Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM 2157 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6143

> MAJORITY (202) 225–5051 MINORITY (202) 225–5074 https://oversight.house.gov

November 5, 2021

Mr. Bob Sternfels Global Managing Partner McKinsey & Company 555 California Street, Suite 4700 San Francisco, CA 94104

Dear Mr. Sternfels:

Over the last decade, McKinsey & Company—one of the largest consulting companies in the world and a major U.S. government contractor—has engaged in a pattern of conduct that raises serious concerns about its business practices, conflicts of interest, and management standards. The company's support for drug companies pushing addictive opioid painkillers and raising prices for life-saving medications, even as McKinsey also advised the federal agency regulating their conduct, may have had a significant negative impact on Americans' health. McKinsey's investments through an internal hedge fund—including in companies benefiting from opioid sales—also raise significant concerns about conflicts of interest. While McKinsey has netted billions of dollars in revenue and widespread recognition as a leading consulting firm, the full scope of its conduct remains shrouded behind a reported "institutional code of silence" and a lack of transparency surrounding the identity of McKinsey's clients or the advice it gives in the largely unregulated management consulting industry. \(\)

The Committee on Oversight and Reform is investigating McKinsey's consulting services on behalf of industries causing public harm, the company's conflicts of interest, and its apparent failure to monitor and prevent harmful practices. The investigation will inform Congress as it considers potential legislative reforms to protect Americans' health, reform questionable business practices in the consulting industry, and fight corruption.

I. CONSULTING ON ABUSIVE CONDUCT IMPACTING AMERICANS' HEALTH

In recent years, McKinsey has provided advice to clients engaged in potentially harmful conduct, including an opioid manufacturer seeking to boost the sales of opioids during a public health crisis and drug manufacturers who sought to rapidly raise the price of prescription drugs. These examples point to possible systemic issues with McKinsey's risk management and internal

¹ How McKinsey Makes Its Own Rules, ProPublica (Dec. 14, 2019) (online at www.propublica.org/article/how-mckinsey-makes-its-own-rules).

controls and raise serious questions about whether the company has taken sufficient steps to prevent or detect questionable conduct.

A. McKinsey's Role in the Opioid Crisis and Conflicts of Interest with FDA

The Committee's investigation into Purdue Pharma, the maker of the pain medication OxyContin, found that McKinsey played a decades-long role in the opioid epidemic by supporting efforts to drive sales of addictive painkillers even as the death toll mounted in communities across America.²

In February 2021, McKinsey reached a \$573 million agreement with 53 attorneys general to resolve allegations of unfair trade practices related to services provided to Purdue Pharma and other pharmaceutical companies for marketing and sales strategies for opioid products.³ During its 15-year relationship with Purdue, McKinsey allegedly "advised Purdue that it could increase OxyContin sales through physician targeting and specific messaging to prescribers"—strategies that would form "the pillars of Purdue's sales tactics for the next fifteen years." Even after Purdue and three of its executives pleaded guilty to misdemeanor charges of misbranding OxyContin in 2007, McKinsey continued to advise the company on how to increase prescription opioid sales. In 2013, McKinsey recommended a marketing campaign that would "Turbocharge Purdue's Sales Engine" by targeting clinicians who were willing to write large numbers of often unnecessary opioid prescriptions.⁵

In 2017, a year in which 47,600 Americans died of opioid overdose, McKinsey proposed that Purdue offer insurers and pharmacy benefit managers like CVS and Anthem a rebate "for every OxyContin overdose attributable to pills they sold."

McKinsey's role advising opioid producers extends beyond Purdue Pharma and includes the "big three" opioid distributors—McKesson, Amerisource Bergen, and Cardinal Health—as

² See, e.g., Committee on Oversight and Reform, *Press Release: Maloney and DeSaulnier Release Documents Following DOJ Settlement with Purdue and Sackler Family* (Oct. 27, 2020) (online at https://oversight.house.gov/news/press-releases/maloney-and-desaulnier-release-documents-following-doj-settlement-with-purdue).

³ McKinsey Agrees to \$573 Million Settlement over Opioid Advice, Wall Street Journal (Feb. 3, 2021) (online at www.wsj.com/articles/mckinsey-agrees-to-573-million-settlement-over-opioid-advice-11612405236).

