

United States Senate
WASHINGTON, DC 20510

August 23, 2021

Dr. Janet Woodcock
Acting Commissioner
U.S. Food and Drug Administration

Dear Acting Commissioner Woodcock,

We are writing to request information about the Food and Drug Administration's (FDA) past work with the consulting firm McKinsey & Company (herein referred to as McKinsey)—a global management consulting firm—and potential conflicts of interest that may have arisen from this work.

Government contracting databases show that the FDA hired McKinsey a number of times beginning in 2008, paying it more than \$140 million.¹ McKinsey appears to be particularly involved with the Center for Drug Evaluation and Research (CDER), which is the FDA's principal division for approving certain classes of drugs including prescription opioids.² At least 17 of the contracts awarded to McKinsey between 2008 and 2021, worth more than \$48 million, called for the firm to work with CDER.³

While working with the FDA, McKinsey also worked for a wide range of actors in the opioid industry, including many of the companies that played a pivotal role in fueling the opioid epidemic that our country now faces. Earlier this year, McKinsey settled claims with 49 State Attorneys General that the company helped Purdue Pharma “turbocharge” sales of OxyContin.⁴ (Publicly available trial exhibits show how McKinsey worked closely with Purdue Pharma to ensure OxyContin remained available to patients.⁵) McKinsey also consulted for opioid

¹ *Advanced Search, Spending by Prime Award*, USASpending.gov, <https://www.usaspending.gov/search/?hash=9c4702cb5b379594a7c36481464f73f7> (last accessed July 21, 2021).

² *Id.*

³ *Id.*

⁴ See Press Release, McKinsey Reaches Agreement with 49 State Attorneys General to Resolve Investigations into Past Work for Opioid Manufacturers (Feb. 4, 2021), <https://www.mckinseyopioidfacts.com/settlement-press-release/>; see also Brian Mann, *McKinsey Apologizes for Helping Purdue Pharma 'Turbocharge' Opioid Sales*, NPR (Dec. 9, 2020), <https://www.npr.org/2020/12/09/944563257/mckinsey-apologizes-for-helping-purdue-pharma-turbocharge-opioid-sales>.

⁵ Brian Mann, *McKinsey Apologizes for Helping Purdue Pharma 'Turbocharge' Opioid Sales*, NPR (Dec. 9, 2020), <https://www.npr.org/2020/12/09/944563257/mckinsey-apologizes-for-helping-purdue-pharma-turbocharge-opioid-sales>.

manufacturers Johnson & Johnson, Mallinckrodt, and Endo International⁶ as well as for major opioid distributors and retailers.⁷

At the same time, McKinsey advised opioid manufacturers on how to avoid FDA oversight. In 2008, McKinsey advised Purdue on how to soften the FDA's proposed Risk Evaluation and Mitigation Strategies (REMS), a drug safety program that requires manufacturers to communicate safety risks to patients, pharmacists, and other health care providers.⁸ Purdue viewed the FDA's consideration of new REMS protocols for opioids, which CDER oversaw, as a major threat to its business.⁹ Working at Purdue's direction, McKinsey built a strategy for Purdue and other opioid manufacturers to "play, delay, pre-empt, and band together," by "jointly develop[ing] FDA response strategy," "shar[ing] abuse mitigation strategies," and "formulat[ing] arguments to defend against strict treatment by the FDA."¹⁰ When the finalized REMS for opioid products was announced in 2012, it was largely devoid of the restrictions that FDA had initially proposed.¹¹ The death toll from opioid overdoses continued to rise in the years that followed.¹²

McKinsey also worked for the FDA on contracts that presented additional potential conflicts of interest. For instance, in 2010 and 2011, the FDA awarded McKinsey more than \$2.4 million in contracts to design a system called "track and trace" that would enhance the FDA's ability to identify and trace certain prescription drugs that are harmful to U.S. consumers.¹³ The "track and trace" system deeply impacted McKinsey clients, including the nation's three largest drug distributors—McKesson, AmerisourceBergen, and Cardinal Health. The contracts explicitly obligated McKinsey to consult with "supply chain stakeholders," a group that presumably includes these three drug distributors, but could also include pharmaceutical manufacturers, pharmacy benefit managers, payers, and insurance companies. The language of the 2010 contract, for instance, dictated that McKinsey "develop a strategic plan for FDA and supply chain stakeholders for identified solutions to close existing gaps in either technology or

⁶ Michael Forsythe and Walt Bogdanich, *McKinsey Settles for Nearly \$600 Million Over Role in Opioids Crisis*, N.Y. TIMES (July 20, 2021), <https://www.nytimes.com/2021/02/03/business/mckinsey-opioids-settlement.html>.

⁷ Jef Feely, *McKinsey Opioid Work Included Advising Distributors, Tribe Says*, BLOOMBERG (June 3, 2021), <https://www.bloomberg.com/news/articles/2021-06-03/mckinsey-opioid-work-included-advising-distributors-tribe-says>.

