Global Investigations Review

The Guide to Monitorships

Editors
Anthony S Barkow, Neil M Barofsky and Thomas J Perrelli

Second Edition

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Publisher's Note

The Guide to Monitorships is published by Global Investigations Review – the online home for everyone who specialises in investigating and resolving suspected corporate wrongdoing.

It flowed from the observation that there was yet no book available that systematically covered all aspects of the institution known as the 'monitorship' – a situation known to be delicate and challenging for all concerned: the company, the monitor, the appointing government agency and all the professionals helping those players.

This guide aims to fill that gap. It does so by addressing all the most common questions and concerns from all the key perspectives. We have been lucky to attract authors who have lived through the challenges they deconstruct and explain.

The guide is a companion to a larger reference work – GIR's *The Practitioner's Guide to Global Investigations* (now in its fourth edition), which walks readers through the issues raised, and the risks to consider, at every stage in the life cycle of a corporate investigation, from discovery to resolution. You should have both books in your library: *The Practitioner's Guide* for the whole picture and *The Guide to Monitorships* for the close-up.

The Guide to Monitorships is supplied in hard copy to all GIR subscribers as part of their subscription. Non-subscribers can read an e-version at www.globalinvestigationsreview.com.

Finally, I would like to thank the editors of this guide for their energy and vision, and the authors and my colleagues for the elan with which they have brought that vision to life.

We collectively welcome any comments or suggestions on how to improve it. Please write to us at insight@globalinvestigationsreview.com.

Preface

Corporate monitorships are an increasingly important tool in the arsenal of law enforcement authorities and, given their widespread use, they appear to have staying power. This guide will help both the experienced and the uninitiated to understand this increasingly important area of legal practice. It is organised into five parts, each of which contains chapters on a particular theme, category or issue.

Part I offers an overview of monitorships. First, Neil M Barofsky – former Assistant US Attorney and Special Inspector General for the Troubled Asset Relief Program, who has served as an independent monitor and runs the monitorship practice at Jenner & Block LLP – and his co-authors Matthew D Cipolla and Erin R Schrantz of Jenner & Block LLP explain how a monitor can approach and remedy a broken corporate culture. They consider several critical questions, such as how a monitor can discover a broken culture; how a monitor can apply 'carrot and stick' and other approaches to address a culture of non-compliance; and the sorts of internal partnership and external pressures that can be brought to bear. Next, former Associate Attorney General Tom Perrelli, independent monitor for Citigroup Inc and the Education Management Corporation, walks through the life cycle of a monitorship, including the process of formulating a monitorship agreement and engagement letter, developing a work plan, building a monitorship team, and creating and publishing interim and final reports.

Nicholas Goldin and Mark Stein of Simpson Thacher & Bartlett – both former prosecutors with extensive experience in conducting investigations across the globe – examine the unique challenges of monitorships arising under the US Foreign Corrupt Practices Act (FCPA). FCPA monitorships, by their nature, involve US laws regulating conduct carried out abroad, and so Goldin and Stein examine the difficulties that may arise from this situation, including potential cultural differences that may affect the relationship between the monitor and the company. Additionally, Alex Lipman, a former federal prosecutor and branch chief in the Enforcement Division of the Securities and Exchange Commission (SEC), and Ashley Baynham, fellow partner at Brown Rudnick LLP, explore how monitorships are used in resolutions with the SEC. Further, Bart M Schwartz of Guidepost Solutions LLC – former chief of the Criminal Division in the Southern District of New York, who later served as independent monitor for General Motors – explores how enforcement agencies decide whether to appoint a monitor and how that monitor is selected. Schwartz provides an overview of different types of monitorships, the various agencies that have appointed monitors in the

past, and the various considerations that go into reaching the decisions to use and select a monitor.

Part II contains three chapters that offer experts' perspectives on monitorships: those of an academic, an in-house attorney and forensic professionals. Professor Mihailis E Diamantis of the University of Iowa provides an academic perspective, describing the unique criminal justice advantages and vulnerabilities of monitorships, and the implications that the appointment of a monitor could have for other types of criminal sanctions. Jeffrey A Taylor, a former US Attorney for the District of Columbia and chief compliance officer of General Motors, who is now executive vice president and chief litigation counsel of Fox Corporation, provides an in-house perspective, examining what issues a company must confront when faced with a monitor, and suggesting strategies that corporations can follow to navigate a monitorship. Finally, Loren Friedman, Thomas Cooper and Nicole Sliger of BDO USA provide insights as forensic professionals by exploring the testing methodologies and metrics used by monitorship teams.

The four chapters in Part III examine the issues that arise in the context of cross-border monitorships and the unique characteristics of monitorships in different areas of the world. Litigator Shaun Wu, who served as a monitor to a large Chinese state-owed enterprise, and his co-authors at Kobre & Kim examine the treatment of monitorships in the East Asia region. Switzerland-based investigators Daniel Bühr and Simone Nadelhofer of LALIVE SA explore the Swiss financial regulatory body's use of monitors. Judith Seddon, an experienced white-collar solicitor in the United Kingdom, and her co-authors at Ropes & Gray International LLP explore how UK monitorships differ from those in the United States. And Gil Soffer, former Associate Deputy Attorney General, former federal prosecutor and a principal drafter of the Morford Memorandum, and his co-authors at Katten Muchin Rosenman LLP consider the myriad issues that arise when a US regulator imposes a cross-border monitorship, examining issues of conflicting privacy and banking laws, the potential for culture clashes, and various other diplomatic and policy issues that corporations and monitors must face in an international context.