⁴ Plaintiff's Complaint, *Commonwealth of Massachusetts v. McKinsey & Company, Inc. United States* (Mass. Sup. Ct.) (Feb. 4, 2021) (online at www.mass.gov/doc/massachusetts-mckinsey-complaint/download).

 $^{^5}$ Committee on Oversight and Reform, $Purdue\,Pharma\,L.P.\,Selected\,Investigation\,Documents\,Part\,I$ (Oct. 27, 2020) (online at

https://oversight.house.gov/sites/democrats.oversight.house.gov/files/102720%20Purdue%20Documents%20Part%20I.pdf); see also Patrick Radden Keefe, The Family That Built an Empire of Pain, New Yorker (Oct. 23, 2017) (online at www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain).

⁶ 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); Plaintiff's Complaint, Commonwealth of Massachusetts v. McKinsey & Company, Inc. United States (Mass. Sup. Ct.) (Feb. 4, 2021) (online at www.mass.gov/doc/massachusetts-mckinsey-complaint/download).

well as relationships with retailers such as CVS and Walmart.⁷ Since 2005, McKinsey has also reportedly consulted for other large opioid producers, including Johnson & Johnson, Mallinckrodt, Endo International, and potentially others.⁸ Having consulted for so many drug manufacturers and distributors, McKinsey may have possessed unique information on opioid sales strategies, positioning the company as a potential conduit of questionable practices in the industry.⁹

While consulting for these manufacturers, McKinsey has also consulted for the agency that regulates opioids, the Food and Drug Administration (FDA)—creating the potential for significant conflicts of interest.

Since 2008, FDA has paid McKinsey over \$140 million, including \$40 million from FDA's Center for Drug Evaluation and Research (CDER), which oversees numerous opioid-related programs. ¹⁰ CDER approves new drugs, including prescription opioids, and oversees the FDA's Sentinel initiative, which is meant to monitor the safety of drugs such as OxyContin once they are on the market. ¹¹

Purdue Pharma's records show that at the same time McKinsey was advising FDA, including offices responsible for opioid programs, the company was also advising Purdue on how to lobby FDA. For instance, in 2008, FDA proposed new safety rules for OxyContin under the agency's Risk Evaluation and Mitigation Strategies (REMS) program—including a requirement that the painkiller could be prescribed only by specially trained pharmacies or health care practitioners. Purdue Pharma opposed the safety measures and, according to documents that have been made public, viewed defeating them as necessary to "save the business." As a result, they requested McKinsey's assistance. ¹² Even though McKinsey was already consulting for

⁷ Petition, *The Cherokee Nation v. McKinsey*, No. CJ-21-76 (D. Ct. Sequoyah Cty, Ok.) (June 2, 2021) (online at www.oscn.net/dockets/GetDocument.aspx?ct=sequoyah&bc=CC21060200000341&cn=CJ-2021-00076&fmt=pdf); *McKinsey Opioid Work Included Advising Distributors, Tribe Says*, Bloomberg (June 3, 2021) (online at www.bloomberg.com/news/articles/2021-06-03/mckinsey-opioid-work-included-advising-distributors-tribe-says#:~:text=The%20Cherokee%20Nation%20is%20the,in%20state%20court%20in%20Oklahoma).

⁸ *Id.*; Petition, *The Cherokee Nation v. McKinsey*, No. CJ-21-76 (D. Ct. Sequoyah Cty, Ok.) (June 2, 2021) (online at www.oscn.net/dockets/GetDocument.aspx?ct=sequoyah&bc=CC21060200000341&cn=CJ-2021-00076&fmt=pdf).

 $^{^{9}}$ Duff McDonald, The Firm: The Story of McKinsey and Its Secret Influence on American Business (2013).

¹⁰ USA Spending, McKinsey & Company Contracts with the Food and Drug Administration Since 2008 (online at www.usaspending.gov/search/?hash=9c4702cb5b379594a7c36481464f73f7) (accessed Nov. 3, 2021).

¹¹ 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); Food and Drug Administration, Advancing Health Through Innovation: New Drug Therapy Approvals 2020 (Jan. 2021) (online at www.fda.gov/media/144982/download).

¹² The Ad Hoc Group of Non-Consenting States' Statement in Support of the Official Committee of Unsecured Creditors' Motions to Compel Production of Purportedly Privileged Documents or for *In Camera* Review, *In re: Purdue Pharma, L.P., et al.*, No. 19-BR-23649 (S.D.N.Y.) (online at https://restructuring.primeclerk.com/purduepharma/Home-DownloadPDF?id1=MTExNzM5Mg=&id2=0).

