, promises, or omissions of material facts regarding the safe, non-addictive and 16 effective use of opioids for long-term chronic, non-acute, and non-cancer pain. They knew that 17 these representations deviated from the FDA-approved use of these drugs and were not supported 18 by actual evidence. The Opioid Marketing Enterprise Members intended that their common 19 purpose and scheme to defraud would, and did, deceive consumers, prescribers, regulators, 20 Plaintiffs, and other intended victims and they used the U.S. Mail and interstate wire facilities 21 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.

11 636. The Opioid Marketing Enterprise Members' predicate acts all had the purpose of
12 creating the opioid epidemic that substantially injured Plaintiffs, while simultaneously generating
13 billion-dollar revenues and profits for the Opioid Marketing Enterprise Members. The predicate
14 acts were committed or caused to be committed by the Opioid Marketing Enterprise Members
15 through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent
16 scheme.

17 637. The Opioid Marketing Enterprise Members' scheme described herein was
18 perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of
19 racketeering activity. McKinsey in particular used mail and wire transmission, directly or
20 indirectly, in furtherance of this scheme by transmitting deliberately false and misleading
21 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.

27 639. Similarly, they caused to be transmitted through the mails and wires false and
28 misleading statements regarding the addiction potential of opioids. Moreover, McKinsey had

1 direct involvement in marketing statements and thus caused the statements to be made,

2 notwithstanding that they knew they were false for the reasons detailed above.

3 640. 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. 4 5 McKinsey intentionally deceived physicians regarding the abuse potential of opioids. It intended 6 prescribers and the public to rely on its false statements. McKinsey intended reliance on these 7 false statements as it was their goal for doctors to prescribe more and higher quantities of these 8 dangerous pills to the public. This scheme was therefore reasonably calculated to deceive not only 9 persons of ordinary prudence and comprehension but also educated physicians in a place of high 10 trust in the community.

11 Predicate Acts

12 641. To carry out, or attempt to carry out, the scheme, the Enterprise Members, each of
13 whom is a person associated-in-fact with the Enterprise, did knowingly conduct or participate in,
14 directly or indirectly, the affairs of the Enterprise through a pattern of racketeering activity within
15 the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and employed the use of the mail and
16 wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

17 642. Specifically, the Enterprise Members have committed, conspired to commit,
18 and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity
19 (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.

1	646. The Enterprise Members used, directed the use of, and/or caused to be used,
2	thousands of interstate mail and wire communications in service of their schemes through
3	common misrepresentations, concealments, and material omissions.
4	647. In devising and executing the illegal schemes, the Opioid Marketing Enterprises
5	Members devised and knowingly carried out a material scheme and/or artifice to defraud
6	Plaintiffs and prescribers and to obtain money by means of materially false or fraudulent
7	pretenses, representations, promises, or omissions of material facts.
8	648. For the purpose of executing the illegal schemes, the Enterprise Members
9	committed these racketeering acts, which number in the thousands, intentionally and knowingly
10	with the specific intent to advance the illegal schemes.
11	649. The Opioid Marketing Enterprise Members' predicate acts of racketeering (18
12	U.S.C. § 1961(1)) include, but are not limited to the conduct described in the Factual Allegations
13	section of this Complaint, and:
14	650. Mail Fraud: The Opioid Marketing Enterprise Members violated 18 U.S.C. § 1341
15	by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or
16	commercial interstate carriers for the purpose of executing the unlawful scheme to design,
17	manufacture, market, and sell the prescription opioids by means of false pretenses,
18	misrepresentations, promises, and omissions.
19	651. Wire Fraud: The Opioid Marketing Enterprise Members violated 18 U.S.C. § 1343
20	by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by
21	wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell
22	the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
23	652. The Opioid Marketing Enterprise Members' use of the U.S. Mail and interstate
24	wire facilities to perpetrate the opioids marketing scheme involved thousands separate instances
25	of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid
26	Marketing Enterprise, including essentially uniform misrepresentations, concealments, and
27	material omissions regarding the beneficial uses and non-addictive qualities for the long-term
28	treatment of chronic, non-acute, and non-cancer pain, with the goal of profiting from the

