



**The Firm and the FDA:
McKinsey & Company's Conflicts of Interest at the
Heart of the Opioid Epidemic**

Interim Majority Staff Report

**Committee on Oversight and Reform
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EXECUTIVE SUMMARY

This interim staff report presents preliminary findings from the Committee’s investigation into McKinsey & Company’s (McKinsey) consulting services for opioid and pharmaceutical companies and McKinsey’s conflicts of interest. The Committee launched this investigation following reports that McKinsey engaged in abusive and deceptive business practices in driving the sales of prescription opioids—which have contributed to an epidemic that has killed more than half a million Americans—while also consulting for federal agencies regulating the opioid market.

The Committee’s investigation has uncovered significant, years-long conflicts of interest at McKinsey, resulting from its work for the federal government at the same time that it was advising opioid manufacturers. Documents show that one opioid manufacturer, Purdue Pharma (Purdue), explicitly tasked McKinsey with providing advice on how to influence the regulatory decisions of the U.S. Food and Drug Administration (FDA), another McKinsey client. The Committee’s investigation has uncovered evidence that McKinsey sought to use its government connections to solicit private sector business. The Committee has also obtained evidence suggesting that McKinsey sought to influence government officials, including Trump Administration Secretary of Health and Human Services (HHS) Alex Azar, to advance the interests of its private sector opioid clients.

The Committee’s investigation has uncovered the following information:

- **At least 22 McKinsey consultants, including senior partners, worked for both FDA and opioid manufacturers on related topics, including at the same time:**
The Committee’s investigation uncovered 37 FDA contracts that were staffed by at least one McKinsey consultant who simultaneously or previously worked for Purdue. These consultants formed part of what one consultant called McKinsey’s “mini ‘army’ here at Purdue.” For example:
 - In 2009, McKinsey staffed a consultant on a project in which the firm recommended Purdue “defend against strict treatment by the FDA” in the agency’s opioid-REMS safety program or “[r]aise legal claims alleging FDA impropriety.” In 2011, McKinsey staffed that same consultant in an FDA office responsible for overseeing elements of that same safety program on a project to define the office’s “role in monitoring drug safety.”
 - In 2011, at least four McKinsey consultants working on a \$1.8 million FDA contract to enhance drug safety and address “the adverse impact of drugs on health in the US” were simultaneously working for Purdue—including on projects designed to persuade FDA of the safety of Purdue’s opioid products. One project involved writing “scripts” for Purdue to use in a meeting with FDA on the safety of pediatric OxyContin.

- One senior McKinsey consultant worked on three FDA projects from 2014 to 2018 to assess the safety of dangerous drugs through the FDA Sentinel Initiative while simultaneously advising Purdue.
- In 2017, a McKinsey partner began work on a \$2.7 million contract to help modernize FDA’s Office of New Drugs—at the same time the McKinsey consultant was advising Purdue on maximizing the market potential of a new opioid and another potentially lucrative new drug which Purdue would soon file with the same FDA office.
- **McKinsey utilized its federal government contracts, connections, and influence to solicit private sector business:** Documents show McKinsey consultants sought to leverage their government contacts and experience to solicit private sector business. For example:
 - In 2009, in a bid to lead a working group of opioid manufacturers, McKinsey highlighted that due to its direct work for regulators, the company had “developed insights into the perspectives of the regulators themselves.”
 - In 2014, a McKinsey partner wrote to Purdue’s Chief Executive Officer (CEO) that McKinsey brought an “unequaled capability based on who we know and what we know,” highlighting the firm’s work for “State and Federal Regulators,” including “FDA, who we have supported for over five years.” Less than a week later, McKinsey confirmed multiple engagements at Purdue, including a project led by a McKinsey partner who frequently consulted for FDA to prepare Purdue for an FDA Advisory Committee meeting on one of its opioids.
 - In 2016, a McKinsey partner encouraged other consultants to share information with Purdue about ongoing drug safety work McKinsey was doing for FDA, saying they should “talk about our work w FDA, specifically sentinel which I think would be v useful for them in opioids.”
- **McKinsey submitted opioid advice to the Trump Administration, including information that went to the HHS Secretary and FDA Commissioner:** Documents show that McKinsey consultants with Purdue ties attempted to influence or did in fact influence public health officials in the Trump Administration on the topic of the opioid epidemic. For example:
 - In 2018, McKinsey consultants drafted a “transition memo” to incoming HHS Secretary Alex Azar. The memo contained input from McKinsey consultants who did work for Purdue, including one consultant who had previously recommended strategies to “Turbocharge Purdue’s Sales Engine” and use a “Wildfire” strategy to sell more opioids. This consultant

recommended that the memo to Secretary Azar emphasize the “important societal benefit” of opioids. The final memo included certain recommendations that appear aligned with the interests of McKinsey’s private sector opioid clients.

- McKinsey consultants discussed the firm’s influence on a speech by FDA Commissioner Gottlieb in 2018 concerning a drug safety monitoring program. They noted that a claim about opioids made by another McKinsey consultant who had worked for both FDA and an opioid manufacturer “got into one of Scott Gottlieb’s public speeches” even though the consultant had “made it up entirely.”
- **McKinsey failed to disclose its serious, longstanding conflicts of interests to FDA, potentially violating contract requirements and federal law:** The Federal Acquisition Regulation (FAR) sets rules for federal agencies, including the FDA, to avoid, neutralize, and mitigate organizational conflicts of interest before awarding contracts. Pursuant to those regulations, many of McKinsey’s FDA contracts affirmatively required contractors submitting proposals to disclose potential organizational conflicts of interest. However, McKinsey produced no evidence to the Committee that it ever disclosed its extensive, ongoing work for opioid manufacturers to FDA. On the contrary, McKinsey appears to have repeatedly certified that there were “no relevant facts or circumstances which would give rise to an organizational conflict of interest.” False certifications on federal contracts can lead to civil or criminal penalties, including under the False Claims Act.
- **McKinsey consultants discussed deleting documents related to their work for Purdue:** Documents obtained by the Committee reveal that as early as May 2017, McKinsey partners discussed ways to keep McKinsey’s documents from being discovered in Purdue’s ongoing lawsuits, including putting presentations on a “neutral template” without Purdue’s logo and only showing “hard” or paper copies of presentations to Purdue. One McKinsey senior partner described the perceived benefit of the latter approach: “It will live only on our laptops and then we can delete.” Public reporting has shown that in July 2018, senior partners at McKinsey discussed destroying their documents related to their work for Purdue. Documents obtained by the Committee show one of these senior partners later emailed himself a note to “delete old pur documents from laptop.”

Despite evidence of conflicts of interest resulting from McKinsey’s work for the federal government and private sector clients, and the possibility that such conflicts may have contributed to America’s deadly opioid epidemic, McKinsey has refused to fully cooperate with the Committee’s investigation. In particular, McKinsey has failed to provide basic information about certain clients and the work McKinsey did for them.

I. INTRODUCTION

McKinsey is one of the world's oldest and most prestigious consulting firms, with reported revenues over \$10 billion per year. Famed for its secrecy, McKinsey does not disclose the names of its clients nor the advice it gives them.¹ Unlike many other industries, such as the banking or the accounting industry, consulting firms are not subject to general regulation.

Over the past 15 years, McKinsey has reaped hundreds of millions of dollars in fees from consulting for the federal government and opioid manufacturers, sometimes simultaneously. From January 2006 to March 2019, the federal government paid McKinsey \$956.2 million in taxpayer funds.² Since 2008, FDA alone has paid McKinsey more than \$140 million, including \$40 million from FDA's Center for Drug Evaluation and Research (CDER), which oversees numerous opioid-related programs. CDER approves new drugs, including prescription opioids, and oversees FDA's Sentinel Initiative, which is meant to monitor the safety of drugs including opioids once they are on the market.

Since at least 2004, McKinsey also consulted for opioid manufacturers including Purdue, Johnson & Johnson, Mallinckrodt Pharmaceuticals, and Endo International. From 2004 to 2019, McKinsey played a pivotal role in increasing Purdue's sales of OxyContin, the prescription pain killer that netted Purdue sales of more than \$35 billion and was a major driver of the opioid epidemic that has killed over half a million people in the United States. McKinsey proposed strategies to "Turbocharge Purdue's Sales Engine" for OxyContin and recommended that Purdue offer rebates to insurers and pharmacy benefit managers (PBMs) for opioid overdoses attributable to OxyContin.

In February 2021, McKinsey reached a \$573 million agreement with 53 attorneys general to resolve allegations that it engaged in unfair trade practices by aggressively promoting the sale of higher doses of opioids for longer periods of time.

Following this landmark settlement and reports of other potential conflicts of interest at the firm, on November 5, 2021, the Committee on Oversight and Reform sent a letter to McKinsey requesting documents and information regarding the company's consulting services for the opioid and pharmaceutical industries and the company's conflicts of interests. Chairwoman Maloney's letter raised concerns that during the time McKinsey advised Purdue and other opioid manufacturers on how to boost the sales of addictive painkillers, McKinsey

¹ Duff McDonald, *The Firm: The Story of McKinsey and Its Secret Influence on American Business* (2013).

² General Services Administration, *Improper Pricing on the McKinsey Professional Services Contract May Cost the United States an Estimated \$69 Million* (July 23, 2019) (A170118/Q/6/P19004) (online at www.gsaig.gov/sites/default/files/audit-reports/A170118_1.pdf).

“also consulted for the agency that regulates opioids, the Food and Drug Administration (FDA)—creating the potential for significant conflicts of interest.”³

As part of its investigation, the Committee has obtained documents confirming substantial conflicts of interest at McKinsey stemming from the company’s consulting work for opioid manufacturers and federal agencies and showing that McKinsey failed to prevent these conflicts of interest from occurring.⁴

The documents provided by McKinsey include engagement and staffing lists for the company’s consulting work for Purdue and FDA, which demonstrate substantial overlap in McKinsey’s work and potential conflicts of interest. However, McKinsey has failed to produce other staffing information requested by the Committee over five months ago, including engagements for certain pharmaceutical companies. McKinsey has also failed to provide core documents concerning the identity of its private sector clients and details of complaints or concerns raised to McKinsey’s risk management committees.⁵

II. FINDINGS

A. McKinsey Consultants Engaged in Overlapping Work for Opioid Manufacturers and FDA

The Committee’s investigation has uncovered evidence that McKinsey consultants advised FDA on opioid-related regulatory matters at the same time they were advising Purdue and other opioid manufacturers on sales and regulatory strategies involving FDA.

Although McKinsey has failed to produce certain responsive documents related to its conflicts of interest, the documents the Committee has obtained illustrate pervasive conflicts of interest at the company. These documents reveal that at least 22 McKinsey consultants worked for both FDA and opioid manufacturers, including several of McKinsey’s senior-most partners in

³ Letter from Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, to Bob Sternfels, Global Managing Partner, McKinsey & Company (Nov. 5, 2021) (online 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>).

⁴ The Committee has released selected documents obtained from McKinsey. (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/McKinseyInvestigation-SelectedDocuments.zip>).

⁵ *Id.* In its November 5, 2021, request letter, the Committee asked McKinsey to produce “[a] list of all McKinsey consultants or employees who consulted or otherwise worked on projects for FDA between 2005 and 2021 and also worked on projects for any opioid- or pharmaceutical-related company at any time during this period, including but not limited to AbbVie, Amgen, Celgene, Sanofi, Purdue, Endo, Mallinckrodt, Janssen, Teva, Actavis, Amerisource Bergen, McKesson, Cardinal Health, CVS, and Walmart. For each McKinsey consultant or employee, please specify a. the nature of their work for the opioid or pharmaceutical company; b. the nature of their work for FDA; c. the dates worked for each organization; d. whether they are still employed by McKinsey; and e. if known, their current employer.” McKinsey has provided staffing list of consultants who worked on select FDA projects. It has not provided the Committee with the names of consultants who have worked for both FDA and other pharmaceutical companies.

the health care and regulatory practices who worked for FDA and opioid manufacturers at the same time.⁶

According to information provided by FDA in response to a request from the Senate and public records requests, McKinsey failed to disclose its commercial relationships with these opioid manufacturers to FDA.⁷

The Committee has also obtained evidence that McKinsey shared information that it received through its consulting work for FDA with other McKinsey consultants, and potentially with private sector clients. Documents show that at least one McKinsey consultant encouraged colleagues to share information obtained from their FDA projects with Purdue. Other McKinsey consultants working for both FDA and Purdue appear to have shared FDA proposals within McKinsey, even when senior FDA officials requested that McKinsey limit the distribution of those proposals to certain consultants.

1. McKinsey Consultants Worked Extensively for Both FDA and Purdue

From 2008 to 2022, McKinsey performed on 76 contracts for the FDA. FDA has paid McKinsey more than \$140 million since 2008, including \$40 million from CDER, which oversees opioid-related programs.⁸ McKinsey provided the Committee with an engagement list for the company's work on 37 FDA matters—fewer than half of the contracts reported in government databases—along with the consultants who worked on those matters.⁹

During this period, McKinsey consultants also worked extensively for Purdue. According to an engagement list obtained by the Committee, from 2004 to 2019, McKinsey consulted on at least 75 separate engagements for Purdue and its affiliates. These engagements ranged in duration from several weeks to over a year, and covered subjects ranging from sales

⁶ McKinsey produced to the Committee staffing information for 37 FDA-McKinsey contracts between 2010 and 2022, even though federal spending data demonstrates that McKinsey performed 76 contracts for FDA between 2008 and 2022. USA Spending, *McKinsey & Company Contracts with the Food and Drug Administration Since 2008* (online at www.usaspending.gov/search/?hash=9c4702cb5b379594a7c36481464f73f7) (accessed Jan. 15, 2022).

⁷ Letter from Acting Associate Commissioner Andrew Tantillo, Food and Drug Administration, to Senator Maggie Hassan et al. (Oct. 22, 2021) (online at www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%2010.22.21.pdf); *McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency*, ProPublica (Oct. 4, 2021) (online at www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency).

⁸ USA Spending, *McKinsey & Company Contracts with the Food and Drug Administration Since 2008* (online at www.usaspending.gov/search/?hash=9c4702cb5b379594a7c36481464f73f7) (accessed Jan. 15, 2022).

⁹ See MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List). McKinsey has represented that the consultants named on this list were the primary consultants for these FDA matters. McKinsey has also provided the Committee with a Supplemental FDA Consultant List reflecting additional staffing on select FDA matters. See MCK-HCOR-0356043 to MCK-HCOR-0356048 (McKinsey FDA Supplemental Consultant List).

strategy to regulatory advice. Documents indicate that in April 2008, McKinsey ratcheted up its consulting work for Purdue after the manufacturer and several senior executives pled guilty to federal charges of misbranding OxyContin.¹⁰ In 2009, one McKinsey consultant sent an email to colleagues referring to McKinsey’s “mini ‘army’ here at Purdue.”¹¹

During this period, numerous McKinsey consultants worked for both FDA and Purdue, both officially and unofficially. Three senior McKinsey consultants—Navjot Singh, Jeff Smith, and Sastry Chilukuri—highlight this crossover and the unclear boundaries between consultants not directly staffed on projects. Another McKinsey senior partner, Arnab Ghatak, played a key role at Purdue and appears to have contributed to work prepared for incoming HHS Secretary Alex Azar, although he did not work directly for FDA.

Navjot Singh

McKinsey Senior Partner Navjot Singh is one of McKinsey’s lead consultants to FDA. Internal McKinsey emails obtained by the Committee show that he also participated unofficially in Purdue matters. In a 2021 FDA subcontract, McKinsey describes Mr. Singh as possessing “10 years of experience driving cross-Center collaboration for FDA, having led 80+ engagements at the Agency.”¹² Of the 37 FDA contracts for which McKinsey provided staffing information to the Committee, Mr. Singh is staffed on 35 of them.¹³ In addition to his work at FDA, Mr. Singh leads McKinsey’s state and local work for McKinsey’s public sector practice in North America.¹⁴

Documents show Mr. Singh played a key role in McKinsey’s efforts to renew its relationship with Purdue in November 2007, advising the lead McKinsey consultants pitching Purdue, attending meetings with Purdue executives—including Purdue’s then-CEO—on the company’s research and development organization, and producing slides for pitch presentations.¹⁵ In one email exchange in December 2007, Mr. Singh told a McKinsey colleague that he would try to join a call for Purdue, but would be “in transit to a meeting at the FDA.”¹⁶ In another email with the subject: “Help on Purdue page,” Mr. Singh stated: “I am now going to

¹⁰ *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, New York Times (May 10, 2007) (online at www.nytimes.com/2007/05/10/business/11drug-web.html); MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List).

