October 22, 2021

The Honorable Chuck Grassley
United States Senate
Washington, D.C. 20510-1501

Dear Senator Grassley:

Thank you for your letter, cosigned by five of your colleagues, regarding the U.S. Food and Drug Administration's (FDA or the Agency) past work with the consulting firm McKinsey & Company (McKinsey).

The opioid crisis is one of the largest and most complex public health tragedies that our nation has ever faced. FDA is fully committed to continuing to look closely at the opioid crisis, learning from what happened, identifying missed opportunities, and taking aggressive steps to address this public health emergency. The Agency takes the issue of our contracting with consulting firms, like McKinsey, seriously and any real or perceived conflicts of interest by firms the Agency has contracted with is of great concern to us.

In your letter you ask seven questions, which we respond to in turn below. Your questions are in bold, followed by FDA's responses.

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.**

   FDA, as part of its solicitation and contract award process, includes Organizational Conflict of Interest (OCI) language and clauses that outline what the contractor must do before, during, and after award. FDA relies on the contractor to assess and report potential OCI and submit mitigation plans for review. This process is in compliance with the requirements regarding OCI as delineated in the Federal Acquisition Regulations.

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.**

   FDA has awarded five contracts/Blanket Purchase Agreement (BPA) orders to McKinsey since 2019. To date, all performance on those contracts/orders has been completed. There are currently zero active or planned contracts with McKinsey. The five contracts/orders are listed and detailed below:

   HHSF223201700022B/HHSF22319001 – The purpose of the task order was to develop a framework that increases successful IT project deliveries across the Center for Drug Evaluation and Research (CDER). Services included development of an implementation framework, establishment of leading practices and tools, and an iterative validation process of outputs and role modeling.

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HHSF223201700022B/HHSF22319002 - The purpose of this order was to deliver a roadmap and implement plans to modernize CDER's new drugs regulatory program, including providing project management support to multiple workstreams comprised of CDER subject matter experts. The scope of this multi-year initiative included the overall reorganization of relevant offices as well as process improvement in areas such as review of applications and post-market safety operations.

HHSF223201700022B/75F40119F19017 – The purpose of this order was to identify Center for Tobacco Products (CTP) Office of Science (OS) leadership's needs and implement the most robust change management leadership model to gain broad consensus and support for the OS leadership's vision.

75F40120P00150 – The purpose of this acquisition was to procure support services from McKinsey for the establishment of a central coordination function for COVID-19 response efforts across CDER and other FDA components to ensure the Center is using its time efficiently and effectively and is best situated to operate from a proactive position to stay ahead of the evolving COVID-19 pandemic. This central function provides support to thirteen (13) unique streams of work across the Center, five (5) cross-cutting functional areas, and countless sub-initiatives ranging from the acceleration of development for treatments for COVID-19, removing barriers to drug supply chains, providing guidance to manufacturers, advising developers on how handle clinical trial conduct issues, and keeping the public informed.

75F40120P00388 - The objectives of this contract were to identify durable process and organizational and programmatic changes that may be implemented without delay to advance the ongoing COVID-19 response efforts, accelerate recovery and to strengthen the FDA's all-hazards preparedness framework to effectively detect and respond to future pandemics or other disasters.

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.**

HHSF223201700022B/HHSF22319001, HHSF223201700022B/HHSF22319002, and HHSF223201700022B/75F40119F19017 were BPA orders, governed by the parent BPA HHSF22320170022B, and contain the below OCI language. The orders themselves do not contain disclosure requirements. 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 outlined below:

Offeror's Certification – Organizational Conflicts of Interest

As a regulatory agency charged with protection of the public health, the Food and Drug Administration (FDA) must maintain public confidence in the integrity of its decisions. The FDA has various policies and procedures that safeguard against both actual and apparent conflict of interest (COI) on the part of its employees. It

is additionally critical that the FDA be assured that there is no actual or apparent COI on the part of either the Contractor's organization or its individual employees in performance of this contract. Offerors submitting quotes to perform work under this contract must assure the protection of the information and data they receive in performance or under this contract from unauthorized use or disclosure, and must avoid actions that would cause a reasonable person to question the impartiality of the Contractor, its employees, or the Government in the performance of this immediate contract and potential participation in future contract actions. The Contractor will be held to the restrictions of the Organizational Conflict of Interest clause, unless an acceptable mitigation of risk plan is proposed, found to be acceptable by the Government, and enforced.

