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FEATURE

When Money and Doritos Don't Suffice

The Crucial Imperative for Integrating Effective Compliance Controls in the Ongoing Opioid Settlements

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Summary: The mass of opioid litigation is far from over, but the results of Oklahoma's settlements with and trial verdict against various pharmaceutical manufacturers reveal that money alone will not suffice. Therefore, any court-imposed resolutions need to include effective compliance controls to prevent a resurgence of the behaviors, decisions and actions that fueled the current public health crisis.

Having covered the ongoing opioid litigation for some time now,[2] it is increasingly clear that monetary damages alone will not suffice to address the current opioid public health crisis. This article explores the necessity of integrating compliance controls and enhanced oversight into any systemic solution.

> *"The poppy's power, in fact, is greater than ever. The molecules derived from it have effectively conquered contemporary America. Opium, heroin, morphine, and a universe of synthetic opioids, including the super powerful painkiller fentanyl, are its proliferating offspring. More than 2 million Americans are now hooked on some kind of opioid …"*
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> *-- Andrew Sullivan, The Poison We Pick, INTELLIGENCER - NEW YORK MAGAZINE (Feb. 2018).*

The Magnitude of the Crisis

A 2018 House Energy and Commerce Committee Report declared that the "opioid epidemic is the worst drug crisis in America's history."[3] Furthermore, the report noted that "[a]ccording to the Centers for Disease Control and Prevention, more than 351,000 lives have been lost to opioid overdoses since 1999, with no signs of abating."[4] In fact, the report concluded the epidemic has a reached a point that it has "helped drive a decline in the U.S. life expectancy at a time when life expectancy is improving in many places around the world."[5] Moreover, data from the CDC indicates that people who are addicted to opioids are 40 times more likely to become addicted to heroin.[6]

The United States also is unique for the volume of opioid medicinal products used. A 2017 report by the International Narcotics Control Board noted that "[i]n 2016, the country with the highest consumption of hydrocodone continued to be the United States, with 33.4 tons, equivalent to 99.1 percent of total global consumption."[7] In that same report, it was noted that the United States consumed 72.9 percent of the world's total of oxycodone for that same time period.[8] However, the opioid crisis is not just about addiction and overdoses. It also impacts the patients who legitimately need access to opioids to function and have a meaningful quality of life.

The current opioid epidemic also is not a newly recognized public health issue. From 1840 to 1915, opium and opiates usage was legal in the United States and they even were included in mainstream medicinal products such as cough suppressants until restricted under the Harrison Narcotic Act of 1914.[9] Therefore, as Judge Polster, who presides over the current Opioid MDL litigation,[10] wrote, "[i]t is accurate to describe the opioid epidemic as a man-made plague."[11] In August 2001, the House Subcommittee on Oversight and Investigations held a public hearing discussing the legitimate and illegitimate uses of OxyContin.[12] In December 2003, the United States General Accounting Office ("GAO") published a report for Congress on the abuse, use, and diversion of OxyContin.[13]

The opioid crisis is also unique in that activities in one location can have an impact on jurisdictions many miles or even states removed. Like alcohol bootlegging before it, opioid diversion takes a risk mitigation approach moving from areas with strong enforcement to areas that are weaker. Consequently, while Florida started out as "ground zero" for diversionary pharmacies, those pharmacies ultimately spread to other states such as Kentucky, West Virginia and Ohio.[14] As a result during a five-year period (2007-2012), 780 million dosage units of hydrocodone and oxycodone were distributed to West Virginia, a state of 1.8 million residents.[15]

With the purchase of the product tied to one location and consumption tied to another, opioid migration also resembles Prohibition-era bootlegging. This phenomenon, the so-called "oxy express," describes the frequent trips made by thousands of individuals to states like Florida to purchase opioids easily and take them back to the state where they reside.[16]

An Untidy Mass of Litigation

Given the magnitude of the opioid crisis, the sheer number of pending opioid legal actions is no surprise. However, like the crisis itself, the current mass of litigation itself is untidy.

The Opioid MDL alone consolidated all pending federal opioid-related cases under the auspices of one federal district (the Northern District of Ohio) and one judge (Judge Daniel Aaron Polster).[17] Although the Opioid MDL has been a major focal point, it only represents a portion of the cases pending against the various pharmaceutical manufacturers, distributors, and pharmacy chains involved with opioids. For example, in reporting that Purdue Pharma reached a tentative settlement over its alleged role in the opioid crisis, *The Washington Post* noted the cases against Purdue involved 23 states and more than 2,000 cities and counties.[18]

Furthermore, while the State Attorneys General and various localities largely have driven the mass of the opioid civil litigation, these cases are fixated on the recovery of monetary damages to fund addiction treatment and reimburse states and localities for increased emergency services responding to the overdoses and other medical issues.