¹¹ MCK-HCOR-0140188.

¹² MCK-HCOR-0351716, Page 16.

¹³ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List); MCK-HCOR-0356043 to MCK-HCOR-0356048 (McKinsey FDA Supplemental Consultant List).

¹⁴ McKinsey & Company, *Navjot Singh* (online at www.mckinsey.com/our-people/navjot-singh) (accessed Feb. 9, 2021)

¹⁵ MCK-HCOR-0338438; MCK-HCOR-0171870; MCK-HCOR-0219074.

¹⁶ MCK-HCOR-0231409.

be in meetings and workshops at FDA the whole day. I come up for air at 6 pm and happy [sic] to take a look at the proposal.”¹⁷

Although Mr. Singh was not formally identified as a consultant to Purdue, he appears to have been held out in communications with Purdue as a potential source of expertise. For instance, a 2007 memo to Purdue’s executive leadership stated that McKinsey would “draw upon colleagues with deep R&D expertise, such as Navjot Singh and Rodney Zimmel.”¹⁸

Internally, Mr. Singh appears to have served as an informal advisor to McKinsey teams working on Purdue matters. In 2009 and 2010, Purdue engaged McKinsey to assist in preparing a regulatory submission to FDA concerning the safety and utility of Purdue’s “BuTrans” opioid dispensing patch.¹⁹ Mr. Singh was listed as a required invitee for three different meetings in January 2010 with the McKinsey consultants working on Purdue’s BuTrans regulatory effort. The purpose of each meeting is listed as “Purdue BTDS AdComm,” referring to the FDA advisory committee considering the BuTrans application.²⁰

A 2014 presentation to Purdue’s new CEO Mark Timney stated that McKinsey would “bring to bear” Mr. Singh’s expertise in “regulatory agencies,” in its work for Purdue, while an email from 2017 referred to “ancient work product” that Mr. Singh and another McKinsey consultant completed for Purdue.²¹

Jeff Smith

McKinsey Partner Jeff Smith is a senior consultant who worked extensively for both FDA and opioid manufacturers. FDA contracts and proposals describe Mr. Smith as a “core member of McKinsey’s client service team to FDA” since 2007 who has served “on multiple engagements with CDER, the Center for Biologics Evaluation and Research (CBER), the Office of the Commissioner, and the Office of Regulatory Affairs.”²² Of the 37 FDA contracts for which McKinsey provided staffing information to the Committee, Mr. Smith is staffed on 28 of them.²³

At the same time that Mr. Smith was working for FDA, internal McKinsey documents show he was also a leader of McKinsey’s consulting work for Purdue. From 2009 to 2017, Mr.

¹⁷ MCK-HCOR-0219074.

¹⁸ MCK-HCOR-0235769, Page 4.

¹⁹ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List).

²⁰ MCK-HCOR-0142034; MCK-HCOR-0141555; MCK-HCOR-0141497.

²¹ MCK-HCOR-0096857, Slide 15; MCK-HCOR-0249715.

²² MCK-HCOR-0351716, Page 16; MCK-HCOR-0341261, Page 19, A-3.

²³ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List); MCK-HCOR-0356043 to MCK-HCOR-0356048 (McKinsey FDA Supplemental Consultant List).

Smith officially consulted on at least eight separate engagements for Purdue.²⁴ A 2013 document, which McKinsey submitted to Purdue for use at an industry conference, stated that Mr. Smith possessed “extensive experience working with Purdue over the past 5 years on OxyContin related topics.”²⁵

Mr. Smith specifically dealt with Purdue’s efforts to obtain FDA approval of its opioid products, including projects on (1) securing regulatory approval at FDA of Purdue’s “BuTrans” opioid patch; (2) clinical studies to show the safety of pediatric OxyContin; and (3) preparing Purdue for an FDA Advisory Committee meeting on the safety of OXN Targiniq, another opioid product.²⁶

By February 2014, Mr. Smith was participating in weekly conference calls with Purdue’s new CEO Mark Timney and a select group of McKinsey consultants.²⁷ By late 2017, at the personal request of Purdue leadership, Mr. Smith was co-leading a project known as “Project Scottsdale” to transform Purdue’s entire business model.²⁸ McKinsey held Mr. Smith out to the opioid manufacturer as the “Leader of McKinsey’s service to regulatory agencies globally.”²⁹

Even when not officially listed as consulting for projects at Purdue, internal McKinsey documents suggest Mr. Smith advised Purdue executives or discussed Purdue-related matters with other McKinsey colleagues consulting for the opioid manufacturer. For instance, although Mr. Smith did not appear to bill any hours to Purdue in 2016, documents obtained by the Committee show that he was invited to join at least 11 meetings or calls with or about Purdue that year.³⁰

Sastry Chilukuri

Former McKinsey Partner Sastry Chilukuri worked extensively for FDA and intermittently on Purdue matters. One McKinsey presentation to FDA in 2015 described him as a “[l]eader of McKinsey’s Healthcare Digital Practice” with “[d]eep FDA IT [information

²⁴ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List).

²⁵ MCK-HCOR-0097018, Page 3.

²⁶ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List); *Id.*; MCK-HCOR-0341765; MCK-HCOR-0020344, Page 5; MCK-HCOR-0021422, Slide 1.

²⁷ E.g., MCK-HCOR-0342253.

²⁸ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List); MCK-HCOR-0034061; MCK-HCOR-0249585; MCK-HCOR-0351289.

²⁹ MCK-HCOR-0337517, Slide 0.

³⁰ MCK-HCOR-0173309; MCK-HCOR-0173310; MCK-HCOR-0173664; MCK-HCOR-0177365; MCK-HCOR-0341403; MCK-HCOR-0341360; MCK-HCOR-0173739; MCK-HCOR-0341710; MCK-HCOR-0177337; MCK-HCOR-0172519; MCK-HCOR-0177693.

technology] experience.”³¹ Of the 37 FDA contracts for which McKinsey provided staffing information to the Committee, Mr. Chilukuri is staffed on 7 of them.³²

Mr. Chilukuri also intermittently worked on matters for Purdue and other opioid manufacturers. In the Spring of 2009, he was officially staffed on one project at Purdue.³³ In addition, documents reveal that he frequently interacted with McKinsey’s opioid consultants, including sharing new ideas to pitch to manufacturers.

In August 2015, Mr. Chilukuri appears to have assisted a McKinsey consulting team working on an opioid-related matter for the pharmaceutical company Endo International.³⁴ Documents show that in 2016 Mr. Chilukuri played a key role in pitching a “big data” proposal to Purdue, and in 2017 he was invited to participate in multiple meetings with McKinsey consultants at Purdue and Purdue executives.³⁵ He appears to have left McKinsey in 2018.³⁶

Arnab Ghatak

Arnab Ghatak served as one of the primary leaders of McKinsey’s consulting teams at Purdue, leading over 30 engagements between 2004 and 2018.³⁷

In 2013, Mr. Ghatak co-led the “Evolve to Excellence” project at Purdue through which McKinsey recommended strategies to “Turbocharge Purdue’s Sales Engine” and use a “Wildfire” sales strategy to “Identify high performance ‘champion’ reps (e.g., Toppers, Rep Field Trainers) and use them to lead their own ‘learning teams’ of reps.”³⁸ Purdue’s “Toppers” incentive program, which McKinsey incorporated into the “Evolve to Excellence” project, rewarded sales representatives for selling more OxyContin. The “Toppers” sales representatives’ regions have accounted for disproportionate rates of pill mills and OxyContin abuse.³⁹

³¹ MCK-HCOR-0353301, Slide 28.

³² MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List); MCK-HCOR-0356043 to MCK-HCOR-0356048 (McKinsey FDA Supplemental Consultant List).

³³ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List).

³⁴ MCK-HCOR-0325631; MCK-HCOR-0289101.

³⁵ MCK-HCOR-0326970; MCK-HCOR-0331848; MCK-HCOR-0257140; MCK-HCOR-0327485; MCK-HCOR-0192010; MCK-HCOR-0181342.

³⁶ *Cyclica Appoints Renowned Healthcare AI Executive, Sastry Chilukuri, to Board of Directors to Help Build the Biotech Pipeline of the Future*, Associated Press (Jan. 7, 2021) (online at <https://apnews.com/article/technology-business-executive-changes-pharmaceutical-manufacturing-health-care-industry-bd3366b31ea240c493c85932a34b2c04>).

³⁷ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List).

³⁸ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List; MCK-HCOR-0097644, Slide 3.

³⁹ Patrick Radden Keefe, *Empire of Pain: The Secret History of the Sackler Dynasty*, 234-235 (2021)

Mr. Ghatak also consulted for other opioid manufacturers. A 2011 McKinsey presentation stated that he would provide “senior counsel” on a project to “turbocharge” Nucynta, a Johnson & Johnson opioid.⁴⁰ In 2015, he appears to have helped implement McKinsey’s strategy for Endo International’s “Sales Force Blitz” of its opioid products.⁴¹

As described below, in January 2018, Mr. Ghatak contributed to a McKinsey-generated transition memo on the opioid crisis that had been prepared for incoming HHS Secretary Alex Azar, despite consulting for Purdue at the time.⁴²

In July 2018, Mr. Ghatak and another McKinsey Senior partner, Martin Elling, discussed destroying documents relating to their work at Purdue.⁴³ In February 2021, McKinsey stated that it had fired both Mr. Ghatak and Mr. Elling.⁴⁴

2. Additional Cross-Over of Consultants

The Committee has identified an additional 19 McKinsey consultants, in addition to the three above, who performed work for both FDA and opioid manufacturers. Documents obtained by the Committee suggest a pattern of assigning the same consultants to work on McKinsey’s projects for FDA and opioid clients. Two of the consultants identified by the Committee as having worked for both FDA and opioid manufacturers currently serve at the highest levels of the firm, with one sitting on McKinsey’s Client Service Risk Committee and the other on the firm’s Shareholders Council, McKinsey’s equivalent of a board of directors.

Three of these additional McKinsey consultants—all McKinsey partners—are discussed below.

Ted Fuhr

Former McKinsey consultant Ted Fuhr worked on five FDA contracts between May 2010 and February 2014 before working on five projects at Purdue Pharma.⁴⁵ While working on FDA contracts, Mr. Fuhr appears to have also unofficially consulted on matters related to Purdue. For instance, on May 5, 2010, Mr. Fuhr started an FDA contract “to assist FDA in evaluating existing global product safety efforts and developing and implementing the Global Product

⁴⁰ MCK-HCOR-0202077; MCK-HCOR-0202079, Slide 4.

⁴¹ MCK-HCOR-0274099; MCK-HCOR-0297705.

⁴² MCK-HCOR-0179910.

⁴³ MCK-HCOR-0173795.

⁴⁴ *States Pressure Drugmakers After McKinsey’s \$600 Million Opioid Settlement*, Wall Street Journal (Feb. 4, 2021) (online at www.wsj.com/articles/states-pressure-drug-makers-after-mckinseys-600-million-opioid-settlement-11612476966).

⁴⁵ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List); MCK-HCOR-0356043 to MCK-HCOR-0356048 (McKinsey FDA Supplemental Consultant List).

Safety Plan.”⁴⁶ Eight days later, on May 13, 2010, Mr. Fuhr was invited to a call with other McKinsey consultants to discuss a request from Purdue, for a matter on which he was not staffed.⁴⁷

In January 2014, Mr. Fuhr worked on a project supporting the FDA’s Office of Generic Drugs at a time when Purdue was facing significant competition from a generic opioid produced by Teva Pharmaceuticals after an adverse court ruling on several patents, threatening OxyContin’s market share.⁴⁸ On January 15, 2014, a McKinsey partner emailed other consultants that “Teva would still need to submit an ANDA [abbreviated new drug application] for a tamper-resistant product and get it approved” by FDA.⁴⁹

One week later, the same McKinsey consultant emailed a senior executive at Purdue and introduced Mr. Fuhr: “We found a partner colleague, Ted Fuhr, who may be the right person to provide the Teva point of view. He knows the regulatory space and generics players and has negotiated against Teva.”⁵⁰ Mr. Fuhr’s project at FDA lasted several more weeks after this email, ending on February 3, 2014.⁵¹

After this introduction, Mr. Fuhr was staffed on five official projects at Purdue Pharma spanning from May 2015 to September 2017.⁵²

Katy George

Katy George is one of the most senior partners at McKinsey, currently serving as a “member of the Shareholders Council, the firm’s equivalent of the board of directors, and the firm’s 15-person global leadership team.”⁵³ From April 2010 to December 2011, Ms. George worked on eight separate FDA engagements, including two projects helping set up a system to track and trace the safety of dangerous drugs such as opioids.⁵⁴

⁴⁶ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List).

⁴⁷ MCK-HCOR-0338249.

⁴⁸ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List); MCK-HCOR-0338318.

⁴⁹ MCK-HCOR-0218285.

⁵⁰ MCK-HCOR-0195217 (emphasis added).

⁵¹ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List).

⁵² MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List); MCK-HCOR-0125363, Page 5; MCK-HCOR-0028381; MCK-HCOR-0085539.

⁵³ McKinsey & Company, *Katy George* (online at www.mckinsey.com/our-people/katy-george) (accessed Feb. 9, 2021).

⁵⁴ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List); MCK-HCOR-0356043 to MCK-HCOR-0356048 (McKinsey FDA Supplemental Consultant List).

Ms. George first staffed a Purdue project in 2004 and appears to have intermittently assisted the manufacturer over the next 12 years. For instance, Ms. George appeared to brief Richard Sackler on foreign business opportunities in 2007, assisted Purdue on a project with FDA regulatory issues related to a Purdue facility in 2009, and assisted with a McKinsey engagement proposal in 2010.⁵⁵ Ms. George officially staffed two projects for Purdue in 2015.⁵⁶

Nora Gardner

Nora Gardner is among the most senior partners at McKinsey. She serves as the Managing Partner of McKinsey's Washington D.C. office and, according to documents provided to the Committee, is a member of the firm's Client Service Risk Committee.⁵⁷

From January 2018 to March 2019, Ms. Gardner consulted on four projects at FDA, including on a project to modernize new drug programs.⁵⁸ In January 2018, Ms. Gardner began a project at FDA to "Design and implement the future state operating model for Oncology Center of Excellence (OCE) that will help to put OCE on a strong footing to achieve its mission."⁵⁹

Documents indicate that during this time, Ms. Gardner was also unofficially participating on Purdue matters. Ms. Gardner received invitations for 15 calls and meetings with Purdue between January 15, 2015, and April 1, 2015, for instance, appearing to join a call on "Purdue Strategy" with Mr. Ghatak and other key McKinsey consultants there on January 29, 2015.⁶⁰

Other Consultants

The Committee has identified at least 16 additional consultants who worked for FDA and opioid manufacturers between 2008 and 2022.⁶¹ The Committee has outlined the contracts for 15 of these consultants falling below the full partner level in the chart below, with check marks

⁵⁵ MCK-HCOR-0086036; MCK-HCOR-0172253; MCK-HCOR-0155555, Pages 14-15; MCK-HCOR-0339527; MCK-HCOR-0172451; MCK-HCOR-0174776; MCK-HCOR-0172142.

⁵⁶ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List).

⁵⁷ McKinsey & Company, *Nora Gardner* (online at www.mckinsey.com/our-people/nora-gardner) (accessed Feb. 28, 2022).

⁵⁸ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List); MCK-HCOR-0356043 to MCK-HCOR-0356048 (McKinsey FDA Supplemental Consultant List).



⁵⁹ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List).

⁶⁰ MCK-HCOR-0176421 (Jan. 15); MCK-HCOR-0191553 (Jan. 29); MCK-HCOR-0192129 (Feb. 10); MCK-HCOR-0190573 (Feb. 18); MCK-HCOR-0176956 (Feb. 25); MCK-HCOR-0189207 (Mar. 3); MCK-HCOR-0191859 (Mar. 10); MCK-HCOR-0178050 (Mar. 11); MCK-HCOR-0189208 (Mar. 17); MCK-HCOR-0176713 (Mar. 18); MCK-HCOR-0191624 (Mar. 24); MCK-HCOR-0177692 (Mar. 25); MCK-HCOR-0177660 (Mar. 29); MCK-HCOR-0190064 (Mar. 31); MCK-HCOR-0189340 (Apr. 1).

