Testimony of

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Before the House Committee on Oversight and Reform

McKinsey & Company’s Conduct and Conflicts at the Heart of the Opioid Epidemic

April 27, 2022

Government business shall be conducted in a manner above reproach and ... with complete impartiality and with preferential treatment for none. Transactions relating to the expenditure of public funds require the highest degree of public trust and an impeccable standard of conduct.¹

Chairwoman Maloney, Ranking Member Comer, and Members of the Committee, thank you for inviting me to testify in this legislative hearing. I am Jessica Tillipman, the Assistant Dean for Government Procurement Law Studies at The George Washington University Law School. In addition to leading the Law School’s Government Procurement Law Program, I teach our Anti-Corruption & Compliance course, which focuses on anti-corruption, ethics, and compliance issues in government procurement.

The Interim Majority Staff Report, “The Firm and the FDA: McKinsey & Company’s Conflicts of Interest at the Heart of the Opioid Epidemic” (hereinafter “Conflicts Report”)² provides a compelling case study in how conflicts and compliance issues significantly undermine the

¹ FAR 3.101-2.
public’s confidence in our procurement system and the contractors that provide the U.S. government with critical goods and services.

I will address only two issues raised in the Report: (1) the longstanding need to update and clarify the current legal framework governing Organizational Conflicts of Interest (OCIs), and (2) the importance of government contractors maintaining strong internal ethics and compliance programs. Before addressing these issues, I offer some historical and legal context.

The U.S. government procurement system aspires to obtain the best goods and services, from the best private sector firms, at the best prices. To attain these goals and ensure that taxpayer dollars are appropriately safeguarded, the Federal Acquisition Regulation (FAR) makes clear that the government procurement process demands the highest commitment to ethical and unbiased conduct. To maintain integrity in the system, entities that do business with the government are subject to a patchwork of requirements, restrictions, and compliance obligations.

In my Anti-Corruption & Compliance course, I refer to this patchwork of rules as the “U.S. Government Procurement Anti-Corruption Ecosystem” - a framework designed to prevent, detect, and mitigate corruption risks in the U.S. government procurement system. It includes principles such as transparency and oversight; critical tools such as whistleblower protections and debarment; and an expansive toolbox of civil and criminal laws that address a wide range of inappropriate and unethical business practices. This anti-corruption “ecosystem” is designed to accomplish four goals: (1) maintain integrity in interactions with government officials, (2) promote fairness, transparency, and competition, (3) ensure contractors are honest in their exchanges with the government, and (4) help maintain integrity throughout the supply chain.

The primary concern raised in the Conflicts Report is the potential conflict of interest between McKinsey’s work for the Food and Drug Administration (FDA) and its pharmaceutical manufacturer clients. The FAR deals with conflicts of interest in two ways: by regulating Personal Conflicts of Interest (PCIs) and Organizational Conflicts of Interest (OCIs). The information provided in the Conflicts Report relates primarily to OCIs, so my comments today focus on this complex area of the law.

The Conflicts Report presents two important questions: (1) whether the current OCI framework adequately addresses potential conflicts between a contractor’s public sector and private sector

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4 The Federal Acquisition Regulations System, Title 48 of the U.S. Code of Federal Regulations, provides a robust set of rules and requirements governing the U.S. Government's procurement process.
5 See generally FAR 3.11 and FAR 52.203-16.
6 See generally FAR 9.5.
work, and, if not, (2) what legislative changes could help avoid conflicts of this nature in the future. With respect to the first question, any objective observer with a basic understanding of the FAR and access to Google would conclude that existing OCI regulations most certainly cover conflicts between a contractor’s public and private sector work. As to the second question, the OCI language in the FAR, which has remained largely unchanged since 1984, should be revisited. As I discuss in greater detail below, it is no longer reflective of modern procurement practices and the sophisticated body of OCI case law that has developed over the past several decades.

**Organizational Conflicts of Interest**

The FAR defines an OCI as occurring when:

> because of other activities or relationships with other persons, a person is unable or potentially unable to render impartial assistance or advice to the government, or the person’s objectivity in performing the contract work is or might otherwise be impaired, or a person has an unfair competitive advantage.  