Part IV has eight chapters that provide subject-matter and sector-specific analyses of different kinds of monitorships. With their co-authors at Wilmer Cutler Pickering Hale and Dorr LLP, former Deputy Attorney General David Ogden and former US Attorney for the District of Columbia Ron Machen, co-monitors in a healthcare fraud monitorship led by the US Department of Justice (US DOJ), explore the appointment of monitors in cases alleging violations of healthcare law. Günter Degitz and Richard Kando of AlixPartners, both former monitors in the financial services industry, examine the use of monitorships in that field. With his co-authors at Kirkland & Ellis LLP, former US District Court Judge, Deputy Attorney General and Acting Attorney General Mark Filip, who returned to private practice and represented BP in the aftermath of the Deepwater Horizon explosion and the company's subsequent monitorship, explores issues unique to environmental and energy monitorships. Glen McGorty, a former federal prosecutor who now serves as the monitor of the New York City District Council of Carpenters and related Taft-Hartley benefit funds, and Joanne Oleksyk of Crowell & Moring LLP lend their perspectives to an examination of union monitorships. Michael J Bresnick of Venable LLP, who served as independent monitor of the residential mortgage-backed securities consumer relief settlement with Deutsche Bank AG, examines consumer-relief fund monitorships. Ellen S Zimiles, Patrick J McArdle and their

co-authors at Guidehouse explore the legal and historical context of sanctions monitorships. Jodi Avergun, a former chief of the Narcotic and Dangerous Drug Section of the US DOJ and former Chief of Staff for the US Drug Enforcement Administration, and her co-authors, former federal prosecutor Todd Blanche and Christian Larson of Cadwalader Wickersham & Taft LLP, discuss the complexities of monitorships within the pharmaceutical industry. And Frances McLeod and her co-authors at Forensic Risk Alliance explore the role of forensic firms in monitorships, examining how these firms can use data analytics and transaction testing to identify relevant issues and risk in a monitored financial institution.

Finally, Part V contains two chapters discussing key issues that arise in connection with monitorships. McKool Smith's Daniel W Levy, a former federal prosecutor who has been appointed to monitor an international financial institution, and Doreen Klein, a former New York County District Attorney, consider the complex issues of privilege and confidentiality surrounding monitorships. Among other things, Levy and Klein examine case law that balances the recognised interests in monitorship confidentiality against other considerations, such as the First Amendment. And former US District Court Judge John Gleeson, now of Debevoise & Plimpton LLP, provides incisive commentary on judicial scrutiny of deferred prosecution agreements (DPAs) and monitorships. Gleeson surveys the law surrounding DPAs and monitorships, including the role and authority of judges in those respects, and separation-of-powers issues.

Acknowledgements

The editors gratefully acknowledge Jenner & Block LLP for its support of this publication, and Jessica Ring Amunson, co-chair of Jenner's appellate and Supreme Court practice, and Jenner associates Jessica Martinez, Ravi Ramanathan and Tessa J G Roberts for their important assistance.

Anthony S Barkow, Neil M Barofsky and Thomas J Perrelli
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The Pharmaceutical Industry and the Controlled Substances Act – A Distinct Breed of Monitorship

Jodi Avergun, Todd Blanche and Christian Larson[1]

Introduction

A distinct component of the healthcare industry includes companies that manufacture, distribute or dispense prescription medicines (hereinafter, pharmaceutical company or companies). In general, these companies are regulated by the Food and Drug Administration, which is an agency of the US Department of Health and Human Services (HHS). Pharmaceutical companies that produce, distribute or dispense controlled substance prescription medicines are also regulated by the Drug Enforcement Administration (DEA), an agency of the US Department of Justice (US DOJ). As The Healthcare Industry chapter describes in depth, civil or criminal settlement agreements for violations of law often result in the appointment of a monitor or an independent review organisation (IRO).

For the most part, pharmaceutical company settlements resulting in a monitorship or IRO have involved violations of a broad array of healthcare laws, including fraudulent claims, kickbacks to prescribers, payments of inappropriate speaker fees, misbranding violations and foreign bribery. What has been less common are settlements stemming primarily from violations of the Controlled Substances Act (CSA). The CSA authorises the DEA to regulate licensed pharmaceutical companies that handle controlled substance prescription drugs, including opioids. Recently, however, as the United States reacts to a national crisis of opioid addiction, settlements of CSA-related allegations have been on the rise.

Since 2017, monitorships or IRO arrangements have been imposed in three cases focused almost exclusively on alleged violations of the CSA. This chapter discusses the history

1 Jodi Avergun is a partner and chair and Todd Blanche is a partner in the white-collar defence and investigations practice at Cadwalader, Wickersham & Taft LLP. Avergun and Blanche were appointed as independent review organisation [IRO] and monitor, respectively, of wholesale distribution companies in the first two cases involving exclusive violations of the Controlled Substances Act. In addition, Blanche is monitor liaison counsel for a company in the healthcare industry that resolved allegations under the US Foreign Corrupt Practices Act in mid-2019. Christian Larson, an associate at the firm, worked as a member of Avergun's IRO team.

and rationale for monitorships in the healthcare industry generally and the pharmaceutical industry specifically. It also describes the relationship between the opioid crisis and US DOJ-imposed or DEA-imposed monitorships involving violations of the CSA. Finally, the chapter details the above-mentioned CSA-related monitorships and offers predictions for the future.

History and rationale for monitorships in the pharmaceutical industry

Pharmaceutical industry monitorships and similar arrangements, such as the appointment of an IRO, result from the resolution of criminal or civil charges (or both) against a company. As the Principles of Federal Prosecution for Business Organizations instruct, a prosecutor deciding whether to file criminal charges against a company must consider the 'collateral consequences [of indictment], including whether there is disproportionate harm to shareholders, pension holders, employees, and others not proven personally culpable, as well as impact on the public arising from the prosecution'.[2] Prosecutors are also to consider 'the adequacy of remedies such as civil or regulatory enforcement actions, including remedies resulting from the corporation's cooperation with relevant government agencies'.[3] In the case of pharmaceutical companies, criminal convictions could result in exclusion of that company from obtaining government contracts and payments from government programmes, and, in the case of companies licensed by the DEA, a denial of registration by the agency. Should these exclusions or denials of registration occur, there is a high likelihood that the company in question would be forced out of business. It follows that if a company that manufactures or distributes prescription medicine is forced out of business, it would have a negative effect on the availability of medicines or patient services. In the case of manufacturers and distributors of life-saving controlled substances, the potential collateral consequences of a criminal conviction are devastating.