⁶¹ In addition to the six partners named above and as discussed in detail in this report, McKinsey partner Joachim Bleys also consulted for FDA and Purdue, occasionally simultaneously.

representing contracts performed for Purdue and FDA.⁶² Several of these consultants also likely participated on matters for Purdue and other opioid manufacturers despite not being listed in official engagement lists. For instance, although Consultant 10 is only listed as officially staffing one contract at Purdue in 2016,⁶³ documents obtained by the Committee suggest he took part in multiple meetings at the manufacturer throughout 2017.⁶⁴ McKinsey staffed several of these consultants on projects at FDA and Purdue simultaneously.⁶⁵

**Additional Known McKinsey Consultants
Serving FDA and Opioid Manufacturers Between 2008 and 2021**

<i>McKinsey Consultant</i>		
Consultant 1	✓ ✓ ✓	✓ ✓
Consultant 2	✓	✓ ✓
Consultant 3	✓	✓
Consultant 4	✓	✓
Consultant 5	✓	✓
Consultant 6	✓	✓
Consultant 7	✓	✓
Consultant 8	✓	✓ ✓ ✓ ✓ ✓
Consultant 9	✓	✓
Consultant 10	✓	✓
Consultant 11	✓ ✓ ✓ ✓ ✓ ✓ ✓	✓
Consultant 12	✓	✓ ✓ ✓
Consultant 13	✓ ✓ ✓	✓
Consultant 14	✓	✓ <small>Mallinckrodt</small>
Consultant 15	✓ ✓ ✓ ✓	✓ ✓ ✓

⁶² McKinsey has not yet provided the Committee with overlapping staffing information for contracts performed for McKinsey’s other opioid clients.

⁶³ For purposes of this report, McKinsey consultants below the level of partner are identified numerically.

⁶⁴ MCK-HCOR-0085178; MCK-HCOR-0086763; MCK-HCOR-0086793.

⁶⁵ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List); MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List); MCK-HCOR-0356043 to MCK-HCOR-0356048 (McKinsey FDA Supplemental Consultant List); MCK-HCOR-0152071. All but one of the consultants above worked for Purdue. Consultant 14 worked for FDA and Mallinckrodt. MCK-HCOR-0341360.

3. *McKinsey's FDA Contracts Overlapped with McKinsey's Work for Opioid Manufacturers, Creating Significant Conflicts of Interest*

All of the 37 FDA contracts for which McKinsey provided staffing information to the Committee were staffed by at least one McKinsey consultant who also consulted for Purdue.⁶⁶

The Committee has identified four illustrative categories of FDA contracts that raise particular conflict of interest concerns.

i. FDA Office of Surveillance and Epidemiology Contracts (2011-2012)

CDER's Office of Surveillance and Epidemiology (OSE) evaluates the safety profiles of drugs available to American consumers, maintaining a system of post-marketing surveillance programs to identify adverse events that did not appear during the drug development process.⁶⁷ McKinsey undertook two contracts related to drug safety at OSE between 2011 and 2012.⁶⁸

The first OSE contract, worth \$1,799,534, charged McKinsey with developing a new concept of operations for the Office. The contract was staffed by nine McKinsey consultants. Four of the nine consultants on the contract were also consulting for Purdue during this time, including partner Jeff Smith.⁶⁹ A fifth McKinsey consultant working on this OSE project, Navjot Singh, had previously participated on Purdue matters, and documents suggest he may have been participating on Purdue and private sector clients on FDA-related issues during this time.⁷⁰

⁶⁶ See MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List); MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List); MCK-HCOR-0356043 to MCK-HCOR-0356048 (McKinsey FDA Supplemental Consultant List). The Committee's November 5, 2021, letter requested "[a] detailed description of any matters McKinsey has worked on for FDA since 2008 involving opioids, generic drugs, biosimilar drugs, drug distribution, drug approval, drug approval processes, track and trace systems, or REMS or drug safety programs, including the dates, subject matter, work performed, and amount FDA paid McKinsey for each project." Letter from Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, to Mr. Bob Sternfels, McKinsey & Company (Nov. 5, 2021) (online 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>).

⁶⁷ Food and Drug Administration, *CDER Office of Surveillance and Epidemiology* (online at www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-office-surveillance-and-epidemiology) (accessed Feb. 23, 2022).

⁶⁸ MCK-HCOR-0352013 to MCK-HCOR-0352019; MCK-HCOR-0351882 to MCK-HCOR-0351888. MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List)

⁶⁹ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List); MCK-HCOR-0356043 to MCK-HCOR-0356048 (McKinsey FDA Supplemental Consultant List); MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List).

⁷⁰ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List). As seen below, Mr. Singh, although not officially listed on the Purdue engagement list, appears in an email where he is asked, and seemingly agrees, to share his regulatory expertise with McKinsey consultants, including those serving Purdue. MCK-HCOR-0194501.

McKinsey's contract with OSE detailed how Congress had provided "FDA with several major new post-marketing authorities, including the authority to require a Risk Evaluation and Mitigation Strategy (REMS) for new and existing products if deemed necessary." The contract continued that "the responsibility for implementing many of the new post-marketing authorities has rested with the Office of Surveillance and Epidemiology (OSE)," resulting in an increase in size and responsibility for the office. In light of this new responsibility, FDA requested that McKinsey define the "[s]trategic goals and objectives for CDER and OSE related to drug safety," including by weighing "the adverse impact of drugs on health in the US."⁷¹ At the time of the 2011 contract, CDER and OSE were engaged in implementing FDA's regulatory authority over REMS for opioids.⁷²

In early 2009, FDA had notified certain opioids manufacturers that their drugs would need a REMS to ensure that the benefits of the drugs continue to outweigh the risks. In the same year, McKinsey advised Purdue on a strategy to weaken the proposed REMS plan and avoid the proposed restrictions for opioids, advising Purdue to "band together" with other opioid-makers to "defend against strict treatment by the FDA," or "Raise legal claims alleging FDA impropriety."⁷³ In July 2010, just six months before the OSE contract began, an FDA advisory committee had overwhelmingly rejected the agency's proposed REMS plan, with experts questioning whether FDA's proposed requirements "would have any significant impact on the epidemic of opioid abuse."⁷⁴

Documents show that while working on the first FDA OSE contract, McKinsey consultant Jeff Smith worked on at least *four* separate projects at Purdue, including regulatory matters before FDA.⁷⁵ One project involved the effectiveness of Purdue's REMS for OxyContin, which was at the time being implemented by the FDA office Mr. Smith was advising on drug safety. Although FDA specifies the requirements of a REMS safety program and approves the program, the manufacturer is responsible for developing and implementing the program.⁷⁶ FDA requires manufacturers to provide reports to allow FDA to assess the effectiveness of a REMS safety plan.⁷⁷ From January through April 2011, Mr. Smith worked on

⁷¹ MCK-HCOR-0352013, Page 3.

⁷² *Id.*

⁷³ MCK-HCOR-0340667, Slide 1; MCK-HCOR-0339718; MCK-HCOR-0225929.

⁷⁴ *FDA Panel Wants More Restrictions on Painkillers*, Associated Press (July 23, 2010) (online at www.denverpost.com/2010/07/23/fda-plans-for-painkiller-restrictions-fall-short-experts-say/).

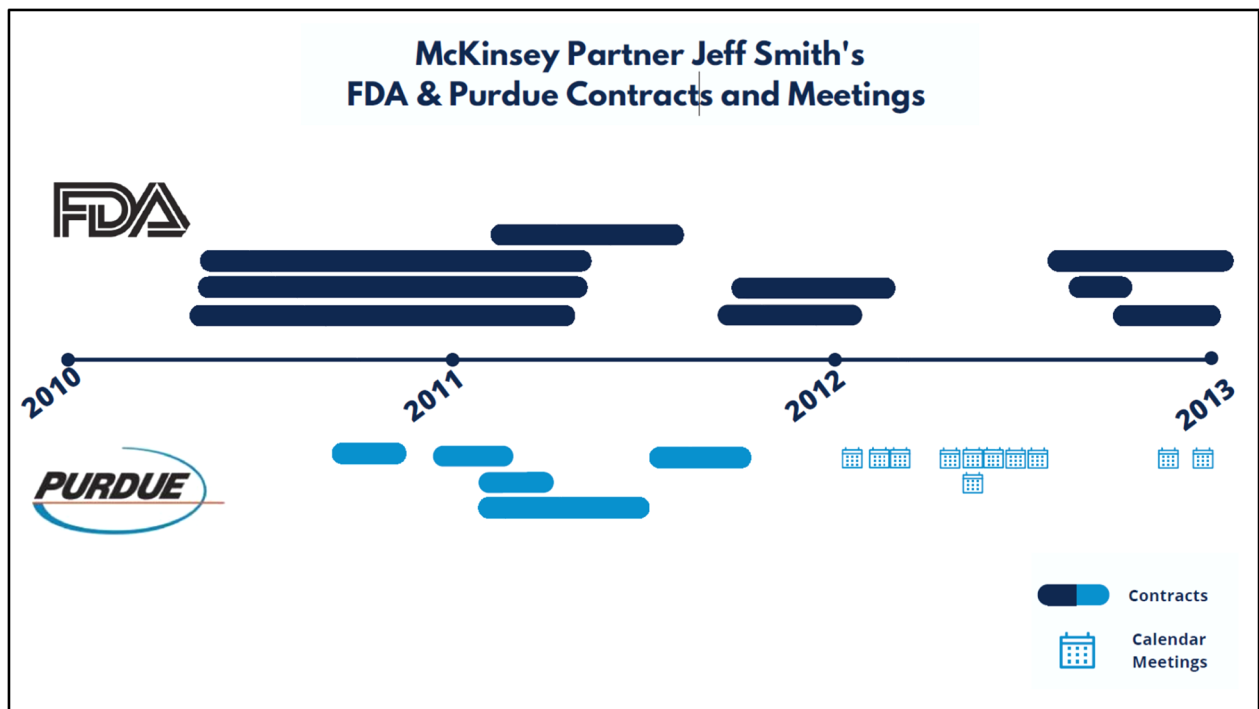
⁷⁵ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List). The four engagement codes for the projects Smith worked on at Purdue during this time are PUP028, PUP029, PUP030, and PUP031.

⁷⁶ Food and Drug Administration, *Frequently Asked Questions (FAQs) About REMS* (online at www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems#:~:text=Does%20FDA%20develop%20the%20individual,developing%20and%20implementing%20the%20program) (accessed Feb. 16, 2022).

⁷⁷ Congressional Research Service, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness* (May 18, 2012) (online at www.everycrsreport.com/files/20120518_R41983_0abd45b649dc957340d1212b0dc62c1655558538.pdf)

a hair testing program at Purdue designed to demonstrate the safety of a newly approved abuse-deterrent formulation of OxyContin, in support of Purdue’s REMS for OxyContin. The program sought, among other goals, to “[e]valuate if REMS meets its goals or needs modification.”⁷⁸ McKinsey noted that this safety testing program could expand Purdue’s business by improving Purdue’s perception by “Regulators” and could lead to “Preference by regulators over generic entrants.”⁷⁹

McKinsey frequently cross-staffed Mr. Smith on FDA and Purdue consulting projects. The below graphic depicts the overlap between Mr. Smith’s known FDA and Purdue consulting work between 2010 and 2013.⁸⁰



⁷⁸ MCK-HCOR-0018792, Slide 126.

⁷⁹ MCK-HCOR-0018792, Slide 163.

⁸⁰ This timeline represents the engagements McKinsey partner Jeff Smith was involved in at both Purdue and FDA between 2010 and 2013. Meetings at or concerning Purdue which took place outside contracts are represented by calendar invites. MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List); MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List). In 2012, when Mr. Smith was not listed in an engagement with Purdue but officially consulting for FDA, he was invited to at least 11 meetings regarding McKinsey’s consulting with Purdue. MCK-HCOR-0341538 (Jan. 18); MCK-HCOR-0341752 (Feb. 13); MCK-HCOR-0170127 (Feb. 16); MCK-HCOR-0170171 (Apr. 19); MCK-HCOR-0341613 (May 9); MCK-HCOR-0341163 (May 9); MCK-HCOR-0341662 (May 16); MCK-HCOR-0341589 (June 26); MCK-HCOR-0172297 (July 19); MCK-HCOR-0170205 (Nov. 5); MCK-HCOR-0173516 (Dec. 20).

One of the other consultants working on the OSE contract with Mr. Smith was Joachim Bleys, who is currently a partner at McKinsey.⁸¹ Documents show that Mr. Bleys worked on eight FDA engagements between 2010 and 2012, despite having previously supported projects for Purdue on its opioid REMS regulatory submission to FDA in 2008 and 2009.⁸² Documents show Purdue executives were focused on defeating FDA safety measures for OxyContin, viewing the effort as potentially “necessary to ‘save the business.’”⁸³ In 2009, the McKinsey team on which Mr. Bleys served suggested Purdue “defend against strict treatment by the FDA” in the agency’s opioid-REMS safety program or “Raise legal claims alleging FDA impropriety.”⁸⁴ Mr. Bleys continued to work on REMS-related contracts at Purdue, even while working on related matters for FDA. In 2011, while working on the OSE contract, Mr. Bleys worked with Mr. Smith on the Purdue hair testing program.⁸⁵

While both were working on the OSE contract, Mr. Smith and another McKinsey consultant, Consultant 1, worked on two additional projects for Purdue related to a clinical trial aimed at demonstrating the safety of pediatric OxyContin.⁸⁶ A key objective of both these projects was to “Prepare Purdue for an interim meeting with FDA including an amendment to the written request”—referring to a request issued by CDER’s Office of Drug Evaluation for Purdue to perform certain clinical trials to show opioid safety.⁸⁷

McKinsey stated that its consultants would “[w]ork with select stakeholders from Medical, Regulatory and Statistics [at Purdue] on the underlying analysis and preparation for a potential interim meeting with FDA” and furnish Purdue with “roles, scripts, rehearsals for meeting.”⁸⁸ In January 2011, Purdue’s CEO had reportedly “identified obtaining FDA approval to sell OxyContin to children” as one of his primary “goals and objectives.”⁸⁹

Documents show that while Mr. Smith and Consultant 1 continued to work with Purdue on the pediatric OxyContin project, Consultant 1 was working on another project for FDA on the drug recall process, involving extensive interviews of CDER officials. An April 1, 2011, document for a McKinsey-FDA contract on reforming the drug recall process, on which Consultant 1 was staffed, stated that McKinsey had “conducted over 40 interviews with FDA

⁸¹ McKinsey & Company, *A New Portfolio Model For Biotech* (online at www.mckinsey.com/industries/life-sciences/our-insights/a-new-portfolio-model-for-biotech) (accessed on Mar. 10, 2022).

⁸² MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List); MCK-HCOR-0356043 to MCK-HCOR-0356048 (McKinsey FDA Supplemental Consultant List).

⁸³ MCK-HCOR-0334973, Page 2.

⁸⁴ MCK-HCOR-0340667, Slide 1; MCK-HCOR-0339718; MCK-HCOR-0225929.

⁸⁵ MCK-HCOR-0018792, Slide 90.

⁸⁶ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List).

⁸⁷ MCK-HCOR-0020344, Page 5.

⁸⁸ *Id.*; MCK-HCOR-0020425.

⁸⁹ Patrick Radden Keefe, *Empire of Pain: The Secret History of the Sackler Dynasty*, 357 (2021).

stakeholders” including 17 FDA officials in the Office of Regulatory Affairs and five officials in CDER.⁹⁰

Navjot Singh, who was also working with Mr. Smith on the FDA OSE contract, also appears to have informally advised McKinsey consultants serving private sector clients at this time, including Purdue. In February 2011, a McKinsey consultant emailed Mr. Singh stating that they were “working through” several “FDA issues” for a private sector client and added: “Would be great to get the Regulatory pov [point of view] and expertise in the Purdue CST [client service team].” Mr. Singh responded: “Look forward to it. Depending on calendars 2 other[s] to include in the mix here are Jeff Smith and Pasha Saraf.”⁹¹ Pasha Saraf was a key McKinsey consultant working for Purdue.⁹²

It is unclear what “FDA issue” Mr. Singh offered his expertise on, or what other material he and the McKinsey consultants may have discussed on the call.⁹³

On August 30, 2011, McKinsey was awarded a second contract by FDA to implement the new model governing OSE’s portfolio. The second OSE contract, like the first, referenced REMS and CDER and OSE’s responsibility over drug safety.⁹⁴ Jeff Smith and Navjot Singh, along with two other McKinsey consultants, co-led this second engagement.⁹⁵

ii. FDA Sentinel Contracts (2014-2018)

In 2008, FDA created the Sentinel Initiative to assess post-approval drug safety signals and “monitor the safety of FDA-regulated medical products, including drugs, vaccines, biologics, and medical devices.”⁹⁶ Sentinel has since become “a core component of the agency’s evolving safety surveillance system,” and “Sentinel data have informed many regulatory decisions made by the Center for Drug Evaluation and Research.”⁹⁷

McKinsey performed three contracts on the FDA Sentinel Initiative at the same time the company was consulting with opioid manufacturers on related issues, often with overlapping consultants, which increased the risk that FDA information might be shared with private sector clients.