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increased sales of the Opioid Marketing Enterprise Members' drugs that occurred because 1 2 consumers, prescribers, regulators, and Plaintiffs relied on the Opioid Marketing Enterprise 3 Members' misrepresentations. These uses of the U.S. Mail or interstate wires included, inter alia: Marketing materials about opioids and their risks and benefits, which the Opioid 4 653. 5 Marketing Enterprise Members sent to health care providers, transmitted through the internet and 6 television, and published across the country, including in counties and cities and on Tribal 7 Reservations and to Plaintiffs; 8 654. Written representations and telephone calls among the Opioid Marketing 9 Enterprise Members and between the Opioid Marketing Enterprise Members regarding the 10 misrepresentations, marketing statements, and claims about opioids, including the non-addictive, 11 safe use of opioids for chronic, long-term pain generally; E-mails, telephone calls, and written communications among the Opioid 12 655. 13 Marketing Enterprise Members agreeing to or implementing the opioids marketing scheme; 14 656. Communications among the Opioid Marketing Enterprise Members and between the Opioid Marketing Enterprise Members and the media regarding the publication, drafting, and 15 16 dissemination of treatment guidelines as part of the Opioid Marketing Enterprise; 17 657. Written and oral communications directed to prescribers, the public, and Plaintiffs 18 that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and 19 658. Receipts of increased profits sent through the U.S. Mail and interstate wire 20 facilities—the wrongful proceeds of the scheme. 659. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate 21 22 wire facilities are not obtainable (e.g., each time a McKinsey trained marketer "calls" or reached 23 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 24 25 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 26 27 of mail and wire fraud) have been hidden and cannot be alleged without access to the books and 28 records maintained by the Opioid Marketing Enterprise Members. Indeed, an essential part of the

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1 successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy.

2 Plaintiffs have, however, described the types of predicate acts of mail and/or wire fraud, including

3 the specific types of fraudulent statements upon which, through the mail and wires, McKinsey

4 engaged in fraudulent activity in furtherance of their scheme.

5

8

scheme.

660. Below, Plaintiffs also describe examples of occasions on which the Opioid

6 Marketing Enterprise Members disseminated misrepresentations and false statements to

7 consumers, prescribers, regulators, and Plaintiffs, and how those acts were in furtherance of the

0	From	То	Date	Description
9	Purdue	Prescribers	2007	Statements that pain relief from opioids improves patients'
10		and Plaintiffs		function and quality of life in advertising and a book
11 12	Purdue	Prescribers	Continuous	Telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function
13	Purdue	FDA advisory committee	September 2009	Presentation prepared by McKinsey indicating that its reformulated OxyContin will deter abuse
14 15	Purdue	Prescribers and Plaintiffs	2010 onwards	Statements that the reformulated OxyContin will deter abuse and therefore doctors can continue to safely prescribe opioids
16	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"
17 18	Purdue	Prescribers and Plaintiffs	Advertising produced in 2016	Advertising from Purdue that "We sell hope in a bottle."
19 20	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
21	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 doce
22 23	Endo	Prescribers and Plaintiffs	2009	tailored as the patients adapt to a certain dose Statements made on an Endo-sponsored website, PainKnowledge.com, indicating that patients who take opioids as prescribed usually do not become addicted
24 25	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
26	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
27 28	Endo	Prescribers and Plaintiffs	Various	Statements made on the Endo-run website, Opana.com, indicating that opioid use does not result in addiction

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Endo	Prescribers and Plaintiffs	Various	Statements made on the Endo-run website, Opana.com, indicating that opioid dependence can be addressed by dosi 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 "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 risk 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" ⁴²⁰
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" ⁴²¹

^{28 420} MCK-MDL2996-0104431, at 0104442 421 MCK-MDL2996-0104840

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1 2	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" ⁴²²	
3	McKinsey	Purdue (with	September 23, 2013	Evolve 2 Excellence PowerPoint planning execution of the scheme and discussing targeted performance metrics	
4		prescribers as the		including "sales management calls per day, calls per year and adhering to target list" ⁴²³	
5		planned target)			
6 7	McKinsey	Purdue	July 30, 2013	Presentation showing "Scope of potential OxyContin growth opportunities" with proposed process including "Generate target list" and using "Reps/DMs [to] perform call planning (including refining target list)" ⁴²⁴	
8		I	I	(mendang remning target not)	
9	661.	Each of th	ese frauduler	nt mailings and interstate wire transmissions constitutes	
10	racketeering	activity and	collectively,	these violations constitute a pattern of racketeering activity,	
11	through which the Opioid Marketing Enterprise Members defrauded and intended to defraud				
12	consumers, prescribers, regulators, Plaintiffs, and other intended victims.				
13	662.	These wer	e not isolated	l incidents. Instead, the Opioid Marketing Enterprise	
14	Members engaged in a pattern of racketeering activity by committing thousands of predicate acts				
15	in a five-year period, in the form of mail and wire fraud, and there remains a threat that such				
16	conduct will continue in the future.				
17	663. Each instance of racketeering activity alleged herein was related, had similar				
18	purposes, involved the same or similar participants and methods of commission, and had similar				
19	results affecting similar victims, including consumers, prescribers, regulators, and Plaintiffs. The				
20	Opioid Mark	teting Enterp	rise Member	s calculated and intentionally crafted the scheme and	
21	common pur	pose of the C	Opioid Marke	eting Enterprise to ensure their own profits remained high.	
22	In designing and implementing the scheme, the Opioid Marketing Enterprise Members				
23	understood and intended that those in the opioid distribution chain rely on the integrity of the				
24	pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific				
25	evidence reg	arding the O	pioid Market	ing Enterprise Members' products.	
26					
27	422 MCK-MDL	2996-0364024			
• •	⁴²² MCK-MDL	2996-0364024			

