



Statement of

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before the

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Chairwoman Maloney, Ranking Member Comer, and Members of the Committee, thank you for the opportunity to be here today to discuss McKinsey & Company. McKinsey is one of the world's leading providers of business and organizational consulting services, serving the largest and most significant American and multinational companies and institutions as well as foundations and not-for-profit entities active in the communities in which we live and work.

I appreciate the opportunity to continue our cooperation with the Committee, discuss our work and our approach to serving clients, both in the private sector and our service to the U.S. government, and share my approach to leading the firm since becoming managing partner in July of last year.

Founded in Chicago by James O. McKinsey in 1926, McKinsey today encompasses more than 38,000 employees globally, with more than 12,000 employees based in the United States. We have offices in 27 U.S. cities and more than 100 additional offices across 65 countries. We are currently serving more than 3,000 clients on more than 4,400 active engagements, and nearly half of our revenue comes from clients headquartered in the United States.

Although we are a global company, wherever we serve clients, our work is rooted in our American values, including the principles of free enterprise, economic growth and mobility, sustainability, business innovation, community development, entrepreneurship, and the rule of law. Our approach to client service is centered on evidence-based empirical research, fact-based problem solving, rigorous data gathering, and deep economic analysis.

Throughout our almost 100-year history, we have approached client service with the knowledge and recognition that our consulting services often require us to work with our clients' most sensitive, confidential, and competitively important information. The protection of information entrusted to us is, therefore, a fundamental value at McKinsey and forms the backbone of our firm's approach to addressing and avoiding potential conflicts of interest in our work.

McKinsey's Policies on Client Confidences, Conflicts of Interest, and Client Service

Our firm has developed – and we continuously refine – a comprehensive set of policies and procedures designed to maintain client confidences, protect client data and information, and

avoid conflicts of interest. We are also open and forthright that our client service extends to companies and institutions that may be competitors.

Our internal policies include some of the following key components: our Code of Professional Conduct, which limits the sharing of client confidential information to colleagues with a legitimate need to know and who are authorized to access the information, and requires employees to adhere to the firm's cybersecurity standards to protect clients' data from unauthorized external access; our Proprietary and Confidential Information Agreement, that obligates all McKinsey employees to maintain client confidences and protect clients' sensitive data and information; our Use of Name Policy, which provides that the names of McKinsey clients, the topics on which McKinsey consults, and the advice McKinsey provides will not be disclosed by McKinsey unless those confidentiality commitments are superseded by a legal obligation or mutual agreement between McKinsey and our clients; and our Client Conflict and Confidentiality Policy, which requires firm members to disclose any potential conflicts of interest, including any situation in which an individual might have, or be perceived to have, divided loyalties, such as family business activities, personal investments, personal relationships, or outside activities. These policies are core to who we are as a firm. We insist all colleagues understand these policies and attest to uphold them annually. Failure of any colleague to abide by them can result in several sanctions up to and including termination.

In providing services to clients, including building each client service project team, we deploy staffing procedures designed to avoid potential conflicts of interest. Under these procedures, members of the firm who have acquired confidential information about a client may not serve another client if that confidential information could materially disadvantage the first client. That determination is fact specific. To apply this restriction, we consider the industry, the nature of the engagement, the anticipated role of the individual, and information gathered over the course of our work. The restriction will last as long as the information has significant competitive value. These policies apply regardless of seniority. Once we assess proposed staffing of an engagement for potential conflicts, McKinsey often provides clients with information about the prior experiences of the partners that will make up the team for that particular engagement.

