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Recent Resolutions Involving Aerospace and Defense Companies Highlight Importance of Third-Party Risk Management and Compliance Culture

Two recent FCPA actions involving aerospace and defense companies underscore the importance of risk management related to the retention and oversight of third parties, especially when operating in higher-risk jurisdictions, and the promotion of a company-wide culture of compliance.

On October 11, 2024, the SEC resolved an action against Moog Inc. concerning the use of a third-party agent to bribe officials in India to secure railway and aerospace contracts and to exclude competitors from public tenders. Days later, DOJ and the SEC resolved parallel actions against RTX/Raytheon for bribing Qatari officials through third parties with ties to the officials to obtain defense contracts.

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Raytheon's case also included related export controls violations and unrelated defective pricing matters, collectively resulting in approximately $1 billion in penalties.

Both the RTX/Raytheon and Moog resolutions describe subsidiary cultures that prioritized profit above compliance and enabled misconduct to persist for extended periods of time. The settlement filings in both cases describe employees openly discussing misconduct and taking steps to help third parties satisfy due diligence requirements and monitoring controls.

RTX/Raytheon

On October 16, 2024, Raytheon Company—a subsidiary of the Arlington, VA-based aerospace and defense company RTX—agreed to pay approximately $360 million to resolve DOJ and SEC investigations related to alleged schemes to bribe Qatari military and other foreign officials to obtain Qatari military defense contracts. Raytheon entered into a three-year DPA in connection with a criminal information unsealed in the Eastern District of New York, charging the company with two counts: conspiracy to violate the anti-bribery provisions of the FCPA and conspiracy to violate the Arms and Export Control Act ("AECA") for willfully failing to disclose the bribes in export licensing applications with the Department of State as required by Part 130 of the International Traffic in Arms Regulations ("ITAR"). The FCPA and ITAR cases are discussed in more detail below.[1]

Separately, Raytheon entered into a three-year DPA in connection with a criminal information filed in the District of Massachusetts, which charged Raytheon with two counts of major fraud against the United States involving defective pricing on certain government contracts. As part of this resolution, Raytheon admitted to engaging in two separate schemes to defraud the Department of Defense ("DOD") in connection with the provision of defense articles and services, including PATRIOT missile systems and a radar system. Raytheon also reached a False Claims Act settlement relating to its defective pricing schemes. In total, Raytheon agreed to pay almost $1 billion to resolve the various actions concerning defective pricing, foreign bribery, and export controls schemes.[2]

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1. U.S. Dep't of Justice Press Release No. 24-1310, "Raytheon Company to Pay Over $950M in Connection with Defective Pricing, Foreign Bribery, and Export Control Schemes" (Oct. 16, 2024), https://www.justice.gov/opa/pr/raytheon-company-pay-over-950m-connection-defective-pricing-foreign-bribery-and-export ("Raytheon DOJ Press Release"); U.S. Sec. & Exch. Comm'n Press Release No. 2024-171, "SEC Charges Virginia-Based RTX Corp. with Violating Foreign Corrupt Practices Act in Connection with Efforts to Obtain Contracts with the Qatari Military" (Oct. 16, 2024), https://www.sec.gov/newsroom/press-releases/2024-171 ("Raytheon SEC Press Release"); Order, *In re RTX Corporation*, Securities Exchange Act Release No. 101353 (Oct. 16, 2024), https://www.sec.gov/files/litigation/admin/2024/34-101353.pdf ("Raytheon SEC Order"); Deferred Prosecution Agreement, *United States v. Raytheon Company*, Case No. 1:24-cr-00399-RER-1 (E.D.N.Y. Oct. 16, 2024) ("Raytheon FCPA DPA").

2. Raytheon DOJ Press Release; Deferred Prosecution Agreement, *United States v. Raytheon Company*, Case No. 1:24-cr-10319-NMG (D. Mass. Oct. 16, 2024) ("Raytheon Defective Pricing DPA"); False Claims Act Settlement, *United States v. Raytheon Company* (Oct. 16, 2024), https://www.justice.gov/opa/media/1373636/dl ("Raytheon FCA Settlement").

