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By Electronic Mail

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By Electronic Mail

Re: Objection to McKinsey's Fee Application

Dear Ramona and Monsita,

Thank you for your efforts in persuading McKinsey to submit a searchable disclosure declaration.[1] I, as well as the interested parties, the Court, and the public, most certainly appreciate it.

Based on McKinsey's disclosure declaration, I write to urge the United States Trustee Program to object to McKinsey's fee application when it is filed, which should be soon. I make this request under Section 2(e) of PRRADA, which permits the court to deny the fees of a professional (1) who has filed an inadequate disclosure statement, (2) who is not a disinterested person, (3) who represents an adverse interest in connection with the case; or (4) who holds an adverse interest in connection with the case.

I also make this request pursuant to *Woods v. City Nat. Bank & Tr. Co. of Chicago*, 312 U.S. 262 (1941), which I reviewed in my letter to you of May 17, 2022. In that case, the Supreme Court held that when a professional in an insolvency case is found to have a direct financial stake in the outcome, its fees **must** be denied: "Where a claimant, who represented members of the investing public, was serving more than one master or was subject to conflicting interests, he should be denied compensation." *Id*., at 268.

[1] All references herein to the McKinsey Declaration are to this resubmitted declaration. (Dkt. 20989, filed May 24, 2022).

Undeniable evidence, almost all from McKinsey itself, conclusively establishes that the Court can and should deny McKinsey's fees. This evidence establishes that:

1. McKinsey was and may still be a creditor in the case and therefore held and may still hold an adverse financial interests in connection with the case

2. McKinsey held an adverse interest in the case arising from Puerto Rico's multi-million dollar claim against it for its role in the opioid crisis.

3. McKinsey's investments in entities that contracted with Puerto Rico during the case created additional actual conflicts of interest.

4. Several McKinsey clients sought and obtained Board approval for their contracts with Puerto Rico while McKinsey was serving the Board.

5. McKinsey had very close business and political connections with Natalie Jaresko, the Board's executive director from 2017 through 2022, which it failed to disclose.

6. McKinsey was not a "disinterested person" in the case.

7. Because McKinsey used of its deeply flawed protocol to search for its connections, its disclosure declaration was inadequate under PRRADA and Rule 2014.[2]

McKinsey's declaration discloses **hundreds** of distinct ways in which it either holds adverse interests, represents adverse interests, or is not disinterested. At the same time, McKinsey's disclosure declaration raises so many questions about the nature and extent its thousands of connections in the case that its declaration must be considered inadequate under PRRADA.

Therefore, under Section 2(e) of PRRADA and the *Woods* case, the Court should deny McKinsey's fees. I urge you to file and pursue a strong objection.

Further, on your motion, the Court has appointed a fee examiner in the case.[3] If necessary to further investigate and adjudicate the factual basis on which to deny McKinsey's fees, I urge you to request the Court to instruct the fee examiner to perform that investigation and submit a report to the Court.

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[2] As I am sure you are aware, Section 2(d)(1) of PRRADA provides: "The United States trustee shall review each verified statement submitted pursuant to subsection (b) and may file with the court comments on such verified statements *before the professionals filing such statements seek compensation* under section 316 or 317 of PROMESA (48 U.S.C. 2176, 2177)." And Section 2(d)(2) of PRRADA provides: "The United States trustee may object to applications filed under section 316 or 317 of PROMESA (48 U.S.C. 2176, 2177) that fail to satisfy the requirements of subsection (b)."

[3] Order Pursuant to PROMESA Sections 316 and 317 and Bankruptcy Code Section 105(A) Appointing a Fee Examiner and Related Relief, Dkt. 1309, entered Sept. 15, 2017.

I. McKinsey's Was and May Still Be a Creditor in the Case and Therefore Held and May Still Hold Adverse Financial Interests in Connection with the Case

McKinsey's disclosure declaration states that the MIO held both direct and indirect investments in Puerto Rico bond debt. McKinsey was, therefore, a creditor and held an adverse financial interest in connection with the case under Section 2(e) of PRRADA. Under that section and the Supreme Court's *Woods* decision, the Court has the authority and mandate to deny McKinsey's fees.

A. McKinsey Held *Direct* Investments in Puerto Rico Bond Debt

The filed proofs of claim for the MIO's investment in Puerto Rico bond debt are:

Creditor - MIO Managed Fund	Debtor	Claim Number	Date	Amount
Compass CSS High Yield LLC	COFINA	18578	5/22/2018	$16,276,085.64
Compass ESMA LP	COFINA	22063	5/25/2018	$1,570,572.67
Compass ESMA LP	Commonwealth of Puerto Rico	32025	5/25/2018	Unliquidated
Compass TSMS LP	Commonwealth of Puerto Rico	34183	5/25/2018	Unliquidated
Compass TSMA LP	COFINA	38948	5/25/2018	$2,277,657.46

In addition, McKinsey's disclosure declaration admits that McKinsey had an "investment-related connection to the Puerto Rico Sales Tax Financing Corporation" and that this investment connection was its direct investment in COFINA bonds through three of the MIO's "Compass" funds - Compass CSS High Yield LLC, Compass ESMA LP, and Compass TSMA LP, in the amount of $58,345,000 par value.[4]

Those proofs of claim and that statement in McKinsey's disclosure declaration, by themselves, are fatal to McKinsey's fee application. They are a public, judicial admissions that McKinsey held adverse financial interests in connection with the case. Under Section 2(e) of PRRADA and *Woods*, this is the very type of connection that requires the Court to deny McKinsey's fees.

Worse, this conflict of interest between the MIO's investment interests in COFINA bonds and McKinsey's consulting role for the Board had a direct impact in the case. Even

[4] McKinsey Declaration, ¶ 37, p. 17. The declaration does not, however, provide this information directly from the MIO. Rather, the declaration states that this disclosure is based on the "Special Counsel Report." *In re the Commonwealth of Puerto Rico*, (D.P.R. No. 17-BK-03293), Final Investigative Report – McKinsey & Company, Inc., Prepared for The Financial Oversight & Management Board for Puerto Rico, by Luskin, Stern & Eisler LLP (filed Feb. 18, 2019), Dkt. 5154, Ex. A.

In the McKinsey Declaration, the declarant, Dimitry Krivin, calls this report the "Special Counsel Report." In this letter, it is referred to as "the Luskin Report" or "the Report.

as McKinsey was a COFINA bondholder, it played an important role in the process of resolving the COFINA claims, as the Luskin Report confirms:[5]

> As disclosed in McKinsey's contract with the Oversight Board and in its fee applications filed with the Court, **McKinsey did provide "mediation support" to the Oversight Board**. McKinsey's role in the mediation was limited to **providing information to the various creditor constituencies** so that creditors could understand the particular provisions of the fiscal plans and the assumptions that underlay them. There were multiple sessions where McKinsey personnel **provided answers to questions** so that all constituencies could be working with the same set of operative facts. The sessions generally involved McKinsey personnel providing answers to questions (in one case more than 1,000) that had been posed by the creditor constituencies ahead of time.

McKinsey, a COFINA bondholder itself, had a direct stake in the outcome of the process by which the COFINA bond claims (including its own) were resolved and in which it provided mediation support to the Board. McKinsey also provided information relevant to this process to the various creditor constituencies and answers to questions posed by the creditor constituencies.

But McKinsey had no business anywhere near that process.

And no one knew of McKinsey's stake in the outcome of these negotiations – not Court, not the mediators, not the Board, and not the other interested parties. No one knew it because McKinsey did not disclose it.

Regarding, MIO's sale of its COFINA bonds, the Luskin Report disclosed:[6]

> In 2014, MIO purchased $58,345,000 par value of COFINA bonds at a steep discount. MIO disposed of $8,345,000 par value in three transactions in the first quarter of 2017, and disposed of the remaining $50,000,000 par value in two transactions in April 2018. The Non-Investable Compass Fund realized a total profit of approximately $765,000 on this investment.

Three issues arise from this disclosure.

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[5] Luskin Report, at pp.76-77 (emphasis added, footnotes omitted).

[6] *Id*., at p. 72. The McKinsey Declaration quotes the Luskin Report on this point but makes it clear that Krivin obtained this information from the Luskin Report, **not from the MIO.** McKinsey Declaration, at ¶ 37, p. 17.

First, when McKinsey sold its COFINA bonds, it failed to first seek the Court's guidance, instructions, and permission regarding how to proceed. This was a further violation its fiduciary duties to the Court, for which it must be held accountable.

McKinsey had a duty to seek the Court's guidance on how to proceed because McKinsey, a fiduciary, had a self-interest in the outcome of that question. Only the Court was in a position to determine (1) whether a sale would improperly profit McKinsey, (2) whether there was a risk that McKinsey might benefit from insider information in connection with any proposed sale, (3) what should be done with the proceeds of any proposed sale, and especially any profits, and (4) whether there were any options that might better remedy the taint of this actual conflict of interest, such as (i) forfeiture of the bonds, (ii) ordering that the bonds be donated to charity or (iii) removing McKinsey from any position of control over the disposition of the bonds.

Instead, McKinsey's unapproved and secret sale of those bonds raises questions about (1) whether and to what extent McKinsey financially profited from the sale; (2) whether McKinsey was in a position to take unlawful advantage of insider information in connection with the sale; and (3) whether McKinsey did in fact take unlawful advantage of insider information in connection with the sale. But no one should have to spend any time, energy or resources investigating any of this. The very fact McKinsey's conduct even raises these questions mandates that its fees should be denied.

Second (and nevertheless), there is one fact that must be determined – the total profits that the MIO, and thus the partners and employees of McKinsey have realized from the MIO's direct or indirect investments in Puerto Rico or any other interested party (discussed below). Under the supervision of the Court, this matter must be thoroughly and independently investigated, documented, verified, and reported to the Court in a public filing, all at McKinsey's expense. Neither McKinsey nor the MIO cannot be allowed to hide behind any claims of confidentiality or "information barriers." McKinsey, the MIO, and their third-party investment managers must provide full access to and disclosure of all information pertinent to this issue.

Third, McKinsey and the MIO must be ordered to disgorge the full of amount of their profits from the MIO's investments in Puerto Rico bond debt and the MIO's investments in other interested parties. As a professional and a fiduciary, McKinsey is prohibited from holding, let alone profiting from, any interests, financial or otherwise, that conflict with the interests of the Commonwealth of Puerto Rico, the Board, or the interested parties in the case. All such profits must be disgorged.

Accordingly, in addition to my request that the Program object to McKinsey's fees, I also request and urge the United States Trustee Program to act to obtain court orders:

(1) To sanction McKinsey for its breach of fiduciary duties in selling its Puerto Rico bonds secretly and without Court authorization and instruction;

(2) To investigate and report to the Court, at McKinsey's expense, the profits that McKinsey and the MIO have realized form their investments in Puerto Rico bond debt and in interested parties; and

(3) To require McKinsey to disgorge all such profits, to be distributed as the Court determines.

B. McKinsey Also Held *Indirect* Investments in Puerto Rico Bond Debt

McKinsey's indirect investments in Puerto Rico bond debt were managed by many third-party managed funds for the MIO. McKinsey's disclosure declaration identifies 137 of these third-party managed funds, including, curiously, "McKinsey & Company, Inc."[7]

McKinsey's disclosure declaration does not disclose the amount of the Puerto Rico bond debt the MIO holds indirectly through third-party fund managers.

C. McKinsey Knows That These Investments Create a Problem for Its Fee Application

McKinsey's disclosure declaration demonstrates that McKinsey knows that when it files its application for fees of over $100 million, the MIO's investments in Puerto Rico bond debt will become a highly problematic obstacle. Its disclosure declaration attempts to preempt the issue by foretelling its responses.

For example, McKinsey's disclosure declaration claims, "MIO is operated separately from McKinsey's consulting services[.]"[8] And, "The operational separation between MIO and McKinsey is designed to restrict the flow of information between MIO staff and McKinsey consultants and ensure that information regarding MIO investments will not influence McKinsey's client engagements and that information from McKinsey's client engagements will not influence MIO's investment decisions."[9]

Further, McKinsey has and undoubtedly will continue to claim that the Luskin Report exonerates it of any wrongdoing in connection with the MIO's investment interests in Puerto Rico bond debt.[10] *It does not.* Indeed, the Luskin Report only serves to corroborate that McKinsey was and may well still be a creditor of Puerto Rico and that it therefore held and holds an adverse interest in connection with the case, and that McKinsey played an important role in the COFINAL negotiations. The many reasons that the Luskin Report does not exonerate McKinsey are reviewed in the attached Appendix.

But McKinsey's claims will not help it when it requests allowance of its fees, because neither PRRADA nor *Woods* creates any exception to the strict rule requiring the denial of a professional's fees when the professional, like McKinsey, holds multiple adverse financial interests.

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[7] The list of these third-party investment managers that invested in Puerto Rico bond debt for the MIO is set forth in Exhibit 1 to this letter.

[8] *Id*., at ¶ 30, p. 13.

[9] *Id*., at ¶ 30, p. 14.

[10] https://www.mckinsey.com/about-us/media/mckinsey-statement-on-independent-third-party-report-on-separation-of-mio-and-mckinsey

McKinsey's responses also utterly lack credibility, as the next sections demonstrates.

D. The Securities and Exchange Commission Sanctioned the MIO $18 million on the Grounds That the MIO's "Operational Separation" Was Inadequate and Created a "Real and Substantial" Risk That the MIO Would Misuse Material Non-Public Information in Connection with the Puerto Rico Case

In an order entered just seven months ago on November 19, 2021 – *an order to which McKinsey agreed* – the Securities and Exchange Commission totally rejected the MIO's claims concerning its "operational separation" from McKinsey.[11] The SEC's $18 million sanction against McKinsey, as well as the findings on which that sanction was based, conclusively obliterate McKinsey's claim of "operational separation" from the MIO.

The SEC's order approving the settlement found that the MIO had no adequate separation from McKinsey in relation to McKinsey's insolvency consulting engagements:[12]

> 16. Throughout the Relevant Period, MIO had access to substantial MNPI [Material Non-Public Information].
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> 17. Active McKinsey partners serving on the Investments Committee, including, through June 2017, the President of McKinsey RTS, possessed and had access to McKinsey Client MNPI by way of their various roles at McKinsey. As McKinsey consultants, Investments Committee members were routinely privy to MNPI relating to, for example, financial results, planned bankruptcy filings, mergers and acquisitions, product pipelines and funding efforts, and material changes in senior management.
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> 18. Investments Committee members also possessed and had access to MIO MNPI as a result of their participation on the Board and its committees. For example, Investments Committee members were aware of MNPI regarding MIO's investment strategies, concentration limits, risk limits, and third-party manager allocations, and had access to MIO's holdings (both direct holdings and holdings in SMAs).
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> 19. MIO directly and indirectly invested hundreds of millions of dollars in the securities of issuers about which Investments Committee members who were active McKinsey partners had access to substantial McKinsey Client MNPI.

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[11] *See In the Matter of MIO Partners, Inc.* (SEC No. 3-20656. Nov. 19, 2021), Order Instituting Administrative and Cease-and-Desist Proceedings, Pursuant to Sections 203(E) and 203(K) of the Investment Advisers Act of 1940, Making Findings, and Imposing Remedial Sanctions and a Cease-And-Desist Order. (Exhibit 2 attached to this letter.)

[12] *Id*., at p. 4. The "Relevant Period" is "from at least 2015 through 2020." *Id*., at ¶ 1, p. 2.

The SEC specifically found that the MIO had access to Material Non-Public Information relating to *Alpha Natural Resources, SunEdison, and Puerto Rico*:[13]

> 20. For example, between October 2015 and June 2017, MIO's third-party managed funds, including certain of its SMAs, bought and sold securities of Alpha Natural Resources, Inc. ("ANR"), SunEdison, Inc. ("SunEdison"), and The Commonwealth of Puerto Rico ("Puerto Rico"). At the time of these transactions, certain Investments Committee members had access to MNPI concerning these issuers.
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> 21. In February 2016, the Investments Committee reviewed and ratified a $70 million allocation change to a third-party fund manager that was heavily invested in ANR senior secured debt. At that time, and in November 2015, when the Investments Committee had preliminarily ratified the allocation, McKinsey RTS was providing restructuring advice to ANR and the President of McKinsey RTS was on the Investments Committee. By June 2016, MIO had increased its total investment in the third-party manager's funds to approximately $272 million and those funds, in turn, had obtained approximately $80 million of ANR's senior secured debt.
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> 22. Between October 2015 and December 2016, MIO's SMAs also invested (via six third-party managers) in another client of McKinsey RTS, SunEdison, while an Investments Committee member led McKinsey RTS.

The SEC then found that McKinsey consulting partners oversaw the MIO's direct investments in Puerto Rico bonds:[14]

> 23. Finally, in January and February of 2017, MIO was directly invested in the municipal bonds of Puerto Rico at the same time McKinsey was providing restructuring advice to the Puerto Rico Financial Oversight & Management Board ("FOMB"), the entity charged with spearheading Puerto Rico's financial turnaround. During this time frame, the Investments Committee, which included active McKinsey partners with access to McKinsey Client MNPI, was empowered under the Investments Committee Charter to oversee MIO's direct investments, including MIO's sale of nearly $1 million worth of Puerto Rican bonds. Further, in addition to MIO's direct investments in Puerto Rico, through at least June 2017, MIO was also invested in Puerto Rico's debt via its SMAs and other third-party managed funds.

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[13] *Id*., at p. 4.

[14] *Id*., at p. 5.

The SEC found that the risk that the MIO would misuse Material Non-Public Information was "real and significant":[15]

> 24. Considering the nature of MIO's business, including the Investments Committee's oversight of MIO's investment decisions, the risk of misuse of MNPI was real and significant.
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> *.*.*
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> 29. MIO's policies and procedures were not reasonably designed, taking into consideration the nature of its business, to prevent the misuse of McKinsey Client MNPI or MIO MNPI. MIO's written policies and procedures did not address the fact that McKinsey personnel on the Investments Committee brought MNPI obtained in their jobs as consultants to public issuers to their roles

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[15] *Id*., pp. 5, 6. Concerning the MIO's investment connections in the *ANR* case, the SEC also further found:

> 26. For example, McKinsey RTS had been retained in August 2015 as ANR's turnaround adviser, worked very closely with ANR management including by being embedded in part of its operations, and prepared a comprehensive business plan that formed the basis for the financial projections underpinning ANR's Chapter 11 plan that helped to establish the value of the securities that were exchanged for ANR's senior secured debt held by MIO. During the course of that consulting work, the President of McKinsey RTS sat on the Investments Committee and had access to MIO MNPI, including that MIO was invested with a third-party manager. The third-party manager had invested in ANR's senior secured debt. In this context, MIO's investments through the third-party manager in ANR's senior secured debt overlapped with McKinsey RTS's consulting work and, as such, there was a risk that McKinsey RTS could influence the reorganization plan in a way that favored MIO's investments.
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> 27. Before confirming ANR's Chapter 11 plan, the Bankruptcy Court, which needed to rely on McKinsey RTS's testimony in order to confirm the plan, ordered McKinsey RTS to disclose MIO's connections to interested parties in the ANR bankruptcy case because of both the relationship between MIO and McKinsey RTS and the presence of McKinsey RTS's President on the MIO Board. In a Bankruptcy Court-ordered in camera submission filed on July 6, 2016, however, McKinsey RTS did not disclose MIO's connection to the third-party manager that was invested in ANR senior secured debt. After reviewing the in camera submission, the Bankruptcy Court confirmed the ANR Chapter 11 plan without disclosure in the bankruptcy proceedings of MIO's interest in ANR senior secured debt via the third-party manager. Pursuant to the confirmed plan, because of their priority, the holders of ANR's senior secured debt received 87.5% of the stock of ANR's successor under the plan, and all other investors and creditors received a de minimis distribution.

Id.

on the MIO Board. In addition, prior to September 2020, none of MIO's written policies or procedures (i) effectively sought to identify whether Investments Committee members may have MNPI that was relevant to their involvement in MIO's investment decisions, or (ii) set forth a recusal procedure reasonably designed to guard against the misuse of McKinsey Client and MIO MNPI.

30. The MIO Collaboration Policy (the "Collaboration Policy"), in effect since at least 2015, was MIO's chief policy governing information sharing between McKinsey and MIO personnel. The Collaboration Policy included a specific carve out for Board and Investments Committee members that situated them above the protective wall and did not prohibit access to MIO portfolio investments.

31. MIO's policies and procedures were likewise not reasonably designed to prevent the misuse of MIO MNPI. The Collaboration Policy did not prohibit Board and Investments Committee members from accessing MIO's investment information and did not contemplate the ways that MIO MNPI could be misused by Investments Committee members in the course of their consulting work for McKinsey clients.

Finally, the SEC found that the MIO violated of the securities laws and that its violations were "willful":[16]

32. As a result of the conduct described above, **Respondent willfully violated Section 204A of the Advisers Act.** Section 204A requires investment advisers subject to Section 204 of the Advisers Act to establish, maintain, and enforce written policies and procedures reasonably designed, taking into consideration the nature of such investment adviser's business, to prevent the misuse of material, nonpublic information by such investment adviser or any person associated with such investment adviser in violation of the Advisers Act or the Securities Exchange Act of 1934 (the "Exchange Act") or the rules or regulations thereunder.

33. As a result of the conduct above, **Respondent willfully violated Section 206(4) of the Advisers Act and Rule 206(4)-7 thereunder**, which require registered investment advisers to adopt and implement written policies and procedures reasonably designed to prevent violations of the Advisers Act and the rules thereunder.

[16] *Id*., at pp. 6-7 (emphasis added).

The SEC's order, *to which the MIO agreed*, required the MIO to cease and desist, censured the MIO, and sanctioned the MIO $18 million:[17]

> A. Respondent cease and desist from committing or causing any violations and any future violations of Sections 204A and 206(4) of the Advisers Act and Rule 206(4)-7 promulgated thereunder.
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> B. Respondent is censured.
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> C. Respondent shall, within 10 days of the entry of this Order, pay a civil monetary penalty in the amount of $18,000,000 to the Securities and Exchange Commission[.]