The term “person” includes companies and other contracting entities. The current framework for analyzing whether an OCI exists derives primarily from FAR Subpart 9.5 and decisional precedent from the Government Accountability Office (GAO) and the U.S. Court of Federal Claims (COFC).

Although OCIs have been regulated since the 1960s, they have garnered increased attention in recent decades due to, among other things, consolidation in the information technology and defense industries, and the government’s increased reliance on contractors to provide services traditionally performed by public servants, “especially where the contractor is tasked with providing advice to the Government.” Experience suggests that OCIs are more likely to occur in contracts involving certain services, such as management support services and consultant or other professional services.

OCIs are generally separated into three categories:

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7 FAR 2.101.
1. **Impaired objectivity** - may arise where a contractor's outside business relationships create an economic incentive to provide biased advice under a government contract;

2. **Biased ground rules** - may occur when, as part of its work under one procurement, the contractor has helped set the procurement’s ground rules, such as writing the statement of work or developing specifications, for another procurement; and

3. **Unequal access to information** - may occur when a contractor obtains access to nonpublic information as part of its contract performance which gives it an advantage in a later competition for a government contract.

Most relevant today is “impaired objectivity.” “In these cases, the concern is that the contractor’s ability to render impartial advice could appear to be undermined by its relationship to the evaluated entity.”

FAR 9.504 requires a Contracting Officer (CO) to “identify and evaluate potential organizational conflicts of interest as early in the acquisition process as possible; and avoid, neutralize, or mitigate significant potential conflicts before contract award.” To fulfill this obligation, CO’s depend on contractors to disclose, among other things, “any facts that may cause a reasonably prudent person to question the Contractor’s impartiality because of the appearance or existence of bias.” Agencies generally demand this information through solicitation provisions or contract clauses which clearly articulate the government’s expectations with regard to the disclosure of facts and circumstances that would give rise to an actual or potential OCI.

Unlike many other provisions in the FAR that ensure compliance through standard solicitation provisions and contract clauses found in FAR Subpart 52, the FAR contains no mandatory OCI solicitation provision or contract clause. Instead, agencies have developed their own language. For example, FDA contracts may contain the following:

> 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

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13 Szeliga, *supra*, note 11, at 660.
14 See, e.g., 48 CFR § 3452.209-70 (requiring, in Department of Education contracts, disclosure of all such relevant information if such a conflict of interest appears to exist to a reasonable person with knowledge of the relevant facts or if such a person would question the impartiality of the contractor). *See also* 48 C.F.R. 1352.209-74 (U.S. Department of Commerce’s OCI clause).
15 *Id. See also* Conflicts Report, *supra* note 2 at 36 (citing OCI language found in FDA contracts).
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.\textsuperscript{16}

**Failure To Disclose OCI’s**

Failure to disclose the information required by an applicable OCI clause can lead to a multitude of adverse consequences, including, but not limited to contract termination, prosecution for the making of false statements (including fines and imprisonment), or suspension or debarment. In addition, a false OCI certification could also trigger potential liability under the False Claims Act, resulting in treble damages and penalties.\textsuperscript{17} The submission of false claims may also be prosecuted criminally.\textsuperscript{18} Criminal penalties for submitting false claims include imprisonment and fines.

Given the potentially severe consequences for failure to disclose an actual or potential OCI, most sophisticated contractors take affirmative steps to identify potential conflicts of interest and, to the best of their ability, mitigate the conflicts by, for example, developing firewalls, executing non-disclosure agreements, or shifting work to a neutral, unaffiliated third party. Although FAR Subpart 9.5 speaks primarily to COs, contractors play a significant role in communicating with the CO to seek ways in which potential OCIs can be mitigated or avoided. Moreover, “an effective mitigation plan may enable a contractor to perform engagements for which it otherwise would not be available.”\textsuperscript{19} Notably, “impaired objectivity” OCIs are often very difficult to mitigate, particularly where the conflict permeates nearly every aspect of the government contract. Moreover, CO’s tend to reject mitigation plans when contractors fail to implement or monitor compliance with them (i.e., when employees breach firewalls to obtain a competitive advantage in a procurement).\textsuperscript{20}