For these reasons, enforcement agencies and pharmaceutical companies strive to pursue settlements that fall short of criminal convictions. These resolutions instead include large financial penalties, require the companies to ensure continuing compliance with laws and regulations, and frequently impose monitors or IROs to accomplish regulators' goals of corporate reform and continuing compliance.

Legal and historical context of monitorships involving pharmaceutical companies

The DEA enforces Titles II and III of the CSA, which creates a closed system for the distribution of controlled substances, including opioids. The CSA requires pharmaceutical manufacturers, distributors, retailers, hospitals and other persons seeking to legally handle controlled substances (DEA registrants) to register with the DEA. Pharmaceuticals manufacturers obtain raw materials and in turn produce and package prescription medications. Pharmaceuticals distributors purchase prescription medicines and other medical products directly from pharmaceutical manufacturers and ship those medicines and products to a

2 See US Department of Justice [US DOJ], Justice Manual [JM], Title 9, Principles of Federal Prosecution of Business Organizations, 9-28.1100.

3 See Principles of Federal Prosecution of Business Organizations, JM 9-28.1200.

distributor's downstream customers. State and federally licensed pharmacies, hospitals and healthcare providers place orders with distributors for the medicines and products they need, and the distributors process and deliver the orders daily.[4] According to the Healthcare Distribution Alliance, a distribution industry association, 92 per cent of all prescription drug sales flow through pharmaceutical distributors to patients via hospitals, pharmacies, long-term care facilities and physician offices.[5]

Of the approximately US$450 billion in annual revenue generated in the pharmaceutical distribution industry, more than 90 per cent is concentrated in just three traditional full-line distributors: AmerisourceBergen, Cardinal Health and McKesson.[6] The remaining 10 per cent of the market by revenue is represented by smaller pharmaceutical distribution companies, which generally service independent pharmacy customers, particular geographical regions or specific types of customers.[7]

Like other healthcare industry monitorships, pharmaceutical industry monitorships – and similar arrangements such as mandatory independent audits or IROs – result from the settlement of a government investigation into a pharmaceutical company's conduct. Enforcement agencies and pharmaceutical companies often pursue settlements with the understanding that a criminal conviction, licence revocation or exclusion from participation in federal healthcare programmes may put a company out of business. In the pharmaceutical distribution segment, a resolution that could force a smaller pharmaceutical distributor's ultimate closure would probably serve to further consolidate an already highly consolidated market, and could have a detrimental effect on the availability and pricing of key medicines. Thus, civil or administrative corporate resolutions that include the imposition of a monitorship, and the potential criminal charges against individuals, are likely outcomes in healthcare fraud, misbranding or CSA cases in this industry segment.

The agency or agencies that negotiate a settlement determine the specific nature of any monitorship. As discussed below, the US Department of Health and Human Services Office of Inspector General (HHS-OIG) and the US DOJ have imposed pharmaceutical industry monitorships and similar arrangements in a variety of contexts, often as a result of coordinated investigations and settlement negotiations.

HHS-OIG enforcement actions

The HHS-OIG has the authority to seek civil monetary penalties and exclusion from federal health programmes for a wide range of prohibited conduct. HHS-OIG cases usually involve investigations of false and fraudulent claims to federal healthcare programmes, kickbacks in exchange for referrals of federal healthcare programme business and patient dumping.[8] The HHS-OIG's exclusion authority is powerful but its all-or-nothing nature limits its

4 Healthcare Distribution Alliance [HDA], 'Pharmaceutical Distributors: Understanding Our Role in the Supply Chain', at https://www.hda.org/about/role-of-distributors.

5 Deloitte and HDA, 2019 Report, 'The role of distributors in the US health care industry', at https://www.hda.org/~/media/pdfs/publications/hda-role-of-distributors-in-the-us-health-care-industry.ashx.

6 id.

7 id.

8 US Department of Health and Human Services Office of Inspector General [HHS-OIG], 'Background', at https://oig.hhs.gov/fraud/enforcement/cmp/background.asp.

use, particularly when the collateral consequences of excluding an entity could reduce the availability of health products or services. In a 2012 interview, Gregory Demske, then the HHS-OIG's assistant inspector general for legal affairs and now chief counsel to the inspector general, said:

> *We've been reluctant to exclude pharmaceutical companies because of the negative effects.*
> . . .
> *There's the cost of disruption of supplying needed drugs to patients and there's harm to innocent employees and shareholders and others. . . . We have not excluded corporations when they have been convicted of offenses. The cases get resolved with criminal and civil resolutions and they enter into a CIA, or corporate integrity agreement.*[9]

In exchange for the company's commitments under a corporate integrity agreement (CIA), the HHS-OIG agrees not to seek the company's exclusion from participation in Medicare, Medicaid or other federal healthcare programmes.[10] These CIAs may include a monitorship component, typically called an IRO. Unlike US DOJ deferred prosecution or non-prosecution resolutions, in which the imposition of a monitorship is the exception, a CIA's inclusion of an IRO to monitor compliance with the CIA is the norm.[11]

HHS-OIG IRO components are generally included as an appendix to a CIA. A typical IRO appendix establishes requirements for engaging the IRO, the IRO's qualifications and the IRO's responsibilities. The reviews envisioned by the IRO appendix are often detailed and discrete; although some appendices permit the IRO to conduct interviews, the IRO does not usually have the authority to conduct wide-ranging enquiries. Rather, the appendix tasks the IRO with answering specific questions or reviewing particular types of information. Each IRO appendix normally requires the IRO to conduct one or more systems reviews or one or more transaction reviews. A systems review requires an IRO to assess a company's systems, policies, processes and procedures for complying with specific regulatory expectations. A transaction review requires an IRO to assess whether a randomly selected number of transactions were conducted in accordance with the company's policies and procedures.