The securities laws are designed to protect the public against fraud and insider trading in securities transactions and to maintain the confidence of the investing public in securities markets. *In re ChinaCast Educ. Corp. Sec. Litig.*, 809 F.3d 471, 479 (9th Cir. 2015) ("the purpose of the securities laws [is] to deter fraud and promote confidence in the securities markets."). The MIO *willfully* violated those laws in connection with its investments in Puerto Rico bond debt.

As noted, the SEC found that the risk that the MIO would misuse Material Non-Public Information was "real and significant." What it meant by that was that the risk of ***insider trading*** by the MIO was "real and significant." On its website, the SEC advises investors:

> Illegal insider trading refers generally to buying or selling a security, in breach of a fiduciary duty or other relationship of trust and confidence, on the basis of material, nonpublic information about the security.[18]

The SEC further advises:

> Because insider trading undermines investor confidence in the fairness and integrity of the securities markets, the SEC has treated the detection and prosecution of insider trading violations as one of its enforcement priorities.[19]

Insider trading is, of course, a crime. *See* 15 U.S.C. § 78j and C.F.R § 240.10b5-1. Persons convicted of insider trading face a sentence of up to 20 years imprisonment and a fine of up to $5 million and an entity can be sentenced to pay a fine of up to $25 million. *See* 15 U.S.C. § 78ff(a).

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[17] *Id*., at p. 7 (emphasis added).

[18] https://www.investor.gov/introduction-investing/investing-basics/glossary/insider-trading

[19] *Id*.

McKinsey is no stranger to the crime of insider trading:

- In 2010, a former McKinsey senior partner, Anil Kumar, pleaded guilty to insider trading for passing confidential client information.[20]

- In 2012, a former global managing partner of McKinsey, Rajat Gupta, was convicted of insider trading, also for passing confidential client information.[21]

- And in 2021, yet another former McKinsey partner, Puneet Diksheet, pleaded guilty to insider trading for using insider information in his personal securities transactions.[22]

The SEC's order shatters McKinsey's credibility concerning the operational separation of the MIO. That order conclusively demonstrates that there is no adequate "operational separation" between the MIO and McKinsey." It conclusively demonstrates that there is no truth in McKinsey's claims that McKinsey consulting partners do not have access to MIO investment information and that MIO investment decision makers do not have access to confidential consulting client information.[23] *And it conclusively demonstrates a "real and significant risk" of insider trading by the MIO in the Puerto Rico case*.[24]

Any professional who creates a "real and significant risk" of insider trading on investment securities connected to an insolvency case must be denied all fees.

McKinsey must be denied all fees.

II. McKinsey Held an Adverse Interest in the Case Arising from Puerto Rico's Multi-Million Dollar Claim Against It for Its Role in the Opioid Crisis

In February 2021, McKinsey agreed to pay 49 states and five territories a total of $596,000,000 for its role in the opioid crisis that had contributed to the deaths of more than 450,000 people over the prior two decades.[25] A month later, McKinsey agreed to pay $45,000,000 to the remaining state, Nevada. **That brought McKinsey's total settlements arising from its role in the opioid crisis to $641,000,000.**[26]

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[20] https://www.justice.gov/archive/usao/nys/pressreleases/July12/kumaranilsentencing.html

[21] https://www.justice.gov/archive/usao/nys/pressreleases/June12/guptarajatverdict.html

[22] https://www.justice.gov/usao-sdny/pr/former-mckinsey-partner-sentenced-24-months-prison-insider-trading-scheme

[23] McKinsey Declaration, at p. 14, ¶ 30.

[24] SEC Order, at p. 5.

[25] https://www.nytimes.com/2021/02/03/business/mckinsey-opioids-settlement.html

[26] https://www.reuters.com/article/us-usa-mckinsey-nevada-idUSKBN2BE2XH

This national settlement included a settlement with the Government of Puerto Rico. To document this settlement, on April 2, 2021, the Government of Puerto Rico filed a Complaint against McKinsey in the Superior Court in San Juan seeking compensation for the damages that McKinsey's role in the opioid crisis caused to government and the people of Puerto Rico.[27] On the same date, a Consent Judgment was submitted to the court, specifying that Puerto Rico will receive $4,338,607.[28]

The Complaint filed by the Government of Puerto Rico identified the harm caused by the opioid crisis:[29]

> 6. Beginning in the mid-1990s, opioid manufacturers pursued aggressive sales strategies to increase sales of their prescription opioids, a plan that resulted in a dramatic rise in opioid prescriptions in the Commonwealth of Puerto Rico. The rise in opioid prescriptions caused an equally devastating rise in opioid abuse, dependence, addiction, and overdose deaths.
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> 7. Prescription opioids continue to kill hundreds of people across the Commonwealth of Puerto Rico every year. Thousands more suffer from negative health consequences short of death and countless others have had their lives ruined by a friend or family member's addiction or death. Every community in the Commonwealth of Puerto Rico suffers from the opioid crisis of addiction and death.
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> *.*.*
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> 29. Opioids have killed thousands in the Commonwealth of Puerto Rico, and continue to ravage the lives of many more, creating one of the largest public health epidemics in the country's history. Economically, the toll is equally grim. The opioid crisis has forced the Commonwealth of Puerto Rico to pay billions of dollars for increased costs in health care, child welfare, criminal justice, and many other programs needed to abate the epidemic.

The Complaint also alleged with specificity the disturbing factual basis for McKinsey's liability under the law of Puerto Rico.[30]

This chronology makes it clear that Puerto Rico held a claim against McKinsey from well before the commencement of McKinsey's work for the Board and until February 2021 when that claim was settled. **Under Section 2(e)(2)(B) of PRRADA, that claim by Puerto Rico against McKinsey was an "adverse interest in connection with the case" that McKinsey held**

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[27] Case No. SJ2021VC00711. A copy of the Complaint is attached as Exhibit 3.

[28] Consent Judgment, p. 13, n. 2. A copy of this Consent Judgment is attached at Exhibit 4.

[29] Complaint, PDF pp. 1-2, 5.

[30] Complaint, PDF pp. 2-5, ¶¶ 8-33.

throughout most of the proceedings in this case. Therefore, on this ground, McKinsey's fees must be denied.

But more must be said about this, and bluntly so.

In the universe of ways in which a professional can hold an adverse interest in connection with an insolvency case, it is hard to conjure one that is more offensive and morally bankrupt than the one that McKinsey created here.

McKinsey's wrongful conduct caused the people of Puerto Rico immeasurable loss, grief, and hardship. It also caused the Commonwealth of Puerto Rico, the Debtor in this case, to incur billions of dollars in health care and other expenses. McKinsey does not dispute any of this. It has publicly admitted its wrongful conduct in the opioid crisis and the harm that it caused.[31]

But McKinsey's conflict of interest with the Government of Puerto Rico was not its only conflict arising from its role in the opioid crisis. The House Oversight and Reform Committee recently released a report finding that at the same time that McKinsey was advising several opioid manufacturers, most notably Purdue Pharma, about how to increase their opioid sales, McKinsey was also advising the Food and Drug Administration while the FDA was attempting to deal with the crisis.[32]

And there was yet more. Already demonstrated above is that McKinsey was simultaneously holding its Puerto Rico bond claims, consulting with the Board, consulting with Purdue Pharma and other manufacturers, consulting with the FDA, and dealing with the financial fallout to itself from the opioid crisis nationwide, including the opioid crisis in Puerto Rico. What is more is that McKinsey was also simultaneously consulting with many health care providers and health care insurers in Puerto Rico, most if not all of whom were no doubt also struggling to deal with the opioid crisis.[33]

McKinsey admittedly caused despair, destruction, and death in Puerto Rico while it was serving as a professional in this insolvency case consulting with Puerto Rico and the Board about resolving Puerto Rico's financial crisis. The conclusion that McKinsey held "an adverse interest in connection with" the Puerto Rico case is surely compelling and accurate under PRRADA.

But we must be mindful that this conclusion that McKinsey held as adverse interest is also a grossly sanitized understatement in legalese that demonstrates no sensitivity or respect for the lives lost and the lives ruined there. We, and McKinsey, owe the people of Puerto Rico more, much more, than that. This was not just an opioid crisis. It was a *humanitarian* crisis.

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[31] https://www.nytimes.com/2020/12/08/business/mckinsey-opioids-oxycontin.html

[32] **The Firm and the FDA: McKinsey & Company's Conflicts of Interest at the Heart of the Opioid Epidemic, Interim Majority Staff Report** (April 13, 2022). This report is attached as Exhibit 5.

[33] These client connections in the health care industry in Puerto Rico are disclosed throughout McKinsey's disclosure declaration.

In effect, McKinsey's fee application will request compensation for assisting the people and the Government of Puerto Rico to recover from the fiscal and humanitarian crisis that McKinsey itself helped in no small part to create before and while it was giving that assistance. That request is grotesque and morally repugnant.

McKinsey states that it acknowledges both the role that it played in this fiscal and humanitarian crisis and the harm that it caused in Puerto Rico and elsewhere. If it truly and fully does acknowledge that, then, as a matter of moral right and compulsion, it should voluntarily forego its request for fees. But if, despite the moral bankruptcy of it, McKinsey remains committed to pursue its fees as it stated in its disclosure declaration,[34] then the court should impose the moral response on McKinsey and deny its request for fees.

III. McKinsey's Investments in Entities That Contracted with Puerto Rico During the Case Created Additional Actual Conflicts of Interest

From 2017 to 2020, McKinsey worked for the Board to develop a plan to privatize the Puerto Rico Electric Power Authority (PREPA). McKinsey, through its internal hedge fund, MIO Partners, held interests in two companies – **NFEnergia** and **Quanta** – that obtained substantial financial benefits from the PREPA restructuring that McKinsey worked on for the Board.

NFEnergia - In 2017, two funds that managed money on behalf of the MIO acquired more than $16 million in a company called Fortress Investment Group, which was the parent of **NFEnergia**.[35] Shortly thereafter, Fortress was acquired by **SoftBank**, a longtime McKinsey client that took control of **NFEnergia** as part of the deal.[36]

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[34] McKinsey Declaration, at p. 2, ¶ 4.

[35] Segantii Capital Management and Nine Masts Capital, two funds that manage money on behalf of MIO, acquired stakes in Fortress Capital Management during 2017. A table of Sengatii's publicly traded holdings in the first quarter of 2017, including its $8.3 million stake in Fortress, is available at:

https://www.sec.gov/Archives/edgar/data/0001544676/000154467617000002/xslForm13F_X01/13F.xml

A table of Nine Masts' publicly traded holdings in the first quarter of 2017, including its nearly $8 million stake in Fortress, is available at:

https://www.sec.gov/Archives/edgar/data/0001569356/000108514617001181/xslForm13F_X01/form13fInfoTable.xml

[36] https://www.fortress.com/shareholders/news/2017-12-27-softbank-group-completes-acquisition-of-fortress-investment-group

These funds made their investments in Fortress just before **NFEnergia** sought a contract worth $1.5 billion to convert two PREPA generation facilities from diesel to natural gas operation.[37] With Board approval, **NFEnergia** was awarded this contract in 2018. MIO's indirect investments in **NFEnergia** gave McKinsey a financial stake in the **NFEnergia** contract.

Quanta – In June 2020, at the end of PREPA's restructuring process, a consortium known as Luma secured a $1.5 billion concession to take control of the island's electricity grid for 15 years.[38] Luma's four members included **Quanta Services Inc**. BlackRock, a longtime McKinsey client and manager of money belonging to MIO Partners, acquired a 10% stake in **Quanta** just before Luma won the PREPA privatization concession.[39] At the time of its purchase, BlackRock's **Quanta** stake was worth approximately $508 million. BlackRock funds managed more than $600 million on behalf of the MIO during this period.[40]

Another fund that managed an undisclosed amount on behalf of the MIO, Key Group Holdings, held a smaller stake in **Quanta**, worth nearly $17 million.[41] Key Group began managing money for the MIO in the early 2010s, if not earlier, and filings with the SEC confirm that it

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[37] Summary of NFEnergia's work for PREPA is included in this white paper from the Institute for Energy Economics and Financial Analysis (IEEFA):

https://ieefa.org/wp-content/uploads/2020/06/Is-Puerto-Ricos-Energy-Future-Rigged_June-2020.pdf

A copy of NFEnergia's PREPA contract is available on the IEEFA website:

https://ieefa.org/wp-content/uploads/2020/06/Fuel-Sale-and-Purchase-Agreement-Contrato-PREPA-NFE-Mar-05-2019.pdf

[38] https://www.theweeklyjournal.com/business/long-awaited-p3-deal-approved-for-prepa-%20s-t-d-system/article_d56acb22-b625-11ea-9c4e-db4476dd19cd.html

[39] BlackRock's disclosure of its acquisition of the Quanta stake is available in its filings to the SEC, available at:

https://www.sec.gov/Archives/edgar/data/1050915/000083423720009439/us74762e1029_050820.txt

[40] MIO's investments with BlackRock are disclosed in the DOL Form 5500 for 2019 filed by the McKinsey Master Retirement Trust, managed by the MIO. The filing is available at:

https://www.efast.dol.gov/5500search/

In the search box, enter "McKinsey Master Retirement Trust", including the quote marks.

[41] Key Group disclosed its Quanta assets in SEC filings that are available at:

https://www.sec.gov/Archives/edgar/data/0001549641/000108514619002951/0001085146-19-002951-index.html

https://www.sec.gov/Archives/edgar/data/1549641/000108514619002951/xslForm13F_X01/form13fInfoTable.xml

continued serving as an adviser to McKinsey's hedge fund as of March 2020.[42] BlackRock's and Key Group's investments in **Quanta** therefore gave McKinsey a financial stake in the Luma contract.

The MIO's investment interests in **Fortress** and **Quanta** gave McKinsey yet another financial stake in the outcome of the case and further financial interests that were adverse to its client in the case. *Woods* holds that these adverse financial interests require the denial of McKinsey's fees.

And once again, these McKinsey investments in entities that obtained billions of dollars in contracts with Puerto Rico, approved by the Board while McKinsey was consulting with the Board, raise many questions. Was McKinsey in a position to use insider information when making these investments? Was the timing of the investments entirely coincidental? Was McKinsey self-dealing? Did other McKinsey clients also invest in and benefit from these transactions?

We should not have to ask questions like these, let alone spend the time, energy, and resources to investigate and answer them. But McKinsey's conduct and our interest in transparency require it. So, yet again, a thorough investigation of these transactions is necessary.

IV. Several McKinsey Clients Sought and Obtained Board Approval for Their Contracts with Puerto Rico While McKinsey Was Serving the Board

Several undisclosed McKinsey clients have profited handsomely from billions of dollars of contracts with Puerto Rico during the case.

Siemens, Naturgy, BNP Paribas, Total and **Tetra Tech** - These McKinsey clients obtained more than $10 billion in revenue from PREPA during the time that McKinsey was advising PREPA. **Siemens** is a German industrial giant. **Naturgy** is a Spanish energy firm. **BNP Paribas** is a French bank. **Total** is a French consortium. And **Tetra Tech** is a California engineering firm.[43] McKinsey did not disclose any of these client connections during the case.

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[42] MIO Partners Form ADV for 2020. Unfortunately, this filing does not appear to be currently available online. I do, however, have a copy and would be happy to forward it to you upon request.

[43] The Siemens PREPA contract is available at the PREPA website:

https://aeepr.com/es-pr/QuienesSomos/Contratos%20Generales/2018-P00176A%20SIEMENS%20INDUSTRY%20INC.pdf

The Naturgy PREPA contract, obtained from Board's database, is available at:

https://drive.google.com/file/d/1Ffh2ale_di3gtxoLOYlrwT5HmxQiERmA/view

The Total PREPA contract, obtained from the PREPA website, is available at:

Continued…

Cardinal Health, Manpower Group, Molina Healthcare, a local branch of Humana, a subsidiary of Anthem, Microsoft, and Oracle - McKinsey was advising the Board while the Board approved contracts between other Puerto Rico agencies and these McKinsey clients: [44]

- The Board approved contracts worth roughly $400 million that the Puerto Rico Department of Health awarded to **Cardinal Health** and **Manpower Group**.

- From 2017 to 2022, the Board approved the Puerto Rico Health Insurance Administration's award of $1.2 billion in contracts to **Molina Healthcare**, a local branch of Humana, and a subsidiary of Anthem.

- The Board also approved the Puerto Rico Information Technology Service's award of IT contracts worth more than $120 million to **Microsoft** and **Oracle**.

Quanta - As noted above, **Quanta** was an MIO investment interest. In addition, **Quanta** was also a McKinsey client during the period in which the firm was overseeing the PREPA privatization process.[45] McKinsey's work on the PREPA restructuring directly benefitted its client **Quanta**, but McKinsey never disclosed that **Quanta** was a client.

Softbank – As noted above, in 2018, NFEnergia, a **SoftBank** subsidiary following the bank's 2017 acquisition of Fortress Investment Group, won a $1.5 billion contract to convert two

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https://aeepr.com/es-pr/QuienesSomos/Contratos%20Generales/2021-P00039%20TOTAL%20PETROLEUM%20PUERTO%20RICO%20CORP.pdf

The Tetra Tech PREPA contract, obtained from the PREPA website, is available at:

https://aeepr.com/es-pr/QuienesSomos/Contratos%20Generales/2019-P00125%20TETRA%20TECH,%20INC.pdf

BNP Paribas's involvement in supplying oil to PREPA is confirmed in bills of lading that are available at:

https://panjiva.com/Freeport-Commodities-Llc/61641663

BNP Paribas's counterparty in these shipments, Freepoint Commodities, is an oil trader that purchased supplies on behalf of PREPA during the period. Freepoint's PREPA contract, obtained from the Board Contract Review database, is available at:

https://drive.google.com/file/d/1G9Rv2zs-pkqP1yoIQOgr7LINavxTPXea/view

[44] These contracts are available through searches for **Cardinal Health**, **Manpower**, **Molina**, **Microsoft**, and **Oracle** at the Board's Contract Review database:

https://oversightboard.pr.gov/contract-review/

[45] I*n re PG&E Corp.*, (Bankr. N.D. Cal., No. 19-30088), Dkt. 5924-4, filed Feb. 26, 2020.

PREPA generation facilities from diesel to natural gas operation.[46] **Softbank** is a longtime McKinsey client.[47]

Puma Energy and **Sonangol** - From 2017 to 2021, the Swiss oil company Puma Energy obtained contracts worth more than $1 billion to supply PREPA facilities with diesel and natural gas.[48] In recent years, McKinsey has worked for **Puma** as well as one of its two parent companies, Angolan national oil company **Sonangol**.[49]

Monarch Alternative Capital, GoldenTree Asset Management, Baupost Group, Varde Partners, Cyrus Capital Partners, and Aurelius Capital - These funds acquired the largest tranches of distressed Puerto Rican debt. All of them have been McKinsey clients since 2017.[50] McKinsey never disclosed these client connections or whether its work for them involved their investments in Puerto Rico.

Like the other conflicts, these client conflicts with contractors and bondholder creditors require your further scrutiny as well. The recent House Oversight and Reform Committee Report, referenced above, powerfully demonstrates a pattern of McKinsey sharing information that it obtained from its government work with its private sector clients. To what extent is that pattern repeated in this case? To what extent was McKinsey, either directly or indirectly, invested in these, or any, contractors or creditors of Puerto Rico? And what advice was McKinsey in a position to give to its clients who benefitted from contracts in Puerto Rico, or actually give them?

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[46] A summary of NFEnergia's work for PREPA is included in this white paper from IEEFA:

https://ieefa.org/wp-content/uploads/2020/06/Is-Puerto-Ricos-Energy-Future-Rigged_June-2020.pdf

A copy of NFEnergia's PREPA contract is available on the IEEFA website:

https://ieefa.org/wp-content/uploads/2020/06/Fuel-Sale-and-Purchase-Agreement-Contrato-PREPA-NFE-Mar-05-2019.pdf

[47] *In re Valaris PLC*, (Bankr. S.D. Tex., No. 20-34114), Dkt. 302, filed Oct. 2, 2020.

I*n re PG&E Corp.*, (Bankr. N.D. Cal., No. 19-30088), Dkt. 5924-4, filed Feb. 26, 2020.

[48] These contracts are available through a search for **Puma** at the Board's Contract Review database:

https://oversightboard.pr.gov/contract-review/

[49] https://www.reuters.com/article/puma-energy-trafigura-beheer-restructuri-idAFL5N20871S

https://www.nytimes.com/2020/01/19/world/africa/isabel-dos-santos-angola.html

[50] *In re PG&E Corp.*, (Bankr. N.D. Cal., No. 19-30088), Dkt. 5924-4, filed Feb. 26, 2020.

V. McKinsey Had a Very Close Business and Political Connections with Natalie Jaresko, the Board's Executive Director from 2017 through 2022, Which It Failed to Disclose

In 2006, Natalie Jaresko co-founded Horizon Capital, an investment firm based in Ukraine.[51] McKinsey alumni hold many of Horizon's executive positions, including a senior partner, its investment director, and its Ukrainian investment director.[52] Horizon promotional materials often boast of the fund's pattern of hiring McKinsey personnel.[53]

McKinsey alumni also worked closely with Jaresko when she was the finance minister of Ukraine from 2014-2016. This relationship was a product of McKinsey's extensive influence in the Ukrainian political system. For instance, a former McKinsey consultant named Alex Danylyuk served as President Petro Poroshenko's deputy chief of staff throughout Jaresko's term as Ukraine's finance minister and then replaced Jaresko as finance minister after her departure.[54]

In November 2016, just 12 days before McKinsey secured its first contract with the Board and just four months before Jaresko was appointed to be its executive director, Horizon created a new entity called Horizon Capital LLC in Puerto Rico.[55] Horizon's principal geographic focus had been on Eastern Europe, so its expansion to Puerto Rico at that point in time raises troubling questions.

