

RICHARD BLUMENTHAL  
CONNECTICUT

COMMITTEES:

AGING

ARMED SERVICES

COMMERCE, SCIENCE, AND TRANSPORTATION

JUDICIARY

VETERANS' AFFAIRS

United States Senate

WASHINGTON, DC 20510

706 HART SENATE OFFICE BUILDING  
WASHINGTON, DC 20510

(202) 224-2823

FAX: (202) 224-9673

90 STATE HOUSE SQUARE, TENTH FLOOR  
HARTFORD, CT 06103

(860) 258-6940

FAX: (860) 258-6958

915 LAFAYETTE BOULEVARD, SUITE 304  
BRIDGEPORT, CT 06604

(203) 330-0598

FAX: (203) 330-0608

<http://blumenthal.senate.gov>

April 14, 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

Dear Inspector General Grimm,

I write to you today to request that the Office of the Inspector General for the Department of Health and Human Services ("HHS OIG") expeditiously open an investigation into the practices of McKinsey & Company ("McKinsey"). At the same time that McKinsey was consulting for the Food and Drug Administration's (FDA) drug-regulation division on pharmaceutical matters, it was also advising pharmaceutical industry clients, including Purdue Pharma and Johnson & Johnson, on the same or similar issue. In fact, at times, the same consultants were advising both the FDA and the private sector companies it regulated on the same issues.<sup>1</sup> It is critical that the OIG's investigate these clear conflicts of interest to understand the impact the McKinsey's conduct had and continues to have on the FDA, and why the FDA's contracting policies and procedures allowed such a breach of existing conflicts of interest rules to occur.

From 2004 to 2019, McKinsey served as the consulting firm for Purdue Pharma, Johnson & Johnson, and others—advising these clients on FDA oversight and drug approval processes.<sup>2</sup> In 2017, McKinsey also began advising Purdue Pharma on its effort to rebuild after addicting millions to their flagship drug, OxyContin.<sup>3</sup> Beginning in 2008, however, Purdue was also consulting for FDA to advise the agency on how to improve oversight of the pharmaceutical industry.<sup>4</sup> These client interests are in direct conflict and yet McKinsey not only continued both

<sup>1</sup> Ian MacDougall, "McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency," *ProPublica*, October 4, 2021, <https://www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency>.

<sup>2</sup> MacDougall, "McKinsey Never Told."

<sup>3</sup> Chris Hamby, Walt Bogdanich, Michael Forsythe, and Jennifer Valentino-DeVries, "McKinsey Opened a Door in Its Firewall Between Pharma Clients and Regulators," (New York City, New York), April 13, 2022, <https://www.nytimes.com/2022/04/13/business/mckinsey-purdue-fda-records.html?referringSource=articleShare>.

<sup>4</sup> MacDougall, "McKinsey Never Told."

representations, but actually used its work for the FDA as leverage to secure pharmaceutical industry work, stressing its relationship with the FDA in an email to Purdue in 2014.<sup>5</sup>

Recent investigations and reporting have shown that McKinsey worked on both sides of the same issues and that its work has had a real impact on the FDA and on HHS as a whole. For example, McKinsey advised Purdue on how to respond to the FDA's 2008 request that Purdue develop a drug safety plan for OxyContin, while also advising FDA on an operating plan for the office developing drug safety plans. Subsequently, in 2012, the FDA released an opioid safety plan that had been significantly watered down compared to prior drafts.<sup>6</sup>

McKinsey's simultaneous work for the FDA and for FDA-regulated entities not only raises significant concerns about the company's failure to adequately disclose and review conflicts of interest, but also creates critical questions regarding the FDA's failure to identify this major conflict of interest. The FDA requires that contractors like McKinsey agree to its Organizational Conflicts of Interest (OCI) policy, but this policy relies entirely on contractors to self-assess and self-report potential conflicts of interest.<sup>7</sup> In the case of McKinsey, this policy evidently failed. Whether intentionally or not, McKinsey failed to adequately assess its conflicts. It is, therefore, imperative that the OIG investigate what exactly happened at FDA and whether similar issues exist with other consultants or within other areas at the FDA.

The breach in policy that resulted in McKinsey's conflicted consulting work at the FDA may have had a significant impact on Americans—particularly those who have suffered from opioid abuse. I respectfully urge the OIG to conduct an investigation to understand what happened in this case, identify and hold accountable individuals or entities responsible for the failures, and ensure that such egregious conflicts of interest and breaches of FDA policy do not occur again.

Thank you for attention and commitment to this important issue.

Sincerely,



Richard Blumenthal  
United States Senator

---

<sup>5</sup> Hamby, Bogdanich, Forsythe, and Valentino-DeVries, "McKinsey Opened a Door."

<sup>6</sup> MacDougall, "McKinsey Never Told."

<sup>7</sup> Hamby, Bogdanich, Forsythe, and Valentino-DeVries, "McKinsey Opened a Door."