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The FCPA Case

According to the DPA, between approximately 2012 and 2016, Raytheon engaged in a scheme to bribe a high-level official at the Qatar Emiri Air Force ("QEAF"), a branch of Qatar's Armed Forces, to obtain and retain military and defense contracts, including from QEAF. Specifically, the DPA highlighted Raytheon's alleged misconduct in connection with the following contracts:

"An effective third-party risk management program relies on employees and a culture that promotes compliance, which itself requires effective controls, training that tests and ensures that employees know what to look for, and management that promotes compliance throughout its operations and locations."

- *The Gulf Cooperation Council ("GCC") Contract and Additions*. Raytheon was party to an air defense contract with the GCC, an intergovernmental union of six member states. Between 2012 and 2013, Raytheon entered into supplemental contracts ("additions") to the GCC Contract. To secure these additions, Raytheon allegedly paid almost $2 million in bribes to the QEAF official responsible for approving the additions through two Qatari third parties (a defense and security consultancy firm and a cybersecurity company) owned by the QEAF official. At the QEAF official's direction, sham air defense studies were added to the scope of work. A Raytheon employee prepared the studies and provided them via off-channel communications to the third-party entities to pass off as their own work, and another employee also helped the third-party entities pass Raytheon's due diligence process. As a result of the alleged bribe scheme, Raytheon earned over $36 million in profits from four additions to the GCC Contract.[3]
- *The JOC Contract*. In 2016, Raytheon entered into a teaming[4] agreement with one of the Qatari entities owned by the QEAF official to obtain the official's assistance in securing potential contract to build a joint operations center (JOC) that would interface with Qatar's several military branches. Under the terms of this agreement, Raytheon agreed to subcontract part of the work associated

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3. Raytheon DOJ Press Release; Raytheon FCPA DPA ¶¶ 12, 14–16, 28, 67.
4. In a teaming agreement, two parties agree to jointly prepare and submit a tender. If successful, one party acts as the main contractor and appoints the other as a subcontractor.

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with the JOC Contract to this entity, despite allegedly knowing that it lacked the capabilities to complete the work. While the Qatari government ultimately did not go forward with the JOC Contract, Raytheon's anticipated profit was over $72 million.[5]

The SEC's order also alleged that from the early 2000s to 2020, Raytheon paid more than $30 million to a Qatari agent who was a relative of the Qatari Emir in connection with additional defense contracts. Despite being retained as Raytheon's representative in Qatar, the agent had no prior background in military defense contracting. The order found that Raytheon continued working with the agent even after numerous Raytheon employees raised concerns about corruption risks.[6]

As part of the DPA, Raytheon agreed to pay a criminal penalty of $230.4 million and forfeiture of nearly $36.7 million. The penalty reflects a 20% reduction off the 20th percentile above the low end of the applicable Guidelines range. In addition, Raytheon consented to the SEC's cease-and-desist order charging violations of the FCPA's anti-bribery and accounting provisions and agreed to pay approximately $49.1 million in disgorgement and prejudgment interest ($7.4 million of which will be credited against the criminal forfeiture) and a civil penalty of $75 million ($22.5 million of which will be credited against the criminal monetary penalty). Both DOJ and the SEC required that Raytheon retain a compliance monitor for a three-year period, the first monitorship imposed in an FCPA case in nearly 2.5 years.[7]

The DPA noted that, in the initial phases of the investigation, Raytheon was at times slow to respond to DOJ's requests and failed to provide relevant information. The SEC order added that Raytheon provided significant cooperation under new management, who also hired new outside counsel, and credited new management's remediation steps, which included terminating employees involved in the misconduct (some of whom were still working with the company despite their known role in the misconduct). DOJ also highlighted Raytheon's remediation efforts, which included recalibrating third-party review and approval processes to lower company risk tolerance; implementing enhanced controls over sales intermediary payments; hiring subject matter experts to oversee its anti-corruption compliance program and third-party management; implementing data analytics to improve third-party monitoring; and developing a multi-pronged communications strategy to enhance ethics and compliance training and communications.[8]