The plain language of FAR 9.5 and the relevant GAO precedent make clear that current law covers scenarios in which a contractor’s other business relationships (including those with private sector clients), “could create an incentive for a contractor to provide biased advice” under its government contracts.\textsuperscript{21} The policies underlying OCI rules emphasize why preventing and mitigating conflicts of this nature are so important:

\textsuperscript{16} Conflicts Report, supra note 2 at 36.
\textsuperscript{18} See 18 U.S.C. § 287.
\textsuperscript{19} Szeliga, supra, note 11, at 660.
\textsuperscript{20} Johnson Controls World Servs., Inc., B-286714.2 (Feb. 13, 2001).
\textsuperscript{21} Szeliga, supra, note 11, at 660.
The failure of a procurement system to address OCIs appropriately can undermine both its legitimacy and anti-corruption goals and may have other undesirable effects. . . OCIs can also reduce the quality and value of the services a government receives, because organizations with OCIs may have competing loyalties that could undermine the quality of their advice to the government. Divided loyalties may include conflicting interests such as maximizing profit versus rendering candid advice to the government. In circumstances where providing impartial advice may be against organizational self-interest, the procuring organization faces performance risk.22

Although these types of issues most frequently arise in the context of *a contractor’s work on one government contract conflicting with its work on another government contract*, FAR Subpart 9.5 is not limited to these types of conflicts. Not only is the plain language of FAR 9.5 broad enough to cover potential conflicts between a contractor’s government and private sector business, FAR 9.508(i) provides an example that explicitly warns contractors away from conflicts of this nature, stating:

> An agency that regulates an industry wishes to develop a system for evaluating and processing license applications. Contractor X helps develop the system and process the applications. Contractor X should be prohibited from acting as a consultant to any of the applicants during its period of performance and for a reasonable period thereafter.

Moreover, GAO has sustained several bid protests in which a conflict between a contractor’s government work and its commercial work has created an impermissible “impaired objectivity” OCI.23 In these situations, an “OCI is most likely to arise where an outside business venture is related directly to the subject matter of the procurement and structured such that there is a real economic incentive for biased performance.”24

In *Washington Utility Group*, GAO determined that the Department of Energy (DOE) had properly excluded a contractor from a procurement competition which involved the preparation and issuance of requests for proposals for renewable energy projects.25 GAO pointed to several “unavoidable” OCIs created by the business interests of a company’s proposed subcontractor

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23 *See, e.g.*, Alion Science and Technology Corp., B-297342, et al., Jan. 9, 2006 (describing the contractor’s “multiple competing financial interests arising from the manufacturing and marketing of its products to the U.S. government, to foreign governments, and to commercial customers.”).


which “presented numerous and substantial potentials for providing biased advice to DOE,” including:

- The subcontractor was working with another firm to develop the type of technology that would be considered for financial assistance under the DOE program;

- The subcontractor’s relationship with certain organizations that had the potential to be funded by DOE could have resulted in the subcontractor having “preconceived opinions regarding certain technologies which could result in biased advice and recommendations provided DOE under the contract.”; and

- The subcontractor was negotiating an agreement to assist utility companies to identify commercial renewable energy opportunities which had “great potential” to influence the advice provided to DOE.

Moreover, GAO highlighted concerns that the subcontractor’s commercial clientele could “benefit from inadvertently obtaining information about the types of projects that DOE would fund.”26 Under these circumstances, GAO found the CO properly concluded that there were “no realistic means to avoid the conflicts identified” where the contractor would be providing advice on several technologies in which its subcontractor had a business interest or may have developed an interest due to its commercial activities.27

Given the wide range of scenarios that may raise concerns about the presence of an unmitigated OCI, the FAR clarifies that the situations and examples in FAR 9.505 and 9.508 are not “all inclusive,” and that conflicts may arise in situations not expressly covered.28 To help entities determine whether their business activities may implicate these provisions, the FAR emphasizes that the regulations’ “underlying principles” should be instructive in determining whether a “significant potential conflict exists,” including “preventing the existence of conflicting roles that might bias a contractor’s judgment.”29

The FAR’s prescriptive warnings are buttressed by the language found in many agency OCI solicitation provisions and contract clauses, which, for example, not only require contractors to identify actual OCIs, but apparent OCIs as well.30 Moreover, these clauses typically also require the immediate disclosure of “the existence of any facts that may cause a reasonably prudent

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26 Id.
27 Id.
28 See generally FAR 9.505, 9.508.
29 FAR 9.505.
30 Conflicts Report, supra note 2 at 36 (citing OCI language found in one of McKinsey’s contracts with the FDA).
person to question the contractor's impartiality because of the appearance or existence of bias.

