

United States Senate  
WASHINGTON, DC 20510

April 5, 2022

The Honorable Christi A. Grimm  
Inspector General  
U.S. Department of Health and Human Services  
Office of Inspector General  
245 Murray Lane, SW  
Washington, D.C. 20528-0305

Dear Inspector General Grimm:

We are writing to request that the Office of Inspector General for the Department of Health and Human Services open an investigation into the failure of consulting firm McKinsey & Company (“McKinsey”) to disclose potential conflicts of interest when McKinsey entered into contracts with the Food and Drug Administration (“FDA”) on issues related to opioids while simultaneously working for numerous opioid companies. We also write to request that your office review FDA’s contracting policies and procedures and determine how the agency can ensure that future contractors adequately disclose all potential conflicts.

For more than a decade, McKinsey has advised companies throughout the opioid industry. McKinsey recently settled with 49 states Attorneys General for \$573 million due to actions that exacerbated the opioid epidemic, including advising Purdue Pharma on how to “turbocharge” sales of OxyContin.<sup>1</sup> Former clients also include opioid manufacturers Johnson & Johnson, Mallinckrodt, and Endo International,<sup>2</sup> as well as major opioid distributors and retailers.<sup>3</sup>

While working for clients involved in manufacturing, distributing, and selling opioids, McKinsey simultaneously worked on projects for FDA, including projects for the FDA center responsible for approving new drugs, like opioids. Government contracting databases show that since 2008, McKinsey has been hired by FDA on numerous occasions, earning more than \$140 million.<sup>4</sup> The firm was deeply involved with the Center for Drug Evaluation and Research (CDER), FDA’s principal center for approving new drugs, including opioids: at least 17 of McKinsey’s FDA

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<sup>1</sup> 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>.

<sup>2</sup> 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>.

<sup>3</sup> 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>.

<sup>4</sup> *Advanced Search, Spending by Prime Award*, USASpending.gov, <https://www.usaspending.gov/search/?hash=9c4702cb5b379594a7c36481464f73f7> (last accessed July 21, 2021).

contracts, totaling more than \$48 million, call on the firm to work with CDER.<sup>5</sup> In 2008, McKinsey began working with Purdue on how to develop its FDA-mandated proposed Risk Evaluation and Mitigation Strategies (REMS), a drug safety program overseen by CDER, that required manufacturers to communicate safety risks to patients, pharmacists, and other health care providers.<sup>6</sup> 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.”<sup>7</sup> When the finalized REMS for opioid products was announced in 2012, it was largely devoid of the restrictions that FDA had initially proposed.<sup>8</sup>

FDA requires that contractors such as McKinsey agree to its Organizational Conflicts of Interest (OCI) policy, as set out by the Federal Acquisition Regulation. Last August, some of our offices sent a letter to FDA, requesting further information about these conflicts of interest and whether McKinsey disclosed the required OCI to the agency during the contracting process. FDA responded to our letter two months later on October 22, 2021, and stated that “FDA is not aware of any disclosures made by McKinsey vis-a-vis OCI in relation to these orders. FDA cannot speculate on why McKinsey did not consider any actual or apparent OCI to be sufficient to require reporting as directed by the contract requirements.”<sup>9</sup> Despite the conflicts implicit in its simultaneous work for opioid companies and for the FDA, McKinsey apparently never notified the agency of potential OCI. And as FDA stated in its recent letter, the responsibility for identifying conflicts of interest fell entirely on McKinsey: “FDA relies on the contractor to assess and report potential OCI and submit mitigation plans for review.”<sup>10</sup> Despite the requirements in its contracts, McKinsey failed to make any disclosures to FDA with regard to its many conflicts of interest and in fact repeatedly warranted just the opposite – that it had no such conflicts.<sup>11</sup>

In its response, FDA also stated that it only became aware of McKinsey’s past work for opioid industry clients in early 2021, when these ties were widely reported on in the media.<sup>12</sup> However, the first reports on McKinsey’s extensive work for Purdue Pharma surfaced in early 2019.<sup>13</sup> In

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<sup>5</sup> Id.

<sup>6</sup> 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).

<sup>7</sup> Id. at 31 of 49, <https://restructuring.primeclerk.com/purduepharma/Home-DownloadPDF?id1=MTEzNzY5Mg==&id2=0>.

<sup>8</sup> *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](https://www.ag.state.mn.us/Office/Communications/2021/docs/McKinsey_Complaint.pdf).

<sup>9</sup> Letter from Acting Associate Commissioner Andrew Tantillo, Food and Drug Administration, to Senator Maggie Hassan et al. (Oct. 22, 2021) <https://www.hassan.senate.gov/imo/media/doc/FDA%20RESPONSE%20HASSAN%2010.22.21.pdf>

<sup>10</sup> Id.

<sup>11</sup> See FDA Response at 2.

<sup>12</sup> See FDA Response at 4.

<sup>13</sup> Michael Forsythe and Walt Bogdanich, *McKinsey Advised Purdue Pharma How to ‘Turbocharge’ Opioid Sales, Lawsuit Says*, New York Times (February 1, 2019), <https://www.nytimes.com/2019/02/01/business/purdue-pharma-mckinsey-oxycotin-opioids.html>

the interim, McKinsey continued to perform work for FDA; contracting databases show that from February 2019 to January 2021, the firm received more than \$20 million in new contracts from the FDA.<sup>14</sup> Despite these reports, FDA did not conduct any additional contract reviews or discuss with McKinsey conflicts of interest and the firm's failure to disclose them in earlier contract applications.<sup>15</sup> Furthermore, it is unclear whether FDA has altered or improved its processes and procedures to prevent similar nondisclosures of conflicts of interest in future contracts.

The Office of the Inspector General for the United States Department of Health & Human Services is uniquely situated to review the actions of McKinsey and FDA as it pertains to these conflicts of interests and the failures to disclose them. As part of your review, we ask that you specifically address the following issues:

1. What OCI disclosures related to its work with opioid companies did McKinsey make, or fail to make, when the firm applied for and was awarded contracts with FDA that related to opioids? Was McKinsey obligated to make any disclosures during the award period?
2. What FDA policies and procedures exist to assess actual or apparent conflicts of interest during the contract application process, and were they followed in the case of the McKinsey awards described above? If they were followed, why did they fail to capture the conflicts of interest identified above? If they were not followed, why not?
3. When did FDA become aware of media reports on McKinsey's work for Purdue Pharma? Why did the agency continue to award the firm contracts after this reporting?
4. Why did FDA not conduct additional contract reviews or outreach to McKinsey to address the firm's previous failure to disclose conflicts of interest once the agency became aware of these failures?
5. How could FDA improve its policies and procedures to prevent similar nondisclosures of conflicts of interest during the contract application process in the future?
6. Have you reviewed similar contract work done by other consulting firms for FDA that raises similar conflict of interest concerns?

At a time when the opioid epidemic is still raging nationwide, we must hold those who fueled it accountable and take action to prevent similar failures in the future. We thank you for your prompt attention to this matter.

Sincerely,

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<sup>14</sup> *Advanced Search, Spending by Prime Award*, USASpending.gov, <https://www.usaspending.gov/search/?hash=9c4702cb5b379594a7c36481464f73f7> (last accessed July 21, 2021).

<sup>15</sup> See FDA Response at 4.



Margaret Wood Hassan  
United States Senator



Patty Murray  
United States Senator



Tammy Baldwin  
United States Senator



Joe Manchin III  
United States Senator



Edward J. Markey  
United States Senator



Elizabeth Warren  
United States Senator



Sheldon Whitehouse  
United States Senator