3, 2021).

FDA at the time, ¹³ the firm proposed that the opioid industry "band together" to "defend against strict treatment by the FDA." Weeks later, McKinsey consultants working for Purdue Pharma reported to McKinsey senior partners that their client was "aware of the critical role we are playing in pulling REMs together." ¹⁴

By July 2012, McKinsey's "band together" strategy had successfully rebuffed stronger REMS safety measures. FDA proposed weaker safety rules for high-dose prescription opioids over the objection of an independent panel of experts who had recommended more rigorous training for prescribers and the reduction of industry influence in the safety measures. ¹⁵ During the three years the initial proposed rules were under consideration, from 2009 to 2012, FDA paid McKinsey at least \$23 million in consulting fees. ¹⁶ It is not known to what extent McKinsey consulted for the opioid industry during this same period, how much McKinsey received in compensation from opioid-related entities, or whether FDA consulted with McKinsey on the decision to reject stronger safety rules.

For years, McKinsey has also advised FDA on numerous other issues relating to opioids, drug safety, and drug approvals, including a "track and trace" system for illegal drugs, monitoring programs to assess drug safety, and streamlining the drug approval process.¹⁷

One FDA project seemingly called upon McKinsey to consult with its private sector clients on FDA regulation. In 2014, McKinsey—which the prior year had recommended Purdue "Turbocharge" its OxyContin sales engine—began work on a contract for FDA's Sentinel initiative, which monitors the safety of drugs already on the market. The Sentinel contract 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." The contract further tasked McKinsey with identifying and interviewing

 $^{^{13}}$ USA Spending, McKinsey & Company Business Processes Contract (online at www.usaspending.gov/award/CONT_AWD_HHSF223200830274G_7524_GS10F0118S_4730) (accessed Nov. 3, 2021).

¹⁴ The Ad Hoc Group of Non-Consenting States' Statement in Support of the Official Committee of Unsecured Creditors' Motions to Compel Production of Purportedly Privileged Documents or for *In Camera* Review, *In re: Purdue Pharma*, *L.P.*, *et al.*, No. 19-BR-23649 (S.D.N.Y.) (online at https://restructuring.primeclerk.com/purduepharma/Home-DownloadPDF?id1=MTExNzM5Mg=&id2=0).

¹⁵ As Tens of Thousands Died, F.D.A. Failed to Police Opioids, New York Times (Dec. 30, 2019) (online at www.nytimes.com/2019/12/30/health/FDA-opioids.html).

¹⁶ USA Spending, McKinsey & Company Contract Value with the Food and Drug Administration Between January 2009 and July 2012 (online at www.usaspending.gov/search/?hash=49fa93f1a4051a74b7fc9b78e569777d) (accessed Nov. 3, 2021).

Administration (online at www.usaspending.gov/award/CONT_AWD_HHSF22311007_7524_HHSF223201010014B_7524) (accessed Nov. 3, 2021); USA Spending, McKinsey & Company Sentinel Contract with the Food and Drug Administration (online at www.usaspending.gov/award/CONT_AWD_HHSF22315005_7524_HHSF223201010014B_7524) (accessed Nov. 3, 2021); USA Spending, McKinsey & Company New Drug Regulatory Modernization Program Contract with the Food and Drug Administration (online at www.usaspending.gov/award/CONT_AWD_75F40119F19002_7524_HHSF223201700022B_7524) (accessed Nov.

"external stakeholders," including "industry organizations" and "drug and device industry leaders." ¹⁸

Despite the potential conflicts of interest involved in this contract, public reporting indicates that McKinsey, which is "famously secretive about its clientele, never disclosed its pharmaceutical company clients to the FDA." ¹⁹ FDA has stated that McKinsey never informed the agency of its private sector relationships with opioid manufacturers, and that it first became aware of McKinsey's work for these companies "in early 2021 when the information was reported in the media." ²⁰

This does not mark the first time McKinsey has been implicated in potential conflicts of interest with a government health regulator. In early 2012, British newspapers reported "allegations of egregious conflicts of interest" in McKinsey's work for the United Kingdom's National Health Service. From 2010 to 2011, McKinsey reportedly advised the British government to "revamp the way it handled health service contracts in ways that would benefit McKinsey's own corporate clients" and shared "those proposals with the private sector clients in advance." ²¹

The Committee needs a full accounting of McKinsey's role in facilitating the American opioid epidemic through its consulting services for drug companies. The Committee also requires information to understand the company's potential conflicts of interest from its consulting relationships with FDA and the opioid industry.