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5. Raytheon DOJ Press Release; Raytheon FCPA DPA ¶¶ 17–21.
6. Raytheon SEC Press Release; Raytheon SEC Order ¶¶ 33–36.
7. Raytheon DOJ Press Release; Raytheon FCPA DPA ¶¶ 4(t), 11, 16; SEC Order ¶¶ IV.C, 63.
8. Raytheon DOJ Press Release; Raytheon FCPA DPA ¶¶ 4(c), 4(e); Raytheon SEC Order ¶¶ 61–62.

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The ITAR Case

DOJ's DPA in the FCPA case—which was also reached with the National Security Division ("NSD"), Counterintelligence and Export Control Section—also included deferred charges that Raytheon employees and agents willfully violated the AECA and ITAR by failing to disclose the fees and commissions paid to the high-level QEAF official to the State Department, Directorate of Defense Trade Controls. This was in contravention of the AECA and ITAR, which require that certain entities applying for export licenses disclose to the State Department certain payments of political contributions, fees, or commissions in connection with their sales of defense articles or services. DOJ imposed a penalty of approximately $21.9 million for the ITAR-related charges, which includes a cooperation and remediation credit of 20% off the applicable penalty. DOJ provided cooperation credit in connection with a number of measures pursuant to the NSD Enforcement Policy for Business Organizations, but noted that Raytheon did not receive full credit for cooperation because, in the initial phase of the investigation, it failed to provide information relevant to the ITAR violations beyond what was requested in the FCPA investigation.[9]

Moog

On October 11, 2024, Moog Inc., a New York-based global provider of technology used in the aerospace and defense markets, agreed to pay more than $1.6 million to resolve the SEC's charges that it violated the FCPA's accounting provisions in connection with bribes paid by Moog's wholly-owned subsidiary in India, Moog Motion Controls Private Limited ("MMCPL").[10]

According to the SEC, between 2020 and 2022, MMCPL employees offered bribes to officials in India to secure business and to keep competitors out of bidding for public tenders. The improper payments were funneled through, among other means, third-party agents and distributors and falsely recorded as legitimate business expenses in Moog's books and records. As a result of deficient internal accounting controls, the conduct went undetected, and Moog was unjustly enriched by approximately $504,926.[11]

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9. Raytheon DOJ Press Release; Raytheon FCPA DPA ¶¶ 71; 4(o)–4(t).

10. Order, *In re Moog Inc.*, Securities Exchange Act Release No. 101307 (Oct. 11, 2024), https://www.sec.gov/files/litigation/admin/2024/34-101307.pdf ("Moog SEC Order"); U.S. Sec. & Exch. Comm'n Press Release No. 2024-170, "SEC Charges U.S.-Based Moog Inc. with FCPA Violations for Subsidiary's Role in Indian Bribery Scheme" (Oct. 11, 2024), https://www.sec.gov/newsroom/press-releases/2024-170 ("Moog SEC Press Release").

11. Moog SEC Order ¶¶ 1–2.

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The SEC's allegations highlight MMCPL's efforts to secure two contracts:

- *South Central Railway Contract*. Beginning in early 2020, MMCPL sought a contract with a railway zone wholly owned by the Indian government. Bids on this project required approval by the Ministry of Railways' research and development organization, on whose supplier list MMCPL historically had found it difficult to be included. MMCPL allegedly used a third-party agent to make bribe payments to get on the approved supplier list. Shortly after engaging the agent, the Moog brand was added to the supplier list for the tender, with one other supplier, and ultimately won the contract for $34,323. The third-party agent invoiced MMCPL for "commission charges," which included the improper payments to government officials, and which were falsely recorded as legitimate contractor services.[12]
- *Hindustan Aeronautics Limited Contract*. In 2021, MMCPL employees allegedly conspired to bribe an official at an Indian public sector aerospace and defense company, Hindustan Aeronautics Limited ("HAL"), to help disqualify other bidders in a public tender for aerospace actuators. HAL awarded MMCPL a contract valued at over $1.3 million. To generate cash sufficient to fund the bribe payment to the HAL official, MMCPL employees instructed a third-party distributor to prepare a sham invoice for MMCPL in the amount of INR 1,540,000 for the construction of a specialized table that was never requisitioned or delivered. The invoice was falsely recorded as a legitimate expense.[13]