To date, the Justice Department also has pursued a much smaller set of enforcement cases against both opioid pharmaceutical manufacturers (e.g., Insys and Indivior)[19] and distributors (e.g., Rochester Drug Co-Operative and Miami-Luken).[20] These cases have involved both corporate entities and individual company executives, but like their civil counterparts, they largely have concentrated on financial resolutions directed at the corporations involved.[21]

Limited Reference Points

Given the complexity of the crisis and the number of defendants involved, so far there are relatively few settlements or verdicts to serve as harbingers on what the future holds. However, using the recent Oklahoma settlements and the trial verdict against Johnson & Johnson ("J&J") as a guide, the scale of the potential financial liability is massive.

Analyzing and extrapolating from the recent Purdue Pharma settlement and the J&J verdict in Oklahoma, it appears that the companies involved do not have enough liquidity to fund all the settlements (Table 1). For example, in the case of Purdue Pharma, it would

TABLE 1: *Analyses of Purdue Pharma Settlement & J&J with Oklahoma*

PURDUE PHARMA SETTLEMENT[22]		
Oklahoma Population	$3.94	Million
US Population	$327.2	Million
Oklahoma as a Percent or US Population	1.2%	Percent
Oklahoma Settlement	$270	Million
Potential National Liability (states only)	$27	Billion
Total Net Worth Sacklers (Forbes)	$13	Billion
Total Shortfall for State Settlements	$14	Billion
Total Revenue Purdue/year	$3	Billion
Potential Net Profit/year (30%)	$900	Million
Total Years to Pay Off State Settlement shortfall (putting 66% of net profits into state settlements)	***24***	***Years***
J&J VERDICT		
U.S. Population (2019)	$329.35	Million
Oklahoma Population (2019)	$3.94	Million
Oklahoma as a Percent of U.S. Population	1.20%	Percent
J&J Judgement	$572	Million
Market Cap J&J (8/26/19)	$337	Billion
Potential State Settlement Judgement	$56	Billion
Settlement as a percent of market capitalization	***17%***	***Percent***

take Purdue 24 years to pay off just the State settlements if every settlement is at least $270 million, while in the case of J&J, the verdict if upheld, represents 17% of the company's current market capitalization. In both instances, this does not account for any potential federal, city, county or patient liability.

Examining some of the other opioid cases (i.e., Insys, Indivior, Miami-Luken, and most recently, Purdue's tentative settlement), these resolutions have the companies involved facing the complete loss of their businesses or bankruptcy.[23]

Potential Impact on Patients and the Health Care System

The limitation in using the cases of Insys, Indivior, and Miami-Luken as reference points is that those companies are relatively small compared to other defendants still embroiled in the universe of opioid litigation. Some of the large defendants under attack for their role in the crisis include J&J, Teva, McKesson, Cardinal Health, AmerisourceBergen, CVS, and Walgreens.

J&J and Teva rank third and twenty-first respectively, by pharmaceutical sales.[24] McKesson, Cardinal Health and AmerisourceBergen ("ABC") combined distribute 85% of the national drug supply.[25] CVS and Walgreens control 41.7% of the U.S. prescription drug market revenue.[26] Although these large defendants arguably have "deep pockets," those pockets are not infinite.

Furthermore, these companies also manufacture, sell, distribute, and dispense more than just opioid products. For example, in his testimony before Congress in 2018, Steven Collis, Chairman, President and Chief Executive Officer of AmerisourceBergen noted that prescription opioids account for less than 2% ($3 billion) of ABC's total revenues.[27] Therefore, the demise of these companies would have a catastrophic effect on the overall U.S. health care system affecting not only those patients with a legitimate need for opioid products but also non-opioid using patients as well. Given this reality of our current pharmaceutical ecosystem, forcing these companies into bankruptcy or worse, regardless of their actual culpability for the opioid crisis, is simply out of the question.

An Imperfect Outcome

If we accept the fact that there is not enough corporate liquidity to fund the critical actions required to stem the crisis (e.g., funding systemic addiction treatment or repaying local emergency response costs for opioid overdoses), and we acknowledge that at least the larger companies involved in the manufacture, sale, distribution and dispensing of opioid products cannot, and probably should not, be driven into extinction because of the greater harm it will cause, then we are left with the need to craft a solution that accepts full monetary recompense is not possible, and many of the former defendants in the opioid cases will continue to manufacture, sell, distribute, and dispense pharmaceutical products. It is an imperfect outcome.

People Are At the "Heart" of the Opioid Crisis

While much of the opioid crisis liability discussion centers on companies, corporations are not "real people," but rather legal liability-reducing investment frameworks. Consequently, the options to punish "bad" corporate entities comes down to money (either by imposing stiff fines and penalties or by denying the company market authorization to sell its products).[28]

However, because corporations are only a legal construct, centering the liability discussions on companies is somewhat disingenuous. Real people are at the heart of this public health crisis. It is human behaviors, decisions, and actions that ultimately are the root cause of this "man-made plague."