⁹⁰ MCK-HCOR-0355751, Page 9.

⁹¹ MCK-HCOR-0194501.

⁹² MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List).

⁹³ MCK-HCOR-0194501.

⁹⁴ MCK-HCOR-0351882 to MCK-HCOR-0351888.

⁹⁵ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List).

⁹⁶ Food and Drug Administration, *FDA’s Sentinel Initiative* (online at www.fda.gov/safety/fdas-sentinel-initiative) (accessed Feb. 8, 2022).

⁹⁷ Dr. Richard Platt et. al, *The FDA Sentinel Initiative - An Evolving National Resource*, New England Journal of Medicine (Nov. 29, 2018) (online at <https://pubmed.ncbi.nlm.nih.gov/30485777/>).

On the first contract in 2014, FDA tasked McKinsey with analyzing the “strengths, limitations and appropriate use” of Sentinel and assessing “how Sentinel data is currently being used by FDA employees to inform regulatory decision making.”⁹⁸ McKinsey was awarded the second contract in 2015, as FDA sought to expand Sentinel’s use.⁹⁹ The agency asked McKinsey to “fully integrate the Sentinel System into CDER regulatory workflows” and “[p]rioritize Sentinel Use Cases based on regulatory need and potential to add value.”¹⁰⁰ McKinsey’s final contract on Sentinel in 2018 involved conducting “activities to define current priorities, assess long-term strategic themes, prioritize strategic options and articulate a five-year strategic plan into an FDA branded report for public release.”¹⁰¹ During this time, FDA was beginning to use Sentinel to understand patterns of opioid use and whether opioids are being used in accordance with approved indications.¹⁰²

In total, FDA has paid McKinsey \$3,910,863 for its work on the Sentinel Initiative.¹⁰³

1. Overlap of Consultants Between FDA’s Sentinel Initiative and Opioid Manufacturers

Documents obtained by the Committee show that Jeff Smith co-led all three Sentinel contracts, and Navjot Singh and Sastry Chilukuri co-led two of the three. From July 2015 through July 2016, Mr. Smith and Mr. Chilukuri co-led the second FDA Sentinel contract.¹⁰⁴

Mr. Smith and Mr. Chilukuri appear to have participated on opioid manufacturer matters at the same time they were working on FDA’s Sentinel Initiative. For instance, while working on the FDA Sentinel contract, Mr. Smith took part in multiple calls and meetings concerning Purdue, including with Purdue executives such as Alan Dunton, Senior Vice President for Research and Development.¹⁰⁵ Mr. Chilukuri appears to have worked on an opioid-related matter tied to another opioid manufacturer, Endo International.¹⁰⁶

During the performance of the second FDA Sentinel contract, McKinsey consultants prepared a proposal for a new Purdue project that would run concurrently with McKinsey’s FDA Sentinel contract. According to the proposal, the project “would involve other McKinsey experts

⁹⁸ MCK-HCOR-0355652, Page 4.

⁹⁹ MCK-HCOR-0351909, Pages 8-9.

¹⁰⁰ *Id.*

¹⁰¹ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List).

¹⁰² Dr. Richard Platt et. al, *The FDA Sentinel Initiative - An Evolving National Resource*, New England Journal of Medicine (Nov. 29, 2018) (online at <https://pubmed.ncbi.nlm.nih.gov/30485777/>).

¹⁰³ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List).

¹⁰⁴ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List).

¹⁰⁵ MCK-HCOR-0173429; MCK-HCOR-0191911; MCK-HCOR-0341403; MCK-HCOR-0272829; MCK-HCOR-0191823; MCK-HCOR-0189800.

¹⁰⁶ MCK-HCOR-0325631; MCK-HCOR-0289101.

with extensive expertise in business development, therapeutic area evolution, and transactions, including Jeff Smith.”¹⁰⁷ McKinsey won the contract, which it referred to internally as “Evaluation and strategic framing of business development opportunities for CEO and Board of Directors.” The project ran from April 25 to June 25, 2016—overlapping with Mr. Smith’s performance of the second FDA Sentinel contract.¹⁰⁸

2. Increased Risk that McKinsey Shared Information About FDA’s Sentinel Contract to Gain Additional Work at Purdue

Documents obtained by the Committee reveal that McKinsey consultants representing Purdue sought out information from consultants representing FDA, who may have shared details about the FDA Sentinel Initiative with Purdue with the goal of securing a contract to track OxyContin’s safety.

In May 2016, while working on the FDA’s Sentinel program, Mr. Smith assisted a team of McKinsey consultants in preparing a new proposal to submit to Purdue for a project designed to provide “real world evidence” of OxyContin’s safety, through which McKinsey would provide data on the drug’s safety from patient-generated and public health data outside of clinical trials.¹⁰⁹

On May 2, 2016, McKinsey partner Arnab Ghatak emailed a group of McKinsey consultants, including Jeff Smith, highlighting that McKinsey could use the Purdue proposal to showcase its FDA work to Purdue. Mr. Ghatak wrote: “Jeff - think it would be great for you or Sastry to talk about our work w FDA, specifically sentinel which I think would be v useful for them [Purdue] in opioids.”

“Jeff - think it would be great for you or Sastry to talk about our work w FDA, specifically sentinel which I think would be v useful for them in opioids.”

– A. Ghatak, McKinsey Partner

When asked who was “running point on prep and integrating the materials,” Mr. Ghatak instructed consultants to send proposal documents to Mr. Smith and another McKinsey

¹⁰⁷ MCK-HCOR-0125427, Slide 6.

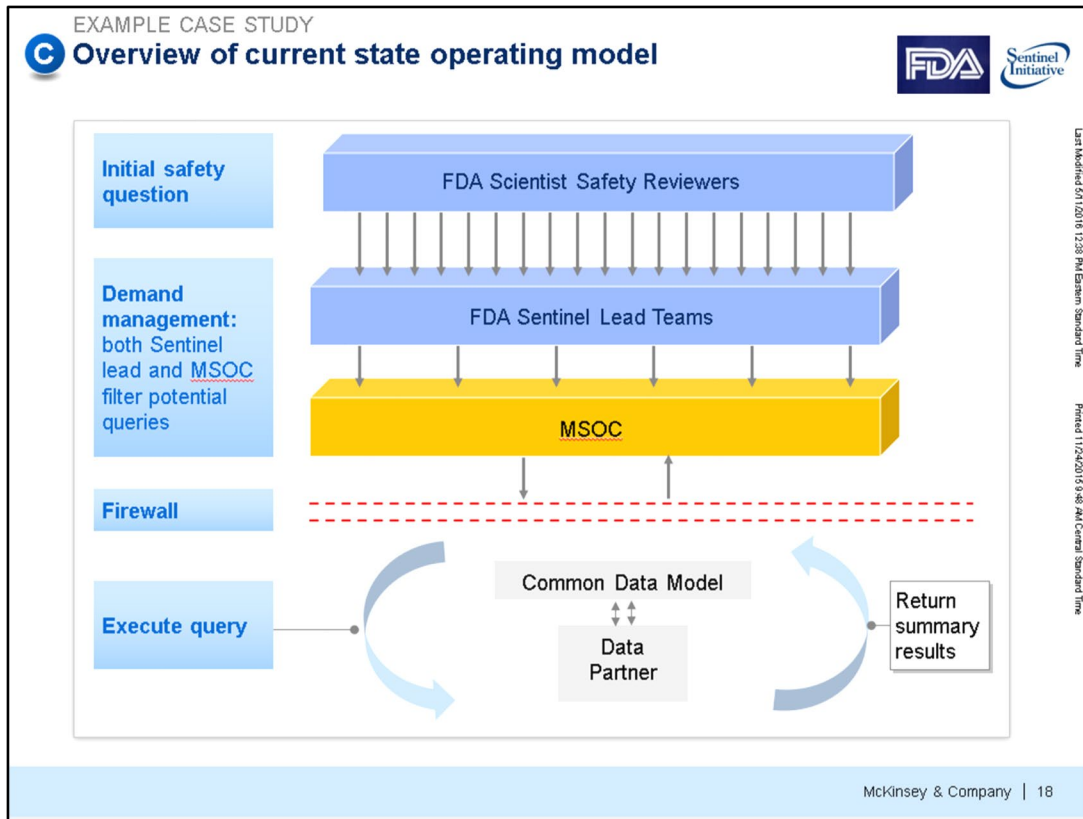
¹⁰⁸ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List).

¹⁰⁹ Real World Evidence reflects data regarding the usage and potential benefits or risks of a medical product derived outside the clinical trial process from sources such as billing records, patient data, and disease registries. Food and Drug Administration, *Real-World Evidence* (online at www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence) (accessed on Mar. 16, 2022).

partner.¹¹⁰ Documents show that multiple preparatory meetings for the Purdue proposal included both Mr. Smith and Mr. Chilukuri, who were both working at FDA at the time.¹¹¹

As part of its May 2016 proposal to Purdue, McKinsey consultants prepared and circulated a PowerPoint presentation showcasing its work on the FDA Sentinel Initiative, even though the FDA contract was ongoing. The presentation included details on McKinsey’s work on Sentinel, including blueprints of the organizational structure used to deploy Sentinel at the agency, as well as FDA’s logo. The presentation highlighted how McKinsey’s work for FDA gave it a “[c]lear understanding of priority use cases for postmarketing surveillance (including alignment around value, trust, and results that affect-regulatory decision making).”¹¹²

May 11, 2016, McKinsey Presentation to Purdue



¹¹⁰ MCK-HCOR-0278700.

¹¹¹ MCK-HCOR-0326970; MCK-HCOR-0331848.

¹¹² MCK-HCOR-0331545, Pages 18, 19, and 48; MCK-HCOR-0332150, Pages 17, 18, and 47.

These slides did not appear in later versions of the presentation, although the presentation continued to refer to McKinsey’s work for the FDA. It is unclear whether these slides were ever shown to Purdue.¹¹³

Separately, McKinsey appears to have influenced FDA’s official statements about Sentinel in between its second and third Sentinel contracts. On February 6, 2018, between McKinsey’s second and third contracts on the Sentinel Initiative, then-FDA Commissioner Scott Gottlieb gave a public speech suggesting the Sentinel System could potentially be used to provide data on the long-term efficacy of opioids.¹¹⁴ In that speech, Commissioner Gottlieb stated that “we should consider how Sentinel might be used to answer questions about efficacy; and how FDA might have tools and resources to take on these questions in certain narrow circumstances where a question around a product’s efficacy also relates to its safety.” He continued that “[o]ne such situation involves the long-term efficacy of opioid drugs and the long-term prescribing of these drugs.”¹¹⁵

Two days later, Mr. Smith complained by email to a colleague that Mr. Chilukuri had overrepresented the capabilities of the Sentinel System and told a “client” (possibly a reference to FDA) that Sentinel can be “used to assess the efficacy of opioids.” Mr. Smith stated that Mr. Chilukuri’s representation “got into one of Scott Gottlieb’s public speeches yesterday, now people are asking how to do it, and it is clear he made it up entirely.”¹¹⁶ Mr. Smith, who at the time was performing other consulting work at both FDA and Purdue, continued: “Now he disappears and I have to figure out how to save face.”¹¹⁷

Four months later, in June 2018, Mr. Smith and Mr. Singh began work on McKinsey’s third FDA Sentinel contract, which tasked McKinsey with conducting “activities to define current priorities, assess long-term strategic themes, prioritize strategic options and articulate a five-year strategic plan into an FDA branded report for public release.”¹¹⁸

iii. FDA / MITRE Subcontract (2016-2017)

From May 2016 to March 2017, McKinsey served as subcontractors for an FDA contract which had been awarded to MITRE—a not-for-profit organization that manages federally funded research and development centers.¹¹⁹ Four of the six McKinsey consultants staffed on the

¹¹³ MCK-HCOR-0330774.

¹¹⁴ Food and Drug Administration, *Remarks as Prepared for Delivery by Commissioner Scott Gottlieb at the Tenth Annual Sentinel Initiative Public Workshop* (Feb. 6, 2018) (online at www.fda.gov/news-events/speeches-fda-officials/remarks-tenth-annual-sentinel-initiative-public-workshop-02072018).

¹¹⁵ *Id.*

¹¹⁶ MCK-HCOR-0341808.

¹¹⁷ *Id.*

¹¹⁸ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List).

¹¹⁹ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List); MITRE, *Corporate Overview* (online at www.mitre.org/about/corporate-overview) (accessed on Mar. 16, 2022).

MITRE subcontract, including Mr. Smith, Mr. Singh, and Mr. Chilukuri, were also working, or had previously worked, on projects related to Purdue.¹²⁰

The MITRE subcontract, valued at \$1,199,405, required McKinsey to identify gaps in clinical evidence to improve regulatory decision-making. Specifically, the contract asked McKinsey to “[r]apidly develop initial overarching framework for key decision points and stakeholders in healthcare decision-making processes” and “draw initial conclusions around existing clinical evidence gaps.” McKinsey was also tasked with identifying “specific stakeholders needed for engagement on this topic—from both within FDA and external to FDA” and was expected to engage with “relevant private-sector stakeholders on any identified clinical evidence gaps and other topics important [to] such stakeholders.”¹²¹

While McKinsey’s subcontract with MITRE focused on addressing “clinical evidence gaps” for FDA trials, McKinsey had previously performed work on clinical trials for Purdue and other private sector clients. For example, Mr. Smith had participated in at least four projects for Purdue that involved designing, running, or presenting data from clinical trials, including accelerating a clinical trial for pediatric OxyContin.¹²² One of these projects had called on McKinsey to “design clinical studies to demonstrate value” of a reformulated version of OxyContin.¹²³

The MITRE subcontract’s requirement that McKinsey identify and engage with “private sector” stakeholders “external to FDA” raises particular conflict of interest concerns, as McKinsey was actively consulting for some of the same private sector stakeholders at the time.¹²⁴

McKinsey worked on at least five engagements at Purdue during its performance of the MITRE subcontract.¹²⁵ While working on this subcontract, Mr. Smith and Mr. Chilukuri both took part in calls concerning Purdue’s opioid business with other consultants performing those contracts.¹²⁶

¹²⁰ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List); MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List).

¹²¹ MCK-HCOR-0355662, Pages 14-16.

¹²² MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List).

¹²³ *Id.*

¹²⁴ MCK-HCOR-035567 4 to MCK-HCOR-0355680.

¹²⁵ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List).

¹²⁶ In September 2016, Mr. Smith took part in a meeting with the subject line “CALL with Arnie Ghatak and Jeff Smith re: Purdue.” MCK-HCOR-0177693. *See also* MCK-HCOR-0172519; MCK-HCOR-0177337; MCK-HCOR-0191809. In January 2017, Mr. Chilukuri was invited to a call titled “Big data/ real world evidence for abuse deterrence at Purdue Pharma.” MCK-HCOR-0326737.

iv. FDA Office of New Drugs Contract (2017-2018)

On November 16, 2017, McKinsey entered into a contract with FDA's Office of New Drugs to modernize CDER's New Drugs Regulatory Program, an award valued at \$2,669,213.¹²⁷ This modernization effort was part of then-FDA Commissioner Gottlieb's effort to streamline drug reviews to shorten the time for a new drug to come to market.¹²⁸ The pharmaceutical industry had long sought to modernize and speed drug reviews, despite concerns from some experts that FDA may have shifted to faster approvals without sufficient data.¹²⁹

FDA's Office of New Drugs oversees investigational studies during the drug development process and assesses the safety and effectiveness of new drugs. McKinsey's 2017 contract with FDA stated that the office needed "a strategic thought partner" to help overhaul FDA's drug review process by performing the "analysis and fact-gathering required to execute the design phase properly, provide external perspectives and benchmarks as appropriate," and implement a "review and redefinition of [Office of New Drug's] major leadership roles, responsibilities, and performance expectations."¹³⁰

Mr. Smith began serving as one of the lead McKinsey partners on the FDA New Drugs contract on December 6, 2017. The FDA contract listed him as the primary McKinsey consultant and Engagement Director.¹³¹ Just two days earlier, Mr. Smith had started another engagement at Purdue, called Project Scottsdale, at the specific request of Purdue's Vice President of Business Operations. Project Scottsdale was a secretive project to transform Purdue's business model by splitting the company into three separate entities and laying off as many as 500 employees or roughly 50% of the workforce.¹³² McKinsey undertook this project as financial institutions began to distance themselves from Purdue due to its role in the opioid epidemic. McKinsey's notes on a draft presentation for Purdue's Board of Directors dated January 2018 stated that "BofA [Bank of America] advised Purdue that ALL banking

¹²⁷ MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List).