The vast majority of pharmaceutical companies currently subject to an HHS-OIG CIA entered into the CIA to settle potential healthcare fraud violations.[12] IRO system reviews in these CIAs cover a company's policies for issues such as the dissemination of products subject to reimbursement under a federal healthcare programme, compensation incentives

9 ExpertBriefings.com, 'The OIG And Excluding Execs: Demske Explains' (7 June 2011), at www.expertbriefings.com/news/the-oig-and-excluding-execs-demske-explains/.

10 HHS-OIG, 'Corporate Integrity Agreements', at https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp.

11 id. ('A comprehensive CIA typically lasts 5 years and includes requirements to . . . retain an independent review organization to conduct annual reviews.'); see also Corporate Prosecution Registry, at http://lib.law.virginia.edu/Garrett/corporate-prosecution-registry/index.html (data shows that approximately 18 per cent of US DOJ deferred prosecution and non-prosecution agreements executed between 1992 and 2019 included a monitor).

12 HHS-OIG, Corporate Integrity Agreement Documents, at https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp.

to sales representatives and payments to healthcare professionals.[13] IRO transaction reviews for CIAs have involved, for example, a sample of 50 payments to physicians, 15 speaker fee arrangements or a review of a company's internal audit of its compliance with applicable healthcare laws.[14]

Although there have been several HHS-OIG settlements with DEA-registered pharmaceutical companies – both distributors and manufacturers – the primary allegations in those cases have been the more common accusations of fraudulent reimbursement or Food, Drug, and Cosmetic Act misbranding.

Currently, there is only one settled case between the HHS-OIG and a pharmaceutical company in which an IRO was appointed as a result of alleged violations of the CSA. In 2015, PharMerica, a national company that operates pharmacies in nursing homes, negotiated an US$8 million civil settlement with the US DOJ and the HHS-OIG resulting in part from its alleged filings of fraudulent claims to Medicare and Medicaid, but also from its alleged violations of the CSA.[15] Specifically, the government alleged that PharMerica pharmacies operating across the country routinely dispensed Schedule II controlled drugs in non-emergency situations without first obtaining a written prescription from a treating physician. According to the complaint, PharMerica's alleged actions violated the CSA by enabling nursing home staff to order narcotics, and pharmacists to dispense them, without confirming that a physician had made a medical judgement as to whether the narcotics were necessary and should be administered to the patient.[16]

In addition to the financial penalty, PharMerica entered into a CIA with the HHS-OIG, which required an IRO to carry out a transaction review of a sample of Schedule II controlled substance prescriptions to determine whether they were dispensed in accordance with the CSA as well as to determine whether the company received any overpayment from a federal healthcare programme in connection with the sampled prescriptions.[17] If sampling demonstrated that 5 per cent or more of the prescriptions were dispensed other than in accordance with the CSA, the IRO was empowered to conduct a review of the company's systems and processes for dispensing Schedule II controlled substances.[18]

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13 See, e.g., Corporate Integrity Agreement between the Office of the Inspector General of the Department of Health and Human Services and Aegerion Pharmaceuticals, Inc. (22 September 2017), at https://oig.hhs.gov/fraud/cia/agreements/Aegerion_Pharmaceuticals_Inc_09222017.pdf.

14 id.; see also Addendum to the Corporate Integrity Agreement between the Office of the Inspector General of the Department of Health and Human Services and Novartis Pharmaceuticals Corporation (19 November 2015), at https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/cia_addendum.pdf; Corporate Integrity Agreement between the Office of the Inspector General of the Department of Health and Human Services and AmerisourceBergen Corporation (28 September 2018), at https://oig.hhs.gov/fraud/cia/agreements/AmersourceBergen_Corporation_09282018.pdf.

15 US DOJ, Justice News, 'Long-Term Care Pharmacy to Pay $31.5 Million to Settle Lawsuit Alleging Violations of Controlled Substances Act and False Claims Act' (14 May 2015), at https://www.justice.gov/opa/pr/long-term-care-pharmacy-pay-315-million-settle-lawsuit-alleging-violations-controlled.

16 Complaint for Damages and Injunctive Relief under the False Claims Act, *United States ex rel. Denk v. PharMerica Corp*. (22 July 2009), No. 09-cv-720 (E.D. Wis.).

17 Corporate Integrity Agreement between the Inspector General of the Department of Health and Human Services and PharmMerica Corporation, at Appendix B, Section 2 (11 May 2015), at https://oig.hhs.gov/fraud/cia/agreements/PharMerica_05112015.pdf.

18 id.

Administrative and enforcement actions

The DEA's Office of Diversion Control is responsible for ensuring that controlled substances remain within the closed distribution system and that drugs such as opioids are transferred only between licensed DEA registrants and patients based on a legitimate medical need as evidenced by a valid prescription. The DEA has the authority to bring an administrative action against any DEA registrant that transfers a controlled substance outside that closed system or for other violations of the CSA. The DEA has the exclusive authority to negotiate and settle administrative actions where the relief sought is equitable and a licence suspension or revocation is sought. If the DEA seeks monetary relief for violations of the CSA, or believes that a registrant has committed crimes, the US DOJ will take over the prosecution and eventual settlement of those cases.

Just like the HHS-OIG, the DEA, acting in partnership with the US DOJ, frequently negotiates settlements with its registrants to resolve investigations into potential violations of the CSA. Prior to the opioid crisis in the United States, the vast majority of settlements with DEA-registered pharmaceutical companies included a civil monetary penalty and a written compliance agreement with the DEA called a Memorandum of Agreement (MOA). These resolutions generally did not involve an independent monitor.