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[51] https://www.linkedin.com/in/njaresko/?originalSubdomain=pr

[52] https://www.linkedin.com/in/denis-tafintsev-9a23451/

https://www.linkedin.com/in/dmitryboroday/

https://ua.linkedin.com/in/denys-sychkov-20796a3b

[53] https://horizoncapital.com.ua/news-post/horizon-capital-investuye-u-purcari-wineries-z-200-miljonnogo-fondu-eegf-iii/

[54] https://www.reuters.com/article/us-ukraine-crisis-government-financemini-idUSKCN0X90KD

[55] Corporate formation documents for Horizon's Puerto Rican entity are available at the Registry of Corporations and Entities:

https://prcorpfiling.f1hst.com/CorpInfo/CorporationInfo.aspx?c=386643-1511

McKinsey's initial contract with the Board, dated November 27, 2016, obtained from the Board's website, is available at:

https://drive.google.com/file/d/1qeH3RM1Ic0q0N0qLb8fa9o-s-la_3AZ3/view

VI. McKinsey Was Not a "Disinterested Person" in the Case

Section 2(e)(2)(A) of PRRADA allows the Court to deny McKinsey's fees if McKinsey was not "a disinterested person (as defined in section 101 of title 11, United States Code) relative to any entity or person on the List of Material Interested Parties."

Section 101(14) of the Bankruptcy Code, 11 U.S.C. § 101(14), defines a "disinterested person" as follows:

> (14) The term "disinterested person" means a person that—
> (A) is not a creditor, an equity security holder, or an insider;
> *.*.*
> (C) does not have an interest materially adverse to the interest of the estate or of any class of creditors or equity security holders, by reason of any direct or indirect relationship to, connection with, or interest in, the debtor, or for any other reason.

McKinsey was a creditor. Puerto Rico owed the MIO and McKinsey millions of dollars because of the MIO's direct and indirect investments in Puerto bond debt.

McKinsey had an interest materially adverse to the interest of Puerto Rico because of its participation in causing the opioid crisis in Puerto Rico and the Government's resulting multi-million dollar legal claim for the compensatory damages.

McKinsey had several interests that were materially adverse to the interests of Puerto Rico because of its investments in entities that contracted with Puerto Rico during the case.

McKinsey had an interest materially adverse to the interest of Puerto Rico because several McKinsey clients sought and obtained board approval for their contracts with Puerto Rico while McKinsey was serving the Board.

McKinsey had an interest materially adverse to the interest of Puerto Rico because of its very close business and political connections with Natalie Jaresko, the Board's executive director from 2017 through 2022, which it failed to disclose.

VII. Because McKinsey Used of Its Deeply Flawed Protocol to Search for Its Connections, Its Disclosure Declaration Was Inadequate Under PRRADA and Rule 2014

Section 2(e)(1) of PRRADA permits the court to deny the fees of a professional that "has filed inadequate disclosure statements under [section 2(b)(1)]." Section 2(b)(1) of PRRADA states:

> In a case commenced under section 304 of PROMESA (48 U.S.C. 2164), no attorney, accountant, appraiser, auctioneer, agent, or other professional person may be compensated under section 316 or 317 of that Act (48 U.S.C. 2176, 2177) unless prior to making a request for compensation, the professional person has filed with the court a verified statement conforming to the disclosure requirements

> of rule 2014(a) of the Federal Rules of Bankruptcy Procedure setting forth the connection of the professional person with any entity or person on the List of Material Interested Parties.

McKinsey is required to disclose all of its connections in the case. In *In re Gulf Coast Orthopedic Center*, 265 B.R. 318, 323 (Bankr. M.D. Fla. 2001), the court emphasized this requirement of Rule 2014:

> Under [Rule 2014] the applicant and the professional must disclose all connections, not merely those which rise to the level of conflict. . . . These disclosure requirements are not discretionary and the duty of the professional to disclose all connections with the Debtor, Debtor-in-Possession, insiders, creditors or parties of interest is a must[.]

McKinsey's disclosure declaration does not comply with Section 2(b)(1) of PRRADA and Rule 2014.

Dimitry Krivin, a McKinsey partner in its "Risk practice," supervised the process for preparing McKinsey's disclosure under PRRADA declaration.[56] He has no experience in consulting with McKinsey's insolvency clients.

Krivin states that he used an internally developed "protocol" to investigate and disclose McKinsey's connections.[57] McKinsey calls its protocol the "Houston Protocol" because it first used it in the *Westmoreland Coal* case filed in Houston. In this letter, it is referred to as "McKinsey's protocol" or "the protocol."

McKinsey's protocol does not facilitate its self-reporting of its connections its compliance with Rule 2014 and PRRADA. On the contrary, in substantial and illegal ways, McKinsey's protocol allows it to continue to unlawfully conceal its connections and to dangerously obstruct the Court's ability to carry out its responsibility to ensure the integrity of the bankruptcy process.

The protocol does that by illegally constricting the disclosures that Rule 2014 and PRRADA require of it. The protocol thereby improperly limits the information that the Court critically needs to evaluate McKinsey's fee application under Section 2(e) of PRRADA because the protocol:

(1) Invents an illegal definition of "Connection" that improperly constricts its disclosure of its connections;

(2) Illegally allows McKinsey to exclude connections that are not actually known, as the protocol itself defines it;

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[56] McKinsey Declaration, pp. 1-2, ¶¶ 1-2.

[57] *Id*., at p. 7, ¶ 18. This protocol is attached to the McKinsey Declaration as Exhibit A.

(3) Illegally allows McKinsey to constrict its disclosure of its investment connections;

(4) Illegally allows McKinsey to exclude adverse party connections from its disclosure declaration; and

(5) Proposes deficient treatment of the proposed questionnaire that unlawfully constricts its disclosure of its connections.

A. McKinsey's Protocol Invents an Illegal Definition of "Connection" That Improperly Constricts Its Disclosure of Its Connections

One way in which McKinsey's protocol illegally constricts its disclosure obligation is in the definition of "Connection":

> **Connection** means, in the context of Section 327 and Rule 2014, an association or relationship with an IPL Party that a reasonable person might find bears on whether the Proposed Professional "holds or represents an interest adverse to the estate" and is "disinterested" under Section 327 and Section 101(14), based on the facts of a particular bankruptcy case.[58]

In other words, according to the McKinsey protocol, McKinsey only needs to disclose a connection if *it* concludes that the relationship is potentially disqualifying.

This definition is outrageously flawed. The Fifth Circuit has held, "The disclosure requirements of Rule 2014(a) are broader than the rules governing disqualification, and an application must disclose all connections regardless of whether they are sufficient to rise to the level of a disqualifying interest under Section 327(a)." *In re Am. Int'l Refinery, Inc.*, 676 F.3d 455, 465 (5th Cir. 2012).[59]

It is, therefore, illegal for the disclosure of connections to be limited to those that "a reasonable person might find bears on whether the Proposed Professional 'holds or represents an interest adverse to the estate' and is 'disinterested'" under the Bankruptcy Code. *It is the Court's responsibility to adjudicate whether a connection bears upon McKinsey's qualifications. McKinsey's definition of "connection" takes that responsibility away from the Court.*

The result is that because the definition of "Connection" in McKinsey' protocol is illegally constricted, McKinsey's disclosure of its connections is deficient.

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[58] McKinsey Protocol, at p. 3.

[59] *See also*, *In re Knight-Celotex, LLC*, 695 F.3d 714, 722 (7th Cir. 2012); *In re Granite Partners, L.P.*, 219 B.R. 22, 35 (Bankr. S.D.N.Y. 1998) ("The scope of disclosure is much broader than the question of disqualification."); *In re Gluth Bros. Construction, Inc.*, 459 B.R. 351, 364 (Bankr. N.D. Ill. 2011) (describing "connections" that must be disclosed under Rule 2014(a) as "considerably broader" than those disclosures required for § 327(a)).

B. McKinsey's Protocol Illegally Allows McKinsey to Exclude Connections That Are Not "Actually Known," As the Protocol Itself Defines It

One particularly perverse way in which McKinsey's protocol allows it to manipulate its disclosures is by creating a "willful blindness" exception to the disclosure obligations of Rule 2014. McKinsey's protocol emphasizes this constriction on its disclosure obligation many times:

- "[T]he Protocol provides that disclosure of Connections should be based on a Proposed Professional's *actual knowledge* of them[.]"[60]
- "**Direct Connection** means a *known Connection* between a Proposed Professional and an IPL Party (other than an Indirect Connection)."[61]
- "**Immediate Indirect Connection** means a *known Connection* between an IPL Party and a Proposed Professional's Unretained Affiliate (including an AMA)."[62]
- "Rule 2014 disclosure should *not impractically require disclosure of unknown information*[.]"[63]
- "A Proposed Professional should: . . . ensure that its retention application discloses all *known Connections* . . . among IPL Parties and such Retained Affiliates."[64]
- "A Proposed Professional (including Retained Affiliates) should disclose all *known Direct Connections,* and also disclose all *Indirect Connections known* to its Unretained Affiliates (including AMAs) and reported to it."[65]

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[60] McKinsey Protocol, at p. 1.

[61] *Id*., at p. 3.

[62] *Id*. In McKinsey's protocol, an "AMA" is an Asset Management Affiliate," which is "an affiliate or division of a Proposed Professional that is actively engaged in managing or owning financial investments." *Id*., at p. 3.

[63] *Id.*, at p. 7.

[64] *Id*.

[65] *Id.*, at p. 8, see also *id.*, at p. 10, ¶ 4.a ("Such Proposed Professional Personnel generally have no knowledge of (and therefore the Proposed Professional does not disclose) debt or equity investments in IPL Parties because of the effectiveness of the Information Barriers applicable to communication and misuse of MNPI and insulating Proposed Professional Personnel from participation in or knowledge of investment decisions."); *id.*, at p. 12, ¶ 6 ("To be sure, Proposed Professionals cannot disclose unknown Connections, and this Protocol does not suggest that they do so."); and *id.*, at pp. 10-11, ¶¶ 4.b, c, d, e.

McKinsey's protocol does include a definition of "knowledge of Connections," but its definition is also seriously deficient:

> For purposes of this Protocol, a Proposed Professional's knowledge of Connections means actual knowledge derived from its new matter intake process and the results of the Proposed Professional's: (a) computer client database check (as described in Paragraph 7, below); (b) any applicable inquiry of its professional personnel (and Unretained Affiliates other than AMAs) by a questionnaire process or otherwise (also as described in Paragraph 7, below); (c) review of the report it receives of its AMA's (if applicable) check for conflicts and Connections (or any other applicable) process; and (d) review of any other process for its Unretained Affiliates (if any, and other than an AMA). All references to "knowledge" in this Protocol refer to actual knowledge.[66]

This definition is seriously deficient because it excuses McKinsey from disclosing connections that it did not engage in a reasonable investigation to find. It also excuses McKinsey from disclosing connections that the reasonable investigations that it did engage in should have discovered but did not. For example, nothing in Rule 2014 excuses McKinsey from disclosing any client connections that its computer client database check did not reveal but should have, or client connections that a partner forgot to include in an answer to a questionnaire, or investment connections that the MIO failed to include in its report of its checks for conflicts and connections.

Rule 2014 has no exceptions for sloppiness.

Because full disclosure is necessary for the Court to carry out its responsibilities under PRRADA, and because the very integrity of the Court's processes is at stake, Rule 2014 requires the professional to disclose *all* connections, not just the connections actually known by the professional.

Worse, this definition of "knowledge of Connections" defiantly incentivizes the professional's negligence, willful blindness, and even bad faith and wrongful intent in performing the investigation necessary to acquire "knowledge of Connections." It thus appears to be designed to provide a defense for McKinsey when, *as here*, it fails to disclose their connections as Rule 2014 requires.

But the concept of "actual knowledge" in McKinsey's protocol is further deficient as result of this provision:

> The disclosure obligations of a Proposed Professional under this Protocol derive from the Proposed Professional's knowledge of Connections (other than de minimis connections), including the

[66] *Id.*

> knowledge of Connections of a Proposed Professional's AMAs (if any) which the AMA *may report* to the Proposed Professional.[67]

This means that the MIO has discretion over whether to report its connections to the proposed professional. But nothing justifies such discretion. If the MIO knows of a connection, the MIO must report it to McKinsey so that McKinsey can disclose it, as Rule 2014 and PRRADA require.

Rule 2014 must be interpreted objectively, and it must be interpreted in a way that encourages McKinsey to perform a thorough investigation of its connections. Krivin, as well as McKinsey consultants working for Puerto Rico and the Board, had the means to look at public documents to determine connections, including SEC reports of holders of over 5% of equity shares and Labor Department Form 5500 reports. Ignoring that information because it was not reported by Questionnaire recipients and does not appear in a conflicts database search or in a report from the MIO does not meet the standard of reasonable inquiry. *See In re Trust Am. Serv. Corp.*, 175 B.R. 413, 421 (Bankr. M.D. Fla. 1994):

> Coopers and Lybrand, however, did not discover conflicts which it should have known existed with related debtors, while simultaneously employed by the Creditors' Committee. The fact Coopers and Lybrand's search did not discover these related debtors suggests the internal conflict search was not performed adequately enough, nor were the proper inquiries made.

The approach of McKinsey's protocol to "knowledge of Connections" purports to specify the exclusive and definitive means by which McKinsey acquires knowledge of a connection. But it is highly constricted. As a result, relevant connections are undisclosed.

Ultimately, the emptiness of that approach to "knowledge of Connections" and "actual knowledge" is demonstrated by one simple but powerful event in the *Alpha Natural Resources* case. Whitebox was a secured creditor that, under the plan, was given stock in the newly formed entity, Contura, that acquired the debtor's most valuable assets. Kevin Carmody, who was McKinsey's Rule 2014 declarant and who failed to disclose this connection, knew that Whitebox was a creditor. However, his actual knowledge of Whitebox's status as a creditor in that case was not a result of any of the exclusive means set forth in the protocol for acquiring "knowledge" of a connection. Carmody did not derive this knowledge from either McKinsey's new matter intake process, McKinsey's computer client database check, a questionnaire process, a review of a report from the MIO, or his review of any process for its McKinsey RTS's Unretained Affiliates. Therefore, under the constricted definition in McKinsey's protocol, he did not have "actual knowledge" of Whitebox. **But he did. Carmody discovered that Whitebox was a creditor simply by working on the case and interacting with the creditors. If McKinsey had used its protocol in the *ANR* case, it would not have disclosed its investment in Whitebox, because Whitebox was not a "known connection" under the protocol.**

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[67] *Id*., at p. 12, ¶ 6 (emphasis added).

Ultimately, McKinsey does not comply with Rule 2014 by disclosing only its "known connections" under McKinsey's protocol. McKinsey only complies with Rule 2014 when it discloses all of its connections.

The result is that because McKinsey's declaration discloses only "known connections" as narrowly defined in its protocol, McKinsey did not disclose all of its connections.

C. McKinsey's Protocol Illegally Allows McKinsey to Constrict Its Disclosure of Its Investment Connections.

McKinsey's protocol conceals from the Court the information that it needs to determine whether McKinsey has investment interests in connection with the case. Because PRRADA and *Woods* mandate the denial of McKinsey's fees if McKinsey holds any of these investment interests, these connections may well be the most important connections that the Court needs McKinsey to disclose.

Krivin determined that MIO is a "Type 2 AMA" under its protocol:[68]

> MIO qualifies as a "Type 2 AMA" under the Protocol, because it (i) employs robust information barriers; (ii) is registered with the SEC and is subject to its regulatory oversight; (iii) obtains most or all of its assets under management from related investors and not from third parties; (iv) does not make direct investments in the debt or equity of individual corporate or governmental issuers, except securities issued by sovereign governments; and (v) had at least one active McKinsey employee on its board of directors during the Consolidated Look-Back Period.

Because Krivin determined that McKinsey's own AMA, the MIO, is a "Type 2 AMA," the protocol constricts McKinsey's disclosure of the MIO's investment connections. Specifically the protocol requires the MIO to disclose only: "*known* (i) Direct Connections of the Proposed Professional, and (ii) Immediate Indirect Connections of [the MIO], in each case *other than de minimis connections*."[69] And McKinsey's protocol then adds this qualification: "Disclosure of known Immediate Indirect Connections (other than *de minimis* connections) of t[the MIO] will consist of identifying the IPL Parties, if any, to which [the MIO] has Immediate Indirect Connections, *if and as reported by [the MIO] to its related Proposed Professional*."[70]

This means that because Krivin concluded that the MIO is a "Type 2 AMA" under the McKinsey protocol, McKinsey was not required to, and did not, disclose all of its MIO investments in connection with the case.

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[68] McKinsey Declaration, p. 16, ¶ 35 (footnote omitted). The protocol defines four "types" of Asset Management Affiliates ("AMAs"). McKinsey Protocol, at p. 5.

[69] McKinsey Protocol, at p. 5, ¶ 5.c (emphasis added).

[70] *Id*., (emphasis added).

First, McKinsey's protocol does not require McKinsey to disclose its investments in connection with the case that are not "known" investments, meaning investments are held by third parties in which the MIO is invested.

Second, McKinsey's protocol does not require it to disclose its *de minimis* investments, however it decides to define that. The illegality of this constriction is discussed in Section 7, below.

Third, McKinsey's protocol only requires it to disclose the investments that the MIO decides to report to McKinsey. There is no basis in Rule 2014 for this arbitrary constriction of McKinsey's disclosure obligations.

Fourth, under the definition of "Information Barriers" in the protocol,[71] only the "Proposed Professional Personnel,"[72] which consists of the "Primary Working Group,"[73] are restricted in having no participation in or knowledge about MIO's investment decisions. If any other partner or employee at McKinsey participates in or knows about the MIO's investment decisions, then the MIO still has what the protocol calls "Information Barriers."

In *In re Glosser Bros., Inc.*, 102 B.R. 38 (Bankr. W.D. Pa. 1989), the court recognized that human frailties make supervising a "chinese wall" difficult. This is perhaps the only published decision addressing a professional's ownership of interests in a debtor and the professional's contention that a "chinese wall" can overcome the consequences of an adverse interest. The court held that it cannot:

> Regarding Bear Stearns' "chinese wall", we admit to being less than confident that this wall is either impenetrable or capable of being monitored by the Creditors' Committee and this Court from a five hundred (500) mile distance. To the contrary, given the recent history regarding other investment bankers, we question the prophylactic quality of this creation. Bear Stearns is too close to the situation to ensure the avoidance of impropriety, and we are too far removed from Bear Stearns to assure it. At the very least, there is the appearance of impropriety.

Id. at 41.[74]

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[71] McKinsey's protocol, at p. 3.

[72] *Id*., at p. 4.

[73] *Id*.

[74] *See also In re Trust Am. Serv. Corp.*, 175 B.R. 413 (Bankr. M.D. Fla. 1994), the court dealt with a proposed "chinese wall" in the context of a client conflict rather than an investment conflict, but the court's conclusion applies equally compellingly here:

Continued…

Beyond that, there is no exception to the mandate in Rule 2014 to disclose all investment connections when a professional has "no participation in or knowledge concerning" its investment that are managed by its Asset Management Affiliate. Rule 2014 has no exception for "information barriers." Rule 2014 knows the stakes are too high to trust such human constructs.

There is one fundamental illegality with all of the limitations that McKinsey's protocol imposes on its obligation to disclose all of the MIO's investments in connection with the case. Both PRRADA and *Woods* mandate the denial of fees of a professional that represents or holds any adverse interest in connection with the case. That mandate is absolute and without exceptions. PRRADA and *Woods* impose that absolute mandate because the stakes are as serious as they can be—the integrity of the court's process.

A disclosure declaration under Rule 2014 must provide the information that the court needs under PRRADA and *Woods* to protect the integrity of its process. And because McKinsey's investment interests in connection with the case mandate denial of its fees, Rule 2014 mandates that McKinsey fully disclose those investment interests.

The result is that McKinsey's disclosure declaration did not disclose all of its investment connections in the case, as Rule 2014 and PRRADA require.[75]

D. McKinsey's Protocol Illegally Allows McKinsey to Exclude Adverse Party Connections from Its Disclosure Declaration

McKinsey's disclosure declaration admits that it does not have a conflicts-checking software database that will allow it to disclosure its adverse party connections:[76]

> McKinsey maintains a global database of client engagements but does not currently have in place any computerized conflicts database akin to the types used by a legal or accounting firm. More

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> **There does not appear to be any authority to suggest when a conflict exists and protective measures as to dissemination such as a "chinese wall," remove the possibility of conflict information being divulged, an adverse interest should be ignored.** A "chinese wall" typically protects a client from the past activities and information of representation of an adverse client. The "chinese wall" is generally not an acceptable means of conflict avoidance where the same professional organization actively represents two adverse interests.

Id., at 421 (emphasis added).

[75] Krivin determined that the MIO "employs robust information barriers," as the protocol's definition of a "Type 2 AMA" requires. Inexplicably, he did that even though just six months earlier, on November 19, 2021, McKinsey agreed to the entry of an order by the Securities and Exchange Commission that found, "Considering the nature of MIO's business, including the Investments Committee's oversight of MIO's investment decisions, the risk of misuse of MNPI [Material Non-Public Information] was real and significant." SEC Order, p. 5, ¶ 24.

[76] McKinsey Declaration, p. 7, ¶ 17.

> specifically, McKinsey's client database stores information relating to clients and client engagements, but does not capture information about third parties because consultants, unlike lawyers, do not always have adverse parties in their engagements.

As McKinsey's protocol appropriately states, the search "process often utilizes computer software."[77] In fact, McKinsey may well be the only professional in large cases that does not have a conflicts-checking database.

This deficiency is more of the same sort of willful blindness that the "actual knowledge" standard in McKinsey's protocol condones.

And this deficiency is all the more inexcusable given McKinsey's ready access to one of the preeminent database builders available: McKinsey. McKinsey's website advertises its own expertise in digital solutions:

- "We work together with clients to build analytics-driven organizations. Read about how we combine the latest techniques with deep industry, functional, and analytics expertise to help clients capture the most value from data."[78]
- "We're helping organizations optimize their application hosting, network, and end-user environments to operate effectively and efficiently at scale."[79]
- "Immature processes and a culture of 'heroics' create pervasive waste in many infrastructure organizations (for example, frequent rework and large queues) that both drive up costs and diminish user experience."[80]
- "[W]e work with clients to build a digital road map to transform their business by helping them answer key questions[.]"[81]

If McKinsey has the expertise that it advertises in big data, artificial intelligence, digital solutions and analytics, there is no good reason why years ago it could not have developed for itself the same kind of efficient and effective conflicts-checking database that other bankruptcy professionals have implemented.