B. McKinsey's Role in Increasing Prescription Drug Costs and More FDA Conflicts

McKinsey has consulted for numerous clients on strategies to raise prescription drug prices in the United States—while also consulting for FDA's Office of Generic Drugs.

¹⁸ 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); Food and Drug Administration, McKinsey Sentinel Contract (June 19, 2014) (online at www.documentcloud.org/documents/21071047-r sentinel assessment award contract sow-redacted-pr).

¹⁹ 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).

²⁰ 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).

²¹ Duff McDonald, *The Firm: The Story of McKinsey and Its Secret Influence on American Business* (2013); see also The Firm That Hijacked the NHS: MoS Investigation Reveals Extraordinary Extent of International Management Consultant's Role in Lansley's Health Reforms, Daily Mail (Feb. 12, 2012) (online at www.dailymail.co.uk/news/article-2099940/NHS-health-reforms-Extent-McKinsey--Companys-role-Andrew-Lansleys-proposals.html).

When Valeant Pharmaceuticals considered buying the rights to two heart medications commonly found on emergency room crash carts, Isuprel and Nitropress, McKinsey consultants advised Valeant Chief Executive Officer (and former McKinsey consultant) J. Michael Pearson that those and other drugs had "material pricing potential." Following McKinsey's advice, Valeant acquired both drugs, raising the price of Isuprel by more than 700% and the price of Nitropress by more than 300%. ²³

Similarly, according to documents obtained by the Committee in its drug pricing investigation, McKinsey consultants advised AbbVie to take actions to block competition with its blockbuster drug, Humira, allowing the company to maintain high monopoly pricing. In August 2010, McKinsey consultants advised AbbVie to take actions to block biosimilar replication of Humira, recommending that the company "[d]ifferentiate the product through extensions/next-gen products" and "[d]elay/block biosimilar through legal/lobbying actions."²⁴ In their pitch slide, "Why McKinsey?," the firm highlighted their "deep expertise working with leading payors, national health systems and key regulatory agencies across global markets."²⁵

A few months after receiving McKinsey's recommendations, AbbVie's CEO directed his team to redouble their efforts to develop "enhancements" to Humira so, as a later presentation discussed, the company could "raise barriers to competitor ability to replicate." In January 2011, AbbVie executives discussed McKinsey's conclusion that "Biosimilar HUMIRA" represented one of the two largest threats to the drug's success and sought to implement an initiative geared toward "mitigation of biosimilar Humira threat" so the company could maintain high prices. ²⁷

According to an internal analysis the Committee obtained from AbbVie, biosimilar competition would have forced a reduction in the price of Humira and saved the U.S. health care system at least \$19 billion dollars from 2016 to 2023.²⁸ In patient complaints obtained by the

²² As McKinsey Sells Advice, Its Hedge Fund May Have a Stake in the Outcome, New York Times (Feb. 19, 2019) (online at www.nytimes.com/2019/02/19/business/mckinsey-hedge-fund.html)

²³ *Id*; Memorandum from Minority Staff, Committee on Oversight and Reform, to Democratic Members, Committee on Oversight and Reform, *Documents Obtained by Committee from Valeant Pharmaceuticals*, 114th Cong. (Feb. 2, 2016) (online at

https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%20Valeant%20Documents0.pdf).

 $^{^{24}}$ ABV-HOR-00034201, at Slide 30. AbbVie spun off from Abbott Labs in 2013. This letter refers to both companies under the name AbbVie.

²⁵ ABV-HOR-00034201, at Slide 15 (emphasis added).

²⁶ ABV-HOR-00031271; ABV-HOR-00034291.

²⁷ ABV-HOR-00031369, at Slide 2.

²⁸ See ABV-HOR-00032198, at Slide 15. The \$19 billion figure is the total "price variance" estimate of biosimilar erosion. The U.S. health care system would have likely saved additional costs from a subset of patients purchasing lower-priced biosimilars rather than Humira.