The SEC described multiple other attempts to rig the bidding process for government contracts and exclude competitors from tenders. According to the order, "[e]mployees freely discussed their misconduct, which reflected a prevailing culture to win business at any cost, including improper means. The widespread misconduct at MMCPL reflected a breakdown in internal accounting controls, training, compliance, and tone at the top of the subsidiary."[14]

Moog consented to the SEC's cease-and-desist order charging violations of the FCPA's books and records and internal accounting controls provisions and agreed to pay disgorgement of $504,926, prejudgment interest of $78,889, and a civil penalty of $1.1 million.[15]

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12. *Id.* ¶¶ 6, 8, 9, 11.
13. *Id.* ¶¶ 13–19.
14. *Id.* ¶ 20–26.
15. *Id.* ¶¶ 28–30.

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In resolving the matter, the SEC noted Moog's cooperation and remediation efforts, which included terminating responsible employees and third parties involved in the misconduct; improving internal accounting controls over third-party payments; strengthening its global compliance organization and creating new positions to address potential risks; enhancing policies and procedures regarding the due diligence process and use of third parties; increasing the frequency of audits and monitoring of distributor and intermediary activities; mandating management approval for all distributor and reseller agreements; and increasing employee training on anti-bribery issues and tender-specific procedures.[16]

"[The Raytheon DPA] may reflect an increasing convergence (and expectation of convergence) between anti-corruption and national security cases where improper payments to foreign officials implicate export controls."

Takeaways

The October resolutions involving RTX/Raytheon and Moog highlight several items for companies to keep in mind.

- **Effective due diligence and monitoring of third parties is not a check-the-box exercise.** Both the Moog and RTX/Raytheon cases featured companies using third parties tied to government officials to win business that had been difficult to obtain. In Qatar, the military procurement process was seen as opaque; in India, it was difficult to obtain approval to appear on the relevant ministry's supplier list. In both cases, red flags were raised by some employees and ignored by others. The SEC's order in the RTX/Raytheon matter made multiple references to aspects of the compliance program operating as "check-the-box" exercises and the "epitome of a paper program."[17] The SEC added that several Raytheon policies and procedures were flouted, including, policies requiring periodic evaluations of the third party's performance and a requirement that representatives submit quarterly activity reports in order to be paid. The SEC order stated that monitoring efforts through the activity reports were "a meaningless, check-the-box exercise that neither enhanced compliance

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16. *Id.* ¶ 32.

17. *See, e.g.*, Raytheon SEC Order ¶¶ 42, 47, 51.

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efforts nor mitigated corruption risks."[18] Developing appropriate policies and procedures is an important step, but implementing and enforcing such policies and procedures is critical.