POTENTIAL CONFLICTS OF INTEREST SPECIFIC TO THIS BPA – Offerors shall review the Statement of Work in detail to identify any particular aspects that may present organizational or individual COI, either actual or apparent

DEFINITION OF CONFLICT OF INTEREST - Conflict of interest means that because of other activities or relationships with other persons or organizations, a person or organization is unable or potentially unable to render impartial assistance or advice to the Government, that the person's or organization's objectivity in performing the contract is or might be otherwise impaired, or that the person or organization has or might acquire an unfair competitive advantage (See FAR 9.501).

Organizational Conflict of Interest (Clause)

(a) *Purpose.* The purpose of this clause is to ensure that the Contractor and its subcontractors:

(1) Are not biased because of their financial, contractual, organizational, or other interests which relate to the work under this Order, and

(2) Do not obtain any unfair competitive advantage over other parties by virtue of their performance of this Order.

(b) *Scope.* This clause applies to performance or participation by the contractor, its parents, affiliates, divisions and subsidiaries, and successors in interest (hereinafter collectively referred to as “contractor”) in the performance of this order as a prime contractor, subcontractor, co-sponsor, joint venturer, consultant, or in any similar capacity.

(c) *Warrant and Disclosure.* The warrant and disclosure requirements apply to both the Contractor and all subcontractors. 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. Such disclosure shall include a description of the actions the Contractor has taken or proposes to take in order to avoid, neutralize, or mitigate any resulting conflict of interest.

(d) *Remedies.* The Contracting Officer may terminate this Order, in whole or in part, if the Contracting Officer deems such termination necessary to avoid, neutralize or mitigate an actual or apparent organizational conflict of interest. If the Contractor fails to disclose facts pertaining to the existence of a potential or actual organizational conflict of interest or misrepresents relevant information to the Contracting Officer, the Government may terminate the Order for default, suspend or debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this Task Order.

(e) *Subcontracts.* The Contractor shall include a clause substantially similar to this clause, including paragraphs (f) and (g), in any subcontract or consultant agreement.

(f) *Prime Contractor Responsibilities*. The Contractor shall determine in writing whether the interests disclosed present an actual, or significant potential for, an organizational conflict of interest. The Contractor shall identify and avoid, neutralize, or mitigate any subcontractor organizational conflict prior to award of the Order to the satisfaction of the Contracting Officer. If the subcontractor's organizational conflict cannot be avoided, neutralized, or mitigated, the Contractor must obtain the written approval of the Contracting Officer prior to entering into the subcontract. If the Contractor becomes aware of a subcontractor's potential or actual organizational conflict of interest after Order award, the Contractor agrees that the Contractor may be required to eliminate the subcontractor from its team, at the Contractor's own risk. The Contractor shall obtain from its subcontractors or consultants the disclosure required in FAR Part 9.507.

(g) Waiver. The Contractor may seek a waiver from the Head of the Contracting Activity by submitting such waiver request to the Contracting Officer, including a full written description of the requested waiver and the reasons in support thereof.

Contract #75F40120P00388 contained the below OCI language. FDA is not aware of any disclosures made by McKinsey vis-a-vis OCI in relation to this award. 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 language below:

ORGANIZATIONAL CONFLICT OF INTEREST

(a) Purpose. The purpose of this clause is to ensure that the contractor and its subcontractors:

(1) Are not biased because of their financial, contractual, organizational, or other interests which relate to the work under this contract, and

(2) Do not obtain any unfair competitive advantage over other parties by virtue of their performance of this contract.

(b) Scope. This clause applies to performance or participation by the contractor, its parents, affiliates, divisions and subsidiaries, and successors in interest (hereinafter collectively referred to as "contractor") in the performance of this contract as a prime contractor, subcontractor, co-sponsor, joint venturer, consultant, or in any similar capacity.

(c) Warrant and Disclosure. The warrant and disclosure requirements apply to both the contractor and all subcontractors. 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. Such disclosure shall include a description of the actions the contractor has taken or proposes to take in order to avoid, neutralize, or mitigate any resulting conflict of interest.

(d) Remedies. The Contracting Officer may terminate this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid, neutralize or mitigate an actual or apparent organizational conflict of interest. If the contractor fails to disclose facts pertaining to the existence of a potential or actual organizational conflict of interest or misrepresents relevant information to the Contracting Officer, the Government may terminate the contract for cause, suspend or debar the contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

(e) Subcontracts. The contractor shall include a clause substantially similar to this clause, including paragraphs (f) and (g), in any subcontract or consultant agreement.