Committee, one caretaker for a Crohn's disease patient described AbbVie's strategy for preventing affordable Humira alternatives from coming to market as "cold, and heartless."²⁹

Around the same time, McKinsey was also consulting with FDA on its generic drug program. In 2012, Congress enacted the Generic Drug User Fee Amendments (GDUFA) to "ensure patients have access to safe, high-quality, and affordable generic drugs." In August 2013, FDA awarded McKinsey a contract worth more than \$700,000 to "Support the Office of Generic Drugs Under the Generic Drug User Fee Amendments."

In June 2013, just prior to being awarded the FDA contract, McKinsey gave a draft presentation to AbbVie's board of directors that emphasized the dangers to the company's profits posed by generic and biosimilar drug competition. In the first slide of the presentation, McKinsey discussed how the industry had faced significant challenges from "both steep LOE [loss of exclusivity] declines and fundamental changes to their core markets through health reform." The remainder of the presentation contained references to the dangers of "patent cliffs" leading to loss of exclusivity, the "exhaustion of 'easy targets' for new compounds" that could expand exclusivity, and the possibility of "increased regulatory scrutiny." 33

II. MCKINSEY INVESTMENT OFFICE PARTNERS AND FINANCIAL CONFLICTS OF INTEREST

In addition to its consulting business, McKinsey maintains a \$12 billion internal hedge fund, McKinsey Investment Office Partners (MIO), which manages the money of McKinsey employees. MIO makes investments in industries or entities that are also the subject of the firm's consulting practice, including the opioid industry, raising potential financial conflicts of interest.

McKinsey is the only major consulting firm that maintains an internal hedge fund. MIO's investments are reportedly "concealed behind a tangle of shell companies in an island tax

²⁹ ABV-HOR-RR-4605, at Page 28.

³⁰ Food and Drug Administration, *Generic Drug User Fee Amendments* (online at www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments) (a ccessed Sept. 20, 2021).

³¹ USA Spending, McKinsey & Company Generic Drug Contract with the Food and Drug Administration (online at www.usaspending.gov/award/CONT_AWD_HHSF22313004_7524_HHSF223201010014B_7524) (accessed Nov. 3, 2021) (original text capitalized).

 $^{^{32}}$ ABV-HOR-0003951, at Slide 1. Exclusivity refers to the period of time when a brand-name drug is protected from generic drug competition.

³³ ABV-HOR-0003951, at Slides 5–6. The presentation also included repeated references to FDA and potential regulatory action, including references to companies "ability to gain product approval and oversight of committee activities" and a slide devoted to FDA's rising level of drug approvals. ABV-HOR-0003951, at Slides 7, 16. Another slide identified unknowns in the market and questioned whether U.S regulators would take action to curb pharma profits, asking, "Will some markets place draconian measures on pricing and intellectual property?" ABV-HOR-0003951, at Slide 19.

haven in the English Channel."³⁴ Because both McKinsey's client list and MIO's investments are non-public, there are significant risks that McKinsey could profit from its insider knowledge of its clients' internal workings without outside scrutiny.

This danger is heightened by the composition of MIO's leadership. Eight current or former McKinsey executives serve on MIO's board.³⁵ Several MIO executives are also former McKinsey consultants.³⁶ This movement of personnel from consulting company to internal money manager increases the risk that information McKinsey obtains in its capacity as consultant could inappropriately influence MIO's investment decisions. As one business ethics expert described the personnel crossover between McKinsey and MIO, "I just don't know how you can see it any other way than a conflict."³⁷

While McKinsey helped opioid manufacturers spur sales, MIO "held stakes in companies that profited from increased usage," including addiction treatment centers and the maker of overdose treatment products. Since 2010, MIO has amassed a \$108 million stake in Deerfield Management Company, which has taken such large stakes in opioid-related ventures that Deerfield has been called "a vertical integration of human misery." Even today, McKinsey could benefit from its \$573 million settlement with the states attorneys general for its role in the opioid epidemic because of MIO's indirect ownership stakes in companies that serve opioid users. MIO's holdings in these companies also raise the question of whether McKinsey's financial interest in opioid usage was properly disclosed to FDA during its work for the agency.³⁸

In addition, MIO invested heavily in Valeant Pharmaceuticals while McKinsey consultants advised Valeant executives that its life-saving drugs possessed "material pricing potential," as discussed above. Valeant subsequently raised the price of two heart medications by 5,785%.³⁹ Other parts of McKinsey's business also appear exposed to potential conflicts of interest due to MIO's investments. For instance, McKinsey advised Puerto Rican authorities on their government's debt repayment while MIO held an undisclosed stake in Puerto Rican bonds. In several cases, McKinsey and its consultants reportedly "stood to profit from their own advice" to clients as a result of MIO's investments, potentially limiting or disincentivizing the firm's

³⁴ As McKinsey Sells Advice, Its Hedge Fund May Have a Stake in the Outcome, New York Times (Feb. 19, 2019) (online at www.nytimes.com/2019/02/19/business/mckinsey-hedge-fund.html).