- **Investments in third-party risk management processes must be supported by a strong culture of compliance—at both the global and the subsidiary levels.** An effective third-party risk management program relies on employees and a culture that promotes compliance, which itself requires effective controls, training that tests and ensures that employees know what to look for, and management that promotes compliance throughout its operations and locations. The SEC order in Moog specifically called out that "[e]mployees freely discussed their misconduct" in a way that reflected "a prevailing culture to win business at any cost" and "a breakdown in internal accounting controls, training, compliance and tone at the top" of the relevant subsidiary.[19] The RTX/Raytheon settlement documents alleged that employees deliberately falsified documents and coached sham third parties tied to foreign officials on how to pass the company's due diligence process. According to the SEC's order in the RTX matter, "[t]he tone at the top of Raytheon and the relevant business unit stressed keeping Qatari Agent on board at all costs, without regard to the numerous red flags of corruption and compliance concerns."[20] These cases highlight not only the need for strong third-party risk management programs in higher-risk jurisdictions, but also the need to effectively communicate to employees on the ground the significance of those programs, the importance of complying with policies and procedures supporting those programs, and the gravity of disciplinary measures and consequences that will be applied to address misconduct (or to reward compliance).
- **First monitorship imposed in an FCPA case in 2.5 years.** As noted, the RTX/Raytheon matter marks the first time a monitorship has been imposed by DOJ and the SEC in an FCPA matter since May 2022. According to the DPA, and consistent with prior DOJ statements, the monitorship was imposed because certain key portions of Raytheon's compliance program are either still being developed or have been newly enhanced and not yet fully implemented or tested in order to demonstrate that they would prevent and detect similar misconduct in the future.[21]

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18. *Id.* ¶¶ 41–42.
19. Moog SEC Order ¶ 26.
20. Raytheon SEC Order ¶ 43.
21. Raytheon FCPA DPA ¶ 4(g).

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- **Aerospace/defense contracting companies back in the spotlight.** RTX/Raytheon and Moog are at least the third and fourth companies in the aerospace and defense industries that have resolved FCPA allegations with U.S. authorities in the past two years.[22] But there have been several others over the last decade or so, including most notably the 2020 case against Airbus, which represented the largest global foreign bribery resolution at the time and a case that similarly included ITAR violations for failing to disclose payments in connection with the sale or export of defense articles or services.[23] The RTX/Raytheon matter included both DOJ's Criminal Division and the NSD and featured both DOJ components' respective voluntary self-disclosure policies in action. Interestingly, the Raytheon DPA notes that the company did not receive full cooperation credit because "in the initial phase of the investigation, before NSD joined the investigation, it failed to provide information relevant to the ITAR violation beyond what was requested in the FCPA investigation."[24] This may reflect an increasing convergence (and expectation of convergence) between anti-corruption and national security cases where improper payments to foreign officials implicate export controls.

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22. Safran S.A. (December 2022 declination by DOJ regarding allegations that a subsidiary made improper payments to a China-based consultant who was a close relative of a Chinese official to obtain train lavatory contracts with the Chinese government); GOL Linhas Aéreas Inteligentes S.A. (September 2022 resolution of DOJ and SEC investigations regarding possible bribery of government officials in Brazil for favorable payroll tax and aviation fuel tax reductions).

23. *See* Debevoise & Plimpton LLP, "Airbus Reaches Record-Breaking Global Settlement," FCPA Update, Vol. 11, No. 7 (Feb. 2020), https://www.debevoise.com/-/media/files/insights/publications/2020/02/fcpa-update_february-2020.pdf?rev=f9c21dd82b53416abb6878b655fe62cf&hash=F9C102C5E82FF1A21DC2BAE48FD994F5.

24. Raytheon FCPA DPA ¶ 4(o).

Chinese Regulators Issue Draft Anti-Corruption Compliance Guidelines for Pharmaceutical Companies

On October 11, 2024, China's State Administration for Market Regulation ("SAMR") released for public comment the "Compliance Guidelines for Pharmaceutical Enterprises to Prevent Commercial Bribery Risks (Draft for Comments)" (the "Draft Guidelines").[1] Once finalized, the Draft Guidelines will be the first national industry-specific anti-corruption guidelines issued by a PRC regulator. The comment period for the Draft Guidelines ended on October 20, 2024, and the final guidelines are likely to be issued in the coming months. The Draft Guidelines are primarily directed at local pharmaceutical companies, but multinationals will find them of use as well. The Draft Guidelines are high-level and general in most respects, and they are noteworthy in that they appear to be the first time a PRC regulator has expressly suggested that companies should conduct internal investigations and consider self-reporting bribery-related misconduct to regulators.