Although the current version of the FAR certainly covers situations involving conflicts between an entity’s government and private sector work, it is no longer reflective of modern procurement practices and OCI case law that has developed over the past several decades. As addressed in greater detail below, the most recent attempt to overhaul the FAR’s OCI regulations in 2011 ultimately failed. The proposed rule would have refined the current regulations and standardized OCI solicitation provisions and contract clauses. Moreover, it also proposed strengthening safeguards with respect to the nonpublic information contractors access during the performance of their government contracts. The Conflicts Report reminds us that it is past time to revisit this initiative.

The Importance of Contractor Ethics & Compliance Programs

All of the issues highlighted in the Conflicts Report must be considered against the backdrop of a growing global consensus on what constitutes an effective corporate ethics and compliance program. Since the mid-aughts, there has been increased attention given to the importance of internal compliance and ethics programs designed to prevent, detect, and mitigate ethics and corruption risks that may develop in the course of a company’s business activities. Given the heightened corruption risks and compliance obligations associated with government contracts, most sophisticated government contractors have invested heavily in ethics and compliance programs to reduce these risks.

Recognizing the increased role of ethics and compliance programs in entities that do business with the U.S. government, FAR 52.203-13 requires contractors to (1) adopt a written code of business ethics and conduct which must be made available to each employee engaged in performance of the contract, (2) maintain an ongoing business ethics awareness and compliance program, and (3) develop an internal control system. FAR 52.203-13 provides contractors with additional details about what an effective compliance program and internal control system should entail, including, among other things, training, procedures designed to ensure timely discovery of improper conduct in connection with Government contracts; and “periodic reviews of business practices, procedures, policies, and internal controls for compliance with the Contractor’s code.

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31 Id.
33 See generally Jessica Tillipman & Vijaya Surampudi, The Compliance Mentorship Program: Improving Ethics and Compliance in Small Government Contractors, 49 PUB. CONT. L.J. 217 (2020) (describing an evolving global effort to encourage companies to dedicate resources to developing anti-corruption compliance programs and maintaining robust internal controls).
34 The FAR exempts small business concerns and contracts for the acquisition of a commercial product or commercial service from this requirement. FAR 52.203-13(c).
of business ethics and conduct and the special requirements of Government contracting.” Even for contractors that fall outside the coverage of this FAR provision, implementing and maintaining a strong ethics and compliance program remains a necessity given its key role in reducing risk, ensuring compliance with the law, and sustaining a culture that promotes ethical conduct.

Many of the world’s largest government contractors have dedicated significant resources to “promote and advance a culture of ethical conduct in every company that provides products and services through government contracting.” Recognizing that ethical transgression by one government contractor has the potential to negatively impact all government contractors, organizations such as the Defense Industry Initiative (DII) and the International Forum for Business Ethical Conduct (IFBEC) are dedicated to establishing and improving business ethics and compliance programs in the government contracts industry. The efforts of DII and IFBEC are buttressed by organizations such as the Society of Corporate Compliance and Ethics (SCCE), which provide support to ethics and compliance professionals across all industries.

Contractors must develop policies and procedures tailored to the unique risks they face. A truly “risk-tailored” compliance program recognizes that not all risks are equal and appreciates that devoting more time to policing high-risk areas is an essential component of an effective compliance program. For example, given the risks associated with a contractor’s failure to properly identify, mitigate, and disclose potential OCIs, most contractors have dedicated compliance policies, procedures, and controls designed to effectively manage this risk. Moreover, in light of the heightened OCI risks associated with contracts involving management support and consulting services, contractors providing services of this nature would be expected to dedicate a greater proportion of their compliance resources to this particular aspect of their compliance program.