For example, in 2008, US Attorney's Offices in seven districts negotiated an agreement with Cardinal Health (Cardinal) resulting from the company's alleged failure to comply with its obligations to prevent diversion of controlled substances by failing to identify and report pharmacy customer orders of unusual size, pattern or frequency (in other words, suspicious orders).[19] Cardinal agreed to pay a US$34 million penalty and entered into a MOA with the DEA in which it agreed to certain enhancements to its anti-diversion compliance programme, particularly in relation to suspicious order reporting. Similarly, in 2008, McKesson, the largest US pharmaceutical distributor by revenue, entered into a comparable agreement with six US Attorney's Offices in which the company agreed to pay US$13 million in penalties and to adhere to certain compliance obligations outlined in an MOA.[20] In 2013, Walgreens agreed to pay US$80 million to settle allegations by the US DOJ that the company's pharmaceutical distribution processes did not fully comply with the CSA.[21] Walgreens also entered

19 US Attorney's Office (Colorado), News, 'Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims that it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances' (2 October 2018), at https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

20 US DOJ, Press release, 'McKesson Corporation Agrees to Pay More than $13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications' (2 May 2008), at https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html; Drug Enforcement Administration, Settlement and Release Agreement and Administrative Memorandum of Agreement (2 May 2008), at https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202008_0.pdf.

21 US Attorney's Office (Southern District of Florida), 'Walgreens Agrees to Pay a Record Settlement of $80 Million For Civil Penalties Under the Controlled Substances Act' (11 June 2013), at https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

into an MOA with the DEA, in which the company agreed to adhere to robust compliance terms dictated by the DEA.[22] In none of these cases, however, did the US DOJ or the DEA impose a monitor in connection with alleged violations of the CSA.[23]

Recently, in the context of the opioid addiction crisis and the increasing public attention devoted to it, the US DOJ has required the appointment of a monitor or IRO in cases involving DEA-registered pharmaceutical companies. Specifically, in a 2017 settlement with McKesson, the US DOJ imposed an IRO. In its 2019 settlement with the Rochester Drug Co-operative, Inc, another of the 10 largest pharmaceutical distributors in the United States, the US DOJ required a monitor. In addition, the US DOJ required a monitor for Practice Fusion, a health data company that accepted US$1 million from a pharmaceutical company in exchange for pushing electronic alerts that encouraged practitioners to prescribe opioids manufactured by the pharmaceutical company. The cases are discussed further below.

McKesson Corporation IRO

In early 2017, the US DOJ and the DEA jointly announced the settlement with McKesson Corporation of potential CSA violations relating to an alleged failure to report suspicious orders.[24] The McKesson IRO was billed as 'the first independent monitor of its kind in a CSA civil penalty settlement'.[25] It involved a civil settlement with 12 US Attorney's Offices and an administrative settlement, evidenced by an MOA with the DEA. Both the civil and administrative documents accuse McKesson of failing to maintain effective controls against the diversion of controlled substances. In addition, the settlement documents accuse McKesson of failing to meet its obligations under both the CSA and a prior 2008 settlement with the US DOJ and the DEA in which McKesson agreed to comply with its obligations to detect and report suspicious orders.

McKesson agreed to pay US$150 million and to a rolling suspension of its DEA registrations at four distribution centres for periods ranging from one to three years each.[26] McKesson also agreed to additional compliance obligations explicitly set forth in the MOA

22 Settlement and Memorandum of Agreement between the US DOJ and Walgreen Co (10 June 2013), at https://www.justice.gov/sites/default/files/usao-sdfl/legacy/2013/06/19/130611-01.WalgreensMOA%26Addendum.pdf.

23 Note, however, that in 2005, the DEA, the US Attorney's Offices for the Eastern District of Texas and the Eastern, Northern and Western Districts of Oklahoma, and the Oklahoma Bureau of Narcotics and Dangerous Drugs resolved a civil enforcement action against Walgreen Co stemming from compliance failures relating to pseudoephedrine distribution. A DEA press release references the appointment of an independent monitor of Walgreen Co stores in Oklahoma and the Eastern District of Texas. See Drug Enforcement Administration, News release (8 August 2005), at https://www.dea.gov/sites/default/files/pubs/states/newsrel/dallas080805.html. However, neither the details of the settlement nor the monitor's duties and reports are public information.

24 US DOJ, Justice News, 'McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs' (17 January 2017), at https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders; Drug Enforcement Administration, 'Largest Settlement In DEA History: McKesson Pays $150 Million' (17 January 2017), at https://www.dea.gov/press-releases/2017/01/17/largest-settlement-dea-history-mckesson-pays-150-million.

25 id.

26 Administrative Memorandum of Agreement between the Drug Enforcement Agency and McKesson Corporation (17 January 2017) at Section II.1, at https://www.justice.gov/opa/press-release/file/928476/download.

with the DEA and agreed to engage an IRO to monitor its continued compliance with the law. The term of the IRO was five years; however, the agreement allowed McKesson to seek permission to self-monitor for the last two years of the review.

The structure of the McKesson IRO closely resembles HHS-OIG IRO structures in respect of both selection process and substantive review. The written settlement documents establish requirements for the IRO's qualifications and selection of the IRO, and establish the IRO's reporting requirements. Substantively, the McKesson IRO was tasked with performing four discrete reviews of sample transactions or files. For example, the settlement required the IRO to assess whether McKesson adequately documented customer threshold change requests, the onboarding process and a sample of event-triggered due diligence processes. The IRO was also required to evaluate the process of compensating personnel in McKesson's regulatory affairs department. Finally, the IRO was tasked with reviewing the parameters of the system used to calculate thresholds for McKesson's independent retail pharmacy customers. The IRO was permitted to conduct interviews with personnel if questions arose in the review of the sampled transactions, and was also permitted to comment on any other compliance issues it noted. The IRO was required to file annual reports with McKesson; these IRO reports were attached to McKesson's own annual reports to the DEA.