Background and Overview

SAMR was created in 2018 to be China's primary market regulator and is the successor of several Chinese regulatory agencies, including the former State Administration of Industry and Commerce ("SAIC"). Like SAIC before it, SAMR is the primary regulator responsible for the Anti-Unfair Competition Act, which includes the administrative prohibition of commercial bribery. Along with the National Supervisory Commission, which is responsible for policing the behavior of government officials and Communist Party cadres, SAMR has been involved in recent anti-corruption sweeps of the healthcare sector, including pharmaceutical companies, hospitals, and health insurance and public purchasing bodies.[2]

According to SAMR, the Draft Guidelines aim to "provide specific, clear, and practical guidance and references for pharmaceutical enterprises to prevent commercial bribery risks and compliance management," [3] are based on relevant local laws and regulations, and drew upon "foreign anti-commercial bribery laws and regulations," "codes of conduct of industry consensus," and

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1. "市场监管总局关于公开征求《医药企业防范商业贿赂风险合规指引（征求意见稿）》意见的公告" (Announcement of the State Administration for Market Regulation on Soliciting Public Opinions on Compliance Guidelines for Pharmaceutical Enterprises to Prevent Commercial Bribery Risks (Draft for Comments)) (Oct. 11, 2024), https://www.samr.gov.cn/hd/zjdc/art/2024/art_8ff267f2f83e49af9754a937f841f37a.html?_refluxos=a10 (hereinafter "Draft Guidelines").
2. *See* Kara Brockmeyer, et al., "The Year 2023 in Review: Steady Enforcement as Laws and Policies Proliferate," FCPA Update, Vol. 15, No. 6 (Jan. 2024), https://www.debevoise.com/insights/publications/2024/01/fcpa-update-january-2024.
3. *See* Draft Guidelines, Appendix 2.

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"domestic administrative enforcement practices."[4] Other recent (unrelated) compliance guidance has been issued in recent years by the State-Owned Assets Supervision and Administration Commission ("SASAC"), including the Guidance on Compliance Management for Central Enterprises (for Trial Implementation) in 2018;[5] the Administrative Regulations on Business Hospitality of State-owned Enterprises jointly issued by SASAC and the Ministry of Finance in 2020 that targeted entertainment and hospitality provided by state-owned enterprises ("2020 SASAC Regulation");[6] and the Measures for the Compliance Management of Central Enterprises issued in 2022.[7] Unlike the SASAC guidelines, which were focused on state-owned enterprises, the Draft Guidelines are designed specifically to address bribery in the healthcare sector and provide guidance to both state-owned and private companies.

The Draft Guidelines address commercial bribery, which is illegal in China and the way in which most bribery in the healthcare sector (public or private) is handled.[8] SAMR is responsible for administrative enforcement of the commercial bribery provisions under the Anti-Unfair Competition Law (which may result in fines and civil penalties); severe instances of commercial bribery can be prosecuted under the Chinese criminal law. Consistent with the Anti-Unfair Competition Law, the Draft Guidelines define "commercial bribery" as "us[ing] money and property or other means to bribe the following parties, in order to obtain transaction opportunities or competitive advantages: (1) transaction counterparty staff; (2) the entity or individual entrusted by the transaction counterparty to handle related matters; or (3) the entity or individual that use power or influence to influence the transaction." The Draft Guidelines encourage "large and medium-sized pharmaceutical enterprises and related third parties" to establish comprehensive compliance management systems to prevent commercial bribery risks, while small enterprises may refer to the Draft Guidelines in order to alert their employees to commercial bribery risks.

The Draft Guidelines are not mandatory, but "provide references" for "pharmaceutical companies" and "related third parties" engaged in activities such as research and development, production, and distribution of "pharmaceutical products (医药产品)" within the PRC."[9] That said, some of the Draft Guidelines'

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4. *Id.*
5. Full Chinese text may be accessed at http://www.sasac.gov.cn/n2588035/c9804413/content.html.
6. Full Chinese text may be accessed at https://www.pkulaw.com/chl/33330c2605355120bdfb.html.
7. Full Chinese text may be accessed at https://www.gov.cn/zhengce/zhengceku/2022-09/19/content_5710633.htm.
8. Public bribery, or bribery of a state functionary, is also punishable under the criminal law (and the recipient may be punished with the death penalty in extreme cases). Simply being a doctor at a public hospital does not make someone a state functionary, so most bribery in the healthcare sector is treated as commercial bribery.
9. Article 3 of the Draft Guidelines.