McKinsey's protocol continues: "For Proposed Professionals with a large number of professionals, this Protocol recommends deployment of adequate software within a reasonable

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[77] *Id.*, at p. 13, ¶ 7.b.

[78] https://www.mckinsey.com/business-functions/mckinsey-analytics/how-we-help-clients

[79] https://www.mckinsey.com/business-functions/digital-mckinsey/how-we-help-clients/infrastructure-and-cloud

[80] *Id.*

[81] https://www.mckinsey.com/business-functions/digital-mckinsey/how-we-help-clients/digital-strategy

time."[82] It has been three years since McKinsey filed the protocol in the *Westmoreland Coal* case - more than a reasonable time for a professional with McKinsey's advertised digital expertise.

Krivin does accurately hint at what may be the most significant risk inherent in a search process that is not based on any conflicts-checking software – the risk of failing to find and disclose adverse parties. Krivin states that the reason that McKinsey does not have conflicts-checking software is that "consultants, unlike lawyers, do not always have adverse parties in their engagements."[83]

But sometimes they do. And when McKinsey does have an adverse party connection, for example, McKinsey's adverse connection with Puerto Rico itself arising from McKinsey's role in the opioid crisis, Rule 2014 and PRRADA require McKinsey to disclose it.

McKinsey's declaration describes three survey questionnaires that were emailed to three different groups within the McKinsey organization – (1) "professional personnel (as distinguished from staff, support, or administrative personnel) of McKinsey's consulting affiliates worldwide"; (2) each director of client services ("DCS") for each of the engagements for a client on the Supplemental PRRADA Client List that matches an entity on the Expanded MIPL and any new engagements during the Supplemental PRRADA Look-Back Period of previously disclosed client matches"; and (3) each member of the Engagement Team still employed by McKinsey.[84] But none of these survey questionnaires requested information about adverse parties.

In fact, nothing in the protocol describes how McKinsey should search for adverse parties in the absence of any conflicts- checking software database.

The protocol makes only this recommendation to McKinsey: "Pending such deployment, a Proposed Professional may retain an independent third-party to assess the adequacy of the alternative procedures the Proposed Professional uses to identify and appropriately disclose Connections."[85]

McKinsey's declaration states that for that purpose it did retain BDO USA, LLP and that: "BDO determined that the procedures performed by the original Working Group 'were reasonable, adequate and consistent with the general guidelines and recommendations in the Protocol.'"[86]

But, as noted, the protocol provides no guidelines or recommendations how McKinsey should search for adverse parties. Accordingly, what BDO is confirming here is that because McKinsey followed its protocol, McKinsey did not search for or disclose adverse party connections, as Rule 2014 and PRRADA require. The BDO conclusion is worthless as any kind

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[82] McKinsey's protocol, at p. 13, ¶ 7.b.

[83] McKinsey Declaration, p. 7, ¶ 17.

[84] McKinsey Declaration, pp. 10-12, ¶¶ 25-28.

[85] McKinsey's protocol, p. 13, ¶ 7.b.

[86] McKinsey Declaration, p. 19, ¶ 40. McKinsey did not attach BDO's report to its declaration, so no information is available regarding its expertise or methodology in reaching its conclusions.

of corroboration that McKinsey's disclosure declaration complies with Rule 2014. On the contrary, BDO confirmed that McKinsey did **not** comply with Rule 2014

The result is that in violation of Rule 2014 and PRRADA, McKinsey's disclosure declaration did not disclose its adverse party connections.

E. McKinsey's Protocol Proposes a Deficient Treatment of the Survey Questionnaires That Unlawfully Constricts Its Disclosure of Its Connections

Questionnaires are an important tool to obtain information about connections and should be used. A conflicts database generally includes information about clients and parties adverse to those clients on matters served by the professional. But it does not include the myriad of other connections that Rule 2014 requires to be disclosed. Nevertheless, the handling of questionnaires suggested in McKinsey's protocol is inadequate for McKinsey to comply with Rule 2014.[87]

First, McKinsey's protocol states that questionnaires should be distributed to "Proposed Professional's professional personnel (as distinguished from staff, support or administrative personnel), and (to the extent, if any, appropriate) Unretained Affiliates (if any) controlled by the Proposed Professional[.]"[88]

But there is no reason to send questionnaires only to Unretained Affiliates controlled by the Proposed Professional. That limitation excuses McKinsey from sending the questionnaire to any other professionals with any other affiliate who may have information that Rule 2014 and PRRADA requires McKinsey to disclose.

Second, the information requested in the survey is inadequate in developing a disclosure declaration that complies with Rule 2014 and PRRADA:[89]

> (i) their known equity or debt investments in the debtor (e.g., excluding Third-Party Managed Investments); and (ii) other connections or relationships with the debtor (other than the Proposed Professional's proposed engagement), the Bankruptcy Court judges, or United States Trustee personnel.

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[87] McKinsey's protocol does not recommend that McKinsey disclose the response rate of any of these surveys and McKinsey did not disclose the response rates in this case. That data would be important in evaluating the effectiveness of the survey process that McKinsey used and, therefore, the reliability and credibility of the declaration itself.

[88] McKinsey's protocol, p. 13, ¶ 7.c.

[89] *Id*.

Absent from the survey is a request for information about any connections to interested parties. And this is confirmed by the Form of Questionnaire that is attached to McKinsey's protocol.[90]

Third, as just quoted, McKinsey's protocol recommends that the questionnaires ask about "(ii) other connections or relationships with the debtor[.]"[91] However, the Form of Questionnaire does not include any such inquiries.

Fourth, the Form of Questionnaire also fails to include any inquiry into other personal, business and professional connections with interested parties. These connections, too, can be significant in evaluating whether the Proposed Professional has any disqualifying current or potential bias, as Rule 2014 and PRRADA require.

For these many reasons, the protocol that McKinsey used is deeply flawed. A serial violator of disclosure rules, McKinsey morphs a clear and simple rule—disclose all connections—into an impenetrably complex set of procedures that are internally inconsistent and incomprehensible to both professionals and the public. The protocol reads not as a manual for clarity, but as an insider's attempt to retrofit the law to its current practices. It is an insult to this Court's authority and responsibility under PRRADA.

McKinsey's disclosures of its connections are not detailed and explicit enough for the Court and the other parties to "gauge whether [McKinsey] is not disinterested or holds an adverse interest." *In re Midway Indus. Contractors, Inc.*, 272 B.R. 651, 662 (N.D. Ill. 2001). Even McKinsey's "arguable conflict[s] must be disclosed if only to be explained away." *Id*.

McKinsey belittled its "responsibility to leave no reasonable stone unturned" when investigating and disclosing its connections under Rule 2014. *In re Martin*, 817 F.2d 175, 182 (1st Cir. 1987). It ignored its mandate that "close or debatable issue ought to be resolved in favor of disclosure." *In re Miners Oil Co.*, 502 B.R. 285, 302 (Bankr. W.D. Va. 2013) (quotation marks and citation omitted).

McKinsey has, once again, perpetrated play a game of "cat and mouse" where it "provides only enough disclosure to whet the appetite of the UST, the court or other parties in interest, and the burden shifts to those entities to make inquiry in an effort to expand the disclosure." *In re Matco Elec. Grp, Inc.*, 383 B.R. 848, 853 (Bankr. N.D.N.Y. 2008).[92]

The Court must be able to rely on McKinsey to *self-report* all of its connections and its conflicts because the Court has "neither the resources nor the time to investigate the veracity of

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[90] *Id.*, at Exhibit B–2 attached to the protocol ("Form of Questionnaire").

[91] *Id.*, at 13, ¶ 7.c.

[92] *See also In re Filene's Basement, Inc*., 239 B.R. 850, 856 (Bankr. D. Mass. 1999) ("[C]oy or incomplete disclosures which leave the court to ferret out pertinent information from other sources are not sufficient.") (quoting *In re Saturley*, 131 B.R. 509, 517 (Bankr. D. Me. 1991).

the information submitted . . . and to root out the existence of undisclosed conflicts of interest." *Kravit, Gass & Weber, S.C. v. Michel* (*In re Crivello*), 134 F.3d 831, 839 (7th Cir. 1998).[93]

McKiney has arrogantly and falsely presented its protocol to this Court as if its use of the protocol were widely accepted. *It is not.* No court has approved either the McKinsey protocol or a McKinsey disclosure declaration that was based on it.

In the *Westmoreland Coal* case,[94] Judge Jones made it clear that he would not approve McKinsey's protocol. In a hearing on April 16, 2019, there was this brief exchange with Mar-Bow's counsel concerning McKinsey's protocol:

> MR. PETRELLA: I guess the initial response to Ms. Gay is: Do they intend to seek the Court's approval of the protocol before they file their disclosures?
>
> THE COURT: I don't know and let me be very clear, **I don't intend on approving them**. [95]

Shortly after that, the Court stated regarding the protocol:

> THE COURT: So am I going to be curious to read it? Absolutely.
>
> **Am I going to approve it? Absolutely not.**
>
> **You know, the standard is what the standard is.** I'm assuming that the protocol will simply be a mechanism, if you will, on how compliance is hoped to be achieved.

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[93] *See also see also In re Granite Partners, L.P.*, 219 B.R. 22, 35 (Bankr. S.D.N.Y. 1998) (the court should not have to "rummage through files or conduct independent fact finding investigations" to determine whether a professional should be disqualified); *In re Hutch Holdings, Inc.*, 532 B.R. 866, 880 (Bankr. S.D. Ga. 2015); *In re EWC, Inc.*, 138 B.R. 276, 280 (Bankr. W.D. Okla. 1992) (courts have no obligation to "seek out conflicts of interest not disclosed" by debtors and professionals); *In re BH & P, Inc.*, 119 B.R. 35, 44 (Bankr. D.N.J. 1990) ("It is not ... the obligation of the bankruptcy court to search the record for possible conflicts of interest."); *Quarles and Brady LLP v. U.S. Trustee* (*In re Jennings*), 199 F. App'x 845, 848 (11th Cir. 2006) ("Bankruptcy courts are not obligated to hunt around and ferret through thousands of pages in search of the basic disclosures required by Rule 2014."); *In re Marine Outlet, Inc.*, 135 B.R. 154, 156 (Bankr. M.D. Fla. 1991) ("There is no duty placed on the United States Trustee or on creditors to search the record for the existence, vel non, of a conflict of interest of a professional sought to be employed. On the contrary, there is a definite affirmative duty placed on a professional to disclose his or her connection with parties whose interest is or may be antagonistic or opposite to the interest of the general estate[.]").

[94] *In re Westmoreland Coal Co.*, (Bankr. S.D. Tex., No. 18-35672), filed Oct. 9, 2018.

[95] *Westmoreland Coal*, Hearing Transcript, April 16, 2019, 41:12-16 (emphasis added).

> So I'm going to read it. I'm going to go through it. I may have comments about it. I don't know what I'm going to do with it. I haven't seen it.
>
> **But in terms of whether or not that changes the required standard under the applicable rules, it does not.** [96]

Subsequently, McKinsey withdrew its fee application before the court could determine the issue of whether McKinsey's disclosure declaration, prepared using the protocol, complied with Rule 2014.

Beyond that, McKinsey has used the protocol to develop its disclosure declaration in only three other cases: *In re PG&E Corp.*;[97] *In re LATAM Airlines Group S.A.*;[98] and *In re Valaris PLC.*[99] However, McKinsey sought employment in these cases as an "ordinary course professional" under Section 363 of the Bankruptcy Code, which does not require either compliance with Rule 2014 or court approval of employment under Section 327. Accordingly, although McKinsey went through the motions of preparing and submitting a disclosure declaration in each case using its protocol, these declarations were never subject to court review or approval.

The requirement for full disclosure of connections under Rule 2014 "goes to the heart of the integrity of the administration of the bankruptcy estate." *United States v. Gellene*, 182 F.3d 578, 588 (7th Cir. 1999).

McKinsey's disclosure declaration obstructs the Court's "fundamental responsibility to monitor the integrity of the proceedings before it." *In re Martin*, 817 F.2d 175, 180 (1st Cir. 1987).[100]

The court in *In re Watson*, 94 B.R. 111, 117 (Bankr. S.D. Ohio 1988), concisely explained: **"The courts are absolutely uniform as to one command: the bankruptcy court must—no matter how unpleasant a task it may be—ensure the integrity of the bankruptcy process. The interests of maintaining public confidence in the bankruptcy system must prevail."**

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[96] *Id*., at 42:8-18 (emphasis added).

[97] *In re PG&E Corp.*, (Bankr. N.D. Cal., No. 18-35672), filed Jan. 29, 2019.

[98] *In re LATAM Airlines Group S.A.*, (Bankr. S.D.N.Y., No. 20-11254), filed May 26, 2020.

[99] *In re Valaris PLC*, (Bankr. S.D. Tex., No. 20-34114), filed Aug. 19, 2020.

[100] *See also In re Sundance Self Storage-El Dorado LP*, 482 B.R. 613, 625 (Bankr. E.D. Cal. 2012) (observing that Rule 2014 is designed to ensure public confidence in the integrity of the bankruptcy process); *In re Michigan General Corp*., 78 B.R. 479, 484 (Bankr. N.D. Tex. 1987); COLLIER ON BANKRUPTCY, § 327.03 at 327–20 (15th ed. 1988) ("As a general principle, professional persons employed by the [debtor in possession] should be free of any conflicting interest which might in the view of the trustee or the bankruptcy court impair the high degree of impartiality and detached judgment expected of them during the administration of a case.").

To remedy the threat that McKinsey's inadequate disclosure declaration creates to the integrity of the PROMESA process and to the public's confidence in that process, PRRADA mandates that McKinsey's fees should be denied.

This letter outlines the primary reasons that the Program should object to McKinsey's fees and Court should deny those fees. Again, I urge the Program to vigorously pursue an objection, and, if necessary, to suggest to the Court that it instruct the Fee examiner to fully investigate whether Section 2(e) of PRRADA, McKinsey fees should be denied. The integrity of the Court and its process in the PROMESA case depends on it, as does the public's confidence in that process.

In addition, for the reasons stated in Part I.A. above, I also request and urge the United States Trustee Program to act to obtain court orders:

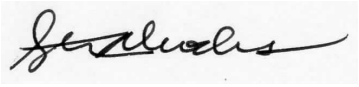
(1) To sanction McKinsey for its breach of fiduciary duties in selling its Puerto Rico bonds secretly and without Court authorization and instruction;

(2) To investigate and report to the Court, at McKinsey's expense, the profits that McKinsey and the MIO have realized form their investments in Puerto Rico bond debt and in interested parties; and

(3) To require McKinsey to disgorge all such profits, to be distributed as the Court determines.

Thank you for your consideration.

Sincerely,



Steven Rhodes

APPENDIX

The Luskin Report Confirms McKinsey's Investment Interests in Puerto Rico Bond Debt

I. The Luskin Report Found That the MIO Held Adverse Investment Interests in the Puerto Rico Case.

The Luskin Report[1] states:

> MIO has held at least five direct or indirect investments in Puerto Rico public debt during the course of McKinsey's engagement by the Oversight Board. It is clear that at all relevant times, MIO's portfolio managers and CIO knew that MIO was invested directly and indirectly in Puerto Rico public debt.[2]
>
> *.*.*
>
> . . . MIO did hold a direct investment in Puerto Rico public debt that it controlled while McKinsey was engaged by the Oversight Board and that, as reported in the press, MIO has held or holds investments in Puerto Rico public debt through third-party funds and separately managed accounts over which MIO exercises no investment discretion. These investments could be perceived as a conflict.[3]
>
> *.*.*
>
> MIO also held a direct investment in COFINA bonds through a Non-Investable Compass Fund. In 2014, MIO purchased $58,345,000 par value of COFINA bonds at a steep discount.[4]

The Luskin Report also identified specific MIO indirect investments in Puerto Rico bond debt exceeding $9 million.[5] However, the Report further revealed that the "MIO did not provide us with a list of Third-Party Managers." As a result, the data in the Report about the MIO's indirect investments is incomplete. Importantly, the Report adds this admission: "Both McKinsey and

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[1] I*n re the Commonwealth of Puerto Rico*, (D.P.R. No. 17-BK-03293), Final Investigative Report – McKinsey & Company, Inc., Prepared for The Financial Oversight & Management Board for Puerto Rico, by Luskin, Stern & Eisler LLP (filed Feb. 18, 2019), Dkt. 5154, Ex. A. In the McKinsey Declaration, the declarant, Dimitry Krivin, calls this report the "Special Counsel Report." In this Appendix, it is referred to as "the Luskin Report" or "the Report."

[2] Luskin Report, at p. 66.

[3] *Id*., at pp. 2-3.

[4] *Id*., at p. 72.

[5] *Id*., at pp. 70-72.

MIO acknowledged that it was possible that there may be additional holdings through Third-Party Funds[.]"[6]

The fact is that to this day, the MIO may still hold investment interests in Puerto Rico bond debt.

Not surprisingly, McKinsey's disclosure declaration does not disclose the amounts of any MIO investments whatsoever.

Here are the key takeaways from the Luskin Report:

- **On the issue of whether McKinsey held an adverse investment interest requiring the denial of its fees under PRRADA and *Woods*, the Luskin Report agrees that McKinsey did hold an adverse investment in connection with the case.**

- **Everything else in the Luskin Report is legally irrelevant under PRRADA and *Woods*.**

PRRADA mandates that the focus must be on whether the professional seeking fees "holds an adverse interest in connection with the case."[7] Nothing else matters.

II. The Luskin Report Does Not Exonerate McKinsey

McKinsey asserts that the Luskin Report exonerates it of any wrongdoing.[8] It does not.

The Luskin Report parrots McKinsey's oft-repeated but oft-debunked claim that there was complete operational separation between the MIO and McKinsey. The Report also asserts that that there was no evidence either that information was shared between the MIO and McKinsey, that the McKinsey consultants working for the Board knew about the MIO's millions of dollars of investments, that these McKinsey consultants altered their behavior because of these investments, that the MIO had access to confidential information, or that the MIO altered its investment strategy because of it.[9]

In other words, according to the Luskin Report, no evidence could be found that McKinsey violated its fiduciary duties or that the MIO committed the crime of insider trading.

The Luskin Report does not exonerate McKinsey for these reasons:

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[6] *Id*., at p. 72.

[7] PRRADA, § 2(e)(2)(B).

[8] https://www.mckinsey.com/about-us/media/mckinsey-statement-on-independent-third-party-report-on-separation-of-mio-and-mckinsey

[9] *See, e.g.*, Luskin Report, at p. 2.

(a) The conclusion in the Luskin Report that there was no evidence of wrongdoing by McKinsey is legally irrelevant under PRRADA and *Woods*.

(b) The Luskin Report did not analyze the risk of wrongdoing by McKinsey and the MIO as required by *Woods.*

(c) The conclusion in the Luskin Report that there was no evidence of wrongdoing lacks credibility because it is based *entirely* on self-serving hearsay statements from unnamed McKinsey and MIO partners and employees who were not under oath.

(d) The finding in the Luskin Report that the Board has been pleased with McKinsey's work is legally irrelevant under PRRADA and *Woods*.

(e) McKinsey's sale of its Puerto Rico bonds during the case is legally irrelevant under PRRADA and *Woods*.

A. The Conclusion in the Luskin Report That There Was No Evidence of Wrongdoing by McKinsey Is Legally Irrelevant Under PRRADA and *Woods*

Those findings might be relevant on the issue of whether McKinsey and the MIO should be indicted, convicted, and sentenced to pay fines of $25 million each for violating the federal criminal securities laws. But on the issue before the Court - whether McKinsey's fees should be allowed under PRRADA and *Woods* - none of them are legally relevant.

As noted above, PRRADA§ 2(e)(2)(B) explicitly allows the court to deny a professional's fees when the professional "holds an adverse interest in connection with the case."

Woods explicitly held that a conflicted professional's compensation must be denied *even if no fraud or unfairness is proven*:[10]

> **It is no answer to say that fraud or unfairness were not shown to have resulted.** Cf. Jackson v. Smith, 254 U.S. 586, 589, 41 S.Ct. 200, 201, 65 L.Ed. 418. The principle enunciated by Chief Justice Taft in a case involving a contract to split fees in violation of the bankruptcy rules, is apposite here: 'What is struck at in the refusal to enforce contracts of this kind is not only actual evil results but their tendency to evil in other cases.' Weil v. Neary, 278 U.S. 160, 173, 49 S.Ct. 144, 149, 73 L.Ed. 243. **Furthermore, the incidence of a particular conflict of interest can seldom be measured with any degree of certainty.** The bankruptcy court need not speculate as to whether the result of the conflict was to delay action where speed was essential, to close the record of past transactions where publicity and investigation were needed, to compromise claims by inattention where vigilant assertion was necessary, or otherwise to dilute the undivided loyalty owed to those

[10] 312 U.S. at 268-69 (emphasis added).

> whom the claimant purported to represent. **Where an actual conflict of interest exists, no more need be shown in this type of case to support a denial of compensation.**

Under *Woods*, when a professional holds an investment interest such as McKinsey admits here (and that the SEC and the Luskin Report itself found), **no proof of wrongdoing is required**, for three distinct reasons. First, wrongdoing can seldom be established "with any degree of certainty."[11] Second, speculation about the prejudicial consequences of the conflict is unnecessary and unproductive. And third, fees must be denied in these circumstances just as much to prevent the risk of wrongdoing in future cases as to punish actual wrongdoing in the present case.

Woods holds that the issue is whether the professional's conduct created any risk of wrongdoing, not whether it committed any actual wrongdoing. In derogation of *Woods*, the Luskin Report focused entirely on whether McKinsey and the MIO committed any actual wrongdoing and ignored whether their conduct created any risk of wrongdoing. That was a fundamental mistake that undermines the credibility of the Report and its usefulness in determining whether McKinsey's fees should be allowed.

For these reasons, it is of no consequence that the Luskin Report found no evidence of crime, fraud or other wrongdoing by McKinsey or the MIO. It is legally irrelevant.