¹²⁸ *F.D.A. Nominee Deflects Criticism About Ties to Drugmakers at Hearing*, New York Times (Apr. 5, 2017) (online at www.nytimes.com/2017/04/05/us/politics/fda-nominee-scott-gottlieb-food-drug-administration-confirmation-hearing.html); BioPharm, *Gottlieb Proposes Modernization of Drug Review Office* (June 4, 2018) (online at www.biopharminternational.com/view/gottlieb-proposes-modernization-drug-review-office).

¹²⁹ *FDA Approves Drugs Faster Than Ever But Relies on Weaker Evidence, Researchers Find*, National Public Radio (Jan. 14, 2020) (online at www.npr.org/sections/health-shots/2020/01/14/796227083/fda-approves-drugs-faster-than-ever-but-relies-on-weaker-evidence-researchers-fi); *FDA Repays Industry by Rushing Risky Drugs to Market*, ProPublica (June 26, 2018) (online at www.propublica.org/article/fda-repays-industry-by-rushing-risky-drugs-to-market).

¹³⁰ MCK-HCOR-0351350, Page 6.

¹³¹ MCK-HCOR-0351350, Pages 16 and 17.

¹³² MCK-HCOR-0342045; MCK-HCOR-0249585; MCK-HCOR-0033942, Slides 3-4; MCK-HCOR-0351289 (detailing Purdue leadership's request for Mr. Smith's personal involvement in Project Scottsdale).

relationships must end due to their perception of reputation risk, ending our Credit Line as of 3/31/2018.”¹³³

Mr. Smith worked closely with Purdue management on Project Scottsdale, including attending dinners with senior officials. In an email to colleagues on December 22, 2017, one McKinsey consultant noted that Purdue’s chief of staff, a former McKinsey consultant himself, “invited us (Jeff, Abhi, team) to a dinner at his home, and we had a very nice evening.”¹³⁴

While McKinsey was working on the contract for FDA’s Office of New Drugs, McKinsey was also advising Purdue on issues related to new drugs that would be submitted for approval to the same office. As part of Project Scottsdale and Purdue’s reorganization, McKinsey reviewed the company’s pipeline of new drugs.¹³⁵ The most valuable of these drugs would be placed in a company called “NewCo,” which would be “built to purpose to source, develop and commercialize a future, *non-opioid* portfolio.”¹³⁶ Purdue believed that Lemborexant, an insomnia drug, held promise.¹³⁷ McKinsey produced slides for Project Scottsdale that detailed the status of Lemborexant as well as the budget for the drug.¹³⁸ Another presentation, produced in February 2018 by a hedge fund working with McKinsey on Purdue’s reorganization, stated: “Positive head-to-head data for Lemborexant justify further resource allocation.”¹³⁹

In March 2018, while Mr. Smith was simultaneously working for both the FDA Office of New Drugs and Purdue, the Purdue announced that it expected to file its new drug application for Lemborexant.¹⁴⁰ On May 21, 2018, Mr. Smith sent an email to Arnab Ghatak referring to a conversation with Purdue’s Vice President of Business Operations, stating that the Purdue official had told him: “Pipeline—generally more positive than they were a few months ago,” and

¹³³ MCK-HCOR-0342045. McKinsey, through Project Scottsdale, appears to have laid the groundwork for Purdue’s bankruptcy filings a year and a half later. NewCo became a centerpiece of Purdue’s bankruptcy plans. McKinsey also worked closely with PJT Partners, a restructuring an investment banking firm, which would later usher Purdue through its bankruptcy. *Purdue Pharma Announces Agreement in Principle on Landmark Opioid Litigation Settlement*, Businesswire (Sept. 15, 2019) (online at www.businesswire.com/news/home/20190915005052/en/Purdue-Pharma-Announces-Agreement-in-Principle-on-Landmark-Opioid-Litigation-Settlement).

¹³⁴ MCK-HCOR-0342154.

¹³⁵ MCK-HCOR-0034569, Slides 21, 22, 23.

¹³⁶ MCK-HCOR-0255591, Slide 1 (emphasis added). This effort was a continuation a long-term McKinsey-Purdue initiative, centered around drugs like Lemborexant, to achieve a “portfolio diversification strategy” beyond opioids. MCK-HCOR-0027081, Slide 1.

¹³⁷ MCK-HCOR-0141703.

¹³⁸ MCK-HCOR-0034569, Slide 21; MCK-HCOR-0034679, Slides 30, 33.

¹³⁹ MCK-HCOR-0034497, Page 24.

¹⁴⁰ *Eisai, Purdue to File Insomnia Drug Following Positive Head-To-Head*, Scrip (Mar. 8, 2018) (online at <https://scrip.pharmaintelligence.informa.com/SC100538/Eisai-Purdue-To-File-Insomnia-Drug-Following-Positive-HeadToHead>).

“referenced positive phase 3 results for lemborexant. She said that they are going to commercialize it.”¹⁴¹

McKinsey also assessed the value of a new opioid as part of Project Scottsdale, one for which Purdue intended to later file new drug application with FDA. An early December 2017 Scottsdale draft presentation contained extensive notes for “MSR,” an “ADF [abuse-deterrent formulation] opioid pain drug” that had been in development since 2014. The draft presentation noted that “commercial viability unclear” and stated: “Filing NDA [new drug application] Q1 > takes at least 12-18 months; revenue will be for after that.”¹⁴² This planned new drug application was scheduled to occur while Mr. Smith was working for the Office of New Drugs.

4. McKinsey Consultants Shared FDA Information with Other Consultants Working for Private Sector Clients

The Committee has uncovered several instances in which McKinsey consultants appear to have received information from FDA related to the agency’s regulation of opioids, which the consultants then shared with McKinsey colleagues working for private sector opioid clients.¹⁴³

In one instance, a McKinsey consultant shared an FDA document concerning the opioid epidemic with another McKinsey consultant who at the time was working on a Purdue contract, though the precise nature of the document is not clear.

On January 23, 2018, an FDA official emailed then-FDA Commissioner Gottlieb and other senior officials a document entitled “Proposals for Consideration.” It is not clear what the proposals were, but later correspondence suggests that they involved spending priorities related to opioids and may have included federal initiatives connected to prescribing behavior that could have impacted McKinsey’s opioid clients.¹⁴⁴

On the same day, Rachel Sherman, then-Principal Deputy Director of FDA, sent a second document to FDA officials, including then-CDER Director Janet Woodcock, with notes about Commissioner Gottlieb’s input on the proposal document: “Scott will up the estimates from 500M to 650M. He would like a second version that gets us to 1B by COB tomorrow (in other words to expand the list).”¹⁴⁵

After sending this email, Ms. Sherman sent the document to McKinsey Senior Partner Navjot Singh, writing: “Doc 2. Thanks! *PS Please keep this to you (feel free to include Jeff,*

¹⁴¹ MCK-HCOR-0141703.

¹⁴² MCK-HCOR-0035338, Slide 11.

¹⁴³ As discussed above, McKinsey consultants circulated material that appeared to have been drawn from the FDA Sentinel Initiative with colleagues working for Purdue. MCK-HCOR-0330664.

¹⁴⁴ MCK-HCOR-0341883 (emphasis added).

¹⁴⁵ *Id.*

*Sastry and Brandon if that would be helpful).*¹⁴⁶ Mr. Singh forwarded the document to a group of McKinsey consultants, including Mr. Smith, who was at the time working on contracts for both FDA and Purdue.

Roughly a week later, on February 2, 2018, despite Ms. Sherman’s request to limit distribution of the document, Mr. Smith forwarded the document to Pasha Saraff, a key McKinsey consultant working for Purdue. Mr. Smith stated: “This is the list of projects that I referenced yesterday with Peter. *I got Rachel to insert the last bucket on the list.*”¹⁴⁷

Mr. Sarraf responded: “Wow !!! gibberish ... a few that will actually lead to anything as best as I can see ... Appropriate opioid prescribing ... whatever. As if we dont know already and thats teh [sic] problem”¹⁴⁸ It is unclear whether Mr. Sarraf shared the document further.

B. McKinsey Utilized Government Contracts to Secure Private Sector Business

Documents obtained by the Committee show that McKinsey consultants repeatedly utilized their government contacts and experience to showcase the firm’s value to opioid manufacturers and solicit private sector business. These representations raise questions about whether McKinsey viewed its federal government contracts as means to gain more lucrative private sector business and whether sharing such information was an abuse of client confidences.

For instance, McKinsey has internal policies to limit distribution of client information. According to McKinsey’s “Use of Name” policy, the “names of our clients, the topics on which we serve them, and the advice we provide, should generally remain confidential.” Although McKinsey allows for disclosure of client work “with prior approval,” the policy provides that such disclosure may only be made “where this reflects a balance of benefits and risks, and the context of the sectors, geographies and client capabilities involved.”¹⁴⁹ Similarly, McKinsey’s “Serving Competitors Policy” recognizes that conflicts occur across the public and private sectors and holds that maintaining “client confidences is among our most important professional responsibilities” and “the DCS [Director of Client Services] is responsible for ensuring that no confidential client information is disclosed outside of the CST [Client Service Team].”¹⁵⁰

Documents show that McKinsey routinely highlighted its federal government relationships in an apparent effort to obtain private sector contracts.

¹⁴⁶ *Id.* (emphasis added).

¹⁴⁷ *Id.* (emphasis added).

¹⁴⁸ *Id.*

¹⁴⁹ MCK-HCOR-0352128, Page 2.

¹⁵⁰ MCK-HCOR-0352196, Page 2.

1. *McKinsey Used FDA Experience to Win Business from Purdue's CEO*

McKinsey appears to have touted its FDA experience directly to Purdue's CEO in order to obtain additional consulting business. In 2014, Purdue hired Mark Timney as its new CEO. On January 23, 2014, after a breakfast meeting with Mr. Timney, McKinsey partners Rob Rosiello and Arnab Ghatak sent a follow-up email to Mr. Timney emphasizing key points from their meeting, including how McKinsey's public sector connections could benefit Purdue:

1. External perspectives. We believe McKinsey brings an unequalled capability based on who we know and what we know. We serve the broadest range of stakeholders that matter for Purdue, including PBMs, payors distributors, integrated delivery networks, State and Federal Regulators. One client we can disclose is the FDA, who we have supported for over five years. As part of the strategy effort, we will reach out to our network and bring to bear the full expertise of our Firm - from our ACA reform institute to our standing Ad boards of KOLs [Key Opinion Leaders] to our R&D experts. We believe we bring a distinctive breadth and depth of external perspectives important to Purdue's strategy effort.¹⁵¹

From: rob_rosiello@mckinsey.com [mailto:rob_rosiello@mckinsey.com]

Sent: Thursday, January 23, 2014 3:40 PM

To: Timney, Mark

Cc: arnab_ghatak@mckinsey.com

Subject:

Mark,

Arnie and I thoroughly enjoyed our breakfast discussion. We are writing to emphasize three points as you decide whether to work with us. We believe these will contribute to the success of your strategy effort and hope they make you comfortable choosing McKinsey for this work.

1. External perspectives. We believe McKinsey brings an unequalled capability based on who we know and what we know. We serve the broadest range of stakeholders that matter for Purdue, including PBMs, payors distributors, integrated delivery networks, State and Federal Regulators. One client we can disclose is the FDA, who we have supported for over five years. As part of the strategy effort, we will reach out to our network and bring to bear the full expertise of our Firm – from our ACA reform institute to our standing Ad boards of KOLs to our R&D experts. We believe we bring a distinctive breadth and depth of external perspectives important to Purdue's strategy effort.

2. Personal references. We know you haven't worked with either of us personally. We are excited to work directly with you on this and are happy to provide personal references if helpful.

3. Fees. As a sign of our commitment to your success, we are willing to make a sizeable investment in this work, including putting fees at risk based on your satisfaction. You have our assurance that we won't let professional fees be the reason for not working together on this strategy.

At the time this email was sent, McKinsey was pitching Purdue on an \$800,000 project to support Purdue's efforts before an FDA Advisory Committee reviewing Targiniq, an opioid that Purdue had been developing for several years. McKinsey consultants, including Mr. Smith, had

¹⁵¹ MCK-HCOR-0099021.

forwarded Mr. Rosiello and Mr. Ghatak details of McKinsey’s proposal on January 22, 2014, the day before the above email to Purdue’s CEO.¹⁵²

Six days later, on January 29, 2014, a McKinsey consultant wrote a group including Mr. Ghatak that “our Purdue CST [Client Service Team] has recently confirmed a number of really important engagements.”¹⁵³ On January 30, 2014, McKinsey began the engagement preparing Purdue for the FDA Advisory Committee on Targiniq. McKinsey partner Jeff Smith co-lead that FDA-facing effort.¹⁵⁴

In addition, Mr. Ghatak and other McKinsey consultants at Purdue appear to have influenced Purdue’s CEO transitions. In March 2013, Mr. Elling emailed Mr. Ghatak and other McKinsey consultants stating, “Confidentially there is a search on for a new CEO at Purdue” and that they had been approached by “colleagues who are helping prep candidates.” Mr. Elling asked Mr. Ghatak and others to begin to prepare documents for “our colleagues” to help them “do a first pass at providing a profile of the company (in-line and pipeline).” He added, “it goes without saying that we should not be speaking of this to any colleagues.” Mr. Elling also stated that “when the time is right we may have a chance to brief some of the final candidates [sic].”¹⁵⁵

Later that year, in August 2013, another McKinsey partner told Mr. Ghatak that he had given a Purdue executive “feedback on ceo candidates...do think we now have good access and dialogue with him.”¹⁵⁶ In January 2014, Purdue announced Mr. Timney’s hiring as President and CEO.¹⁵⁷

In March 2018, Mr. Elling explained in an email how he had “been successfully managing the CEO transitions at [redacted] Purdue.”¹⁵⁸

2. McKinsey Highlighted Its “Insights into the Perspectives of Regulators” in Attempt to Win Lead Role in Opioid Manufacturer Industry Group

A draft McKinsey presentation from May 2009 appears to make McKinsey’s case for leading an Industry Working Group of two-dozen opioid manufacturers to develop class-wide FDA REMS. One slide asserted McKinsey’s “distinctive capabilities to support you in this effort” and listed among the firm’s qualifications, “Extensive experience serving Regulatory in industry and government.” The slide noted that McKinsey had “Supported regulatory bodies

¹⁵² MCK-HCOR-0231695.

¹⁵³ MCK-HCOR-0197410.

¹⁵⁴ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List).

¹⁵⁵ MCK-HCOR-0100789.

¹⁵⁶ MCK-HCOR-0097967.

¹⁵⁷ *Purdue Pharma L.P. Names Mark Timney President and Chief Executive Officer*, Biospace (Jan. 27, 2014) (online at www.biospace.com/article/releases/purdue-pharma-l-p-names-b-mark-timney-b-president-and-chief-executive-officer/).

¹⁵⁸ MCK-HCOR-0173821.

directly, and *as such have developed insights into the perspectives of the regulators themselves.*”¹⁵⁹

In another slide, McKinsey highlighted its previous successes for private sector clients in front of FDA, such as McKinsey’s impact in “Rapidly improving relationships with FDA and evidence of growing trust” for one large pharmaceutical company.¹⁶⁰

We believe McKinsey brings distinctive capabilities to support you in this effort (2/2)

- Extensive experience serving Regulatory in industry and government**
 - Developed distinctive expertise in Regulatory issues through supporting major pharmacos in redesigning their Regulatory functions.
 - Supported regulatory bodies directly, and as such have developed insights into the perspectives of the regulators themselves
- Proprietary Regulatory and Pain advisory boards**
 - Due to the large number of studies we do within pharmaceuticals, we have developed a group of ex-regulators to counsel us during projects.
 - We would leverage this group of advisors as we support you
- Deep expertise in pain management, including opioid space**
 - Multiple engagements over 10+ years in pain management
 - Deep understanding of evolving changes that opioids face, including
 - Evolving diversion and abuse problem and surveillance approaches
 - Challenges of developing and testing “tamper resistant” formulations
- Extensive experience managing long, highly complex projects**
 - Project managed post-merger integration over a period of years for some of the largest corporate mergers in history, inside and outside of pharmaceuticals
 - Developed a proprietary set of tools for managing highly complex processes and webs of stakeholder groups

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The draft presentation also included several criticisms of new FDA safety regulations. One category of the PowerPoint is labeled “Burden on the healthcare system.” Subsequent slides state: “Risk that REMS will unduly burden healthcare system and disrupt patient access to opioids.”¹⁶¹

McKinsey has not produced information to the Committee indicating whether McKinsey obtained the contract or not.