Key aspects of the McKesson IRO differ from the HHS-OIG model. Uniquely, the McKesson IRO is required to report to the company, not directly to the DEA or the US DOJ. And whereas many HHS-OIG CIAs merely grant the HHS-OIG the right to reject a company's chosen IRO, McKesson's agreement outlined a selection process identical to those laid out in other DOJ monitorships. Specifically, the US DOJ and the DEA selected the IRO from the qualified candidates proposed by McKesson.[27] And whereas many HHS-OIG IROs are tasked with conducting arm's-length reviews based solely on transactional documents, the McKesson settlement, like a traditional US DOJ monitorship, permitted the IRO to conduct interviews with members of McKesson's regulatory affairs department if questions arose about transactions being sampled.[28] Although the ability to conduct interviews was similar to powers accorded to a typical US DOJ-imposed monitor, the scope of the McKesson IRO's interview powers was limited solely to McKesson's decisions about the aforementioned specific transactional samples.

Rochester Drug Co-operative monitorship

In April 2019, the US DOJ and the DEA jointly announced criminal charges against Rochester Drug Co-operative, Inc (RDC), one of the 10 largest pharmaceutical distributors

27 See, e.g., Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and PharMerica Corporation (11 May 2015) at Appendix A, Sections A.1, A.2, at https://oig.hhs.gov/fraud/cia/agreements/PharMerica_05112015.pdf; see also Compliance Addendum to the Administrative Memorandum of Agreement between the Drug Enforcement Agency and McKesson Corporation (17 January 2017) at Section IV.A, at https://www.justice.gov/opa/press-release/file/928481/download.

28 See Compliance Addendum to the Administrative Memorandum of Agreement between the DEA and McKesson (footnote 27, above) at Section V.A.

in the United States.[29] Announcing that the prosecution was the first of its kind, the US DOJ filed criminal charges against RDC, under the statute normally reserved for street drug traffickers.[30] In its press release, the US DOJ claimed: 'RDC supplied large quantities of oxycodone, fentanyl, and other dangerous opioids to pharmacy customers that its own compliance personnel determined were dispensing those drugs to individuals who had no legitimate medical need for them.'[31] The US DOJ also charged RDC with conspiracy to defraud the DEA by misrepresenting the company's due diligence practices and controls against diversion, and by knowingly failing to report suspicious orders from the company's pharmacy customers.[32]

To settle the charges, RDC entered into a deferred prosecution agreement (DPA) in which it admitted the charged conduct, agreed to a U$20 million penalty and entered into a compliance addendum requiring RDC to strengthen its procedures and systems for conducting due diligence on pharmacy customers, and for identifying and reporting suspicious orders of controlled substances.[33] The DPA called for RDC, among other things, to establish a compliance committee and to appoint two independent directors to this committee who were experts in controlled substance law and compliance. RDC was also required to retain an independent compliance monitor to oversee the company's fulfilment of its compliance obligations.[34]

The RDC monitorship is similar to a standard US DOJ monitorship, in that the company proposes candidates and US DOJ makes the final selection.[35] The term of the monitorship is three years.[36] The duties of the monitor are as broad as seen in more common monitorships under the US Foreign Corrupt Practices Act. Among other things, the RDC monitor must (1) evaluate the effectiveness of RDC's processes, procedures and programmes to ensure compliance with the CSA, (2) assess whether RDC complies with its processes, procedures and programmes, and with the reporting requirements of the CSA related to preventing diversion, (3) assess the qualifications of new RDC compliance employees and (4) assess the commitment of RDC's board of directors and senior management to compliance.[37]

The RDC monitor has 'authority to take such reasonable steps as . . . may be necessary to fulfill the [m]andate' and RDC is required to grant the monitor access to the company's

29 US Attorney's Office (SDNY), 'Manhattan U.S. Attorney and DEA Announce Charges Against Rochester Drug Co-Operative And Two Executives For Unlawfully Distributing Controlled Substances' (23 April 2019), at https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-and-dea-announce-charges-against-rochester-drug-co-operative-and.

30 id.; US Attorney's Office (SDNY), 'Re: Rochester Drug Co-operative – Deferred Prosecution Agreement' (22 April 2019), Information at ¶¶ 20 to 22, at https://www.justice.gov/usao-sdny/press-release/file/1156381/download.

31 See footnote 29.

32 US Attorney's Office (SDNY), 'Re: Rochester Drug Co-operative – Deferred Prosecution Agreement' (22 April 2019), Information, Exhibit B at ¶ 24, at https://www.justice.gov/usao-sdny/press-release/file/1156381/download.

33 id., at 1, 7; id. at Compliance Addendum, Exhibit D at ¶¶ 5 and 6.

34 id. at Independent Compliance Monitor Mandate, Exhibit E at ¶ 1.

35 id., at ¶ 2.

36 id., at ¶ 1.

37 id., at ¶ 3.

information, documents, records, facilities and employees.[38] In addition, the monitor is required to recommend 'tasks and efforts' that RDC should implement to ensure the fulfilment of the company's compliance obligations under its settlement agreement.[39] The monitor is also tasked with periodically reporting to the US DOJ on RDC's progress in implementing the monitor's recommendations and any violations of the CSA that the monitor discovers.[40]

In addition to the monitor's mandate, RDC itself was required to enhance significantly its compliance processes and governance structures. These terms, too, are reminiscent of a typical US DOJ monitorship agreement. For example, RDC is required to design and implement improved procedures and systems designed to meet the company's compliance obligations under the CSA. Of particular note is a requirement that RDC 'shall suspend . . . distribution of controlled substances' to any pharmacy customer for which RDC has identified a possible indicator of diversion (red flag), unless and until RDC has specific and articulable facts that resolve the red flag.[41] This goes far beyond what the CSA itself requires. The process of resolving a red flag is likely to be time-consuming and detail-oriented. It is not unrealistic to think that pausing shipments while investigating red flags, combined with a monitor's independent assessment of each individual order to which these obligations might apply, could quickly bring the company's operations to a halt. Perhaps for that reason, the RDC settlement agreement contains a provision that permits RDC to notify the monitor of any material provision in the compliance addendum that the company believes is 'unduly burdensome' and to propose an alternative approach to achieve the same objective.[42] This flexibility is quite unusual in a typical monitorship agreement.[43]