⁴²² MCK-MDL2996-0364024 ⁴²³ MCK-MDL2996-0316833, at 0316834 ⁴²⁴ MCK-MDL2996-0303399 28

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664. Opioid Marketing Enterprise Members' pattern of racketeering activity alleged 1 2 herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, 3 the Opioid Marketing Enterprise Members are distinct from the Opioid Marketing Enterprise. The racketeering activities conducted by the Opioid Marketing Enterprise 4 665. 5 Members amounted to a common course of conduct, with a similar pattern and purpose, intended 6 to deceive consumers, prescribers, regulators, and Plaintiffs. Each separate use of the U.S. Mail 7 and/or interstate wire facilities employed by the Opioid Marketing Enterprise was related, had 8 similar intended purposes, involved similar participants and methods of execution, and had the 9 same results affecting the same victims, including consumers, prescribers, regulators, and 10 Plaintiffs. The Opioid Marketing Enterprise Members have engaged in the pattern of racketeering 11 activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise. 12 13 666. Each of the Opioid Marketing Enterprise Members aided and abetted others in the 14 violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 15 1341 and 1343 offenses. As described herein, the Opioid Marketing Enterprise Members engaged in a 16 667. 17 pattern of related and continuous predicate acts for many years. The predicate acts constituted a 18 variety of unlawful activities, each conducted with the common purpose of obtaining significant 19 money and revenue from the marketing and sale of their highly addictive and dangerous drugs. 20 The predicate acts also had the same or similar results, participants, victims, and methods of 21 commission. The predicate acts were related and not isolated events. 22 668. The Opioid Marketing Enterprise Members' violations of law and pattern of 23 racketeering activity directly and proximately caused Plaintiffs injury in their business and property. The Opioid Marketing Enterprise Members' pattern of racketeering activity logically, 24 25 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 26 27 Marketing Enterprise Members as a whole and McKinsey in particular knew that the opioids were 28 unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use

1	not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.
2	Nevertheless, the Opioid Marketing Enterprise Members engaged in a scheme of deception that
3	utilized the mail and wires in order to carry out the Opioid Marketing Enterprise's fraudulent
4	scheme, thereby increasing sales of their opioid products.
5	669. It was foreseeable and expected that the Opioid Marketing Enterprise Members
6	creating and then participating in the Opioid Marketing Enterprise through a pattern of
7	racketeering activities to carry out their fraudulent scheme would lead to a nationwide opioid
8	epidemic, including increased opioid addiction and overdose and the injuries that occurred as a
9	result.
10	The Enterprise Was Well Aware of Risks of Abuse Before It "Turbocharged" its Marketing
11	<u>Scheme.</u>
12	670. These devastating results were eminently foreseeable by the Opioid Marketing
13	Enterprise Members.
14	671. When Purdue pleaded guilty in 2007, it was evident that Purdue's behavior and
15	excessive prescribing was directly linked to a drug addiction crisis that caused severe and
16	extensive damage to America. Purdue's methods included "using aggressive marketing tactics to
17	convince doctors to unnecessarily prescribe opioids – frivolous prescriptions that experts say
18	helped fuel a drug addiction crisis that has ravaged America for decades."425
19	672. McKinsey cannot deny knowledge regarding Purdue's 2007 guilty plea. At that
20	point, McKinsey knew that opioids were addictive. McKinsey knew that OxyContin was being
21	widely abused and causing harm to people and entities like Plaintiffs. And McKinsey knew that
22	Purdue had been fraudulently marketing OxyContin as less addictive, less subject to abuse, and
23	less likely to cause withdrawal. And yet, years later, in 2013, McKinsey orchestrated a scheme to
24	continue to aggressively promote opioids despite knowledge that people were still dying from
25	overdoses.
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^{28 &}lt;sup>425</sup> Jan Hoffman & Katie Benner, *Purdue Pharma Pleads Guilty to Criminal Charges for Opioid Sales*, N.Y. Times (updated Dec. 17, 2020), https://www.nytimes.com/2020/10/21/health/purdue-opioids-criminal-charges.html.