¹⁵⁹ MCK-HCOR-0139861, Slide 33 (emphasis added).

¹⁶⁰ MCK-HCOR-0139861, Slide 63 (emphasis added).

¹⁶¹ *Id.*, Slides 3, 4, 5.

3. *McKinsey Highlighted Its “Unique Relationships” with Centers for Medicare & Medicaid Services (CMS) Officials*

McKinsey consultants also highlighted the firm’s connections with other federal agencies to opioid manufacturers. For instance, in November 2008, McKinsey submitted a project proposal to Purdue titled “Maximizing profits from Tramadol OD,” a type of opioid. In that presentation, McKinsey outlined the extent of its health care consulting business, implying that its connections with payors, hospitals, and government agencies could help achieve fuller reimbursement for Tramadol. On one slide, titled “Examples of who we serve,” McKinsey stated that it possesses “[u]nique relationships with CMS officials, industry associations and government-sponsored programs (e.g., NHS, TennCare, SingHealth),” referring to U.S. and foreign government health programs.¹⁶²

C. McKinsey Failed to Disclose Serious Conflicts of Interest

McKinsey’s business relationships with opioid manufacturers appear to have posed significant organizational conflicts of interest for its consulting contracts with FDA—conflicts that are regulated and restricted by federal acquisition rules and the terms of many of McKinsey’s FDA contracts. McKinsey’s organizational conflicts of interest were likely exacerbated by its routine practice of staffing consultants at FDA and opioid manufacturers on projects with related subject matters.

McKinsey does not appear to have disclosed any of these conflicts of interest to FDA.

1. *Many of McKinsey’s FDA Contracts Required Disclosure of Potential Conflicts of Interest Pursuant to the Federal Acquisition Regulation*

FDA procurement activities are governed by the Federal Acquisition Regulation (FAR), which includes rules for agencies to avoid, neutralize, and mitigate organizational conflicts of interests (OCI).¹⁶³ The FAR states:

Organizational conflict of interest means that because of other activities or relationships with other persons, a person is unable or potentially unable to render impartial assistance or advice to the Government, or the person’s objectivity in performing the contract work is or might be otherwise impaired, or a person has an unfair competitive advantage.¹⁶⁴

¹⁶² MCK-HCOR-0037100, Slide 18.

¹⁶³ See 48 C.F.R. §§ 9.5 et seq. (commonly cited as Federal Acquisition Regulation (FAR) Subpart 9.5).

¹⁶⁴ 48 C.F.R. § 2.101.

An “impaired objectivity” conflict of interest “arises where a firm’s ability to render impartial advice to the government would be undermined by the firm’s competing interests.”¹⁶⁵ Government contractors, including consultants, must comply with these regulations.¹⁶⁶

Put plainly, a conflict of interest occurs when a contractor possesses, as the result of other business relationships, the incentive to provide biased advice under a government contract.¹⁶⁷ The FAR thus protects government agencies from hiring contractors or advisors with “competing loyalties that could undermine the quality of their advice to the government.”¹⁶⁸

In order to meet their duties under FAR Subpart 9.5 to “avoid, neutralize, or mitigate significant potential conflicts before contract award,” contracting officers rely on truthful disclosures from contractors. Federal agencies typically include language in their solicitations and contracts that highlight the duty to disclose potential OCIs, particularly in procurements for consultant or professional services where the risk of an OCI is greater.

Similar to other agencies, FDA “relies on the contractor to assess and report potential OCI and submit mitigation plans for review” before they are awarded a government contract.¹⁶⁹ Agency officials rely on these disclosures “to ensure that they have the information they need to consider whether a contractor’s other business relationships risk slanting its judgment.”¹⁷⁰ Some conflicts cannot be properly mitigated. In other instances, an agency may determine that a mitigation plan is appropriate to allow a contractor to “minimize the impact of prospective [conflicts] by establishing strategies to resolve anticipated conflicts,” for example, by firewalling conflicted individuals from certain information or tasks.¹⁷¹

¹⁶⁵ See 48 C.F.R. §§ 9.505-3, 9.505(a); see *Aetna Gov’t Health Plans, Inc.; Foundation Health Fed. Servs., Inc.*, B-254397 et al., July 27, 1995, 95-2 CPD ¶ 129 at 13; *Leidos, Inc.*, B-417994, Dec. 17, 2019, 2019 CPD ¶ 425.

¹⁶⁶ See, e.g., 48 C.F.R. §§ 9.507-1, 2.

¹⁶⁷ Keith R. Szeliga, *Conflict and Intrigue in Government Contracts: A Guide to Identifying and Mitigating Organizational Conflicts Of Interest*, Public Contract Law Journal Vol. 35, No. 4 (Summer 2006) (online at www.sheppardmullin.com/article-475).

¹⁶⁸ Michael Pangia, *Developing an Organizational Conflicts of Interest Framework*, Public Law Journal (Summer 2018) (online at www.jstor.org/stable/27010294?refreqid=excelsior%3Af971760c7e2935912b3651289f117a31).

¹⁶⁹ Letter from Acting Associate Commissioner Andrew Tantillo, Food and Drug Administration, to Senator Maggie Hassan et al. (Oct. 22, 2021) (online at www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%2010.22.21.pdf).

¹⁷⁰ *McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency*, ProPublica (Oct. 4, 2021) (online at www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency).

¹⁷¹ Keith R. Szeliga, *Conflict and Intrigue in Government Contracts: A Guide to Identifying and Mitigating Organizational Conflicts Of Interest*, Public Contract Law Journal Vol. 35, No. 4 (Summer 2006) (online at www.sheppardmullin.com/article-475).

The FAR warns that “organizational conflicts of interest are more likely to occur in contracts involving ... [c]onsultant or other professional services.”¹⁷²

Many of McKinsey’s FDA contracts obtained by the Committee explicitly reference the FAR’s section governing OCIs, FAR Subpart 9.5, and put affirmative duties on McKinsey to disclose potential OCIs. For instance, one contract, which covers ten of McKinsey’s 37 engagements with FDA, contains the following language:

The Contractor warrants that, to the best of the Contractor’s knowledge and belief, there are no relevant facts or circumstances which would give rise to an organizational conflict of interest, as defined in FAR Subpart 9.5, and that the Contractor has disclosed all relevant information regarding any actual or potential conflict. The Contractor agrees it shall make an immediate and full disclosure, in writing, to the Contracting Officer of any potential or actual organizational conflict of interest or the existence of any facts that may cause a reasonably prudent person to question the Contractor’s impartiality because of the appearance or existence of bias or an unfair competitive advantage.¹⁷³

Making a false certification on a federal contract can lead to contract termination, suspension or debarment from future federal contracts, and civil or criminal penalties.¹⁷⁴ The FAR states a number of grounds for debarment of federal contractors, including but not limited to willful failure to perform in accordance with the terms of one or more contracts and commission of an offense “indicating a lack of business integrity or business honesty that seriously and directly affects the present responsibility of a Government contractor.”¹⁷⁵

The False Claims Act (FCA) makes it illegal for contractors to “knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval” or “knowingly make, use or cause to be made or used, a false record or statement material to a false or fraudulent claim.”¹⁷⁶ Knowing violations of the FCA include situations where a federal contractor deliberately remained ignorant of the claim’s falsehood or recklessly disregarded the truth or

¹⁷² 48 C.F.R. § 9.502.

¹⁷³ MCK-HCOR-0351504, Page 20.

¹⁷⁴ Congressional Research Service, *Selected Legal Tools for Maintaining Government Contractor Accountability* (Sept. 26, 2018) (online at www.crs.gov/Reports/R45322).

¹⁷⁵ *Id.*; 48 C.F.R. § 9.406-2.

¹⁷⁶ 31 U.S.C. § 3729(a)(1)(A)–(G) (2018). Congressional Research Service, *Selected Legal Tools for Maintaining Government Contractor Accountability* (Sept. 26, 2018) (online at www.crs.gov/Reports/R45322).

falsehood of the claim.¹⁷⁷ Contractors who violate the FCA can be subject to civil penalties of up to \$23,607 per offense, treble damages, and other legal costs.¹⁷⁸

18 U.S.C. § 287 establishes criminal liability for false claims against any person, organization, or a contractor when they knowingly submit a false or fraudulent claim to the government when the intent is to receive payment or approval.¹⁷⁹

2. *McKinsey Had Extensive Conflicts of Interest in Apparent Violation of the Federal Acquisition Regulation and Contract Terms*

Despite the clear requirements in federal law, McKinsey appears to have repeatedly created serious, undisclosed conflicts of interest by consulting for both the FDA and opioid manufacturers, including on related matters and with overlapping staffing of consultants who shared information between clients.

As described above, McKinsey worked on several contracts at FDA regarding the safety and monitoring of dangerous drugs, including the 2011 contracts in the Office of Surveillance and Epidemiology and the three Sentinel Contracts from 2014 through 2018. During the same periods, McKinsey was working for or attempting to win additional business from Purdue to measure and compile findings about OxyContin's safety for FDA's review. McKinsey advised FDA on the structure and priorities of its surveillance offices and systems while simultaneously advising one of the nation's largest opioid manufacturers how to demonstrate the safety of its opioids to FDA. McKinsey's contracts for a federal regulator and a regulated entity could lead a reasonable person to question whether the firm's "ability to render impartial advice to the government [was] undermined by the firm's competing interests."¹⁸⁰

McKinsey's practice of staffing consultants on FDA projects who also consulted opioid manufacturers appeared to impair its objectivity. Some of the FDA and Purdue contracts on which McKinsey staffed consultants had seemingly conflicting aims. For instance, in 2009, McKinsey staffed a consultant on a project in which the firm recommended Purdue "defend against strict treatment by the FDA" in the agency's opioid-REMS safety program or otherwise "Raise legal claims alleging FDA impropriety."¹⁸¹ Yet in 2011, McKinsey staffed that same

¹⁷⁷ Department of Justice, *The False Claims Act: A Primer* (Apr. 22, 2011) (online at www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf).

¹⁷⁸ Congressional Research Service, *Selected Legal Tools for Maintaining Government Contractor Accountability* (Sept. 26, 2018) (online at www.crs.gov/Reports/R45322); Federal Register, Civil Monetary Penalty Inflation Adjustment (Jan. 13, 2022) (online at www.federalregister.gov/documents/2022/01/13/2022-00506/civil-monetary-penalty-inflation-adjustment).

¹⁷⁹ See 18 U.S.C. § 287.

¹⁸⁰ See 48 C.F.R. §§ 9.505-3, 9.505(a); *Aetna Gov't Health Plans, Inc.; Foundation Health Fed. Servs., Inc.*, B-254397 et al., July 27, 1995, 95-2 CPD 129 at 13; *Leidos, Inc.*, B-417994, Dec. 17, 2019, 2019 CPD ¶ 425.

¹⁸¹ MCK-HCOR-0340667, Slide 1; MCK-HCOR-0339718; MCK-HCOR-0225929.

consultant in an FDA office responsible for overseeing elements of that same REMS program on a project to define that office’s “role in monitoring drug safety.”¹⁸²

The Committee has seen only limited evidence that McKinsey’s staffing practices and overlapping contracts raised any conflicts of interest concerns within the firm. To the contrary and as explained above, the practice continued unabated for an extended period of time, involved numerous McKinsey partners and staff, and resulted in consultants discussing their client matters with other consultants in federal or private sector practice areas.

3. No Evidence that McKinsey Disclosed Conflicts

Despite the extensive evidence of organizational conflicts of interest at McKinsey, FDA stated in response to a request from several Senators that it was “not aware of any disclosures made by McKinsey vis-a-vis OCI [organizational conflicts of interest] in relation to” the 10 contracts that included specific language on organizational conflicts. FDA further stated that it only became aware that McKinsey had taken on opioid manufacturers as clients “in early 2021 when the information was reported in the media.”¹⁸³

In response to a ProPublica inquiry in 2021, FDA stated that it was unable to locate any files where McKinsey disclosed its conflicts of interest to FDA.¹⁸⁴

On November 5, 2021, the Committee requested that McKinsey provide “All documents disclosing or referring to a conflict of interest with FDA since 2008.”¹⁸⁵ McKinsey has not produced any documents responsive to that request.

Based on information and documents available to the Committee, it appears that McKinsey failed to disclose its private sector engagements that could reasonably be seen as impairing its objectivity in relation to its FDA contracts, in violation of FAR Subpart 9.5 and the related disclosure requirements of several contracts.

¹⁸² MCK-HCOR-0352013; MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List) (Joachim Bleys).

¹⁸³ Letter from Acting Associate Commissioner Andrew Tantillo, Food and Drug Administration, to Senator Maggie Hassan et al. (Oct. 22, 2021) (online at www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%2010.22.21.pdf).

¹⁸⁴ *McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency*, ProPublica (Oct. 4, 2021) (online at www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency).

¹⁸⁵ Letter from Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, to Mr. Bob Sternfels, McKinsey & Company (Nov. 5, 2021) (online 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>).

4. *McKinsey Was Aware of Its Duties to Avoid and Disclose Conflicts of Interest Under Its Contracts and the FAR*

McKinsey provided the Committee with a detailed “Organizational Conflicts of Interest Policy” for raising and assessing conflicts in relation to government contracts under federal regulations. The stated purpose of that policy is to “ensure compliance with U.S. Government organizational conflict of interest (“OCI”) requirements.”¹⁸⁶ The policy states that McKinsey’s standard to determine whether a business interest presents “even the appearance of an OCI is whether the business interest in question would cause a reasonable person with knowledge of the relevant facts to question the impartiality of [McKinsey] in performing work under the solicitation or task order in question.”¹⁸⁷

McKinsey’s policy on conflicts of interest also states that it “will seek to minimize the scope of disclosures to what is absolutely necessary.” The policy provides that unless McKinsey can avoid a conflict through internal processes, “the potential conflict will be reported ... to the public sector client’s Contracting Officer with a mitigation proposal.” The policy recognizes that disclosure may result in the contracting office determining that McKinsey is “conflicted from serving on the public sector engagement, or as part of the contracting process may require McKinsey to perform further measures to mitigate any OCI.”¹⁸⁸

McKinsey has not provided documents to the Committee showing that it adequately disclosed any relationship with a specific pharmaceutical company in line with this policy. While McKinsey has stated that its “proposals to the FDA frequently mentioned the company’s and personnel’s experience with the pharmaceutical industry, making the FDA aware of this aspect of McKinsey’s work in the field,” McKinsey’s isolated and vague references to its private sector clients in the documents produced to the Committee did not lay out any information necessary to assess its conflicts with opioid manufacturers or convey its conflicts in the manner required by McKinsey’s firm policy, which states that the “potential conflict will be reported, as described below, to the public sector client’s Contracting Officer with a mitigation proposal.”¹⁸⁹

¹⁸⁶ MCK-HCOR-0352178, Page 1.

¹⁸⁷ *Id.*, Page 2.

¹⁸⁸ *Id.*, Pages 2 and 4.

¹⁸⁹ *Watchdog Urged to Probe McKinsey Over Work with FDA, Opioid Manufacturers*, ABC News (Apr. 5, 2022) (online at <https://abcnews.go.com/US/watchdog-urged-probe-mckinsey-work-fda-opioid-manufacturers/story?id=83869544>); MCK-HCOR-0352178, Page 3. One of McKinsey’s technical proposals submitted to the FDA in 2019 contained a two-page biography for Mr. Smith, including a subsection explaining that Mr. Smith’s “Recent Relevant Experience” included leading a team “developing an abuse-deterrent technology for opioid analgesics” for a pharmaceutical company. MCK-HCOR-0341261, A-4. Mr. Smith’s biography does not list his numerous opioid-related engagements at Purdue over the past decade, does not disclose that he worked for FDA and Purdue simultaneously, and does not mention Purdue by name, despite the Massachusetts Attorney General filing a civil complaint against the company earlier that year and extensive reporting of that lawsuit. The project description also does not appear to match Mr. Smith’s experience at Purdue and potentially represents a description of his work for a different opioid company.

The extent to which McKinsey’s management followed this guidance for its contracts with FDA is unclear. In addition, McKinsey’s potential opioid-related conflicts of interest may extend to its work for numerous other federal and state government entities. A McKinsey spreadsheet obtained by the Committee identifies potential opioid-related engagements at:

- **Federal agencies**, including the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention (CDC), and the Substance Abuse and Mental Health Services Administration;
- **States and state agencies**, including Virginia, Missouri, Massachusetts, New Hampshire, Delaware, Vermont, Ohio Medicaid, Ohio Corrections, and Alabama Medicaid; and
- **Local governments**, including New York City and elsewhere.¹⁹⁰

The McKinsey Organizational Conflicts of Interest Policy states that it may be used “[w]here appropriate” as “guidance when responding to state and local procurements.”¹⁹¹

D. McKinsey Consultants Working for Opioid Manufacturers Influenced Policy Documents McKinsey Submitted to Government Clients

Documents obtained by the Committee suggest that McKinsey may have sought to use its influence with government clients to advocate for policy positions or selectively share information with government officials that benefited its private sector clients. In several cases, McKinsey consultants serving government clients sought out advice on public policy matters from consultants serving private sector clients.