(f) Prime Contractor Responsibilities. Contractor shall determine in writing whether the interests disclosed present an actual, or significant potential for, an organizational conflict of interest. The contractor shall identify and avoid, neutralize, or mitigate any subcontractor organizational conflict prior to award of the contract to the satisfaction of the Contracting Officer. If the subcontractor's organizational conflict cannot be avoided, neutralized, or mitigated, the contractor must obtain the written approval of the Contracting Officer prior to entering into the subcontract. If the contractor becomes aware of a subcontractor's potential or actual organizational conflict of interest after contract award, the contractor agrees that the Contractor may be required to eliminate the subcontractor from its team, at the contractor's own risk. The contractor shall obtain from its subcontractors or consultants the disclosure required in FAR Part 9.507.

(g) Waiver. The contractor may seek a waiver from the Head of the Contracting Activity by submitting such waiver request to the Contracting Officer, including a full written description of the requested waiver and the reasons in support thereof.

(h) As a regulatory agency charged with protection of the public health, the Food and Drug Administration (FDA) must maintain public confidence in the integrity of its decisions. The FDA has various policies and procedures that safeguard against both actual and apparent conflict of interest (COI) on the part of its employees. It is additionally critical that the FDA be assured that there is no actual or apparent COI on the part of either the Contractor's organization or its individual employees in performance of this contract action.

(i) Offerors submitting proposals to perform work under this contract must assure the protection of the information and data they receive in performance or under this contract from unauthorized use or disclosure, and must avoid actions that would cause a reasonable person to question the impartiality of the Contractor, its employees, or the Government in the performance of this immediate contract and potential participation in future actions. Contractor will be held to the restrictions of the Organizational Conflict of Interest clause, unless an acceptable mitigation of risk plan is proposed, found acceptable by the Government and enforced.

(j) POTENTIAL CONFLICTS OF INTEREST SPECIFIC TO THIS CONTRACT- Offerors shall review the Statement of Work included in each RFTOP in detail to identify any 47 particular aspects that may present organizational or individual COI, either actual or apparent.

(k) DEFINITION OF CONFLICT OF INTEREST - Conflict of interest means that because of other activities or relationships with other persons or organizations, a person or organization is unable or potentially unable to render impartial assistance or advice to the Government, that the person's or organization's objectivity in performing the contract is or might be otherwise impaired, or that the person or organization has or might acquire an unfair competitive advantage (See FAR 9.501).

Contract #75F40120P00150 – Did not contain disclosure requirements. FDA is not aware of any conflict-of-interest disclosures made by McKinsey in relation to this award.

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.**

FDA became aware in early 2021 when the information was reported in the media. FDA had previous contracts with McKinsey that covered the broad scope of the Agency's activities with drug products, for example, those focused on improving Agency processes or creating visibility into supply chains. However, FDA has not consulted McKinsey about processes or review issues associated with any specific drug product or specific product class, including opioids. As none of FDA's contracts were specifically related to opioids, no additional contract reviews or outreach to McKinsey occurred.

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.**

As noted in answer four, FDA became aware in early 2021 when the information was reported in the media. FDA had previous contracts with McKinsey that cover the broad scope of the Agency's activities with drug products, for example, those focused on improving processes or creating visibility into supply chains. However, FDA has not consulted McKinsey about distribution or retail sales associated with any specific drug product or specific product class, including opioids. As none of FDA's contracts were specifically related to opioids, opioid distribution, or retail sales of opioids, no additional contract reviews or outreach to McKinsey occurred.

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?**

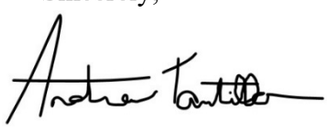
As described above, FDA, as part of its solicitation and contract award process, includes OCI language and clauses that outline what the contractor must do before, during, and after award. FDA relies on the contractor to assess and report potential OCI and submit mitigation plans for review.

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.**

FDA was not aware that this contract could impact McKinsey's private sector clients. This contract was a single award BPA based on an existing McKinsey contract on the Federal Supply schedule and once it was determined that McKinsey could complete the work requested no other bidders were required to bid.

FDA is committed to addressing the opioid crisis and will continue to explore all possibilities to deliver immediate and long-term solutions.

Sincerely,



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