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⁴²⁷ See, e.g., https://www.bostonglobe.com/metro/regionals/south/2014/10/25/hypodermic-needles-litter-landscape-south-boston/pzgmgbyjYFCD967TePDyiM/story.html

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higher doses of opioids; (c) tailoring marketing messages to conceal their addictive principles;
 and (d) by reducing the training of sales representatives.

- 3 679. In 2012, when the consent decree expired (which obligated Purdue to submit
 4 annual compliance reports regarding its marketing), McKinsey helped Purdue reengage in its
 5 nefarious conduct of targeting and deceiving doctors about the abuse potential of opioids.
- 6 680. After Purdue's guilty plea, McKinsey identified physicians—that had already been
 7 influenced by Purdue's misrepresentations and were thus already high prescribers—as optimal
 8 targets for a massive marketing push to sell more OxyContin. McKinsey monitored the
 9 prescription behaviors of individual doctors and utilized the prescriber-level data and urged
 10 Purdue to allocate its time and resources to high prescribing physicians.
- 11 681. By November 2013, McKinsey had obtained the physician-level data it had
 12 previously requested and continued to study ways to sell additional OxyContin prescriptions by
 13 refining and targeting the sales pitch to them.
- 14 682. In 2013, Project Turbocharge began. McKinsey proposed Project Turbocharge, a
 15 marketing strategy to increase opioids sales by hundreds of millions of dollars annually. With
 16 McKinsey's assistance, Purdue trained its sales representatives to operate using McKinsey's
 17 strategy for selling OxyContin. It is not coincidental to the Enterprise scheme that as soon as the
 18 constraints associated with its guilty plea and consent agreement ended, McKinsey assisted
 19 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."⁴²⁸
- 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.
- 26

 ⁴²⁸ 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-purdueoxycontin-opioids.html

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.

8 686. As a result, Plaintiffs have shouldered the burden of these anticipated increased
9 services and harm to business and property that are inherently tied to opioid abuse and misuse,
10 and both the increased services and harms were reasonably and actually expected from increased
11 prescribing.

12 687. The Enterprise's goal was to increase opioid prescribing, and the Enterprise
13 Members knew that doing so would also result in the need for increased medical services. It was
14 also foreseeable that increased prescriptions would also result in increased costs to Plaintiffs and
15 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.

23 Plaintiffs' Business and Property Have Been Damaged by the Enterprise's RICO 24 Violations.

25 689. The Opioid Marketing Enterprise Members' creation of, and then participation in,
26 the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their
27 fraudulent scheme has injured TPP Plaintiffs and the TPP Class in the form of substantial losses
28 of money and property that logically, directly, and foreseeably arise from the opioid addiction

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epidemic. The injuries to TPP Plaintiffs and the TPP Class, as alleged throughout this complaint,
 and expressly incorporated herein by reference, include:

a. costs paid and incurred by Plaintiffs and the Class for prescription opioid
drugs manufactured, marketed, sold, or distributed by Purdue and other Opioid Marketing
Enterprise Defendants, for purposes other than resale (intended for consumption by its covered
participants, their dependents, and covered retirees);

b. Costs paid and incurred by Plaintiffs and the Class for treatment related to
the misuse, addiction and/or overdose of opioid drugs by their covered participants, their
dependents, and covered retirees' healthcare and medical care, additional therapeutic, and
prescription drug purchases, and other treatments for patients suffering from opioid related
addiction or disease, opioid use disorder, neonatal abstinence syndrome, and other opioid induced
disorders and opioid related illnesses and medical conditions including overdoses and deaths;

c. Costs paid and incurred by Plaintiffs and the Class associated with
emergency responses for their covered participants, their dependents, and covered retirees by first
responders to opioid overdoses;

d. Costs paid and incurred by Plaintiffs and the Class for providing mentalhealth services, treatment, counseling, rehabilitation services, and social services to covered
participants, their dependents, and covered retirees who are victims of the opioid epidemic.

19

B. <u>Unjust Enrichment</u>

20 690. McKinsey had a duty to take reasonable steps not to encourage the overmarketing
21 and over-prescribing of a controlled substance known at the time to be addictive and known at the
22 time to be a threat to public health.

Rather than prevent or mitigate the wide proliferation of opioids, for years
McKinsey devised, and assisted Purdue with implementing, a sales and marketing campaign,
including Project Turbocharge, that would dramatically increase the amount of OxyContin
prescribed and distributed to individuals across the country, many of whose prescriptions were
covered in whole or in part by their health plans. In the process, McKinsey continually devised

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1	misleading claims regarding OxyContin as part of its efforts to get health care providers to write
2	more and more OxyContin prescriptions.