The Committee’s investigation has uncovered evidence that McKinsey’s Healthcare Systems and Services practice—a government and policy facing health care practice at McKinsey—sought input from members of its private sector pharmaceutical practice, who served Purdue and other opioid manufacturers. Documents also reveal that McKinsey submitted opioid-related policy memos to the Trump Administration that may have promoted the interests of McKinsey’s private sector clients while running contrary to the stated goal of McKinsey’s health care practice to make “healthcare better, more affordable, and more accessible for millions of people around the world.”¹⁹²

¹⁹⁰ MCK-HCOR-0127852.

¹⁹¹ MCK-HCOR-0352178, Page 1.

¹⁹² McKinsey & Company, *Healthcare Systems & Services* (online at www.mckinsey.com/industries/healthcare-systems-and-services/how-we-help-clients) (accessed Feb. 22, 2022).

1. McKinsey Sent HHS Secretary Azar a Policy Memo Influenced by Consultants Working for Opioid Manufacturers and Had Previously Unknown Contacts with Secretary Azar

In January 2017, Alex Azar left his position as President of pharmaceutical company Eli Lilly and Company.¹⁹³ Shortly thereafter, he emailed McKinsey consultant Martin Elling, a lead consultant for Purdue, for help with his job search, requesting “ideas you may have and advice on how to look at and for opportunities.”¹⁹⁴

From: Alex Azar [Redacted]
To: Martin Elling <martin_elling@mckinsey.com>
Date: 02/06/2017 09:33 AM
Subject: Connecting on job search

Martin (and would you mind forwarding to Dan, as I don't have his email), I don't know if you know this, but I left Lilly at the end of January as part of the CEO succession and reorganization. All my decision. It was time to pursue what I really want to do, which is lead my own company. I'd really value sitting with you guys and talking through ideas you may have and advice on how to look at and for opportunities. Things are flying fast and furious at me, but I'd like to impose some discipline on my thinking and approach to ensure I'm making the next move as thoughtfully as possible.

Best,
Alex

Alex M. Azar II
[Redacted]
@AlexAzar
<https://www.linkedin.com/in/azaralex>

A meeting invitation obtained by the Committee indicates that May 1, 2017, Mr. Elling and other McKinsey consultants hosted Mr. Azar at McKinsey's New York office “RE: Connecting on job search.”¹⁹⁵

On November 13, 2017, then-President Trump nominated Alex Azar to be the Secretary of Health and Human Services.¹⁹⁶ On January 24, 2018, the Senate confirmed his nomination.

According to documents obtained by the Committee, shortly thereafter, McKinsey consultants privately sent Secretary Azar a six-page transition memo entitled, “Setting the course for the US Department of Health and Human Services.” The memo covered six broad topics—the third of which was “tackling the opioid epidemic.” According to this memo, McKinsey

¹⁹³ *Azar Received Millions from Eli Lilly in Last Year, Disclosures Show*, Politico (Nov. 20, 2017) (online at www.politico.com/story/2017/11/20/azar-eli-lilly-millions-severance-hhs-251107).

¹⁹⁴ MCK-HCOR-0173743, Page 4.

¹⁹⁵ *Id.*, Page 1.

¹⁹⁶ *Trump Picks Ex-Pharma Executive Azar to Lead HHS*, Politico (Nov. 13, 2017) (online at www.politico.com/story/2017/11/13/alex-azar-hhs-secretary-trump-244837).

consultants had prepared a similar memo for former President Trump’s first HHS Secretary, Tom Price to address “several operational perspectives for HHS.”¹⁹⁷ Based on internal McKinsey emails, the transition memo to Secretary Azar was reviewed or edited by consultants working for opioid manufacturers.¹⁹⁸ McKinsey noted in the Secretary Azar memo that, “McKinsey is a non-partisan firm; we do not provide policy advice or recommendations. Accordingly, we provide only our perspectives on the potential ramifications of various policy options, including for the private sector.”¹⁹⁹ However, the memo prepared for Secretary Azar contained “strategic priorities” that appear to be functionally identical to recommendations, and noted policy-oriented “actions” that HHS “might consider.”²⁰⁰

McKinsey began preparing the memo to Secretary Azar prior to his confirmation. On January 17, 2018, Stephanie Carlton, the partner who co-leads McKinsey’s Center for US Health System Reform, wrote to two senior McKinsey partners in the pharmaceutical practice, both of whom had previously served opioid manufacturers, noting that McKinsey was sending a transition memo to incoming Secretary Azar, and seeking their input.²⁰¹ Ms. Carlton wrote that another McKinsey partner “is sending a transition memo to Alex Azar (as soon as the full Senate vote happens). The full memo is attached, but 2 sections in particular I wanted to flag for you: drug prices and opioids.” In the email body, Ms. Carlton excerpted two sections titled “Tackling the opioid epidemic” and “Addressing drug prices.”²⁰² That evening, another McKinsey partner forwarded the memo to other McKinsey consultants serving opioid clients for their feedback.²⁰³

The next morning, Senior Partner Navjot Singh wrote that given “conflicts between McKinsey should “tread carefully” with respect to the memo. He cautioned:

Given the conflicts between the Industry and what the Secretary of HHS might want to do we should tread carefully eg I would be careful about people who serve Opioid Manufacturers (sorry Martin [Elling] and Arnie [Ghatak]) influencing the opioid section. Perfectly fine to share wisdom but maybe let people who are at a distance take the pen who maybe our HHS colleagues [sic].²⁰⁴

An additional response by Mr. Singh was redacted by McKinsey, but Mr. Singh added that he would be “[h]appy to discuss this live.”²⁰⁵

¹⁹⁷ *Id.*, Page 1.

¹⁹⁸ MCK-HCOR-0085425.

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ MCK-HCOR-0179904, Page 2.

²⁰² MCK-HCOR-0173927; MCK-HCOR-0179984, Page 3.

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ *Id.*

Despite expressing a concern that McKinsey should “drive the debate with data and facts,” in a subsequent email and having previously participated on Purdue matters himself, Mr. Singh stated: “I am happy to take the pen and make some line edits to stress these areas.”²⁰⁶ It is unclear what line edits Mr. Singh made.

Despite Mr. Singh’s warning, the following day Mr. Ghatak, who had led more than 30 engagements at Purdue and was working on a Purdue contract at this time, provided extensive feedback on the Azar memo that would appear to strongly benefit his clients in the opioid industry.²⁰⁷

In the internal email transmitting his feedback to his McKinsey colleagues, Mr. Ghatak stated, “First for disclosure, I serve a manufacturer of opioids.”

Mr. Ghatak then suggested adding caveats in the memo that would shift focus away from opioid manufacturers, noting that the opioid crisis “is not purely about prescription drugs, a large part of it involves heroin.” Mr. Ghatak stated, “I think it is important to acknowledge that the opioid crisis is multi-factorial,” and he continued, “In fact, think we could suggest a big data approach to better understanding these issues so the root issues can be addressed.”²⁰⁸

Mr. Ghatak also suggested edits shifting the blame for the crisis away from his client’s drug, OxyContin, and onto generic formulations, noting that “the vast volume of prescriptions (90%+) are actually generics and many of the branded ones now have abuse deterrent properties but the generics don’t.” Mr. Ghatak proposed: “One really powerful move could be to require that all opioids reimbursed by HHS must have abuse deterrent formulations.”²⁰⁹

“One really powerful move could be to require that all opioids reimbursed by HHS must have abuse deterrent formulations.”

McKinsey Senior Partner Arnab Ghatak, January 2018

Mr. Ghatak’s recommendation to convert the opioid market to branded, “abuse deterrent” formulations appeared to align with a long-standing priority of McKinsey’s work for Purdue, intended to stave off generic competition for OxyContin.

Specifically, since 2014, McKinsey and Mr. Ghatak had pushed what the firm referred to as the “ADF Strategy” at Purdue. Under McKinsey’s recommendation, Purdue would submit an

²⁰⁶ MCK-HCOR-0179997.

²⁰⁷ MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List).

²⁰⁸ MCK-HCOR-0179910, Page 2.

²⁰⁹ *Id.*

application for an abuse-deterrent formulation of OxyContin, withdraw its existing application for OxyContin “for reasons of safety” and thereby “Trigger an investigation by FDA for whether [the application] was pulled for safety; an affirmative finding results in withdrawal of all non-AD generics.”²¹⁰ One presentation notes, “The value of the ADF strategy evaluated here is based on a strategy of ‘FDA conversion’: e.g. removal of non-ADF generics from the market.”²¹¹

“The value of the ADF strategy evaluated here is based on a strategy of ‘FDA conversion’: e.g. removal of non-ADF generics from the market”

McKinsey Presentation to Purdue, August 2014

Under this strategy, McKinsey convinced Purdue to withdraw its own drug application for the original OxyContin, which it had promoted as safe for over a decade, based on alleged safety concerns. This, in turn, led FDA to investigate whether the old formulation of OxyContin, and all generic imitations, should be pulled from the market for safety reasons based on the original patent holder’s withdrawal.

A variation of this strategy appeared to work. On the day Purdue’s original patent for OxyContin was set to expire, FDA declared the benefits of OxyContin “no longer outweigh” the risks and limited generic competition.²¹² McKinsey described this as “FDA Conversion” of the market. McKinsey estimated the “Revenue upside to Purdue/Rhodes with market conversion could be \$380-400M per year for ~3 years (\$1.1B cumulatively).”²¹³

McKinsey recommended this strategy to Purdue despite unclear benefits of “abuse-deterrent” opioids and reformulated OxyContin in reducing addiction or abuse. In 2016, Dr. Tom Frieden, then-Director of the CDC, reported that his staff could not find “any evidence showing [abuse-deterrent formulations of opioids] actually reduce rates of addiction, overdoses, or deaths.”²¹⁴ In 2020, the FDA released findings that “evidence was not robust that the reformulation caused a reduction in overall OxyContin abuse.”²¹⁵

²¹⁰ MCK-HCOR-0224231, Slide 7.

²¹¹ MCK-HCOR-0099226, Slide 2.

²¹² Patrick Radden Keefe, *Empire of Pain: The Secret History of the Sackler Dynasty*, 308 (2021).

²¹³ MCK-HCOR-0099226, Slide 2.

²¹⁴ *Drugmakers Push Profitable, But Unproven, Opioid Solution*, Associated Press (Dec. 16, 2016) (online at <https://apnews.com/article/2179dcb0023847879d291804d7c9270b>).

²¹⁵ Food and Drug Administration, *Literature Review: Impact of Reformulated OxyContin on Abuse and Opioid-related Morbidity and Mortality* (Sept. 10-11, 2020) (online at www.fda.gov/media/141974/download).

Mr. Ghatak's recommendation in the 2018 Secretary Azar transition memo to limit HHS reimbursements to ADF opioids appeared consistent with long-standing advice McKinsey provided to Purdue on how to limit generic competition to its opioid drugs.

Mr. Ghatak also suggested adding language to the Secretary Azar memo that acknowledged the value of the opioids his clients manufactured, noting, "we don't mention *that opioids do serve an important societal benefit*, especially to chronic patients in severe pain." He continued, "its [sic] just important to mention that side of the equation for balance."²¹⁶

Some McKinsey partners expressed concern about Mr. Ghatak offering feedback on the Secretary Azar memo. Thomas Latkovic, a senior partner who works with non-profit and government clients, told other McKinsey consultants on a separate email chain that he did not believe soliciting Mr. Ghatak's input was a "fair request or a good idea," and warned: "This whole opioids thing is super sensitive with PMP [pharmaceutical and medical products] practice." Mr. Latkovic relayed that Mr. Ghatak had previously told him that "the word 'epidemic' and/or 'crisis' are hyperbolic." Mr. Latkovic later reiterated, "I'm trying to highlight the hornet's nest you are entering."²¹⁷ Another consultant on the chain responded, "Yeah. Will become CSRC [Client Services Risk Committee] issue," referring to an internal committee within McKinsey that helps manage the firm's business risks.²¹⁸

That same day, Mr. Latkovic received a draft of the memo incorporating Mr. Ghatak's suggestions.²¹⁹ Mr. Latkovic pushed back on many of Mr. Ghatak's recommendations, including Mr. Ghatak's assertion that opioids provide a benefit to patients in pain. He wrote that "mentioning that opioids helps people in pain is actually a debatable point," and noted that some policy actions to address the opioid crisis were "bad for Arnie's client."²²⁰

²¹⁶ MCK-HCOR-0179910, Page 3 (emphasis added).

²¹⁷ MCK-HCOR-0261294.

²¹⁸ *Id.*

²¹⁹ MCK-HCOR-0261196.

²²⁰ *Id.* (emphasis added).

Steph – I don't have time until tonight to send more detail (if needed) but I don't think most of his suggestions were helpful and are unnecessary from a risk review standpoint.

That said, the stuff in first paragraph is most problematic ... the CDC guidelines are a joke and we should not anchor on them. I would not mention. And mentioning that opioids helps people in pain is actually a debatable point. At a macro level we have not seen a decrease in the number of americans that claim to be in pain despite massive increase in opioids. That's why some state/payors are going well beyond CDC guidelines. This is bad for Arnie's client. It's also tonally counter productive to "qualify" that opioids are valuable. I'm trying to be diplomatic.

So issue to me is the first paragraph. If the tradeoff is to offer goobley gook vs. remove context, I'd remove context all together. It's really not helpful anyway. We can assume opioids, including heroin, is a big deal to him. So might just have intro say we know it's a big deal we've invested a lot to understand it and here are our view.

Stuff after first paragraph is fine.

Thx
Tom

Tom Latkovic | Senior Partner
McKinsey & Company | 950 Main Avenue, Suite 1200, Cleveland, OH, 44113

Redacted
Assistant: [REDACTED]

Later that evening, Ms. Carlton sent Mr. Ghatak an updated version of the memo, incorporating some of his feedback.²²¹ Ms. Carlton thanked Mr. Ghatak for his suggestions, and stated, "I've incorporated your suggestions into the rest of the language." While Ms. Carlton stated that she had not implemented all of Mr. Ghatak's recommendations, she informed him that they would "definitely keep those [sic] in mind for future live conversations."²²²

One paragraph detailing the costs and extent of the opioid epidemic was removed. The original version of the transition memo had read, "Despite significant attention and effort, the opioid crisis continues to inflict devastating consequences on the health and wellbeing of people in this country," and discussed the loss of life, impact on life expectancy, and ongoing issues with opioid prescribing practices in Medicaid and Medicare. However, the new version read: "You are well aware of the major challenges associated with the opioid, and associated heroin, epidemic."²²³

Several of Mr. Ghatak's suggested edits, including those introducing language on generic formulations of opioids and acknowledging that "the opioid crisis is multi-factorial" remained.²²⁴

In the final version of the transition memo, opioid manufacturers are only mentioned once: "Players across the value chain, including branded and generic manufacturers, as well as

²²¹ MCK-HCOR-0179910.

²²² *Id.*

²²³ *Id.*; MCK-HCOR-0179997.

²²⁴ MCK-HCOR-0179910.

distributors, will have an important role to play.”²²⁵ The section of the transition memo originally titled “Addressing drug prices” was renamed “Ensuring the value of pharmaceuticals.”²²⁶

The Committee has obtained evidence that the McKinsey memo was sent to Secretary Azar, but has not confirmed precisely when the transition memo was sent.²²⁷

On January 25, 2018, one day after Secretary Azar’s confirmation, McKinsey Senior Partner Martin Elling, whom Secretary Azar had earlier emailed seeking job advice, and another McKinsey partner emailed Secretary Azar to offer their congratulations. Mr. Elling wrote: “We’d love to arrange a meeting with the head of our healthcare practice to share perspectives and learn your personal priorities.” On January 27, 2018, Secretary Azar responded: “Thanks guys. Very grateful for all your help.”²²⁸

Begin forwarded message:
From: "Alex Azar" [Redacted]
Date: January 27, 2018 at 10:37:35 PM EST
To: martin_elling@mckinsey.com
Cc: dan_tinkoff@mckinsey.com
Subject: [EXT]Re: One giant step! Congratulations

Thanks guys. Very grateful for all your help. Let me get my sea legs over there and we can chat about the practice and connection to HHS.
Best,
Alex
Work email will be: alex.azar@hhs.gov

On Jan 25, 2018, at 9:17 AM, martin_elling@mckinsey.com wrote:
Alex-
I am just landing from Asia and saw the news. I am so very excited for you at your confirmation to Secretary of HHS. This is a monumental personal achievement that will allow you a platform to help improve the health of all Americans and influence trends that will help billions of people beyond our shores.