B. The Luskin Report Did Not Analyze the Risk of Wrongdoing by McKinsey and the MIO as Required by *Woods*

The Luskin Report did not analyze the risk of wrongdoing by McKinsey and the MIO as required by *Woods* likely because its authors lacked the expertise to perform that kind of analysis. It is an analysis that requires expertise – expertise in investigating securities fraud (including insider trading) and in identifying and investigating the red flags that create a "real and significant" risk that Material Non-Public Information might have been misused. This is the expertise of those on the staff of the SEC Division of Enforcement who did investigate the MIO and whose expertise cannot be questioned. But nothing in the Report suggests that its authors have that expertise or that they consulted with any such experts. The absence of expertise to support the conclusions in the Luskin Report about the absence of evidence of wrongdoing severely undermines the credibility of those conclusions.

This lack of expertise comes into full relief at least twice in the Report. In its Introduction, the Report states:[12]

> As the [press] articles make clear, however, there is enough publicly-available information to enable a determined investigator to uncover, for example, that three of MIO's investment funds filed proofs of claim in the Title III proceedings or that MIO might have

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[11] 312 U.S. at 268 (emphasis added).

[12] *Id*., at pp. 4-5.

> an indirect investment in Puerto Rico public debt through a third-party asset manager that has been active in the Title III proceedings.

Later, the Report finds: "From December 8, 2006, through June 9, 2017, Jon Garcia, who is the president of McKinsey RTS, served on the Investments Committee of the MIO Board. . . . McKinsey RTS employees have provided services to the Oversight Board."[13]

But in both of these circumstances, the Report analyzed whether there was any actual wrongdoing. When it found none, it stopped there. The Report did not analyze whether either of these circumstances created a *risk* of wrongdoing. Investigators with expertise at the SEC knew the importance of that issue and did analyze it. The result was an $18,000,000 sanction, a censure and a cease and desist order.

Yet the Luskin Report never analyzed whether these circumstances created a "real and substantial" risk of information sharing that would be totally unacceptable in an insolvency proceeding.

C. The Conclusion in the Luskin Report That There Was No Evidence of Wrongdoing Lacks Credibility Because It Is Based *Entirely* on Self-Serving Hearsay

The conclusion in the Luskin Report that there was no evidence of wrongdoing must be rejected for another reason. It is based *entirely* on self-serving hearsay statements in interviews with unnamed McKinsey and MIO partners and employees, who, apparently, were not under oath. Here are some examples of this:

- "The MIO Board is generally not provided any information related to Direct Investments made by MIO, nor is the MIO Board provided a specific rationale underlying individual direct investment decisions."[14] **The footnote attached to this text cites as its evidence: "MIO Interviews, Dec. 7, 2018, Feb. 1, 2019."**[15]

- "The McKinsey and MIO personnel we interviewed confirmed their participation in the training programs, their periodic certifications, and their compliance with the policies and procedures."[16] **The only evidence cited in support of this finding is: "McKinsey Interviews, Nov. 20, 2018, Dec. 12, 2018, Feb. 1, 2019; MIO Interviews, Dec. 7, 2018, Jan. 11, 2019, Feb. 1, 2019."**[17]

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[13] Luskin Report, at p. 53, n. 140.

[14] Luskin Report, at p. 53.

[15] *Id*., at p. 53, n. 141.

[16] *Id*., at p. 66.

[17] *Id*., at p. 66, n. 178.

- "MIO made the decision to dispose of the investment [in COFINA bonds] independently and without information received from the consulting side of McKinsey.[18] **The only evidence cited in support of this finding is: "MIO Interviews, Dec. 7, 2018, Jan. 11, 2019.**

- MIO has represented to LS&E that it does not currently have any other Direct Investments in Puerto Rico public debt. **The Report cites no evidence in support of this and does not identify how this MIO representation was made.**

Another example of this relates to conclusions in the Report that are based on hearsay statements from unnamed witnesses that are not only self-serving and not provided under oath, but also from a deeply conflicted witness. In minimizing McKinsey's role in the mediation and settlement negotiations concerning the COFINA bond debt,[19] the Report cites mostly McKinsey interviews and one Proskauer interview.[20] The Proskauer firm is outside counsel for the Board but has also served as *McKinsey's* counsel in its litigation with the United States Trustee Program. Mar-Bow and Jay Alix for the past six years and is still McKinsey's counsel in *Alix v. McKinsey*.[21] Because the Report cites and relies on statements from a Proskauer attorney, this conflict in that firm's client representations casts even further doubt on the credibility of the conclusions in the Report.

The hearsay statements from McKinsey and MIO partners and employees proves only that they were all smart enough not to incriminate themselves on numerous federal crimes. Those statements are hardly proof that no wrongdoing occurred.

Here is what we do know: As the SEC found, McKinsey and the MIO created a "real and significant" risk that they would misuse confidential information in connection with the Puerto Rico case. Under *Woods*, that is all that matters.

D. The Finding in the Luskin Report That the Board Has Been Pleased with McKinsey's Work Is Legally Irrelevant Under PRRADA and *Woods*

The Luskin Report states that the Board has been pleased with its work.[22] As a result (and perhaps because the Board's outside counsel is also McKinsey's outside counsel), the Board is unlikely to object to McKinsey's fees. Undoubtedly, when applying for approval of its fees and when dealing with objections to its fee application, McKinsey will boast that its client, the Board, has not objected to its fees and was pleased with its work.

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[18] *Id*., at p. 72.

[19] *Id*., at pp. 72-77.

[20] *Id*., at pp.76-77, nn. 203-206.

[21] Some of this litigation is described in the Luskin Report. *See* pp. 8-14.

[22] *Id*., at p. 38.

But under *Woods*, the Board's support for McKinsey's fee application is irrelevant:[23]

> A fiduciary who represents security holders in a reorganization may not perfect his claim to compensation by insisting that although he had conflicting interests, he served his several masters equally well or that his primary loyalty was not weakened by the pull of his secondary one.

And the Supreme Court concisely explained why the Board's support for McKinsey's fee application is irrelevant:[24]

> Only strict adherence to these equitable principles can keep the standard of conduct for fiduciaries 'at a level higher than that trodden by the crowd.' See Mr. Justice Cardozo in Meinhard v. Salmon, 249 N.Y. 458, 464, 164 N.E. 545, 546, 62 A.L.R. 1.

The Supreme Court's teaching here is that unlike in the ordinary business world, a professional in an insolvency process has obligations that are much broader than those to the professional's client. There are also obligations to the interested parties and to the court and its process. As a result, the fact that the professional's client is pleased does not end the inquiry. If a professional's conduct in this case created a risk of harm to those other parties or to the court's process, as McKinsey's conduct did in this case, that conduct must be addressed firmly in order to eliminate similar risks of harm in future cases, whether by the same professional or other professionals.

E. McKinsey's Sale of Its Puerto Rico Bonds During the Case Is Legally Irrelevant Under PRRADA and *Woods*

Regarding, MIO's sale of its COFINA bonds, the Luskin Report disclosed:[25]

> In 2014, MIO purchased $58,345,000 par value of COFINA bonds at a steep discount. MIO disposed of $8,345,000 par value in three transactions in the first quarter of 2017, and disposed of the remaining $50,000,000 par value in two transactions in April 2018. The Non-Investable Compass Fund realized a total profit of approximately $765,000 on this investment.

McKinsey's fees should nevertheless be denied. As noted above, *Woods* made it clear that because the consequences to other interested parties resulting from a professional's actual conflict of interest can never be accurately identified or measured, no proof of harm is required to deny fees.

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[23] 312 U.S. at 269.

[24] *Id*.

[25] *Id*., at p. 72. The McKinsey Declaration quotes the Luskin Report on this point but makes it clear that Krivin obtained this information from the Luskin Report, *not from the MIO*. McKinsey Declaration, at ¶ 37, p. 17.

See also, *In re eToys, Inc.*, 331 B.R. 176, 193 (Bankr. D. Del. 2005) ("Harm to the estate is not necessary to a decision to order disgorgement of fees where there is a conflict of interest."); *In re Hammer*, No. BAP WW- 06-1373-MODJ, 2007 WL 7540944, at *8 (B.A.P. 9th Cir. Oct. 11, 2007); *In re Balco Equities Ltd., Inc.*, 345 B.R. 87, 115 (Bankr. S.D.N.Y. 2006).

Here, the consequences to other parties resulting from McKinsey's actual conflict of interest may well have lingered after it "remedied" that conflict by selling the bonds. But, as noted, *Woods* teaches that those consequences can never be known or measured. Neither the Court, the interested parties nor the public will ever know whether McKinsey's investment in the Puerto Rico bonds influenced either its advice to the Board or even the outcome of the case.

What is certain, however, is that the damage that McKinsey's actual conflict of interest caused to the Court's process and to the confidence of the parties and the public in that process can never be repaired. What is further certain is that because of McKinsey's status as a creditor in the case, *Woods* compels the denial of McKinsey's fees.

EXHIBIT LIST

1. Third-party investment managers that invested in Puerto Rico bond debt for the MIO

2. *In the Matter of MIO Partners, Inc.* (SEC No. 3-20656. Nov. 19, 2021), Order Instituting Administrative and Cease-and-Desist Proceedings, Pursuant to Sections 203(E) and 203(K) of the Investment Advisers Act of 1940, Making Findings, and Imposing Remedial Sanctions and a Cease-And-Desist Order

3. Complaint, *Government of Puerto Rico v. McKinsey*, Case No. SJ2021VC00711

4. Consent Judgment, *Government of Puerto Rico v. McKinsey*, Case No. SJ2021VC00711

5. The Firm and the FDA: McKinsey & Company's Conflicts of Interest at the Heart of the Opioid Epidemic, Interim Majority Staff Report (April 13, 2022)

EXHIBIT 1

MIO Third Party Investment Managers
Complied from McKinsey's Disclosure Declaration

1. Aeolus
2. Alliance Capital Management
3. AllianceBernstein
4. Alternative Strategy Advisors
5. American Enterprise Investment Services Inc.
6. Angelo Gordon & Co.
7. Apollo Global Management, LLC
8. Appaloosa Management
9. Arch Mortgage Insurance Company
10. Aristeia Capital, LLC
11. Aristeia Capital, LLC
12. Aristeia Horizons, L.P.
13. Aristeia International Limited
14. Autonomy Americas LLC
15. Autonomy Capital (Jersey) LP
16. AvePoint, Inc.
17. AXA Equitable Life Insurance Company
18. AXA Rosenberg Investment Management
19. Barclays Global Investors
20. BB&T Securities, LLC
21. Blackrock Corporate Fund
22. Blackrock Corporate High Yield Fund
23. Blackrock Debt Strategies Fund
24. BlackRock Investments
25. BlackRock Russell 3000 Index Fund
26. Blackrock TIPS
27. Blackstone/GSO Strategic Credit Fund
28. Blue Mountain Capital Markets
29. BNP Paribas Asset Management USA
30. Brandywine Global Investment Management
31. BRV Capital Management
32. Canyon Capital Advisors
33. Capula Investment Management
34. Capula Management Limited
35. Cogent Energy
36. Cogent Energy Investment Management
37. Community Cornerstones, Inc.
38. Compass Highfields I Fund
39. Compass Highfields II Fund
40. Elliot International Limited
41. Elliot International LP
42. FCO Advisors LP
43. FCO Select Credit
44. FCO Special Opportunities (Al) LP
45. FCO Special Opportunities (El) LLC
46. Fidelity Investments
47. First Hospital Panamericano, Inc.
48. Fischer Francis Trees & Watts

49. Franklin California Tax-Free Income Fund
50. Franklin Resources Inc
51. Franklin Street Associates
52. Franklin Templeton Investments
53. Genesis Capital
54. Global Multi-Sector Credit Portfolio (Lux)
55. GMO Credit Opportunities Fund, L.P.
56. GMO Funds Public Limited Company - GMO Global Real Return (UCITS) Fund
57. GMO Global Real Return (UCITS) Fund, a sub-fund of GMO Funds plc
58. GMO Implementation Fund, a series of GMO Trust GMO Credit Opportunities Fund, L.P.
59. GMO Trust - GMO Implementation Fund
60. Goldman Sachs & Co. LLC
61. Grantham, Mayo, Van Otterloo & Co.
62. Highfields Capital
63. Highfields Capital I L.P.
64. Highfields Capital II LP
65. Highfields Capital III L.P.
66. Highfields Capital Management
67. Highfields I Fund
68. Highfields II Fund
69. Horizon Capital
70. Impilo
71. Integral ILS
72. Intellectual Ventures Management
73. Invention Development Fund I
74. Key Group Holdings
75. Loomis Sayles Funds I - Loomis Sayles Institutional High Income Fund
76. Loomis Sayles Funds II - Loomis Sayles Strategic Income Fund (MutualFund:NECZ.X)
77. Markel Europe
78. McKinsey & Company, Inc.
79. Mellon Capital Management Corporation
80. Metropolitan West Asset Management
81. Monarch Alternative Capital LP
82. Moore Capital Advisors LLC
83. Moore Capital Management, LP
84. Morgan Grenfell
85. Morgan Grenfell Municipal Bond Fund
86. Murray Capital Management
87. New Stream Secured Capital Fund
88. Northern Trust Company/OCH-ZJFF Capital Management
89. Nuveen Maryland Quality Municipal Income Fund, a Massachusetts Business Trust
90. Och-Ziff Capital Management Group
91. Oppenheimer & Co.
92. Ospraie Group
93. Ospraie Management
94. OZ Credit Opportunities Master Fund, Ltd.
95. OZ Domestic Partners
96. OZ Management II, LP
97. OZ Management LP
98. OZ Master Fund, Ltd.

99. OZSCII, LP
100. Pandora Select Fund
101. Pandora Select Partners LP
102. Pandora Select Partners, LP as Transferee of Syncora Guarantee Inc.
103. Perficient
104. Permira Advisers
105. QS Investors
106. QS Investors (SSGA)
107. Sage Partners Limited
108. Sanford C. Bernstein & Co., LLC
109. Sculptor Capital LP
110. Sculptor Capital Management, Inc.
111. Sindicatum Carbon & Energy Management
112. SPDR Series Trust - SPDR Nuveen S&P High Yield Municipal Bond ETF, A
113. Massachusetts Business Trust
114. State Street Global Advisors
115. State Street Russell 3000
116. Strategic Value Global Opportunities Fund
117. Symphony Asset Management
118. The Ospraie Fund LTD
119. TradeWind Energy, Inc.
120. Tradewinds Energy Barceloneta, LLC
121. UHS of Puerto Rico, Inc.
122. USAA Investment Management Company
123. Voya Institutional Trust Company
124. Voya Prime Rate US
125. VR Advisory Services
126. VR Advisory Services, LTD.
127. VR Global Partners, L.P.
128. White Box Advisors LLC
129. Whitebox Asymmetric Partners, LP
130. Whitebox Credit Arbitrage Fund
131. Whitebox GT Fund, LP
132. Whitebox GT Fund, LP as Transferee of Syncora Guarantee Inc.
133. Whitebox Institutional Partners, L.P.
134. Whitebox Multi-Strategy Fund
135. Whitebox Multi-Strategy Partners, L.P.
136. Whitebox Pandora Select Fund
137. Whitebox Term Credit Fund I L.P
138. Winston Partners Private Equity

EXHIBIT 2

UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

INVESTMENT ADVISERS ACT OF 1940
Release No. 5912 / November 19, 2021

ADMINISTRATIVE PROCEEDING
File No. 3-20656

In the Matter of **MIO PARTNERS, INC.** **Respondent.**	**ORDER INSTITUTING ADMINISTRATIVE AND CEASE-AND-DESIST PROCEEDINGS, PURSUANT TO SECTIONS 203(e) AND 203(k) OF THE INVESTMENT ADVISERS ACT OF 1940, MAKING FINDINGS, AND IMPOSING REMEDIAL SANCTIONS AND A CEASE-AND-DESIST ORDER**

I.

The Securities and Exchange Commission ("Commission") deems it appropriate and in the public interest that public administrative and cease-and-desist proceedings be, and hereby are, instituted pursuant to Sections 203(e) and 203(k) of the Investment Advisers Act of 1940 ("Advisers Act") against MIO Partners, Inc. ("MIO" or "Respondent").

II.

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the "Offer") which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission's jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Administrative and Cease-And-Desist Proceedings, Pursuant to Sections 203(e) and 203(k) of the Investment Advisers Act of 1940, Making Findings, and Imposing Remedial Sanctions and a Cease-and-Desist Order ("Order"), as set forth below.

III.

On the basis of this Order and Respondent's Offer, the Commission finds[1] that:

Summary

1. These proceedings arise out of the failures of MIO, a registered investment adviser, from at least 2015 through 2020 (the "Relevant Period"), to establish, maintain, and enforce written policies and procedures reasonably designed, taking into consideration the nature of its business, to prevent the misuse of material non-public information ("MNPI").

2. MIO, a subsidiary of management consulting firm McKinsey & Company ("McKinsey"), provides investment options exclusively to current and former McKinsey partners and employees.

3. Active McKinsey partners who were members of the Investments Committee of MIO's Board of Directors (the "Board") (i) obtained material non-public information concerning issuers as a result of their consulting work on behalf of clients ("McKinsey Client MNPI"), and (ii) had access to material non-public information concerning the investments made by MIO funds as a result of their participation on the MIO Investments Committee ("MIO MNPI").

4. Allowing active McKinsey partners, individuals who had access to MNPI about issuers in which MIO funds were invested, to oversee and monitor MIO's investment decisions presented an ongoing risk of misuse of MNPI. MIO did not have policies and procedures reasonably designed to address the risks associated with its organizational structure.

Respondent

5. MIO, also known as McKinsey Investment Office, is a Delaware corporation headquartered in New York, New York. MIO is a subsidiary of McKinsey and has been registered with the Commission as an investment adviser since 1992. MIO reported total regulatory assets under management of $31 billion as of December 31, 2020.

Other Relevant Entities

6. McKinsey is a global management consulting firm headquartered in New York, New York. McKinsey provides consulting and other services to public companies and other entities that issue securities, as well as broker-dealers, investment advisers, and other registrants and self-regulatory organizations.

7. McKinsey Recovery & Transformation Services U.S., LLC. ("McKinsey RTS") is McKinsey's wholly-owned turnaround advisory and crisis management unit.

[1] The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

Background

A. The Business, Operational Structure, and Oversight of MIO

8. MIO provides investment options exclusively to current and former partners and employees of McKinsey. During the Relevant Period, MIO invested approximately 90% of MIO client assets indirectly, through third-party managers who exercise their own investment discretion (i.e., a so-called "fund-of-funds" strategy), and the remaining approximately 10% directly, by purchasing and selling securities.

9. For MIO's direct investments, MIO had investment discretion (i.e., MIO made the decision regarding whether to buy or sell each security subject to a direct trading policy which prohibited, except in specified circumstances, direct investment in the debt or equity of corporations) and had full knowledge of all securities held, including the number of shares of each security.

10. For MIO's indirect investments via third-party managers, a little less than half were invested in separately managed accounts ("SMAs"), which were accounts within a MIO owned and operated special purpose fund. In the SMA structure, MIO contracted with a third-party manager to manage the SMAs; however, because MIO maintained in its records information reflecting all of the securities held by the SMAs, as well as all transactions executed by the SMAs, MIO had full knowledge of all securities held by the SMAs, including the number of shares of each security. For the remaining third-party managed funds, MIO's investments were held in a third-party manager's fund. MIO did not typically possess information reflecting all securities holdings and transactions in these accounts, but MIO frequently had access to securities holdings by way of public filings and communications with the third-party manager, including investor updates.

11. During the Relevant Period, MIO's team of portfolio managers, led by MIO's Chief Investment Officer ("CIO"), maintained day-to-day responsibility over MIO's investments. MIO's CIO reported to the Board, which oversaw MIO's operations. Prior to September 2020, the Board primarily comprised active McKinsey partners.

12. MIO's Board Charter (the "Charter") set forth the Board's roles and responsibilities and outlined the mandates of various Board committees, including, for example, the Investments Committee. According to the Charter in place since November 2018, the Investments Committee shall, *inter alia*, "[o]versee and monitor investments to be made by each Fund including direct investments, commitments to managers, additions to or withdrawals from existing managers, or material changes in circumstances or arrangements with existing managers."

13. Prior to November 2017, the Charter further empowered the Investments Committee to formally ratify MIO investment decisions, meaning that the Investments Committee was authorized to approve investment decisions, which could pertain to both actual and planned allocations to third-party managers and direct investments.

14. Throughout the Relevant Period, MIO's investment decisions remained "subject to review and monitoring" by the Investments Committee.

15. Investments Committee members had a fiduciary duty to MIO's clients and, as such, were required to oversee and monitor MIO's investment decisions consistent with that fiduciary duty.

B. MIO's Access to MNPI

16. Throughout the Relevant Period, MIO had access to substantial MNPI.

17. Active McKinsey partners serving on the Investments Committee, including, through June 2017, the President of McKinsey RTS, possessed and had access to McKinsey Client MNPI by way of their various roles at McKinsey. As McKinsey consultants, Investments Committee members were routinely privy to MNPI relating to, for example, financial results, planned bankruptcy filings, mergers and acquisitions, product pipelines and funding efforts, and material changes in senior management.

18. Investments Committee members also possessed and had access to MIO MNPI as a result of their participation on the Board and its committees. For example, Investments Committee members were aware of MNPI regarding MIO's investment strategies, concentration limits, risk limits, and third-party manager allocations, and had access to MIO's holdings (both direct holdings and holdings in SMAs).

C. MIO Was Directly and Indirectly Invested in Issuers About Which Board Members Had Access to McKinsey Client MNPI

19. MIO directly and indirectly invested hundreds of millions of dollars in the securities of issuers about which Investments Committee members who were active McKinsey partners had access to substantial McKinsey Client MNPI.

20. For example, between October 2015 and June 2017, MIO's third-party managed funds, including certain of its SMAs, bought and sold securities of Alpha Natural Resources, Inc. ("ANR"), SunEdison, Inc. ("SunEdison"), and The Commonwealth of Puerto Rico ("Puerto Rico"). At the time of these transactions, certain Investments Committee members had access to MNPI concerning these issuers.