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"specifications and requirements (规范要求)" and "risks (风险)" are already enshrined in PRC law and are therefore mandatory. The drafting note released by SAMR with the Draft Guidelines note that many of these requirements and risks are based on pre-existing legal requirements (in which case they are already mandatory and companies "should" comply with them) or industry best practices (in which case the Draft Guidelines recommend that companies "may" comply with them.

Specifications and Requirements ("规范要求")

- **Should ("应当"):** Based on explicit requirements in existing laws, regulations, and international and national compliance standards.
- **May ("可以"):** Based on industry consensus that meets the requirements of the Health Commission, including competent authorities such as the NMPA and the NHC.
- **Suggested ("建议"):** Based on experiences and practices of pharmaceutical enterprises.
- **Advocated / Encouraged ("倡导" or "鼓励"):** Would be beneficial for long-term anti-commercial-bribery mechanisms of enterprises and the development of the industry.[10]

"The Draft Guidelines are high-level and general in most respects, and they are noteworthy in that they appear to be the first time a PRC regulator has expressly suggested that companies should conduct internal investigations and consider self-reporting bribery-related misconduct to regulators."

Different Levels of Risks (风险)

- **Prohibit ("禁止"):** Specifically prohibited by laws and regulations, and including those activities determined to be commercial bribery by market administrative departments in recent cases.
- **Avoid ("避免"):** Not stipulated in the law but involving activities likely associated with commercial bribery violations based on current law enforcement practices and industry consensus.

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10. The drafting note appears to use "advocated" and "encouraged" interchangeably. Both Chinese words"倡导 (advocated)" and "鼓励 (encouraged)" are used throughout the Draft Guidelines when discussing specifications and requirements. It remains to be seen if the final draft will use one universal Chinese word and whether SAMR will release additional explanatory notes.

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- **Restrict ("限制") / Pay attention to ("关注"):** Medium and low-risk business operational activities that do not meet corporate compliance principles and may lead to commercial bribery under certain conditions that companies should reasonably restrict or pay appropriate attention to.[11]

Internal Investigations and Self-Reporting

The Draft Guidelines consist of 32 pages and include 49 provisions, divided into four chapters covering different aspects and scenarios of compliance risk management, as follows: (1) General Principles; (2) Establishment of Compliance Management System to Prevent Commercial Bribery Risks for Pharmaceutical Enterprises; (3) Identification and Prevention of Commercial Bribery Risks for Pharmaceutical Enterprises; and (4) Handling of Commercial Bribery Risks for Pharmaceutical Enterprises.

Chapter III of the Draft Guidelines encourages pharmaceutical enterprises to conduct internal investigations and self-report suspected commercial bribery to SAMR when "risks" identified in the Draft Guidelines are discovered. In particular, Article 44 of the Draft Guidelines states that a pharmaceutical company: (1) *should* immediately stop high-risk activities; (2) *may* conduct an investigation by itself or by engaging third-party professionals; and (3) *may* assess the results of the investigation and formulate an internal assessment report.[12] Article 45 states that pharmaceutical enterprises *should* timely implement effective remedial measures based on the risk assessment results, including but not limited to: holding relevant parties and third parties accountable; rectifying any negative consequences of the behavior; revising internal policies and procedures; improving management processes; strengthening compliance training; and improving internal compliance programs to prevent commercial bribery risks.[13] The same article also *encourages* pharmaceutical companies to continuously refine their long-term compliance mechanisms to avoid the reoccurrence of similar risks.[14]