McKinsey's Policies for U.S. Government Service

For more than 70 years, McKinsey has proudly served the U.S. government as a client. When we serve the government, we do so through a separate legal entity with separate operational structures and separate information technology where required. Moreover, additional policies apply to our U.S. government service, including our Organizational Conflicts of Interest Policy, which follows the requirements of the Federal Acquisition Regulation. Under our Organizational Conflicts of Interest Policy, McKinsey assesses potential conflicts by determining "whether the business interest in question would cause a reasonable person with knowledge of the relevant facts to question the impartiality" of McKinsey's work. The assessment of potential organizational conflicts of interest involves a multi-step process with analysis and advice of legal counsel that results in appropriate disclosures to the government, as required by regulations and any specific contractual obligations.

McKinsey's Continuous Improvement of Policies and Practices

As our firm grows and the environment in which we and our clients operate increases in complexity, we fully recognize that we must continue to evolve and strengthen our approach to governance and client service. Those continuous improvement efforts include substantially strengthening our policies related to client and engagement selection, implemented in 2019, and launching a more rigorous framework and set of criteria to determine which clients we serve and on what topics. That new Client Service Policy requires us to evaluate affirmatively whether to perform services for a client under a framework we call CITIO, which entails an assessment of the Country, Institution, Topic, Individual, and Operational considerations of each engagement. The CITIO framework applies globally, across all client work, without exception. In our estimation, it is by far the most comprehensive and complete client service framework in our industry, and it exceeds the practices of our peer firms. The CITIO framework ensures that we take a consistent and complete approach to evaluating the clients we serve and on which topics, and the effects of our work. We routinely limit or decline potential work based on our CITIO evaluation of potential clients and engagements.

The implementation of the Client Service Policy established clear rules for work we will not perform. For example, we do not serve tobacco companies, opioid manufacturers, dual use technology companies in certain countries, and pharmaceutical companies on projects seeking to deviate from industry pricing norms or circumvent regulatory structures or legal conventions. In the government sector, we do not serve defense, intelligence, justice, or police institutions in non-democratic countries, assessed using objective third-party criteria (the Economist Intelligence Unit Democracy Index score of 6 or below), with limited exceptions for international aid and humanitarian work which must be approved by the firm's risk leadership. We also do not serve political parties, political advocacy groups, legislatures, or individual legislators' offices, nor do we take part in political advocacy or lobbying on behalf of our clients.

Over the past several years, we have substantially increased our internal personnel resources in areas of risk, legal, and compliance, tripling the size of these functions since 2015. In the last four years, our investments in professional staff, compliance, training, technology, and related activities have topped \$600 million, including hiring two new global leaders, a General Counsel and a Chief Compliance Officer, both of whom bring decades of public company experience across different industries. We have also increased the influence and authority of our internal governance committees. For example, client service matters that require consideration beyond our standard processes are escalated to the Client Service Risk Committee, a global committee of senior firm leaders and risk professionals that provides advice and decisions on the most complex risks we face in our client service. These leaders provide internally transparent and independent supervision of the firm's decisions related to client service. Each year, the Committee and the risk function collectively review thousands of potential client engagements to ensure that those projects adhere to our policies and include appropriate guardrails when needed to address identified risks. Where it is not possible, the Committee directs that the firm decline the potential engagement. We have also established an advisory group of leaders to offer an external perspective on our approach and to serve as a sounding board for our efforts at ongoing and continuous improvement. We have simultaneously increased accountability across each of our practice areas by designating select senior partners as responsible for enhancing the risk management within their practice group.

As I have said from my first day as Global Managing Partner, we will never rest in improving our firm and that process will always be ongoing. In addition to the policies and practices noted above, our Risk, Audit, and Governance Committee of our board of directors, known internally as our Shareholders Council, continues to focus on our conflicts of interest policies and procedures to determine how we can further improve our standards and processes.