21. In February 2016, the Investments Committee reviewed and ratified a $70 million allocation change to a third-party fund manager that was heavily invested in ANR senior secured debt. At that time, and in November 2015, when the Investments Committee had preliminarily ratified the allocation, McKinsey RTS was providing restructuring advice to ANR and the President of McKinsey RTS was on the Investments Committee. By June 2016, MIO had increased its total investment in the third-party manager's funds to approximately $272 million and those funds, in turn, had obtained approximately $80 million of ANR's senior secured debt.

22. Between October 2015 and December 2016, MIO's SMAs also invested (via six third-party managers) in another client of McKinsey RTS, SunEdison, while an Investments Committee member led McKinsey RTS.

23. Finally, in January and February of 2017, MIO was directly invested in the municipal bonds of Puerto Rico at the same time McKinsey was providing restructuring advice to the Puerto Rico Financial Oversight & Management Board ("FOMB"), the entity charged with spearheading Puerto Rico's financial turnaround. During this time frame, the Investments Committee, which included active McKinsey partners with access to McKinsey Client MNPI, was empowered under the Investments Committee Charter to oversee MIO's direct investments, including MIO's sale of nearly $1 million worth of Puerto Rican bonds. Further, in addition to MIO's direct investments in Puerto Rico, through at least June 2017, MIO was also invested in Puerto Rico's debt via its SMAs and other third-party managed funds.

24. Considering the nature of MIO's business, including the Investments Committee's oversight of MIO's investment decisions, the risk of misuse of MNPI was real and significant.

D. McKinsey Provided Consulting Services to Clients About Which It Had Access to MIO MNPI

25. In numerous instances, McKinsey provided consulting services to clients in which MIO funds were invested and about which MIO MNPI was potentially relevant.

26. For example, McKinsey RTS had been retained in August 2015 as ANR's turnaround adviser, worked very closely with ANR management including by being embedded in part of its operations, and prepared a comprehensive business plan that formed the basis for the financial projections underpinning ANR's Chapter 11 plan that helped to establish the value of the securities that were exchanged for ANR's senior secured debt held by MIO. During the course of that consulting work, the President of McKinsey RTS sat on the Investments Committee and had access to MIO MNPI, including that MIO was invested with a third-party manager. The third-party manager had invested in ANR's senior secured debt. In this context, MIO's investments through the third-party manager in ANR's senior secured debt overlapped with McKinsey RTS's consulting work and, as such, there was a risk that McKinsey RTS could influence the reorganization plan in a way that favored MIO's investments.

27. Before confirming ANR's Chapter 11 plan, the Bankruptcy Court, which needed to rely on McKinsey RTS's testimony in order to confirm the plan, ordered McKinsey RTS to disclose MIO's connections to interested parties in the ANR bankruptcy case because of both the relationship between MIO and McKinsey RTS and the presence of McKinsey RTS's President on the MIO Board. In a Bankruptcy Court-ordered in camera submission filed on July 6, 2016, however, McKinsey RTS did not disclose MIO's connection to the third-party manager that was invested in ANR senior secured debt. After reviewing the in camera submission, the Bankruptcy Court confirmed the ANR Chapter 11 plan without disclosure in the bankruptcy proceedings of MIO's interest in ANR senior secured debt via the third-party manager. Pursuant to the confirmed plan, because of their priority, the holders of ANR's senior secured debt received 87.5% of the stock of ANR's successor under the plan, and all other investors and creditors received a de minimis distribution.

28. Subsequently, the United States Trustee reached settlements with McKinsey and McKinsey RTS regarding, among other things, the adequacy and completeness of their

disclosures of their connections to MIO in certain bankruptcy cases, *see* Alpha Natural Resources, Case No. 19-00302 (Bankr. E.D. Va.); SunEdison, Case No. 16-10992 (Bankr. S.D.N.Y); Westmoreland Coal Company, Case No. 18-35672 (Bankr. S.D. Tex.), and released claims in 11 other bankruptcy cases.

E. MIO's Policies and Procedures Were Not Reasonably Designed to Prevent the Misuse of MNPI

29. MIO's policies and procedures were not reasonably designed, taking into consideration the nature of its business, to prevent the misuse of McKinsey Client MNPI or MIO MNPI. MIO's written policies and procedures did not address the fact that McKinsey personnel on the Investments Committee brought MNPI obtained in their jobs as consultants to public issuers to their roles on the MIO Board. In addition, prior to September 2020, none of MIO's written policies or procedures (i) effectively sought to identify whether Investments Committee members may have MNPI that was relevant to their involvement in MIO's investment decisions, or (ii) set forth a recusal procedure reasonably designed to guard against the misuse of McKinsey Client and MIO MNPI.

30. The MIO Collaboration Policy (the "Collaboration Policy"), in effect since at least 2015, was MIO's chief policy governing information sharing between McKinsey and MIO personnel. The Collaboration Policy included a specific carve out for Board and Investments Committee members that situated them above the protective wall and did not prohibit access to MIO portfolio investments.

31. MIO's policies and procedures were likewise not reasonably designed to prevent the misuse of MIO MNPI. The Collaboration Policy did not prohibit Board and Investments Committee members from accessing MIO's investment information and did not contemplate the ways that MIO MNPI could be misused by Investments Committee members in the course of their consulting work for McKinsey clients.

Violations

32. As a result of the conduct described above, Respondent willfully[2] violated Section 204A of the Advisers Act. Section 204A requires investment advisers subject to Section 204 of the Advisers Act to establish, maintain, and enforce written policies and procedures reasonably designed, taking into consideration the nature of such investment adviser's business, to prevent the misuse of material, nonpublic information by such investment adviser or any person associated with such investment adviser in violation of the Advisers Act or the Securities Exchange Act of 1934 (the "Exchange Act") or the rules or regulations thereunder.

33. As a result of the conduct above, Respondent willfully violated Section 206(4) of the Advisers Act and Rule 206(4)-7 thereunder, which require registered investment advisers to

[2] "Willfully," for purposes of imposing relief under Section 203(e) of the Advisers Act "'means no more than that the person charged with the duty knows what he is doing.'" *Wonsover v. SEC*, 205 F.3d 408, 414 (D.C. Cir 2000) (quoting *Hughes v. SEC*, 174 F.2d 969, 977 (D.C. Cir. 1949)). There is no requirement that the actor "also be aware that he is violating one of the Rules or Acts." *Tager v. SEC*, 344 F.2d 5, 8 (2d Cir. 1965).

adopt and implement written policies and procedures reasonably designed to prevent violations of the Advisers Act and the rules thereunder.

IV.

In view of the foregoing, the Commission deems it appropriate and in the public interest to impose the sanctions agreed to in Respondent's Offer.

Accordingly, pursuant to Sections 203(e) and 203(k) of the Advisers Act, it is hereby ORDERED that:

A. Respondent cease and desist from committing or causing any violations and any future violations of Sections 204A and 206(4) of the Advisers Act and Rule 206(4)-7 promulgated thereunder.

B. Respondent is censured.

C. Respondent shall, within 10 days of the entry of this Order, pay a civil monetary penalty in the amount of $18,000,000 to the Securities and Exchange Commission for transfer to the general fund of the United States Treasury, subject to Exchange Act Section 21F(g)(3). If timely payment is not made, additional interest shall accrue pursuant to 31 U.S.C. §3717.

Payment must be made in one of the following ways:

(1) Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;
(2) Respondent may make direct payment from a bank account via Pay.gov through the SEC website at http://www.sec.gov/about/offices/ofm.htm; or
(3) Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center
Accounts Receivable Branch
HQ Bldg., Room 181, AMZ-341
6500 South MacArthur Boulevard
Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying MIO as a Respondent in these proceedings, and the file number of these proceedings; a copy of the cover letter and check or money order must be sent to Thomas P. Smith, Jr., Assistant Regional Director, Enforcement Division, Securities and Exchange Commission, 200 Vesey Street, Suite 400, New York, NY 10281.

D. Amounts ordered to be paid as civil money penalties pursuant to this Order shall be treated as penalties paid to the government for all purposes, including all tax purposes. To

preserve the deterrent effect of the civil penalty, MIO agrees that in any Related Investor Action, it shall not argue that it is entitled to, nor shall it benefit by, off set or reduction of any award of compensatory damages by the amount of any part of Respondent's payment of a civil penalty in this action ("Penalty Offset"). If the court in any Related Investor Action grants such a Penalty Offset, notify the Commission's counsel in this action and pay the amount of the Penalty Offset to the Securities and Exchange Commission. Such a payment shall not be deemed an additional civil penalty and shall not be deemed to change the amount of the civil penalty imposed in this proceeding. For the purposes of this paragraph, a "related Investor Action" means a private damages action brought against Respondent by or on behalf of one or more investors based on substantially the same facts as alleged in the Order instituted by the Commission in this proceeding.

By the Commission.

Vanessa A. Countryman
Secretary

EXHIBIT 3

THE GOVERNMENT OF PUERTO RICO
COURT OF FIRST INSTANCE
SUPERIOR COURT, SAN JUAN PART

THE GOVERNMENT OF PUERTO RICO Plaintiff, v. **MCKINSEY & COMPANY, INC., UNITED STATES** Defendants.	CASE NO. _____

COMPLAINT FOR PERMANENT INJUNCTION AND OTHER RELIEF

Comes now the Plaintiff, the Government of Puerto Rico, and brings this action against Defendant McKinsey and Company, Inc., United States ("McKinsey" or "Defendant") for violating the Puerto Rico Antitrust Act, Law No. 77 of June 25, 1964, and states as follows:

I. Parties

1. Plaintiff is the Government of Puerto Rico. The Government is charged with, among other things, enforcing and seeking redress for violations of Puerto Rico Antitrust Act.

2. The Attorney General is authorized to bring this action in his *parens patriae* capacity, as the Commonwealth of Puerto Rico has a quasi-sovereign interest in the health and well-being— physically and economically— of its citizens who have suffered because of McKinsey's conduct. The Commonwealth of Puerto Rico, as a legal entity, has suffered damages and losses as a direct and proximate result of McKinsey's conduct in violation of 10 L.P.R.A. § 259.

3. Defendant McKinsey is a privately owned entity headquartered in New York, N.Y. At all times relevant to this proceeding, McKinsey did business in the Commonwealth of Puerto Rico.

II. Jurisdiction and Venue

4. The Court has jurisdiction over the Defendant pursuant to 32A L.P.R.A. App'x. III R. 4.7 because McKinsey has transacted business within the state at all times relevant to this Complaint.

5. This Court has jurisdiction over the parties in this matter pursuant to 10 L.P.R.A. §269.

III. Factual Allegations

6. Beginning in the mid-1990s, opioid manufacturers pursued aggressive sales strategies to increase sales of their prescription opioids, a plan that resulted in a dramatic rise in opioid

prescriptions in the Commonwealth of Puerto Rico. The rise in opioid prescriptions caused an equally devastating rise in opioid abuse, dependence, addiction, and overdose deaths.

7. Prescription opioids continue to kill hundreds of people across the Commonwealth of Puerto Rico every year. Thousands more suffer from negative health consequences short of death and countless others have had their lives ruined by a friend or family member's addiction or death. Every community in the Commonwealth of Puerto Rico suffers from the opioid crisis of addiction and death.

8. McKinsey worked with entities involved in manufacturing and selling opioids and thereby contributed to the opioid crisis.

9. McKinsey is one of the world's largest consulting companies. Its partners work worldwide for corporations and governments across diverse industries. Its influence is vast because of its best-in-class reputation. McKinsey sells the notion that it can take whatever a company or government is doing and make them do it better.

10. The State brings this action against McKinsey for the consulting services it provided to opioid companies in connection with designing the companies' marketing plans and programs that helped cause and contributed to the opioid crisis. McKinsey sold its ideas to OxyContin maker Purdue Pharma, L.P. ("Purdue") for more than fifteen years, from 2004 to 2019, including before and after Purdue's 2007 guilty plea for felony misbranding.

11. McKinsey advised Purdue and other manufacturers to target prescribers who write the most prescriptions, for the most patients, and thereby make the most money for McKinsey's clients.

12. Early in their relationship, McKinsey advised Purdue that it could increase OxyContin sales through physician targeting and specific messaging to prescribers. These McKinsey strategies formed the pillars of Purdue's sales tactics for the next fifteen years.

13. In 2008, McKinsey worked with Purdue to develop its FDA mandated risk evaluation and mitigation strategy ("REMS"). McKinsey advised Purdue to "band together" with other opioid manufacturers toward a class REMS to "formulate arguments to defend against strict treatment by the FDA." Ultimately, the FDA adopted a class-wide REMS that resulted in high-dose OxyContin remaining subject to the same oversight as lower-dose opioids.

14. In 2009, Purdue hired McKinsey to increase "brand loyalty" to OxyContin. McKinsey recommended the best ways to ensure loyalty to the brand by targeting specific patients, including patients new to opioids, and developing targeted messaging for specific prescribers.

15. Purdue thereafter adopted McKinsey's proposed prescriber messaging and patient targeting advice and incorporated them into Purdue's marketing and sales strategies.

16. In 2013, McKinsey conducted another analysis of Oxycontin growth opportunities for Purdue, and laid out new plans to increase sales of OxyContin. Among the key components of McKinsey's plan adopted by Purdue were to:

a. focus sales calls on high-volume opioid prescribers, including those who wrote as many as 25 times as many OxyContin scripts as their lower volume counterparts;

b. remove sales representative discretion in target prescribers;

c. focus Purdue's marketing messaging to titrate to higher, more lucrative dosages;

d. significantly increase the number of sales visits to high-volume prescribers; and

e. create an "alternative model for how patients receive OxyContin," including direct distribution to patients and pharmacies, to help address the "product access" problem.

17. Purdue approved McKinsey's plan, and together with McKinsey, moved to implement the plan to "Turbocharg[e] Purdue's Sales Engine," under the name Evolve 2 Excellence ("E2E"). E2E significantly increased Purdue's opioid sales, in particular, for OxyContin.

18. McKinsey partners participated as part of an Executive Oversight Team and Project Management Office, reporting to Purdue's Executive, the Purdue board, and with the Sacklers, individually. McKinsey worked side by side with Purdue and helped Purdue plan and implement E2E, assisting with sales representative training, productivity, messaging, and call plans, IT systems, promotional strategies, and market forecasting.

19. In developing the targeted messaging to increase sales of OxyContin, McKinsey conducted significant market research, including through ridealongs with Purdue sales representatives to learn how they promoted OxyContin. McKinsey carefully monitored Purdue sales representatives and provided guidance on prescriber messaging and adhering to target prescriber lists. McKinsey advised that sales representatives do more to promote the so-called abuse deterrent properties of a reformulated version of OxyContin to address prescriber concerns about abuse risk.

20. When a large pharmacy chain took steps to scrutinize suspicious opioid orders, McKinsey stressed to Purdue's owners the "need to take action" on this "urgent" issue affecting OxyContin. McKinsey told Purdue's owners to engage in senior level discussions with the pharmacy chain, increase efforts with patient advocacy groups to clamor against dispensing limits, and accelerate

considerations of an alternative distribution channel, such as delivering OxyContin directly to patients through mail-order pharmacies.

21. After E2E, McKinsey continued to work with Purdue, including on a project that identified the growing addiction crisis as a profit-making opportunity. McKinsey told Purdue that it should strive to become a provider across the spectrum of drug abuse and addiction because of the opportunities it presented. McKinsey advised Purdue to get into the manufacturing and marketing of opioid rescue and treatment medications in order to profit from the realities of dependence, addiction, and abuse. Indeed, in 2018, Purdue owner Dr. Richard Sackler received a patent for a drug to treat opioid addiction.

22. McKinsey also partnered with Purdue to test a program called FieldGuide, a proprietary software that McKinsey sought to license to other manufacturers. This software would enable other opioid manufacturers to target and aggressively pursue high-volume prescribers.

23. McKinsey continued to design and develop ways that Purdue could increase sales of OxyContin well after the opioid epidemic peaked. One proposal McKinsey recommended was for Purdue pay "additional rebates on any new OxyContin related overdose or opioid use disorder diagnosis." McKinsey advised Purdue on its strategies to obtain and maintain broad formulary coverage for OxyContin with insurers and pharmacy benefit managers, even as payors began reducing coverage for OxyContin as the opioid crisis mounted.

24. Subsequently, in the wake of hundreds of thousands of opioid deaths and thousands of lawsuits, McKinsey proposed a plan for Purdue's exit from the opioid business whereby Purdue would continue selling opioids as a way to fund new Purdue ventures. According to McKinsey, this change was necessary because of the negative events that materially compromised the Purdue brand.

25. McKinsey's work for opioid manufacturers extended beyond Purdue. McKinsey collected millions of dollars designing and implementing marketing programs for the country's largest opioid manufacturers, including Johnson & Johnson and Endo, increasing the sale and use of opioids in the Commonwealth of Puerto Rico. McKinsey designed and implemented for other opioid manufacturers marketing plans similar to those it created for Purdue.

26. At the same time McKinsey was working for opioid companies, McKinsey also consulted with governments and non-profits working to abate the raging opioid crisis—a crisis that McKinsey's own research showed was caused in large part by prescription opioids.

27. There are indications that individuals at McKinsey considered destroying or deleting documents related to their work for Purdue.

28. In 2019, McKinsey announced that it no longer worked for Purdue or other opioid manufacturers. But the harm created by McKinsey's marketing plans for opioid manufacturers has not stopped.

29. Opioids have killed thousands in the Commonwealth of Puerto Rico, and continue to ravage the lives of many more, creating one of the largest public health epidemics in the country's history. Economically, the toll is equally grim. The opioid crisis has forced the Commonwealth of Puerto Rico to pay billions of dollars for increased costs in health care, child welfare, criminal justice, and many other programs needed to abate the epidemic.

30. Months after McKinsey stopped its opioid work, Purdue filed for bankruptcy. More than a hundred thousand individuals filed claims for personal injuries. States and local governments filed claims for trillions of dollars incurred as a result of the opioid crisis. Another McKinsey client, opioid manufacturer Mallinckrodt plc, similarly filed for bankruptcy protection in October 2020.

31. In 2019, an Oklahoma state court found that McKinsey client Johnson & Johnson helped cause the opioid epidemic in Oklahoma, ordering it to pay $465 million to help abate the crisis.

32. In 2020, Purdue pleaded guilty to three felonies as a result of conduct spanning a decade – from 2007 to 2017 – during which Purdue worked side-by-side with McKinsey to design and implement marketing campaigns to increase dangerous opioid sales.

33. In 2020, Purdue and the members of the Sackler family who owned Purdue also settled civil claims by the Department of Justice for hundreds of millions of dollars. The materials filed in connection with that plea and settlement agreements contain a statement of facts regarding McKinsey's conduct and involvement in the conduct leading to the civil claims against Purdue and the Sackler family.

IV. Claims for Relief

Violation of Unfair and Deceptive Acts or Practices in Trade or Commerce, 10 L.P.R.A. § 259

34. Plaintiff realleges and incorporates by reference each and every allegation contained in the preceding paragraphs as if they were set out herein.

35. In the course of its business, McKinsey unfairly and unconscionably worked with certain of its opioid manufacturing clients to aggressively promote and sell more opioids to more patients for longer periods of time.

36. Such actions constitute **u**nfair trade practices that violated 10 L.P.R.A. **§** 259.

37. The acts or practices described herein occurred in trade or commerce as defined in Puerto Rico Antitrust Act.

38. These acts or practices injured consumers in the Commonwealth of Puerto Rico. McKinsey's actions directly and proximately caused the Commonwealth of Puerto Rico's injuries.

V. Request for Relief

WHEREFORE, Plaintiff respectfully requests that this Honorable Court enter an Order:

a. Adjudging and decreeing that McKinsey has engaged in the acts or practices complained of herein, and that such constitute unfair acts or practices in violation of 10 L.P.R.A. § 259;

b. Issuing a permanent injunction prohibiting McKinsey, its agents, servants, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair trade practices;

c. Ordering McKinsey to pay damages for violation of the laws set forth above of the Commonwealth of Puerto Rico;

d. Ordering McKinsey to pay all costs for the prosecution and investigation of this action;

e. Ordering such other and further relief as the Court may deem just and proper.

RESPECTFULLY SUBMITTED.

In San Juan, Puerto Rico, this 4th day of February, 2021

PLAINTIFF COMMONWEALTH OF PUERTO RICO
P.O. Box 9020192
San Juan, Puerto Rico 00902-0192
Tel: (787) 721-2900, ext. 1201, 1204

HON. DOMINGO EMANUELLI HERNÁNDEZ
ATTORNEY GENERAL

/s/Johan M. Rosa Rodríguez
Johan M. Rosa Rodriguez
TSPR: 16819
Assistant Attorney General
Antitrust Division
jorosa@justicia.pr.gov

EXHIBIT 4

THE GOVERNMENT OF PUERTO RICO
COURT OF FIRST INSTANCE
SUPERIOR COURT, SAN JUAN PART

THE GOVERNMENT OF PUERTO RICO Plaintiff, v. **MCKINSEY & COMPANY, INC. UNITED STATES** Defendants.	CASE NO. _____

FINAL CONSENT JUDGMENT/CONSENT ORDER/STIPULATED JUDGMENT

Plaintiff, the Commonwealth of Puerto Rico (the "Plaintiff") has filed a Complaint for a permanent injunction, damages and other relief in this matter pursuant to Puerto Rico Antitrust Act, Law No. 77 of June 25, 1964 alleging that Defendant McKinsey & Company, Inc. United States ("McKinsey" or "Defendant"), committed violations of 10 L.P.R.A. § 259. Plaintiff, by its counsel, and McKinsey, by its counsel, have agreed to the entry of this Final Consent Judgment/Consent Order ("Judgment/Order") by the Court without trial or adjudication of any issue of fact or law, and without finding or admission of wrongdoing or liability of any kind.

IT IS HEREBY ORDERED THAT:

I. FINDINGS

A. For purposes of this proceeding only, this Court has jurisdiction over the subject matter of this lawsuit and over the Parties (as defined below). This Judgment/Order shall not be construed or used as a waiver of any jurisdictional defense McKinsey may raise in any other proceeding.