³⁵ Consulting Giant McKinsey Allegedly Fed the Opioid Crisis. Nowan Affiliate May Profit from Treating Addicts, NBC News (online at www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969).

³⁶ The Story McKinsey Didn't Want Written, Institutional Investor (July 8, 2019) (online at www.institutionalinvestor.com/article/b1g5zjdcr97k2y/The-Story-McKinsey-Didn-t-Want-Written).

³⁷ *Id*.

³⁸ Consulting Giant McKinsey Allegedly Fed the Opioid Crisis. Now an Affiliate May Profit from Treating Addicts, NBC News (Feb. 8, 2021) (online at www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969).

³⁹ As McKinsey Sells Advice, Its Hedge Fund May Have a Stake in the Outcome, New York Times (Feb. 19, 2019) (online at www.nytimes.com/2019/02/19/business/mckinsey-hedge-fund.html).

from advising against economically inadvisable or unethical practices, such as rapidly raising the price of life-saving medication. 40

McKinsey's bankruptcy consulting practice and MIO's investments reveal additional financial conflicts of interest. Between 2002 and 2016, *The Wall Street Journal* found that McKinsey "had a financial interest" in half of the bankruptcy matters on which its bankruptcy consulting practice worked due to investments by MIO. ⁴¹ In addition, from 2006 to 2017, McKinsey partner Jon Garcia simultaneously served as the head of McKinsey's restructuring practice while also serving on the MIO board and, for at least part of that time, its investment committee. Garcia reportedly advised companies about which debtors to pay first while also possessing the discretion as a member of the investment committee to ratify MIO's investments in those same debtors. ⁴² In February 2019, McKinsey agreed to a \$15 million settlement with the Department of Justice to settle claims that it systematically failed to disclose conflicts of interest related to its consulting work for three companies. ⁴³

MIO's opaque financial holdings raise the question of whether a consulting firm should be allowed to advise companies, governments, and individuals while maintaining a hedge fund with financial interests related to that advice, without disclosing potential conflicts of interest. McKinsey's unique relationship with MIO may indicate the need for reforms to enhance disclosure and prevent certain conflicts of interest.

III. DOCUMENT AND INFORMATION REQUESTS

The Committee is seeking to understand the full scope of McKinsey's monitoring failures, conflicts of interest, and consulting in furtherance of abusive practices. In order to assist the Committee with its investigation and inform potential reforms, the Committee requests that you produce the following documents and information by November 19, 2021:

1. A list of all McKinsey domestic clients in the following categories from 2010 to the present that have paid McKinsey a cumulative fee of over \$1 million during that period, including: (1) a description of each project conducted for the client, (2) the date range of the contract or engagement, and (3) the amount of payment received:⁴⁴

⁴⁰ As McKinsey Sells Advice, Its Hedge Fund May Have a Stake in the Outcome, New York Times (Feb. 19, 2019) (online at www.nytimes.com/2019/02/19/business/mckinsey-hedge-fund.html).

⁴¹ McKinsey Investments Weren't Disclosed in Bankruptcy Cases, Wall Street Journal (June 19, 2019) (online at www.wsj.com/articles/mckinsey-investments-werent-disclosed-in-bankruptcy-cases-1529423138).

⁴² *Id.*; *The Story McKinsey Didn't Want Written*, Institutional Investor (July 8, 2019) (online at www.institutionalinvestor.com/article/blg5zjdcr97k2y/The-Story-McKinsey-Didn-t-Want-Written).

 $^{^{43} \}it McKinsey Will Return \$15 \it Million in Fees over Disclosure Failures, New York Times (Feb. 19, 2019) (online at www.nytimes.com/2019/02/19/business/mckinsey-bankruptcy-settlement.html).$

⁴⁴ This request includes the beneficial owner of any subsidiary or legally related organization. Successor or subsidiary entities should be treated as one entity for the purposes of this calculation.