The Committee's Staff Report on McKinsey's Work for Purdue and the FDA

I would like to turn to the Committee's recent staff report about McKinsey's work for Purdue Pharma and the FDA. McKinsey's work for Purdue was focused on legitimate prescribers and an abuse deterrent formulation. Nevertheless, we have recognized and publicly expressed that we did not adequately acknowledge the unfolding epidemic, and that our work fell short of our standards. As a result, in 2019, we decided to end all work on opioid-specific business globally, and we have committed to being part of the solution to this serious challenge. As part of that commitment, in early 2021, we proactively engaged with state attorneys general across the country to reach a settlement that provides more than \$600 million to prevention, treatment, and recovery efforts across the country. Rather than litigating with the states, we worked with the attorneys general to provide critical support to hard-hit communities nationwide. At that time, the attorneys general publicly praised McKinsey's "good faith and responsible corporate citizenship in reaching this resolution."¹ We also agreed to release publicly hundreds of thousands of pages of materials in the interest of transparency and learning from the past. We simultaneously made commitments regarding increased transparency in state and local government engagements, and we are implementing changes to increase the duration of our document retention.

In discussing our work for the FDA, the Committee's recent staff report drew inaccurate conclusions. Most importantly, McKinsey *did not* serve both the FDA and Purdue on opioid related matters. As both McKinsey and the FDA have made clear, our work for the FDA focused on administrative and operational topics, including improvements to organizational structures, business processes, and technology. McKinsey did not advise the FDA on regulatory policy or on specific pharmaceutical products or classes of products, including opioids. In a response to a congressional inquiry on the topic, the FDA stated that the "FDA has not consulted McKinsey about processes or review issues associated with any specific drug product or specific product class, including opioids,"² and the "FDA has not consulted McKinsey about distribution or retail sales associated with any specific drug product or specific product class, including opioids."³ Regarding its contracts with McKinsey, the FDA stated that "none of FDA's contracts were specifically related to opioids, opioid distribution, or retail sales of opioids."⁴

¹ *E.g., Commonwealth of Massachusetts v. McKinsey & Company, Inc.*, Consent J. at 2 (Feb. 4, 2021).

² Letter from Andrew Tantillo, Acting Associate Commissioner for Legislative Affairs, Food and Drug Administration to Senator Maggie Hassan at 6 (Oct. 22, 2021).

³ *Id.* at 7.

⁴ *Id.*

The staff report's conclusions are undermined by three significant flaws in its approach. First, it determined, without support, that there was a conflict based on the time period of the work, without examining the nature of the work to determine if the work was, in fact, in conflict. Second, it applied an incorrect conflicts standard by inaccurately suggesting that McKinsey's work on broad, systemic issues that had nothing to do with opioids created a conflict simply because the FDA also regulates opioids. This is inconsistent with the governing law and the established practices of professional firms that contract with the U.S. government. Third, it took speculative leaps to reach unwarranted findings, drawing inaccurate conclusions about individual consultants' roles. For example, the report suggested that appearing on an e-mail about an unrelated topic constituted working on an FDA matter, or speculating that FDA confidential information may have been divulged merely because McKinsey consultants spoke to each other or also served private sector clients.

Finally, the staff report mischaracterized McKinsey's cooperation with the Committee. The documents described in the report as "obtained" by the Committee were expeditiously provided voluntarily by McKinsey to the Committee. Nearly all of the cited documents were provided in November 2021, within two weeks of the Committee's initial request letter. In total, McKinsey produced more than 350,000 pages of materials voluntarily to the Committee and remained in constant contact with the staff to understand and respond to their priorities throughout the investigation.

The following sections provide additional information regarding issues raised in the Committee's investigation and the Committee's recent staff report.

McKinsey's Work for the FDA Cited in the Committee's Staff Report

For nearly 15 years, the FDA has contracted with McKinsey to provide consulting services. We are proud of the work we have done for the U.S. government and firmly believe our efforts have helped make the FDA a stronger and more effective agency. Our engagements include both numerous prime contracts with the FDA and several subcontracts under various prime contractors serving FDA programs. We estimate that about 60% of our engagements for the FDA have been in the area of business process improvements. We estimate that an additional 20% of our engagements focused on reorganization issues. Finally, we estimate that about 20% of our engagements focused on technology enablement. None of McKinsey's work for the FDA has involved specific regulatory policies or decisions, or specific regulatory outcomes.