B. The terms of this Judgment/Order shall be governed by the laws of the Commonwealth of Puerto Rico.

C. Entry of this Judgment/Order is in the public interest and reflects a negotiated agreement among the Parties.

D. The Parties have agreed to resolve the issues resulting from the Covered Conduct (as defined below) by entering into this Judgment/Order.

E. McKinsey has cooperated with the Signatory Attorney General's (as defined below) investigation and is willing to enter into this Judgment/Order regarding the Covered Conduct in order to resolve the Signatory Attorney General's claims and concerns under the Puerto Rico Antitrust Act as to the matters addressed in this Judgment/Order and thereby avoid significant expense, inconvenience, and uncertainty.

F. "MultiState Executive Committee" means the Attorneys General and staffs representing California, Colorado, Connecticut, Massachusetts, New York, North Carolina, Oregon, Oklahoma, Tennessee, and Vermont.

G. The Signatory Attorney General acknowledges McKinsey's good faith and responsible corporate citizenship in reaching this resolution.

H. McKinsey is entering into this Judgment/Order solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which McKinsey expressly denies. McKinsey does not admit any violation of the State Consumer Protection Laws (as defined below) and set forth in footnote 1) and does not admit any wrongdoing that was or could have been alleged by the Signatory Attorney General before the date of the Judgment/Order. No part of this

Judgment/Order, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by McKinsey.

I. This Judgment/Order shall not be construed or used as a waiver or limitation of any defense otherwise available to McKinsey in any other action, or of McKinsey's right to defend itself from, or make any arguments in, any other regulatory, governmental, private individual, or class claims or suits relating to the subject matter or terms of this Judgment/Order. This Judgment/Order is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Notwithstanding the foregoing, the Signatory Attorney General may file an action to enforce the terms of this Judgment/Order.

J. No part of this Judgment/Order shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that the Signatory Attorney General may file an action to enforce the terms of this Judgment/Order. It is the intent of the Parties that this Judgment/Order shall not be binding or admissible in any other matter, including, but not limited to, any investigation or litigation, other than in connection with the enforcement of this Judgment/Order. This Judgment/Order is not enforceable by any persons or entities besides the Signatory Attorney General, McKinsey and this Court.

II. DEFINITIONS

The following definitions shall be used in construing the Judgment/Order:

A. "Covered Conduct" means any and all acts, failures to act, conduct, statements, errors, omissions, events, breaches of duty, services, advice, work, deliverables, engagements, transactions, or other activity of any kind whatsoever, occurring up to and including the Effective Date arising from or related in any way to (i) the discovery, development, manufacture, marketing, promotion, advertising, recall, withdrawal, distribution, monitoring, supply, sale, prescribing, reimbursement, use, regulation, or abuse of any

opioid, or (ii) the treatment of opioid abuse or efforts to combat the opioid crisis, or (iii) the characteristics, properties, risks, or benefits of any opioid, or (iv) the spoliation of any materials in connection with or concerning any of the foregoing.

B. "Effective Date" means the date on which a copy of the Judgment/Order, duly executed by McKinsey and by the Signatory Attorney General, is approved by, and becomes a Judgment/Order of the Court.

C. "McKinsey" means McKinsey & Company, Inc. United States, a Delaware Corporation, and all its current or former officers, directors, partners, employees, representatives, agents, affiliates, parents, subsidiaries, operating companies, predecessors, assigns and successors.

D. "Parties" means McKinsey and the Signatory Attorney General.

E. "Signatory Attorney General" means the Attorney General of the Commonwealth of Puerto Rico, or his/her authorized designee, who has agreed to this Judgment/Order.

F. "Settling State" means the state that has agreed to this Judgment/Order.

G. "State Consumer Protection Laws" means the consumer protection laws cited in footnote 1.[1]

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[1] ALABAMA – Alabama Deceptive Trade Practices Act § 8-19-1 et seq. (2002); ALASKA – Alaska Unfair Trade Practices and Consumer Protection Act AS 45.50.471 – 45.50.561; AMERICAN SAMOA – Consumer Protection Act, A.S.C.A. §§ 27.0401 et seq.; ARIZONA - Consumer Fraud Act, A.R.S. §44-1521 et seq.; ARKANSAS – Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101, et seq.; CALIFORNIA – Bus. & Prof Code §§ 17200 et seq. and 17500 et seq.; COLORADO – Colorado Consumer Protection Act, Colo. Rev. Stat. § 6-1-101 et seq.; CONNECTICUT – Connecticut Unfair Trade Practices Act, Conn. Gen Stat. §§ 42-110a through 42-110q; DELAWARE – Delaware Consumer Fraud Act, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, District of Columbia Consumer Protection Procedures Act, D.C. Code §§ 28-3901 et seq.; FLORIDA – Florida Deceptive and Unfair Trade Practices Act, Part II, Chapter 501, Florida Statutes, 501.201 et. seq.; GEORGIA - Fair Business Practices Act, O.C.G.A. Sections 10-1-390 et seq.; GUAM - Trade Practices and Consumer Protection, 5 G.C.A. Ch. 32 et seq.; HAWAII – Uniform Deceptive Trade Practice Act, Haw. Rev. Stat. Chpt. 481A and Haw. Rev. Stat. Chpt. 480; IDAHO – Idaho Consumer Protection Act, Idaho Code § 48-601 et seq.; ILLINOIS – Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2 et seq.; INDIANA – Deceptive Consumer Sales Act, Ind. Code §§ 24-5-0.5-0.1 to 24-5-0.5-12; IOWA - Iowa Consumer Fraud Act, Iowa Code Section 714.16; KANSAS - Kansas Consumer Protection Act, K.S.A. 50-623 et seq.; KENTUCKY – Kentucky Consumer Protection Act, KRS Ch. 367.110, et seq.; LOUISIANA – Unfair Trade-Practices and Consumer Protection Law, LSA-R.S. 51:1401, et seq.; MAINE – Unfair Trade Practices Act, 5 M.R.S.A. § 207 et seq.; MARYLAND - Maryland Consumer Protection Act, Md. Code Ann., Com. Law §§ 13-101 et seq.; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN – Michigan Consumer Protection Act, MCL § 445.901 et seq.; MINNESOTA – Minn. Stat. §§325D.44,

H. Any reference to a written document shall mean a physical paper copy of the document, electronic version of the document, or electronic access to such document.

III. INJUNCTIVE RELIEF

It is ordered that:

A. McKinsey shall not accept any future engagements relating to the discovery, development, manufacture, marketing, promotion, advertising, recall, withdrawal, monitoring, sale, prescribing, use or abuse of any Opioid or other opioid-based Schedule II or III controlled substance;

B. Nothing in Section III.A above is intended to prohibit McKinsey from offering its services to: (1) clients who, as part of their overall business, develop, manufacture, market, promote, advertise, recall, withdraw, distribute, monitor, supply, sell or prescribe opioids or other opioid-based Schedule II or III controlled substances, so long as the subject matter of the engagement does not specifically relate to opioids or other opioid-based Schedule

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325F.69; MISSISSIPPI - Mississippi Consumer Protection Act, Miss. Code Ann.§ 75-24-1, et seq.; MISSOURI – Missouri Merchandising Practices Act, Mo. Rev. Stat. §§ 407.010 et seq.; MONTANA – Montana Consumer Protection Act §§ 30-14-101 et seq.; NEBRASKA – Consumer Protection Act, Neb. Rev. Stat. §§ 59-1601 et seq. and Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. §§ 87-301 et seq.;; NEW HAMPSHIRE – NH RSA §358-A et seq; NEW JERSEY – New Jersey Consumer Fraud Act, NJSA 56:8-1 et seq.; NEW MEXICO – NMSA 1978, § 57-12-1 et seq.; NEW YORK – General Business Law Art. 22-A, §§ 349-50, and Executive Law § 63(12); NORTH CAROLINA – North Carolina Unfair and Deceptive Trade Practices Act, N.C.G.S. § 75-1.1, et seq.; NORTH DAKOTA – Unlawful Sales or Advertising Practices, N.D. Cent. Code § 51-15-02 et seq.; NORTHERN MARIANA ISLANDS – Consumer Protection Act, 4 N. Mar. I. Code §§ 5201 et seq.; OHIO – Ohio Consumer Sales Practices Act, R.C. 1345.01, et seq.; OKLAHOMA – Oklahoma Consumer Protection Act 15 O.S. §§ 751 et seq.; OREGON – Oregon Unlawful Trade Practices Act, Or. Rev. Stat. § 646.605 et seq.; PENNSYLVANIA – Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. 201-1 et seq.; PUERTO RICO – Puerto Rico Antitrust Act, 10 L.P.R.A. § 259; RHODE ISLAND – Deceptive Trade Practices Act, Rhode Island Gen. Laws § 6-13.1-1, et seq.; SOUTH CAROLINA – South Carolina Unfair Trade Practices Act, S.C. Code Ann. § 39-5-10 et seq.; SOUTH DAKOTA – South Dakota Deceptive Trade Practices and Consumer Protection, SDCL ch. 37-24; TENNESSEE – Tennessee Consumer Protection Act, Tenn. Code Ann. 47-18-101 et seq.; TEXAS – Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. And Com. Code 17.41, et seq.; UTAH - Consumer Sales Practices Act, Utah Code Ann. §§ 13-11-1 et seq.; VERMONT – Vermont Consumer Protection Act, 9 V.S.A. § 2451, et seq.; VIRGIN ISLANDS – Virgin Islands Consumer Protection Law, 12A V.I.C. §§ 101 et seq.; VIRGINIA-Virginia Consumer Protection Act, Va Code Ann. §59.1-196 et seq.; WISCONSIN – Wis. Stat. § 100.18 (Fraudulent Representations); WYOMING – Wyoming Consumer Protection Act, Wyo. Stat. Ann. §§ 40-12-101 through -114..

II or III controlled substances; or (2) health care providers, health plans, non-profit entities, governments, and quasi-governmental agencies, or any other client that is not a pharmaceutical manufacturer, for purposes of addressing a humanitarian health crisis, drug abuse prevention, treatment, and mitigation or abatement efforts, or other public health benefit;

C. Within eighteen months of the Effective Date for paragraph 4 below, and within twenty-four months of the Effective Date for paragraphs 1-3 below, McKinsey shall develop and implement a document retention policy that provides as follows:

1. McKinsey shall maintain a centralized document storage system ("Storage System") such as a document management system or a file sharing platform.
2. Unless prohibited by state, federal, or foreign law, McKinsey shall require its partners and employees, to the extent possible on a best-efforts basis, to create and maintain a final working papers file ("Final Working Papers File") relating to client engagements on the Storage System. The Final Working Papers File shall include, but not be limited to, letters of proposal, contracts, memoranda, invoices, contracted deliverables, and close-out memoranda.
3. McKinsey shall retain the Final Working Papers File for a minimum of seven years.
4. McKinsey shall retain all communications and documents exchanged on any electronic mail (including associated attachments) or instant message system that McKinsey authorizes its personnel to use for five years;
5. Nothing in this section shall prevent McKinsey from: (a) deleting documents or data as required by any state, federal, or foreign law or regulation, or (b) deleting documents or data as contractually required by a third party where such contractual

requirement is reasonably necessary to allow the third party to comply with any state, federal, or foreign law or regulation.

D. McKinsey shall implement a written policy requiring the termination of any employee that engages in the intentional spoliation of evidence for an improper purpose;

E. In the next calendar year after the Effective Date, McKinsey shall include in the annual acknowledgement that all McKinsey partners are required to certify a section describing the terms and conditions of this Judgement/Order, and McKinsey shall further hold additional annual training for partners in the Pharmaceuticals & Medical Products practice concerning the terms and conditions of this Judgement/Order;

F. Revisions to Client conflict policy pertaining to Government Clients (defined below), which shall be implemented within 60 days of the Effective Date.

1. McKinsey agrees to revise its conflict policy pertaining to potential engagements by any Settling State, county government, or municipal government (or any government agency of the aforementioned) ("Government Client") to require a written disclosure of any material conflict ("Conflict Disclosure") when (A) responding in writing to a request for proposal; (B) formally proposing work; (C) tendering an engagement letter to a Government Client; or (D) beginning work for a Government Client in the absence of an engagement letter, proposal, or request for proposal, whichever occurs first ("Triggering Event").

2. A material conflict exists for purposes of this Section III.F when, at the time of any Triggering Event, McKinsey is advising or in the past three years has previously advised an industry client on work which, in the view of a neutral and detached observer, is or was materially adverse to the work McKinsey would perform for the

Government Client, such that when McKinsey is working or has worked to advance the goals or interests of the industry client it is likely to harm the goals or interests it is working to advance of the Government Client.

3. Within 90 days of the Effective Date, McKinsey shall review each current engagement with a Government Client and provide a Conflict Disclosure where it would be otherwise required under this Section III.F for a new Government Client.
4. Nothing in this Section III.F shall supersede or affect any legal or contractual obligation McKinsey may have pertaining to confidentiality, conflicts, or engagement of clients ("Client Obligations"). The Conflict Disclosure shall not require McKinsey to violate any confidentiality obligations McKinsey has with its clients, and McKinsey satisfies its obligations under this section by providing a Conflict Disclosure (A) identifying the relevant industry; and (B) generally describing the work McKinsey performs for its industry client (without identifying its client). If for whatever reason McKinsey determines that its Client Obligations preclude a Conflict Disclosure, McKinsey agrees to decline the work for the Government Client.

G. McKinsey shall not use, assist, or employ any Third Party to engage in any activity that McKinsey itself would be prohibited from engaging in pursuant to this Judgment/Order.

H. The foregoing injunctive terms may be amended by agreement between McKinsey and the Commonwealth of Puerto Rico without this Court's approval or amendment of this Judgment/Order.

IV. PUBLIC ACCESS TO MCKINSEY DOCUMENTS

It is ordered that:

A. **Documents Subject to Public Disclosure**

1. The following documents shall be produced by McKinsey to each Settling State and are subject to public disclosure in perpetuity as part of a document disclosure program, except for the redactions authorized by Section B:

All non-privileged documents McKinsey produced to any of the Settling States in response to investigative demands or other formal or informal requests related to opioids in 2019, 2020, or 2021, prior to the date of this Judgment/Order, that fall within the following categories:

a. All communications with Purdue Pharma LP ("Purdue");
b. All documents reflecting or concerning McKinsey's work for Purdue;
c. All communications with Endo Pharmaceuticals ("Endo"), Johnson & Johnson, or Mallinckrodt Pharmaceuticals ("Mallinckrodt") related to opioids;
d. All documents reflecting or concerning McKinsey's work related to opioids for Endo, Johnson & Johnson, or Mallinckrodt;
e. All documents and communications sent or received by individual consultants agreed upon by McKinsey and the Settling States related to opioids or the opioid crisis;
f. All documents listed by Bates number in Appendix A.

2. All documents produced under this provision shall be provided in electronic format with all related metadata. McKinsey and the Settling States will work cooperatively to develop technical specifications for the productions.

B. Information That May Be Redacted

The following categories of information are exempt from public disclosure:

1. Information subject to trade secret protection. A "trade secret" is information, including a formula, pattern, compilation, program, device, method, technique or process, that (a) derives independent economic value, actual or potential, from not being generally known to the public or

to other persons who can obtain economic value from its disclosure and use; and (b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. Even if the information falls within the definition, "trade secret" does not include information reflecting opioid sales or promotional strategies, tactics, targeting, or data, or internal communications related to sales or promotion of opioids.

2. Confidential personal information. "Confidential personal information" means individual Social Security or tax identification numbers, personal financial account numbers, passport numbers, driver license numbers, home addresses, home telephone numbers, personal email addresses, and other personally identifiable information protected by law from disclosure. "Confidential personal information" does not include the names of officers, directors, employees, agents, or attorneys of McKinsey, Purdue, Endo, Johnson & Johnson, or Mallinckrodt, or of a government agency.

3. Information that is inappropriate for public disclosure because it is subject to personal privacy interests recognized by law (*e.g.*, HIPAA), or contractual rights of third parties (including McKinsey's clients) that McKinsey may not abrogate. McKinsey shall make its best efforts to ensure that disclosure into the document repository is not limited or prohibited by contractual rights of Purdue with regard to any documents, or by contractual rights of Endo, Johnson & Johnson, or Mallinckrodt with regard to documents related to opioids.

4. Information regarding McKinsey partners' or employees' personal or professional matters unrelated to McKinsey or opioids, including but not limited to emails produced by McKinsey custodians discussing vacation or sick leave, family, or other personal matters.

C. Redaction of Documents Containing Protected Information

1. Whenever a document contains information subject to a claim of exemption pursuant to Section B, McKinsey shall produce the document in redacted form. Such redactions shall indicate that

trade secret and/or private information, as appropriate, has been redacted. Redactions shall be limited to the minimum redactions possible to protect the legally recognized individual privacy interests and trade secrets identified above.

2. McKinsey shall produce to each Settling State a log noting each document redacted. The log shall also provide fields stating the basis for redacting the document, with sufficient detail to allow an assessment of the merits of the assertion. The log is subject to public disclosure in perpetuity. The log shall be produced simultaneously with the production of documents required by Section IV.F.

3. In addition to the redacted documents, McKinsey shall, upon any Settling State's request, also produce all documents identified in Section IV.A above in unredacted form to such Settling State at the same time. The redacted documents produced by McKinsey may be publicly disclosed in accordance with Section IV.E below. The unredacted documents produced by McKinsey to a Settling State shall be available only to such State unless McKinsey's claim of exemption under Section IV.B is successfully challenged in accordance with Section IV.C.4 or the trade secret designation expires in accordance with Section IV.D.

4. Anyone, including members of the public and the press,-may challenge the appropriateness of redactions by providing notice to McKinsey and a Settling State, which Settling State shall review the challenge and inform McKinsey of whether the challenge has sufficient merit to warrant triggering the remaining provisions of this paragraph. If the challenge is not resolved by agreement, it must be resolved in the first instance by a third party jointly appointed by the Settling State and McKinsey to resolve such challenges. The decision of the third party may be appealed to a court with enforcement authority over this Judgment/Order. If not so appealed, the third party's decision is final. In connection with such challenge, a Settling State may provide copies

of relevant unredacted documents to the parties or the decisionmaker, subject to appropriate confidentiality and/or in camera review protections, as determined by the decisionmaker.

D. Review of Trade Secret Redactions

Seven years after McKinsey completes the production of its documents in accordance with Section IV.F and upon notice by a Settling State, McKinsey shall review all trade secret assertions made in accordance with Section IV.B.—The newly unredacted documents may then be publicly disclosed by a Settling State in accordance with Section IV.E. McKinsey shall produce to each Settling State an updated redaction log justifying its designations of the remaining trade secret redactions.

E. Public Disclosure through a Document Repository

Each Settling State may publicly disclose all documents covered by Section IV.A through a public repository maintained by a governmental, non-profit, or academic institution. Each Settling State may specify the terms of any such repository's use of those documents, including allowing the repository to index and make searchable all documents subject to public disclosure, including the metadata associated with those documents. When providing the documents covered by Section IV.A to a public repository, no Settling State shall include or attach within the document set any characterization of the content of the documents. For the avoidance of doubt, nothing in this paragraph shall prohibit any Settling State from publicly discussing the documents covered by Section IV.A.

F. Timeline for Production

McKinsey shall produce all documents required by Section IV.A within nine months from the Effective Date.

G. Costs

The Settling States may allocate funds from the Settlement to fund the allocable share of all reasonable costs and expenses associated with the public disclosure and storage of McKinsey's documents through any public repository.

V. PAYMENT

1. McKinsey shall pay a total amount of $573,919,331 ("the Settlement Amount"). Of the Settlement Amount, $558,919,331 shall be allocated among the Settling States as agreed to by the Settling States. It is the intent of the Parties that the $558,919,331 paid to the participating States will be used, to the extent practicable, to remediate the harms caused to the Settling States and their citizens by the opioid epidemic within each State and to recover the costs incurred by the Settling State in investigating and pursuing these claims.[2] McKinsey shall pay the $15,000,000 balance of the Settlement Amount to the National Association of Attorneys General ("NAAG Fund"). The NAAG Fund shall be used: first, to reimburse NAAG for the costs and expenses of the States' opioid investigations in the amount of $7,000,000 and second to reimburse participating States for documented costs and expenses associated with the investigation of McKinsey submitted by or before March 1, 2021, subject to reasonable parameters to be set by NAAG. The remaining balance of the NAAG Fund shall be used to fund the establishment of an online repository of opioid industry documents for the benefit of the public.

2. McKinsey shall pay a total amount of $573,919,331 as follows: 1) the initial payment of $478,266,111 including the $15,000,000 payment to NAAG, shall be paid by 60 days after the Effective Date; 2) the second payment of $23,913,305 shall be paid no later than one year from the date of the initial payment; 3) the third payment of $23,913,305 shall be paid no later than two years from the date of the initial payment; 4) the fourth payment of $23,913,305 shall be paid no

[2] Puerto Rico will recerive $4,338,607.

later than three years from the date of the initial payment; and 5) the fifth payment of $23,913,305 shall be paid no later than four years from the date of the initial payment.

3. McKinsey will not seek indemnification from any entity with respect to this Judgment/Order, provided, however, that the foregoing limitation shall not be construed to apply to any claim by McKinsey under any policies or contracts of insurance insuring McKinsey.

VI. ENFORCEMENT

A. For the purposes of resolving disputes with respect to compliance with this Judgment/Order, should any of the Signatory Attorneys General have a reasonable basis to believe that McKinsey has engaged in a practice that violates a provision of this Judgment/Order subsequent to the Effective Date, then such Signatory Attorney General shall notify McKinsey in writing of the specific objection, identify with particularity the provision of this Judgment/Order that the practice appears to violate, and give McKinsey 30 days to respond to the notification; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General believes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

B. Upon receipt of written notice, McKinsey shall provide a good faith written response to the Signatory Attorney General's notification, containing either a statement explaining why McKinsey believes it is in compliance with the Judgment/Order, or a detailed explanation of how the alleged violation occurred and a statement explaining how McKinsey intends to remedy the alleged breach. Nothing in this section shall be interpreted to limit the Commonwealth of Puerto Rico's civil investigative demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable law, and McKinsey reserves all of its rights in responding to a CID or investigative subpoena issued pursuant to such authority.