Additionally, Chapter III of the Draft Guidelines *encourages* pharmaceutical companies to voluntarily report to the market regulation administrative department and attach relevant evidentiary materials when they discover that their "business operations involve suspected commercial bribery." Such voluntary reports *should* include:

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11. We note that the word "限制(restrict)" is not used in the current Draft Guidelines.
12. Article 44 of the Draft Guidelines.
13. Article 45 of the Draft Guidelines.
14. *Id.*

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- The source of the allegations and the investigation process;
- Information about the subject(s) involved;
- Facts currently known;
- Remedial measures already taken;
- Information about the company's existing or to-be-established compliance management system to prevent commercial bribery risks; and
- A catchall category of other matters to be reported.[15]

According to the Draft Guidelines, SAMR will treat self-reporting as a factor that it may take into account in reducing administrative penalties, provided that the pharmaceutical company either: (1) proactively reports illegal acts before SAMR gets involved in the investigation; or (2) proactively reports illegal acts after SAMR gets involved, but before it learns the details of the illegal acts, and takes effective measures to mitigate any harmful consequences.

While regulatory expectations regarding factors such as internal investigation, remediation, and self-reporting will be familiar from the UK Ministry of Justice Bribery Act Guidance or the U.S. DOJ's Corporate Enforcement Policy, the Draft Guidelines represent the first time Chinese state regulators have endorsed and encouraged internal investigations and self-reporting in industry-specific guidance.

Guidance for High-Risk Activities, Including Speaker Fees

Chapter III of the Draft Guidelines also discusses prevention of bribery risks in high-risk activities, identifying nine categories of high-risk behavior: academic visits and communications (学术拜访交流), hospitality (接待), "consulting services" (咨询服务), outsourcing services (外包服务), discounts, rebates, and commissions (折扣、折让及佣金), donations, sponsorships, and grants (捐赠、赞助、资助), free placement of medical equipment (医疗设备无偿投放), clinical research (临床研究), and retail sales (零售终端销售). These are well-established areas of risk that have been the subject of multiple US investigations.[16]

Each of the above sections addresses the relevant activities, but unfortunately do not provide the kind of detailed guidance companies would find most helpful. For example, there are no recommendations regarding specific thresholds for hospitality or other expenses. The Draft Guidelines list various practices that pharmaceutical companies should either prohibit or establish standards for in connection

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15. Article 46 of the Draft Guidelines.

16. *See* Kara Brockmeyer, Bruce E. Yannett, et al., "Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry," FCPA Update, Vol. 12, No. 1 (Aug. 2020), https://www.debevoise.com/insights/publications/2020/08/fcpa-update-august-2020.

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with hospitality, including possibly prohibiting the provision of "travel (旅游), fitness(健身), and entertainment(娱乐)."[17] It is unclear why these activities were selected for prohibition, and it is possible that more detail or different rules will be included in the final guidelines.

The "consulting services" section addresses instances in which "pharmaceutical enterprises hire healthcare professionals to provide professional services [based on] their professional knowledge, experience and methodology and pay them reasonable remuneration."[18] This includes "when pharmaceutical enterprises hire healthcare professionals to provide lectures, classes, research, or other consulting services. The Draft Guidelines state that such services *should* be based on authentic, reasonable, and legal business needs," suggesting that companies paying for these services will need to document carefully each of the business needs.

It is important to remember that the Draft Guidelines are still in draft form and currently lack specific guidance for most situations (including hospitality) companies need to address. In the context of the ongoing anti-corruption campaign targeting the domestic healthcare industry, companies would be well advised maintain a cautious approach when dealing with healthcare professionals in China. That said, the Draft Guidelines and (eventually) the final version will provide useful guidance to Chinese enterprises in the healthcare sector, as well as leverage for domestic and international companies in requiring local business partners to adopt effective compliance programs.

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17. Article 15 and 16 of the Draft Guidelines. From the text, the current draft prohibits provision of all kinds of travel, fitness, and entertainment. It remains to be seen if the final draft will qualify the prohibited entertainment provided based on reasonableness or value.

18. Article 17 of the Draft Guidelines.

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