3 692. For McKinsey's work increasing opioid sales for Purdue in violation of 4 McKinsey's duties, McKinsey was compensated out of Purdue's income from the sale of opioids. 5 693. McKinsey therefore received a benefit from the sale and distribution of 6 prescription opioids paid for, in whole or part, by Plaintiffs and the proposed class. 7 694. This compensation for increasing the sales of Purdue's deadly products constitutes 8 money in the possession of McKinsey that, in equity and good conscience, McKinsey ought not be allowed to retain. 9 10 C. Fraud by Concealment McKinsey is liable for both fraudulent concealment and non-disclosure. See, e.g., 11 695. 12 Restatement (Second) of Torts §§ 550-51 (1977). 13 696. McKinsey committed fraud by acting to conceal and advising the concealment of 14 the true dangers of opioids and Purdue's prior and ongoing misconduct while working to increase 15 sales of opioids through its work for Purdue and others, and concealing all of this information from regulators, the public, and Plaintiffs and the class. 16 17 A reasonable consumer would not have expected that the opioids promoted by 697. 18 McKinsey via its clients were unreasonably dangerous and addictive and that McKinsey's clients 19 were failing to follow state and federal law, including the Controlled Substances Act. 20 698. McKinsey knew that these facts about opioids would be important to TPPs like 21 Plaintiffs. McKinsey ensured that Plaintiffs and the class did not discover this information 22 through actively concealing it. McKinsey intended for Plaintiffs and the class to rely on its 23 omissions—which they did by indirectly purchasing, paying, and reimbursing for opioids intended for consumption by its members, retirees, and their families and for substance abuse 24 25 treatment. 699. McKinsey had a duty to disclose the true dangers of opioids. These important facts 26 27 were known and/or accessible only to McKinsey, due to its detailed involvement in its clients' 28 sales and marketing strategies. McKinsey also knew the addictive and potentially harmful nature

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of opioids was not known to or reasonably discoverable by Plaintiffs and the class. If McKinsey
 had disclosed these material facts, Plaintiffs and the class would have seen them.

700. McKinsey also had a duty to disclose the true nature of opioids in light of its
affirmative statements, by and through its clients, about opioids with respect to their safety and
side effects, among other factors. In its clients' campaigns, McKinsey intentionally concealed,
suppressed, and failed to disclose to Plaintiffs and the class that opioids were unsafe and could
result in life threatening, and indeed life-ending, side effects.

8 701. McKinsey knew these statements were misleading, deceptive, and incomplete
9 without the disclosure of the additional facts set forth above regarding the nature of opioids.
10 Because McKinsey, by and through its clients, volunteered to provide information about the
11 opioids that McKinsey's clients offered for sale indirectly to Plaintiffs and the class, McKinsey
12 had the duty to disclose the whole truth. It did not.

13 702. McKinsey did not fulfill its duties to disclose to Plaintiffs and the class. Instead, it
14 actively concealed the truth during regulatory processes and throughout its clients' marketing and
15 sale of opioids.

16 703. McKinsey's deceptive actions harmed Plaintiffs and the class. Because McKinsey
17 fraudulently concealed the truth about opioids' dangers, Plaintiffs and the class suffered economic
18 losses. Plaintiffs and the class suffered damages including but not limited to indirect payments for
19 opioids and for substance abuse treatment. Accordingly, McKinsey is liable to Plaintiffs and the
20 class for damages in an amount to be proven at trial.

704. McKinsey's acts were done wantonly, maliciously, oppressively, deliberately, with
intent to defraud; in reckless disregard of the rights of Plaintiffs and the class; and to enrich itself.
Its misconduct warrants an assessment of punitive damages in an amount sufficient to deter such
conduct in the future, which amount shall be determined according to proof at trial.

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X.

PRAYER FOR RELIEF

Plaintiffs seek all legal and equitable relief permitted by law, including:

27 1. Certification at an early practical time of the class described herein, and to any
28 appropriate subclasses;

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1		2.	Appointment of Plaintiffs and their counsel to represent the class;
2		3.	Compensatory damages;
3		4.	Restitution;
4		5.	Disgorgement of profits;
5		6.	Punitive and/or exemplary damages;
6		7.	Treble damages;
7		8.	Injunctive/equitable relief;
8		9.	Pre- and post-judgment interest; and
9		10.	Attorneys' fees and costs.
10	XI.	JURY	Y DEMAND
11		Plaint	tiffs demand a trial by jury on all issues so triable.
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