C. The Signatory Attorney General may agree, in writing, to provide McKinsey with additional time beyond the 30 days to respond to a notice provided under section V.A. above without Court approval.

D. Upon giving McKinsey 30 days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to inspect and copy relevant, non-privileged, non-work product records and documents in the possession, custody, or control of McKinsey that relate to McKinsey's compliance with each provision of this Judgment/Order pursuant to that State's CID or investigative subpoena authority.

E. The Signatory Attorney General may assert any claim that McKinsey has violated this Judgment/Order in a separate civil action to enforce compliance with this Judgment/Order, or may seek any other relief afforded by law for violations of the Judgment/Order, but only after providing McKinsey an opportunity to respond to the notification described in paragraph V.A above; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General believes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

VII. RELEASE

A. Released Claims. By its execution of this Judgment/Order, the Commonwealth of Puerto Rico releases and forever discharges McKinsey and its past and present officers, directors, partners, employees, representatives, agents, affiliates, parents, subsidiaries, operating companies, predecessors, assigns and successors (collectively, the "Releasees") from the following: all claims the Signatory Attorney General is authorized by law to bring arising from or related to the Covered Conduct, including, without limitation, any and all acts, failures to act, conduct, statements, errors, omissions, breaches of duty, services, advice, work, engagements, events, transactions or other activity of any kind whatsoever occurring

up to and including the effective date of the Judgment/Order. Released claims will include, without limitation, claims that were or could have been brought by a Settling State under its State's consumer protection and unfair trade practices law, RICO laws, false claims laws and claims for public nuisance, together with any related common law and equitable claims for damages or other relief.

B. Claims Not Covered: Notwithstanding any term of this Judgment/Order, specifically reserved and excluded from the release in Paragraph VII. A. as to any entity or person, including Released Parties, are any and all of the following:

1. Any criminal liability that any person and/or entity, including Released Parties, has or may have to the Commonwealth of Puerto Rico.

2. Any civil or administrative liability that any person and/or entity, including Released Parties, has or may have to the Commonwealth of Puerto Rico not covered by the release in Paragraph V.A above, including the following claims:

    (a) state or federal antitrust violations;
    (b) any claims arising under state tax laws;
    (c) any claims arising under state securities laws;
    (d) any action to enforce this consent judgment and any subsequent related orders and judgments.

3. Any liability under the Commonwealth of Puerto Rico above-cited Consumer Protection Laws which any person and/or entity, including Released Parties, has or may have to individual consumers. Nothing herein precludes the Released Party from asserting any claims or defenses that may be available to it under the law in any court action.

VIII. ADDITIONAL PROVISIONS

A. Nothing in this Judgment/Order shall be construed to authorize or require any action by McKinsey in violation of applicable federal, state, or other laws.

B. Modification. This Judgment/Order may be modified by a stipulation of the Parties as approved by the Court, or by court proceedings resulting in a modified judgment of the Court, except to the extent as otherwise provided herein. For purposes of modifying this

Judgment/Order, McKinsey may contact any member of the MultiState Executive Committee for purposes of coordinating this process.

C. The acceptance of this Judgment/Order by the Commonwealth of Puerto Rico shall not be deemed approval by the Commonwealth of Puerto Rico of any of McKinsey's business practices. Further, neither McKinsey nor anyone acting on its behalf shall state or imply, or cause to be stated or implied, that the Commonwealth of Puerto Rico or any other governmental unit of Commonwealth of Puerto Rico has approved, sanctioned or authorized any practice, act, or conduct of McKinsey.

D. Any failure by any party to this Judgment/Order to insist upon the strict performance by any other party of any of the provisions of this Judgment/Order shall not be deemed a waiver of any of the provisions of this Judgment/Order, and such party, notwithstanding such failure, shall have the right thereafter to insist upon the specific performance of any and all of the provisions of this Judgment/Order.

E. Entire Agreement: This Judgment/Order represents the full and complete terms of the settlement entered into by the Parties hereto, except as the parties have otherwise agreed. In any action undertaken by the Parties, no prior versions of this Judgment/Order and no prior versions of any of its terms that were not entered by the Court in this Judgment/Order, may be introduced for any purpose whatsoever.

F. Jurisdiction: This Court retains jurisdiction of this Judgment/Order and the Parties hereto for the purpose of enforcing and modifying this Judgment/Order and for the purpose of granting such additional relief as may be necessary and appropriate.

G. If any provision of this Judgment/Order shall be held unenforceable, the Judgment/Order shall be construed as if such provision did not exist.

H. Counterparts: This Judgment/Order may be executed in counterparts, and a facsimile or .pdf signature shall be deemed to be, and shall have the same force and effect as, an original signature.

I. Notice: All Notices under this Judgment/Order shall be provided to the following via email and Overnight Mail:

Defendant:

Mr. James Bernard
Stroock & Stroock & Lavan LLP
180 Maiden Lane
New York, NY 10038
jbernard@stroock.com

Signatory Attorney General:

Hon. Domingo Emanuelli Hernández
PO Box 9020192
San Juan, Puerto Rico 00902-0192

APPROVAL BY COURT

APPROVED FOR FILING and SO ORDERED this _____ day of _____, 2021

_____
Judge

Approved:

For Defendant McKinsey & Company, Inc. United States

_____ February 4, 2021
Jonathan Slonim Date
Assistant Secretary
McKinsey & Company, Inc.

Local Counsel for McKinsey & Company, Inc. United States

_____ 2/3/21
Héctor Reichard Date
Reichard & Escalera LLC
Po Box 364148
San Juan, PR 00936 4148
787-777-8801
reichard@reichardescalera.com
RUA 2451

For Plaintiff Commonwealth of Puerto Rico

Johan M. Rosa Rodríguez February 4, 2021
Johan M. Rosa Rodríguez Date
RUA: 16819

Appendix A

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EXHIBIT 5

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
U.S. House of Representatives

April 13, 2022

oversight.house.gov

TABLE OF CONTENTS

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

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[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

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[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

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[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 Zemmel."[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]

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[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

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[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]

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[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).

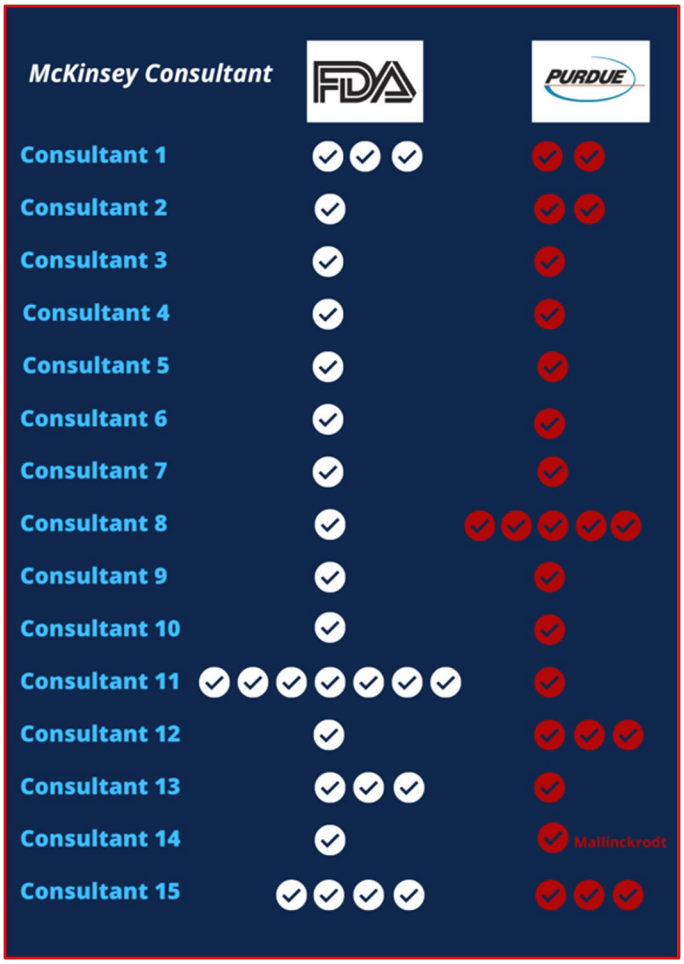
[59] MCK-HCOR-0355686 to MCK-HCOR-0355698 (McKinsey FDA Engagement List).

[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



[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]

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[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

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[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/).

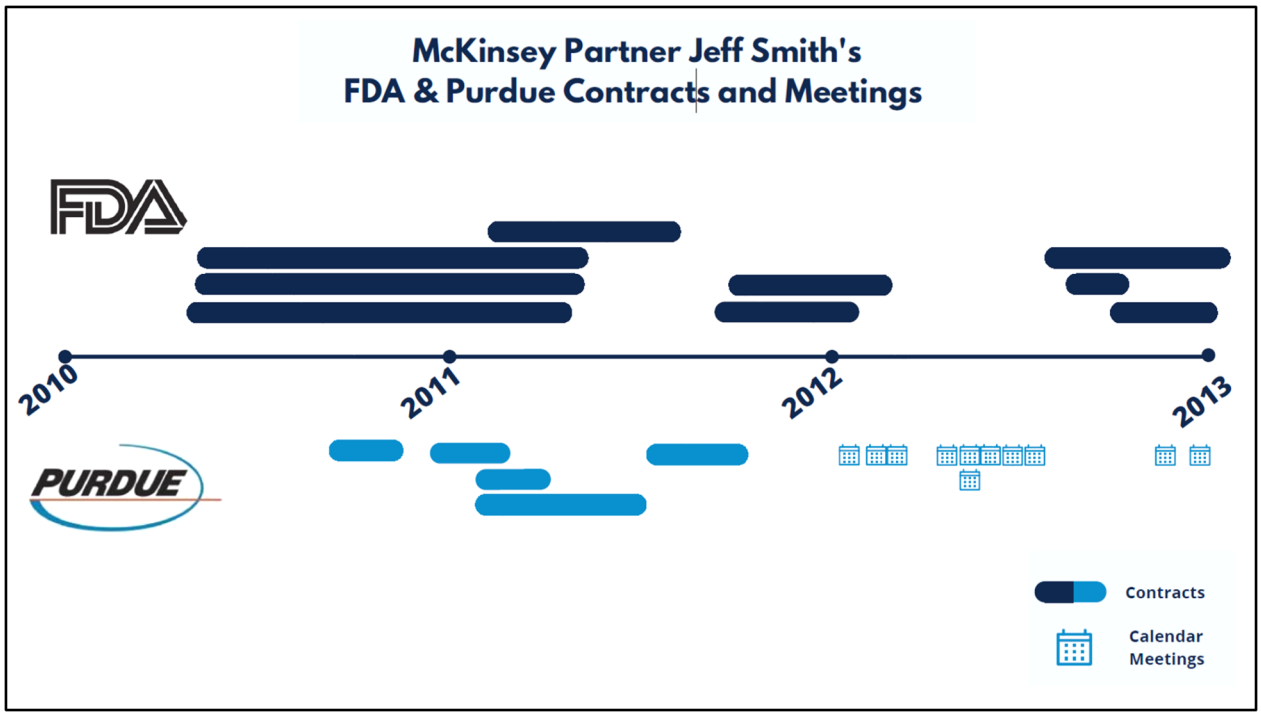
[75] MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List). The four engagement codes for the projects Smith worked on at Purdue during this time are PUP028, PUP029, PUP030, and PUP031.

[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

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[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.

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[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

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[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.

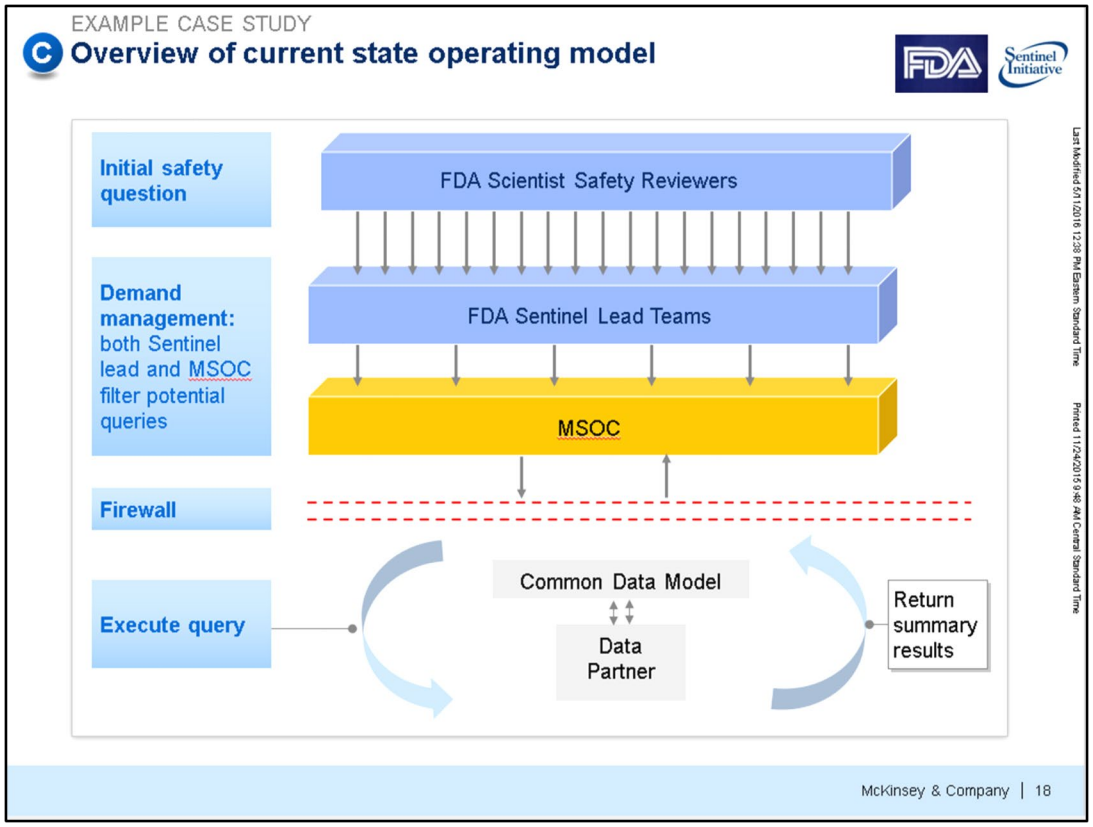
[108] MCK-HCOR-0174550 to MCK-HCOR-0174698 (McKinsey Purdue Engagement List).

[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]

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[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

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[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,*

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[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.

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[146] *Id*. (emphasis added).

[147] *Id*. (emphasis added).

[148] *Id*.

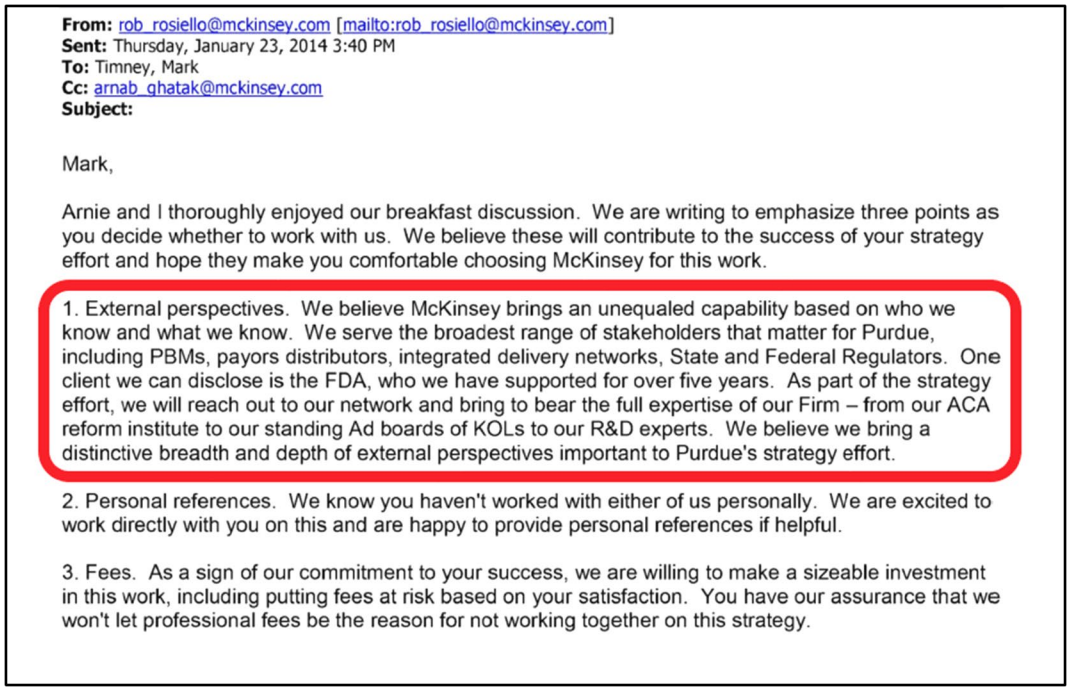
[149] MCK-HCOR-0352128, Page 2.

[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 unequaled 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 unequaled 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-led 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 canidates [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

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[152] MCK-HCOR-0231695.

[153] MCK-HCOR-0197410.

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

[155] MCK-HCOR-0100789.

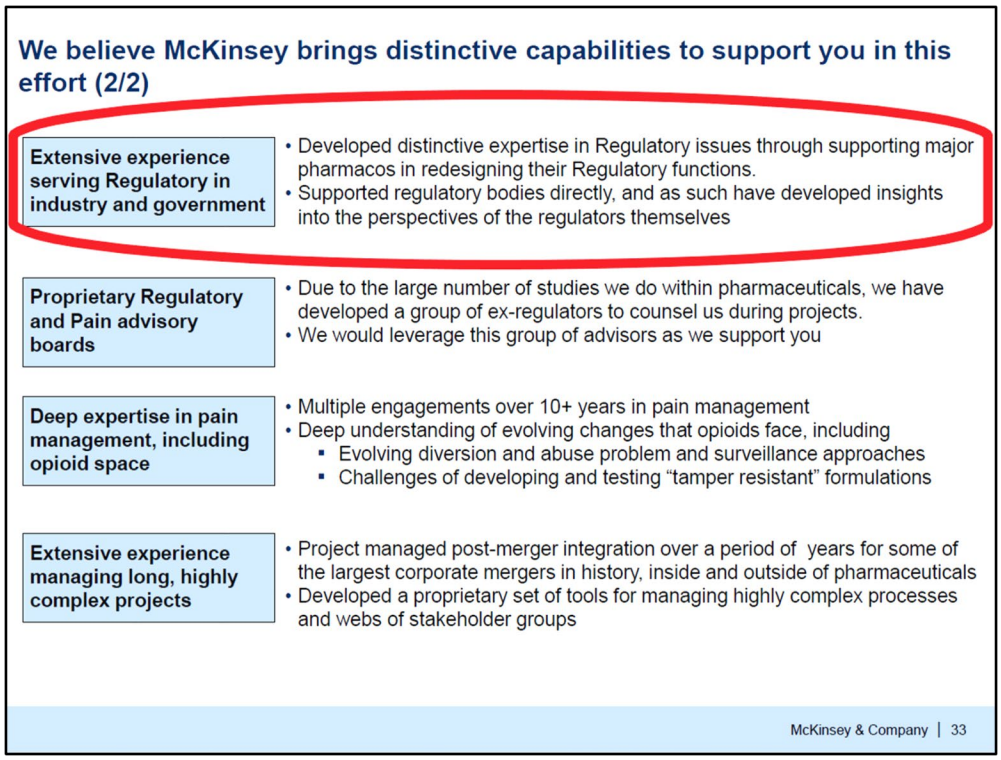
[156] MCK-HCOR-0097967.

[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]

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[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

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[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

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[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.

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[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]

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[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]

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[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

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[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]

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[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 helps 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

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[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]

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[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.

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[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 that [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]

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[245] MCK-HCOR-0351073.

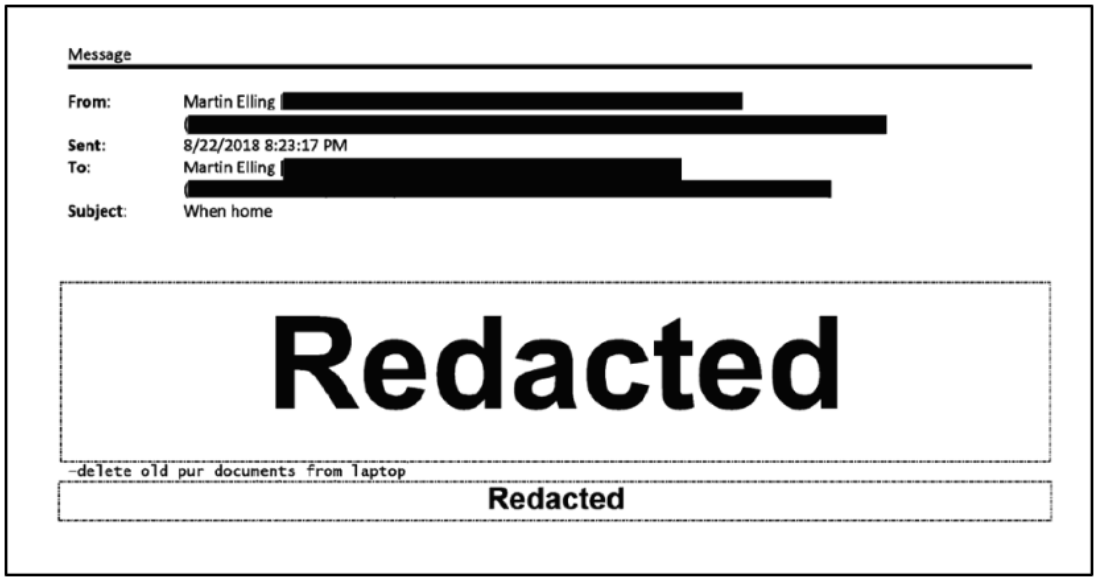
[246] MCK-HCOR-0097466.

[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.


Message

From: Martin Elling [redacted]

Sent: 8/22/2018 8:23:17 PM

To: Martin Elling [redacted]

Subject: When home

Redacted

-delete old pur documents from laptop

Redacted

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 spoilation 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.