Practice Fusion oversight organisation

In early 2020, the US DOJ settled criminal and civil charges with Practice Fusion, a health information technology developer, for its role in soliciting and receiving kickbacks from a manufacturer of opioids to influence patient treatment decisions. While not itself a pharmaceutical company, Practice Fusion admitted to manipulating its electronic health records software to influence physicians to prescribe a particular company's opioids more frequently than the physicians might otherwise have done. Specifically, Practice Fusion admitted that it extracted a US$1 million 'sponsorship' payment from a major manufacturer of opioids in return for pushing electronic alerts to Practice Fusion's prescriber customers with the goal of causing the prescribers to increase prescriptions for the manufacturer's extended release opioid products. Practice Fusion entered into a DPA with the US DOJ and agreed to pay a total

38 id., at ¶¶ 3, 8.

39 id., at ¶¶ 3, 4.

40 id., at ¶¶ 5, 11.

41 Rochester Drug Co-operative – Deferred Prosecution Agreement (footnote 32, above), Compliance Addendum, Exhibit D at ¶ 5.

42 id., at Compliance Addendum, Exhibit D at ¶ 11.

43 Note, however, the similar language in the Practice Fusion compliance addendum discussed below.

of more than US$26 million in criminal fines and forfeitures. In addition, Practice Fusion separately settled civil claims that it submitted false claims to federal healthcare programmes tainted by the kickback schemes in which Practice Fusion admitted it engaged.[44]

As part of the resolution, Practice Fusion entered into a compliance addendum that sets forth a number of stringent compliance obligations for the company relating to its organisational structure and the process and substance of clinical decision support alerts it pushes to prescribers through its electronic health records system.[45] The company was also required to retain an oversight organisation that is tasked with reviewing and approving any sponsored clinical decision support alerts before Practice Fusion implements them and with creating a comprehensive compliance programme to prevent a recurrence of the prior conduct.[46]

The Practice Fusion oversight organisation's structure and mandate closely follow those of the RDC monitor, with two notable differences. First, whereas the RDC monitor is tasked with making recommendations about how RDC can comply with its compliance obligations, the Practice Fusion oversight organisation must affirmatively approve or disprove certain support alerts relating to health treatments.[47] Second, Practice Fusion is under more strongly prescribed requirements to follow its oversight organisation's recommendations. Specifically, the oversight organisation is required to make recommendations that Practice Fusion 'shall adopt and implement' unless the company convinces the oversight organisation and the US Attorney's Office that a recommendation is 'unduly burdensome, inconsistent with applicable law or regulation, impractical, or otherwise inadvisable' and Practice Fusion proposes an alternative recommendation to achieve the same objective or purpose.[48]

The future

US enforcement agencies' continued focus on opioid addiction is likely to result in continued scrutiny of pharmaceutical companies. The imposition of monitors and IROs in CSA cases is still in its infancy, but at least two trends suggest that there may be more to come. First, the DEA may adopt a more data-focused approach to its regulation of the approximately 1,400 pharmaceutical manufacturers, distributors and other DEA registrants. Any focus on data would make the increased use of IROs appropriate, just as the HHS-OIG has done in its data-focused efforts to settle potential healthcare fraud violations. Second, criminal CSA

44 US DOJ, Justice News, 'Electronic Health Records Vendor to Pay $145 Million to resolve Criminal and Civil Investigations' (27 January 2020), at https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0.

45 Compliance Addendum, *USA v. Practice Fusion, Inc.*, No. 2:20-cr-00011-wks (D. Vt, 27 January 2020), ECF No. 2-5.

46 id., at Section 8.

47 Rochester Drug Co-operative – Deferred Prosecution Agreement (footnote 32, above), Independent Compliance Monitor Mandate, Exhibit E at ¶ 3; see also Compliance Addendum, *USA v. Practice Fusion, Inc.* (footnote 45, above), at Section 8.

48 Compliance Addendum, *USA v. Practice Fusion, Inc.*, No. 2:20-cr-00011-wks (footnote 45, above), at ¶ 6.

cases against pharmaceutical companies, including RDC and Miami-Luken,[49] make clear that the US DOJ is willing to aggressively pursue the most severe sanctions against pharmaceutical companies – sanctions that are potentially life-ending for a company. The government's continued zealous enforcement of the CSA, coupled with legitimate concerns about putting healthcare companies out of business, suggest that there are likely to be additional DPAs and non-prosecution agreements (NPAs) with a monitorship component for pharmaceutical companies that are accused of violating the CSA.[50]

US DOJ's use of pharmaceutical monitorships

The US DOJ's Prescription Interdiction and Litigation Task Force and recent enforcement actions suggest that the US DOJ is less likely than ever to allow a pharmaceutical company to simply pay a fine and walk away from a charged CSA violation. Although the US DOJ is well-equipped to investigate, prosecute, or settle violations of the CSA, it does not have the resources to enforce and continuously assess the numerous and, at times, technical compliance terms agreed as part of a corporate settlement. Thus, the US DOJ is unlikely to abandon the incorporation of monitorships into DPAs or NPAs with pharmaceutical companies.