From your testimony it is clear you have ambitious goals for the role which is exciting. We’d love to arrange a meeting with the head of our healthcare practice to share perspectives and learn your personal priorities. Let us know if that is helpful.

Again, congratulations on this tremendous step onto a platform of profound influence on everyday people’s lives.

Other McKinsey consultants enjoyed a close relationship with HHS during Secretary Azar’s tenure, even those who may have potentially advised Purdue. In 2014, McKinsey stated in a presentation to Purdue that it would “bring to bear” the expertise of select McKinsey

²²⁵ MCK-HCOR-0085425, Page 5.

²²⁶ *Id.*, Page 6.

²²⁷ MCK-HCOR-0173887. A senior McKinsey partner wrote to Mr. Elling about Azar: “BTW, here is the transition memo we wrote for him. I had emailed this to him last week but may be helpful for him to receive from you as well.” Mr. Elling replied: “Ok. I can send to him mentioning your reach out. So he knows we are coordinating.”

²²⁸ MCK-HCOR-0173887, Page 2.

experts, including Paul Mango, a McKinsey partner in the “Payor Provider” practice and expert in “ACA Reform.”²²⁹ In July 2018, Mr. Mango joined CMS as Chief of Staff to then-CMS Administrator Seema Verma, who had been appointed by former President Trump.²³⁰

According to federal spending data, in September 2018, McKinsey won a contract at CMS valued at \$8.6 million—its first contract at CMS in six years.²³¹ In July 2019, Secretary Azar named Mr. Mango his Deputy Chief of Staff for Policy, a position he served in until the end of the Trump Administration.²³²

2. *McKinsey Prepared an Unsolicited Opioid Policy Memo for HHS*

In October 2018, McKinsey consultants prepared an unsolicited policy memo for HHS and CMS on opioids. Others at the firm raised limited concerns that this memo advocated positions favorable to McKinsey’s private sector clients, but do not appear to have taken steps to prevent the memo from being sent.

On October 23, 2018, a McKinsey consultant in the health care practice internally shared a “perspective memo” on the Opioid Crisis Response Act (OCRA), a broad bipartisan bill that directed funding to federal agencies to establish or expand programs dealing with substance use disorder prevention, treatment and recovery.²³³ The McKinsey consultant noted that her team “would like to share it with senior folks at HHS and potentially Seema,”²³⁴ likely a reference to CMS Administrator Seema Verma.²³⁵

One of the primary drafters of the memo appears to be a McKinsey junior consultant, Consultant 16, who until earlier that year served as a consultant at Purdue.²³⁶ While consulting for Purdue, Consultant 16 had worked on “innovative contracting”—McKinsey’s term for

²²⁹ MCK-HCOR-0096857, Slide 15.

²³⁰ Centers for Medicare & Medicaid Services, *Press Release: CMS Welcomes New Leadership Team, Makes Additional Staffing Announcement* (July 24, 2018) (www.cms.gov/newsroom/press-releases/cms-welcomes-new-leadership-team-makes-additional-staffing-announcement).

²³¹ USASpending, *Contract Summary for PIID 75FCMC18F0099 Between Department of Health and Human Services and McKinsey & Company* (online at www.usaspending.gov/award/CONT_AWD_75FCMC18F0099_7530_GS10F0118S_4730) (accessed Feb. 23, 2022).

²³² Department of Health & Human Services, *Press Release: HHS Secretary Azar Statement on Continuing Leadership Expansion* (July 5, 2019) (online at <https://public3.pagefreezer.com/browse/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/about/news/2019/07/05/hhs-secretary-azar-statement-on-continuing-leadership-expansion.html>).

²³³ MCK-HCOR-0170799, Page 3; S. 2680, 115th Cong. (2018).

²³⁴ MCK-HCOR-0170799, Page 3.

²³⁵ *Id.*

²³⁶ MCK-HCOR-0170785, Page 3.

contracts that would, in part, provide insurers and pharmacy benefit managers a rebate “for every OxyContin overdose attributable to pills they sold.”²³⁷

The McKinsey health care practice team shared the OCRA policy memo with Ellen Rosen, McKinsey’s Global Manager of Publications, and Julie Lane, the Global External Relations Manager of the health care practice, who, according to a “modified risk review process” devised by the team “were supposed to “make sure (sic) no big red flags.”²³⁸ This process also included, “eliminat[ing] any logos or other forms of branding from the memos,” and having “1 thought partner from each sector read each memos [sic].”²³⁹ Upon review of the memo, both Ms. Rosen and Ms. Lane raised concerns about the utility and propriety of sharing the memo with HHS and CMS.

On October 29, 2018, Ms. Rosen wrote back to one of the memo’s drafters, “I started reading your memo and will confess that I’m a bit puzzled... Is this memo part of a client engagement? A roundabout way of submitting an LOP [letter of proposal] for a future engagement? Otherwise, why are we giving advice to a federal agency about a federal law, especially since we are not lawyers?”²⁴⁰

After receiving clarification that the memo was not part of client engagement or a proposal, Ms. Rosen responded. “Apropos your original question about whether the memo needs additional review, the answer is no. In fact, given that the memo is being sent from a CST [client service team] to a client (even a public-sector client), there is no reason that either [Ms. Lane] or I would have to risk-review it.” Ms. Rosen continued:

I didn’t spot anything particularly risky in the memo, given the bad press the firm has received because of south Africa and, especially, Saudi Arabia, my personal view is that for the time being we should minimize the number of things we send to public-sector clients (other than engagement deliverables). *But people with pay grades far above mine have decided differently, and their judgment wins.*²⁴¹

²³⁷ See *McKinsey Settles for Nearly \$600 Million over Role in Opioid Crisis*, New York Times (Feb. 3, 2021) (online at www.nytimes.com/2021/02/03/business/mckinsey-opioids-settlement.html); MCK-HCOR-0000246; MCK-HCOR-0000251; MCK-HCOR-0001019, Pages 6-11.

²³⁸ MCK-HCOR-0170785, Page 3.

²³⁹ *Id.*

²⁴⁰ MCK-HCOR-0170799, Page 2.

²⁴¹ *Id.*, Page 1. (emphasis added). McKinsey’s work for foreign governments had come under scrutiny that month after reports that the Saudi Arabian government may have used a McKinsey report to identify and jail dissidents. See *Saudis’ Image Makers: A Troll Army and a Twitter Insider*, New York Times (Oct. 20, 2018) (online at www.nytimes.com/2018/10/20/us/politics/saudi-image-campaign-twitter.html?dlbk). McKinsey was also embroiled in a corruption scandal related to its work for the South African government which journalists credited to the firm’s “aggressive push into more government consulting.” See *How McKinsey Lost Its Way in South Africa*, New York Times (June 26, 2018) (online at www.nytimes.com/2018/06/26/world/africa/mckinsey-south-africa-eskom.html).

Ms. Lane also expressed concerns. The next day, on October 30, 2018, she wrote, “My main concern is that this could be misinterpreted as if we are advocating on behalf of our private sector and other clients to HHS to take specific actions around provider programs, state programs, etc.”²⁴² It is unclear what further action McKinsey took with the OCRA memo.

“My main concern is that this could be misinterpreted as if we are advocating on behalf of our private sector and other clients to HHS to take specific actions around provider programs, state programs, etc.”

Julie Lane, McKinsey Healthcare Practice

McKinsey had previously sent other opioid policy memos to CMS, even when the firm was seemingly not providing consulting services to CMS. A January 2018 email from a McKinsey consultant to Tom Latkovic stated, “The statistics and recommendations included in our Azar memo were largely culled from the Oct 2017 white paper for CMS, ‘Saving lives now: Perspectives on Accelerating CMS’s Impact in Solving the Opioid Crisis.’”²⁴³ According to publicly available federal spending data, McKinsey did not have any ongoing federal contracts at CMS at the time it reportedly submitted the 2017 white paper.²⁴⁴

This evidence raises significant questions about how McKinsey’s practice of seeking input from consultants who had served or were serving opioid manufacturers impacted the work product of McKinsey’s government and policy facing health care practice, and about how these recommendations influenced the federal government’s opioid policies.

E. Document Destruction

The Committee has also obtained evidence that McKinsey consultants discussed destroying or hiding documents concerning the firm’s work for Purdue.

In May 2017—more than two years before McKinsey announced it would no longer work for opioid manufacturers—Mr. Ghatak and McKinsey partner Laura Moran discussed over text message how to ensure McKinsey documents would not get pulled into Purdue’s ongoing litigation.

²⁴² MCK-HCOR-0170799.

²⁴³ MCK-HCOR-0261306, Page 2.

²⁴⁴ USA Spending, *McKinsey & Company Contracts with the Centers for Medicare and Medicaid Services Since 2008* (online at <https://www.usaspending.gov/search/?hash=e8ef63dc11ba5bf988e7296b8d0e9036>) (accessed Mar. 22, 2022).

In one exchange, Ms. Moran stated that McKinsey had informed Purdue that consultants would not “email them the opioid decks” and McKinsey would “just do hard copy on these.” When Mr. Ghatak asked why, Ms. Moran stated that emailing decks “creates a trail to the inline discussion. These guys will be deposed. Best our emails are not sucked into it.” Mr. Ghatak agreed that McKinsey would “project” their presentation “off our laptop for the opioid discussion.” When Ms. Moran suggested putting the presentation on a “neutral template. Not Purdue,” Mr. Ghatak responded “Why? It will live only on our laptops and then we can delete as part of WP.”²⁴⁵

Documents obtained by the Committee suggest that “WP” referred to “Working Papers,” the McKinsey processing system whereby “Documents classified as ‘Client’ for more than six months will be deleted.”²⁴⁶

Documents indicate that efforts to delete documents and shield McKinsey’s work for Purdue may have accelerated in 2018. On April 11, 2018, Mr. Elling emailed Pablo Illanes, another McKinsey partner, about “documents from the strategy work we did with JJ at Purdue.” Mr. Elling instructed Mr. Illanes that it “is important that you sanitize any pages you think you may want to use before sharing even within the team. We can’t have Purdue’s strat[egy] floating around. Then please erase the originals.” Mr. Illanes responded, “Understood. Thank you Martin. I will not share.”²⁴⁷

On July 4, 2018, five months after collaborating on the transition memo to HHS Secretary Alex Azar, Mr. Elling and Mr. Ghatak exchanged emails, which have previously been reported, about destroying documents relating to McKinsey’s work for Purdue. Mr. Elling wrote: “It probably makes sense to have a quick conversation with the risk committee to see if we should be doing anything other than [sic] eliminating all our documents and emails. Suspect not but as things get tougher there someone might turn to us.” Mr. Ghatak responded: “Thanks for the heads up. Will do.”²⁴⁸

New documents obtained by the Committee suggest that Mr. Elling may have taken further steps to eliminate his documents relating to Purdue. On August 14, 2018, the State of New York filed a lawsuit against Purdue for engaging in deceptive and illegal practices in boosting the sales of its opioid drugs.²⁴⁹ Eight days later, on August 22, 2018, Mr. Elling sent an email to himself with the subject line “When home.” McKinsey heavily redacted the email, but one line reads “delete old pur documents from laptop.”²⁵⁰

²⁴⁵ MCK-HCOR-0351073.

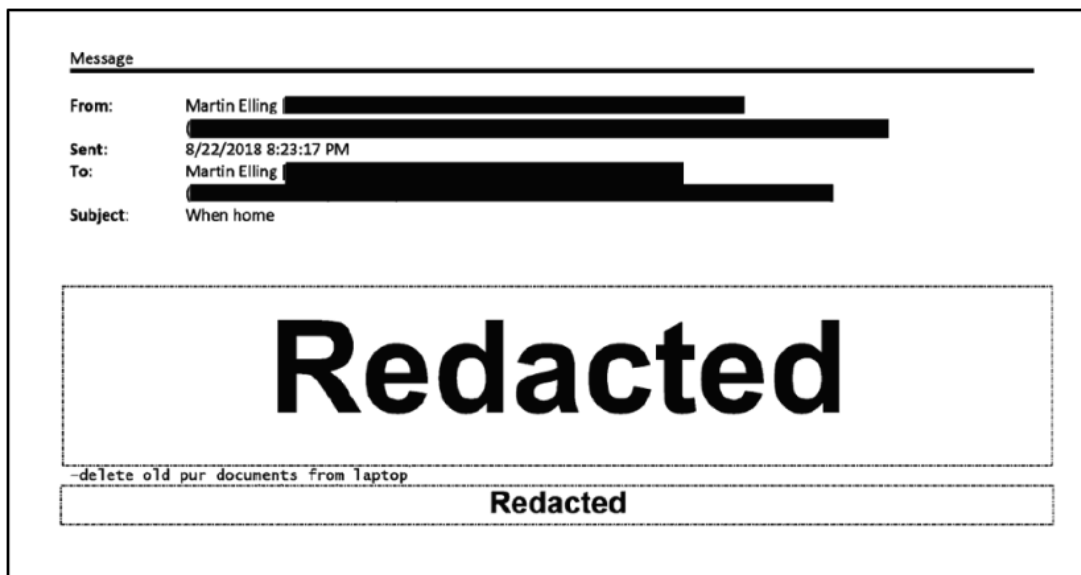
²⁴⁶ MCK-HCOR-0097466.

²⁴⁷ MCK-HCOR-0173804.

²⁴⁸ MCK-HCOR-0173795; *McKinsey Settles for Nearly \$600 Million Over Role in Opioid Crisis*, New York Times, (Feb. 3, 2021) (online at www.nytimes.com/2021/02/03/business/mckinsey-opioids-settlement.html).

²⁴⁹ *New York Sues Oxycontin Maker Purdue Over Opioid Epidemic*, Albany Times Union (Aug. 14, 2021) (online at www.timesunion.com/news/article/New-York-sues-OxyContin-maker-Purdue-13155011.php).

²⁵⁰ MCK-HCOR-0173790.



The documents obtained in this investigation raise questions about the full scope of McKinsey’s efforts to shield or destroy documents. The evidence also raises concerns about the extent to which McKinsey’s document management practices may have been used to conceal key documents and information about conflicts and harmful conduct from Congress and the public’s view.²⁵¹

III. CONCLUSION

The Committee’s investigation has confirmed that McKinsey had significant and long-running conflicts of interest due to its overlapping and conflicting work for FDA and opioid manufacturers. These conflicts spanned more than ten years and 37 FDA contracts, costing taxpayers more than \$65 million. McKinsey’s failure to disclose or meaningfully address these conflicts appears potentially to have violated federal law and contract requirements and may have contributed to one of the worst public health epidemics in our nation’s history.

The Committee found that McKinsey frequently staffed consultants on both FDA and opioid manufacturer projects, including at the exact same time, increasing the risk of biased advice to federal officials who had hired McKinsey to help stem the nation’s opioid addiction crisis. McKinsey, in turn, repeatedly leveraged the firm’s work for FDA and other federal agencies to solicit new private sector business or serve existing private sector clients, despite McKinsey’s own client confidentiality policies. These serious conflicts of interest also impacted McKinsey’s advice to high-level government officials, with members of McKinsey’s

²⁵¹ McKinsey’s settlement agreement with 53 states attorneys general in February 2021 required the firm to implement a detailed document retention policy within 18 months and implement a written policy requiring the termination of any employee that engages in the intentional spoliation of evidence. Commonwealth of Massachusetts, *Assented-To Motion for Entry of Judgment* (Feb. 4, 2021) (online at www.mass.gov/doc/massachusetts-mckinsey-consent-judgment).

government health care practice incorporating feedback from consultants serving private sector opioid clients and altering work product in ways that appeared to serve those clients' interests.

This interim report addresses McKinsey's conflicts with respect to only one type of client: opioid manufacturers. Over five months ago, the Committee requested information on McKinsey's consulting for other pharmaceutical companies, drug distributors, and drug retailers—as well as key documents on McKinsey's risk management practices. McKinsey has failed to provide most of the key documents that would allow the Committee to fully assess how its consulting practices and conflicts of interest have affected the health and safety of the American people.

McKinsey's conduct raises significant questions about the lack of regulation over consulting companies that advise both the federal government and private sector clients. The Committee remains committed to uncovering the full scope of McKinsey's consulting in furtherance of abusive practices and conflicts of interest across the federal government.