A robust and proactive approach to OCI compliance would likely include:

- Clear and accessible policies and procedures designed to identify OCI risks and requirements;

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38 Society of Corporate Compliance and Ethics, at https://www.corporatecompliance.org/.
39 For example, the Conflicts Report links to a copy of McKinsey’s “Organizational Conflicts of Interest Policy,” which is designed to assist employees with identifying, assessing, and potentially disclosing OCIs in the context of the company’s federal government contracts work.
• Processes and internal controls designed to ensure actual practices are compliant and consistent with internal policies and regulatory/contractual requirements;

• A regular testing protocol to assess the effectiveness of internal controls related to OCI compliance;

• Remediation of any identified weaknesses in policies, procedures, or practices;

• Firm-wide training of employees on OCI requirements, with more extensive training for employees most likely to encounter or manage OCI-related issues;

• Ensuring senior management’s words and actions demonstrate a commitment to OCI compliance;

• Requiring and encouraging employees to identify and report facts that could give rise to a potential OCI;

• Conducting a rigorous OCI analysis before submitting any proposals to the government and fully complying with any OCI reporting obligations; and

• Maintaining stringent controls relating to the safeguarding of nonpublic information acquired or accessed during the performance of a government contract.

Merely adopting an OCI policy is not enough. The effectiveness of an institution’s ethics and compliance program depends upon whether it is followed in practice. An official “policy” that appears strong and protective is virtually meaningless if ignored. Ethics and compliance professionals disparage “paper programs”—compliance policies and procedures that appear robust but are neither implemented nor followed in practice. In its “Evaluation of Corporate Compliance Programs” guidance, the Department of Justice (DOJ) has identified three “fundamental questions” for evaluating the effectiveness of a compliance program:

1. Is the compliance program well designed?

2. Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?

3. Does the compliance program work in practice?40

To be clear, an occasional violation or deviation from policies and procedures does not necessarily mean that a compliance program is ineffective, as no entity is immune from human transgression. However, evidence of a systemic disregard for compliance policies and procedures, particularly when committed by senior leaders, is often strong evidence of a weak culture of compliance.

**The Path Forward**

A 2007 Report of the Acquisition Advisory Panel to the Office of Federal Procurement Policy and the United States Congress noted:

> [T]he trend toward more reliance on contractors . . . raises the possibility that the government’s decision-making processes can be undermined. . . . [u]nless the contractor employees performing these tasks are focused upon the interests of the United States, as opposed to their personal interests or those of the contractor who employs them, there is a risk that inappropriate decisions will be made.\(^{41}\)

Despite widespread acknowledgment that increased reliance on contractors could create fertile ground for conflicts of interest, government regulation of these potential hazards has not kept pace. Over a decade ago, various government audits and studies identified significant issues stemming from the government’s increased reliance on contractors to provide services traditionally performed by public servants.\(^{42}\) Although progress has been made,\(^{43}\) some issues persist.

The current framework governing OCIs and contractor access to nonpublic information are outdated, inconsistent with modern procurement practices, and fail to address the growing risks associated with the government’s increasing reliance on contractors to provide services which include advice and the exercise of judgment.

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\(^{42}\) See, e.g., **U.S. Gov't Accountability Off., GAO-10-693, Stronger Safeguards Needed For Contractor Access To Sensitive Information** 30 (2010) (recommending more thorough protections when contractors are allowed access to sensitive information); **Admin. Conf. Of The U.S., 2011-3, Compliance Standards For Government Contractor Employees – Personal Conflicts Of Interest And Use Of Certain Non-Public Information**, 76 Fed. Reg. 48792 (Aug. 9, 2011) (discussing a proposed rule addressing PCIs and recommending model language in the FAR to be used in contracts that pose particular risks of government contractor employee personal conflicts of interest or misuse of nonpublic information).

\(^{43}\) On November 2, 2011, the FAR Council issued a final rule, creating FAR Subpart 3.11, titled “Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions,” and a new contract clause at FAR 52.203-16, titled “Preventing Personal Conflicts of Interest.”
In 2011, the FAR Council\textsuperscript{44} engaged in a thoughtful and somewhat Herculean task of attempting to refine OCI rules to make the regulation more reflective of modern procurement practices and the sophisticated body of OCI case law that has developed over the past several decades. Although the proposed rule was never implemented and ultimately withdrawn (ten years later, on March 19, 2021),\textsuperscript{45} the proposed rule addressed numerous outstanding issues, including:

- **Relocating the FAR’s OCI Provisions:** After concluding that OCI issues are more closely aligned with “business practice” issues than contractor qualifications, the proposed rule recommended relocating the FAR’s OCI provisions from FAR 9.5 to a new FAR Subpart 3.12.