- a. health care sector clients;
- b. clients of McKinsey's bankruptcy and restructuring practice; and
- c. federal government clients;
- 2. A detailed description of McKinsey's risk, board, management, and conflicts committees; a list of their members; all codes of conduct; all policies and procedures related to conflicts of interest, or legal, ethical, or reputational risks; and any internal reports on risk and conflict management at McKinsey from 2005 to the present;
- 3. A list of individual matters, complaints, or concerns raised to McKinsey's risk or conflicts committees or through its formal or informal risk or conflicts procedures since 2008 regarding (1) conflicts of interests; (2) opioids, health care, pharmaceutical, or drug consulting; (3) consulting for the federal government; and (4) MIO, including a description of the matter, the date, any steps taken in response, and any documents or communications relating to those matters, complaints, or concerns;
- 4. All opioid-related contracts, presentations, slides, memoranda, board of directors' reports, or other work product prepared for any opioid manufacturer or subsidiary operating in the United States between 2005 and 2021, including but not limited to Purdue, Johnson & Johnson, Mallinckrodt, Endo International, Teva, Actavis, and Abbott Laboratories;
- 5. All documents referencing or relating to a rebate, discount, transfer of funds, or other financial benefit for any company involved in the sale of a product resulting in opioid or drug overdose;
- 6. All opioid-related contracts, presentations, slides, memoranda, board of directors' reports, or other work product prepared for any opioid distributor, retailer, or subsidiary thereof operating in the United States between 2005 and 2021, including but not limited to McKesson, Amerisource Bergen, Cardinal Health, CVS, and Walmart;
- 7. All drug pricing, commercialization, marketing, regulatory, or sales-related contracts, presentations, slides, memoranda, board of directors' reports, or other work product prepared for any pharmaceutical company or subsidiary operating in the United States between 2005 and 2021, including but not limited to AbbVie, Amgen, Celgene, and Sanofi;
- 8. 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;
- 9. All presentations, memoranda, reports, or other work product prepared for FDA between 2005 and 2021 relating to opioids, generic drugs, drug approval, drug approval processes, REMS, track and trace systems, or other programs affecting the opioid or pharmaceutical industry;
- 10. 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;
- 11. All documents and communications referring to McKinsey's representation of any drug company or industry group before FDA since 2008;
- 12. All documents disclosing or referring to a conflict of interest with FDA since 2008;
- 13. A list of all McKinsey employees, past or present, who have also worked or volunteered for service on MIO at any point since 2005;
- 14. A list of all current and historical MIO direct or indirect investments, holdings, assets, or shares—including the relevant amount, timing, investment name, nature, and fund for each investment—in any:
 - a. rehabilitation centers, addiction treatment centers, opioid treatment or recovery programs, overdose treatment product manufacturers, medication-assisted treatment product manufacturers, or health care recovery programs;

- b. pharmaceutical companies producing opioids or drugs, opioid distributors, or opioid retailers; or,
- c. companies in bankruptcy or other distressed assets; and
- 15. All communications to or from MIO employees relating to McKinsey's consulting clients.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee's request. Please contact Committee staff at (202) 225-5051 if you have any questions about this request.

Sincerely,

Carolyn B. Maloney

Chairwoman

Enclosure

cc: The Honorable James Comer, Ranking Member

Responding to Oversight Committee Document Requests

- 1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.
- 2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.
- 3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.
- 4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.
- 5. Documents produced in electronic format should be organized, identified, and indexed electronically.
- 6. Electronic document productions should be prepared according to the following standards:
 - a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.
 - b. Document numbers in the load file should match document Bates numbers and TIF file names.
 - c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.
 - d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

- 7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.
- 8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.
- 9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.
- 10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.
- 11. The pendency of or potential for litigation shall not be a basis to withhold any information.
- 12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.
- 13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.
- 14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.
- 15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.
- 16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.
- 17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

- 18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.
- 19. All documents shall be Bates-stamped sequentially and produced sequentially.
- 20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.
- 21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

- 1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
- 2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

- message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.
- 3. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.
- 4. The term "including" shall be construed broadly to mean "including, but not limited to."
- 5. The term "Company" means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.
- 6. The term "identify," when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; (b) the individual's business or personal address and phone number; and (c) any and all known aliases.
- 7. The term "related to" or "referring or relating to," with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.
- 8. The term "employee" means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.
- 9. The term "individual" means all natural persons and all persons or entities acting on their behalf.