⁸ Press Release, Attorney General Ellison joins \$573M multistate settlement with McKinsey & Company (Feb. 4, 2021); see also *What is REMS?*, FDA.GOV, <https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/whats-rems> (last updated Jan. 26, 2018).

⁹ *In re: Purdue Pharma, L.P.*, Case No. 19-23649, Ad Hoc Group of Non-Consenting States' Statement Suppt. Official Comm. Unsecured Creditors' Mots. Comp. Production Purportedly Privileged Docs. for In Camera Review at 7-8 of 16 (S.D.N.Y. Nov. 18, 2020), <https://restructuring.primeclerk.com/purduepharma/Home-DownloadPDF?id1=MTExNzM5Mg==&id2=0>.

¹⁰ *Id.* at 31 of 49, <https://restructuring.primeclerk.com/purduepharma/Home-DownloadPDF?id1=MTExNzM5Mg==&id2=0>.

¹¹ *FDA Reconsiders Painkiller Training Requirements for Doctors*, NBC News (May 2, 2016), <https://www.nbcnews.com/health/health-news/fda-reconsiders-painkiller-training-requirements-doctors-n565866>; see also *State of Minnesota v. McKinsey & Co., Inc.*, Compl. ¶ 12 (Dist. Ct., 2d Jud. Dist. Feb. 4, 2021), https://www.ag.state.mn.us/Office/Communications/2021/docs/McKinsey_Complaint.pdf.

¹² Overdose Death Rates, National Institute on Drug Abuse, <https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates>

¹³ FDA contract HHSF223201010014B, date of order September 15, 2010; FDA contract HHSF223201010014B, date of order August 31, 2011.

systems.”¹⁴ In short, the FDA contracted with McKinsey to help build a system that could potentially place a significant new burden on its other clients. In addition, the 2010 and 2011 contracts strongly suggest that McKinsey, while representing the FDA, was actively engaging with its private-sector clients that were the targets of this new regulatory process—an obvious conflict of interest.

Even after McKinsey’s ties to the opioid industry became public, the company continued to earn significant revenues from the FDA. For example, contracting databases show that from February 2019 (when news of McKinsey’s extensive work for Purdue Pharma first broke) to January 2021, the consulting firm received more than \$20 million in new contracts from the FDA.¹⁵

Given McKinsey’s extensive work for opioid manufacturers and other pharmaceutical manufacturers regulated by the FDA at the time it was awarded opioid-related contracts, we ask that your agency provide our offices with answers to the following questions, along with supporting documentation, by September 20th, 2021.

1. How does the FDA check for conflicts of interest before, during, and after it awards a contract? Please provide any documentation or memoranda that outlines this policy.
2. What is the FDA’s current relationship to McKinsey? How many contracts has the FDA awarded to McKinsey since 2019? Please provide a detailed description of each contract.
3. McKinsey’s FDA contracts included detailed obligations to disclose potential conflicts of interest. What disclosures did McKinsey make to the FDA with regard to such conflicts, whether stemming from its client relationships or from investments made through MIO Partners—its internal hedge fund? If McKinsey did not make disclosures to the FDA, explain why not.
4. When did the FDA become aware that McKinsey had taken on opioid manufacturers as clients? Did these disclosures prompt a review of McKinsey’s existing contracts for conflicts of interest? If not, why not? Was there any communication with McKinsey officials with regard to the potential for conflicts? If so, please provide copies of all such communications.
5. When did the FDA become aware that McKinsey’s clients also included several major opioid distributors and retailers? Did these disclosures prompt any review of McKinsey’s existing FDA contracts for conflicts of interest? Was there any communication with McKinsey officials with regard to the potential for conflicts? If so, please provide copies of all such communications.

¹⁴ FDA contract HHSF223201010014B, date of order September 15, 2010.

¹⁵ *Advanced Search, Spending by Prime Award*, USASpending.gov, <https://www.usaspending.gov/search/?hash=c3a94fe1c525e4818ff26785fe56aa07> (last accessed July 21, 2021).

6. Did the FDA verify the company's written policy with regard to employees working on opposite sides of the same issue? For example, can McKinsey employees who consulted for the FDA collaborate with colleagues who consulted for Purdue Pharma? Are they permitted to communicate with one another? If so, why?
7. When the FDA hired McKinsey to help build its "track and trace" system, was it aware that such work could impact the business of McKinsey's clients in the private sector? Did the agency consider other bidders for this work, who were not encumbered by such client relationships and potential conflicts of interest? If so, please explain the process for awarding contracts to business who may have conflicts of interest with their clients.

Sincerely,



Margaret Wood Hassan
United States Senator



Charles Grassley
United States Senator



Sheldon Whitehouse
United States Senator



Edward J. Markey
United States Senator



Joe Manchin III
United States Senator



Elizabeth Warren
United States Senator