Within the Center for Drug Evaluation and Research ("CDER"), for example, McKinsey's work has focused on modernization efforts aimed at improving CDER's organization and process design. Importantly, McKinsey's work for CDER focused on process improvements and did not involve advising on the content of any safety standards, or the safety of any products or class of products, whether opioids or other drugs. In particular, McKinsey's work for CDER's Sentinel initiative focused on creating a national electronic system for monitoring the safety of FDA-regulated medical products on the market. McKinsey's work focused on business process improvement and organizational support to assist the FDA in its application and implementation of the system, expanding the FDA's ability to conduct post-market safety surveillance. McKinsey did not advise on the safety standards themselves. As

part of our cooperation with the Committee on these matters, we provided details of our past engagements with the agency.

Importantly, in undertaking engagements with the FDA, McKinsey was transparent about our professionals' work for pharmaceutical companies, including on opioid matters. For example, in reviewing proposals and other materials submitted by McKinsey to the FDA, we found more than 40 instances in which McKinsey disclosed Jeff Smith's client service to pharmaceutical companies, including more than 20 instances that referenced work on opioid matters. Similarly, we found more than 30 instances in which McKinsey disclosed Navjot Singh's client service to pharmaceutical companies.

Inaccuracies in the Committee's Staff Report

As noted above, the Committee's recent staff report contained significant inaccuracies. Although the inaccuracies are too numerous to catalog in this testimony, several are noteworthy both in relation to our work and specific colleagues:

- The staff report incorrectly stated that McKinsey “received information from FDA related to the agency’s regulation of opioids” and then shared the information with “McKinsey colleagues working for private sector opioid clients.” As evidence, the Committee reproduced a draft presentation slide prepared by McKinsey for Purdue and stated that it revealed the “blueprints of the organizational structure used to deploy Sentinel at the agency.” Contrary to the report’s allegations, the content of the slide was publicly published by the FDA more than eight months before the draft slide prepared for Purdue. The information was publicly available at the time that the draft presentation was prepared, and that information remains posted on the FDA’s website today.⁵ As far as we are aware, the draft slide also was never shared with Purdue.
- The staff report stated that “an email from 2017 referred to ‘ancient work product’ that [Navjot] Singh and another McKinsey consultant completed for Purdue.” Contrary to the report’s assertion, the work product referenced in this e-mail was unrelated to Purdue and instead was an article that Dr. Singh and others authored in 2009 about pharmaceutical research and development investment. The article was first published in *In Vivo: The Business & Medicine Report* in November 2009 and republished on McKinsey’s website.⁶
- The staff report stated that “[d]ocuments show Purdue executives were focused on defeating FDA safety measures for OxyContin,” citing an e-mail exchange between McKinsey employees. The cited e-mail, however, nowhere references “defeating FDA safety measures.”

⁵ The document is available at <https://www.fda.gov/files/about%20fda/published/Sentinel-Program-Interim-Assessment.pdf>.

⁶ The article is available at <https://www.mckinsey.com/industries/life-sciences/our-insights/new-frontiers-in-pharma-r-and-38d-investment>.

- The staff report suggested that McKinsey's responses to the Committee's requests were incomplete, stating that McKinsey provided a list of FDA engagements that contained "fewer than half of the contracts reported in government databases." The Committee, however, did not request a list of all FDA engagements. McKinsey provided a list of the requested matters.

As part of our ongoing cooperation with the Committee's inquiries and to help the Committee better understand our work, we will submit a chart identifying dozens of substantive misstatements, inaccuracies, and mischaracterizations in the Committee's staff report in the coming days. We hope that this effort to provide accurate information to Congress and the public is useful to the Committee's efforts.

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Thank you for the invitation to be here today. I would be happy to answer your questions.