However, cost is an constant consideration. Under the terms of an 11 October 2018 memorandum issued by the Assistant Attorney General of the US DOJ's Criminal Division (the Benczkowski Memorandum), the US DOJ will seek the imposition of a monitor only where there is a 'demonstrated need . . . and clear benefit to be derived . . . relative to the projected costs and burdens'.[51] In evaluating potential costs, the Benczkowski Memorandum requires the US DOJ to consider not only the projected monetary costs to the company but also 'whether the proposed scope of a monitor's role is appropriately tailored to avoid unnecessary burdens to the business' operations'.[52] In both the *Practice Fusion* and *RDC* DPAs, the US DOJ required monitors to take on an active role in approving or disproving a monitored company's operational decisions. The monetary and operational expense of such close involvement by a monitor in a company's daily decisions is required only where the US DOJ considers that the underlying misconduct and limitations to any remedial efforts warrant the high cost of close monitoring. Conversely, a monitor with a more proscribed mandate,

49 See Indictment, *USA v. Rattini, et al.*, No. 1:19-cr-00081-MWM (S.D. Ohio, 17 July 2019), ECF No. 7 (indicting wholesale pharmaceutical distributor Miami-Luken, Inc. for conspiracy to violate the CSA criminal provision normally reserved for street drug traffickers; Dayton Daily News, 'Rise and fall of Miami-Luken: Local firm blamed for opioid shipments' (6 January 2019), at https://www.daytondailynews.com/news/rise-and-fall-miami-luken-local-firm-blamed-for-opioid-shipments/vRP21oJE9JhFPkKNmiEfeK/ (noting that Miami-Luken went out of business prior to the US DOJ filing its indictment).

50 See, e.g., comments of Geoffrey Berman, US Attorney for the Southern District of New York, 'Charges Announced Against RDC Drug & 2 Executives For Unlawfully Distributing Controlled Substances', at https://www.youtube.com/watch?v=_Q2QYGdEKQs ('our office will do everything in its power to bring to justice anyone responsible for unlawfully fueling this opioid epidemic. . . . There are implications to a guilty plea that could impact [RDC's] ability to stay in business'; 'there are hundreds of individuals employed by RDC who could lose their jobs'; 'we believed that RDC could be reformed . . . through a monitor that would be placed at the company').

51 Brian A Benczkowski, US DOJ, 'Selection of Monitors in Criminal Division Matters' (11 October 2018) at Section A, at https://www.justice.gov/opa/speech/file/1100531/download.

52 id.

for example, in the form of a review of a randomly selected sample of transactions, may cost significantly less, and may be appropriate when the underlying misconduct is less severe, or the company has already meaningfully remediated identified compliance failures.

Conclusion

The practice of imposing monitorships on pharmaceutical companies settling alleged or admitted violations of the CSA is still new. Both the unique aspects of the CSA and the complexity of the technical systems used by pharmaceutical companies to comply with the CSA set a CSA-related monitorship apart from a more standard US DOJ-imposed monitorship in an anti-corruption setting. A person or organisation experienced both with the pharmaceutical industry and government is well-equipped to serve in a monitor role. Although the current number of persons so qualified may be limited, lawyers involved in the thousands of cases stemming from the opioid crisis are fast gaining experience that would make them well-suited for future CSA-related monitorships, if and when the DEA and the US DOJ impose them.

Appendix 1

About the Authors

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Jodi Avergun is a noted white collar expert who specialises in the pharmaceutical and financial services industries. She represents corporations and individuals in criminal and regulatory matters involving the US Foreign Corrupt Practices Act, securities enforcement and healthcare matters. Jodi has successfully represented both companies and senior executives in internal investigations, matters before regulatory bodies including the Securities and Exchange Commission and the Drug Enforcement Administration (DEA), and in civil and criminal matters in federal court. She has also designed and implemented compliance programmes.

She is a former Chief of the Narcotic and Dangerous Drug Section of the US Department of Justice's Criminal Division, a former Chief of Staff of the DEA and a former Assistant US Attorney in the Eastern District of New York. Jodi represents clients in cases involving both traditional and unusual applications of the Controlled Substances Act (CSA), including large and small wholesale distributors, manufacturers, retail chains and pharmacists, and is the first appointed monitor to oversee a CSA settlement. She successfully represented employees of FedEx in grand jury investigations and at trial, and successfully represented the clubs of the NFL in CSA-related matters.

Jodi is recognised in *Who's Who Legal: Investigations* 2017 and 2019 and was profiled in Global Investigations Review's '2018 Women in Investigations'. She is also regularly named a SuperLawyer by *Washingtonian Magazine*.

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A former Assistant US Attorney for the Southern District of New York for nine years, Todd has extensive experience in investigating all manner of white-collar crime. As co-chief of the White Plains Division, he supervised investigations and prosecutions involving public corruption, securities fraud, bank and wire frauds, Medicare and federal programme frauds, violations of the Racketeer Influenced and Corrupt Organization Statute, violent crimes and other criminal violations. He also served as co-chief of the Violent Crimes Unit. Todd has extensive trial experience, serving as counsel in 15 federal jury trials. Todd was a recipient of the Director's Award from the US Department of Justice for Superior Performance as an Assistant US Attorney.

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Prior to joining Cadwalader, Christian worked on financial crime matters with the International Monetary Fund and the US Department of Justice Asset Forfeiture and Money Laundering Section. From 2011 to 2014, the US Department of State seconded Christian to the Organization for Security and Cooperation in Europe (OSCE), where he supported 57 countries in developing and implementing international standards to combat money laundering and corruption. While with the OSCE, Christian trained governments and industry professionals throughout Europe and central Asia and served as head of the OSCE delegation to the Financial Action Task Force.

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Since *WorldCom*, the United States Department of Justice and other agencies have imposed more than 80 monitorships on a variety of companies, including some of the world's best-known names. The terms of these monitorships and the industries in which they have been employed vary widely. Yet many of the legal issues they raise are the same. To date, there has been no in-depth work that examines them.

GIR's *The Guide to Monitorships* fills that gap. Written by contributors with first-hand experience of working with or as monitors, it discusses all the key issues, from every stakeholder's perspective, making it an invaluable resource for anyone interested in understanding or practising in the area.

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