- **Amending Existing FAR Coverage and Introducing New Solicitation Provisions and Contract Clauses:** Recognizing the need to assist contracting officers in implementing the Government’s OCI policy, the FAR Council recommended amending existing FAR coverage to clarify key terms and provide more detailed guidance regarding how contracting officers should identify and address OCIs. It also introduced new solicitation provisions and contract clauses after determining that it would be beneficial to have standard language in the FAR that could be tailored if appropriate (rather than relying on agency-specific solicitation provisions and contract clauses).

- **Enhancing Protections Related to Contractor Access of Nonpublic Information:** Citing to government reports that raised concerns regarding the safeguarding of nonpublic information contractors may obtain while performing government contracts, the FAR Council proposed new FAR clauses which would contractually obligate contractors to protect all nonpublic information to which they obtain access by means of contract performance. The FAR Council also proposed requiring all employees who may access nonpublic information to sign nondisclosure agreements and that the obligations arising from these agreements will be enforceable by both the Government and third-party information owners.

The Conflicts Report once again reminds us that we need to revisit this effort – not only to bring greater clarity to the existing regulations, but to create a more uniform approach across federal agencies when it comes to addressing the risks associated with OCIs and the protection of nonpublic information.

Some suggest that the concerns that led to the 2011 rule have since subsided. Yet this high-profile incident reminds us that there is still much room for improvement in the current rules.

\textsuperscript{44}The FAR Council membership consists of the Administrator for Federal Procurement Policy, the Secretary of Defense, the Administrator of National Aeronautics and Space, and the Administrator of General Services. See https://www.acquisition.gov/far-council-members.

\textsuperscript{45}Organizational Conflicts of Interest, 86 Fed. Reg. 14863 (March 19, 2021).
Indeed, one need only look at the evolution of many of the procurement systems' most important anti-corruption laws to see how this is true:

- After discovering widespread fraud committed by contractors during the Civil War, Congress enacted the False Claims Act.

- In the wake of the Watergate scandal, Congress passed numerous important ethics and anti-corruption laws, including the Ethics in Government Act and Foreign Corrupt Practices Act.

- After a major multi-agency investigation nicknamed “Operation Ill Wind” uncovered a widespread scheme in which contractors and consultants obtained confidential bid and proposal information related to Department of Defense procurements in exchange for bribes, Congress enacted the Procurement Integrity Act.

- After one of the most senior acquisition officials in the Air Force, Darlene Druyun, admitted to illegally favoring Boeing Company on a number of Air Force contracts because of, among other things, her employment negotiations with the company, the importance of maintaining integrity during employment negotiations became more prominent in industry ethics guidance and trainings.

- The revelation that Leonard Glenn Francis (“Fat Leonard”) had bribed a large number of Navy officials in exchange for, among other things, classified ship schedules and confidential procurement information, it forced the Navy and other government agencies to assess the quality of their own ethics and compliance processes.

In each of these cases, it took high-profile scandals to spur legislative action and increased attention to the importance of ethics and integrity in the government procurement system. The laws and compliance enhancements resulting from these incidents and others form the backbone of our modern-day government procurement anti-corruption ecosystem – shaping the way government officials and contractors are expected to conduct themselves in the United States and abroad.

Unlike headline-generating topics such as bribery and fraud, OCIs are often viewed as a highly technical litigation issue that rarely garners attention outside of law firm client advisories. The Conflicts Report reminds us that OCIs are an integrity issue that have the potential to undermine the quality and value of the services a government receives. When taxpayer dollars are at stake, a contractor’s undivided loyalties are paramount. It’s time to revisit the work the FAR Council began over a decade ago with respect to organizational conflicts of interest and bring greater awareness and compliance attention to this important issue.
Thank you for the opportunity to discuss this important matter with you. I would be pleased to answer any questions.