Reviewing some of the publicly available information, including released court documents,[29] highlights a pattern of inappropriate behaviors, decisions, and actions by company executives and employees that fueled the crisis. Unfortunately, there is no shortage of egregious, and cringe-worthy, examples; they are easy to find, and below is just a small representative sample:

1. Mallinckrodt National Account Manager, Victor Borelli, told a distributor customer that the opioid products he was selling were "'Just like Doritos keep eating, we'll make more.'"[30]

2. Karen Harper, who oversaw Mallinckrodt's controlled substances compliance efforts, admitted in her deposition that "'[t]here were times that we shipped an order before the [required] review was complete, but we never shipped suspicious orders.'"[31]

3. J&J sale representative, Drue Diesselhorst, testified that over the 68 times she called on Dr. Harvey Jenkins, who allegedly was running "a pill mill", she never saw anything suspicious during her sales calls despite the fact that before Harvey's arrest, undercover officers "reported the illegality was so flagrant that obviously stoned patients would line up outside [his office] even before the clinic opened," and she commented that "'[m]y job was to be a sales rep, [m]y job was not to figure out the red flags.'"[32]

4. Jennifer Norris, Vice President and General Counsel of Cardinal Health, stated in her deposition that "'Cardinal Health does not have an obligation to the general public. Cardinal Health has an obligation to perform its duties in accordance with the law, the statute, regulations, and guidance.'"[33]

Addressing the "Root Cause"

Although some industry and legal observers may be tempted to dismiss these types of comments as being isolated, off-hand or "rogue" statements, that would be naïve. These types of comments instead demonstrate a wholesale breakdown of corporate governance, corporate culture, and individual accountability. Therefore, substantial efforts will be required to prevent the "bad" corporate actors, which continue to operate when the litigation fallout settles, from simply reverting to past behaviors, decisions, and actions leading to a second, future crisis (opioid-related or not).

Consequently, any effective court-imposed resolutions must address the controls necessary to prevent the recurrence of these inappropriate behaviors, decisions, and actions. At this moment, neither plaintiffs' counsel, State Attorneys General, Federal regulators, or even judges are focusing on this component of a potential overall solution. Fortunately, however, a framework exists to address, and hopefully prevent, a dreaded recurrence.

Federal Sentencing Guidelines Are the Foundation of the Solution

As an initial starting point, the U.S. Federal Sentencing Guidelines ("FSGs") establish the standard, generally accepted framework of an effective compliance program intended to promote "an organizational culture that encourages ethical conduct and a commitment to compliance with the law."[36] A primary purpose of these programs is to:

> not only encourage corporations to exemplify "good corporate citizenship," but also provide a means to "rehabilitate" corporations that have engaged in criminal conduct ....[37]

Or put in less esoteric terms, in the words of Assistant Attorney General Brian Benczkowski "[e]ffective compliance programs play a critical role in preventing misconduct " and therefore are part of "broader efforts ... to help promote corporate behaviors that benefit the American public ...."[38]

Since "good corporate citizenship" and creating a "culture that encourages ethical conduct" which promote "corporate behaviors that benefit the American public" are the bedrock upon which the FSGs are built, the tenets of corporate compliance provide a solid foundation for designing and implementing the controls necessary to address the behaviors, decisions, and actions of the executives and employees of former corporate opioid litigation defendants which must continue operating to avoid a cataphoric failure of the current U.S. health care system.

But It Will Take Much More

Although the FSGs provide a solid foundation for developing the necessary controls to prevent a recurrence of the types of behaviors, decisions, and actions central to the opioid suits, the FSG framework will require substantial enhancements to achieve real effectiveness. Corporate compliance programs were never intended to be static but 'implemented, reviewed, and revised, as appropriate, in an effective manner.'"[39]

Since the goal must be the establishment of truly effective (not just paper) programs , achieving this goal means taking a hard look at what "effective compliance" truly means, not just in terms of the Federal Sentencing Guidelines, but also at the tools, techniques, and best compliance practices that have developed over time (e.g., executive compensation clawback provisions, required use of outside Board advisors, Government monitors, and independent review organizations, etc.).

These programs must be led by individuals with enough independence and authority to stop inappropriate activities at their inception, if not before. These individuals also must receive the full support of the Government regulatory authorities charged with maintaining the acceptable corporate behavioral guardrails.

Just as the massive litigation required a support team, designing, implementing, overseeing, and enforcing the necessary controls to address the egregious behaviors, decisions, and actions, will require a concerted and concentrated team effort harnessing independent and recognized compliance experts, from both the public and private sectors.

Conclusion

Clearly, a monetary-only solution to address the opioid crisis is both untenable and undesirable. Thus, other controls and mechanisms are essential to address the prior inappropriate activities involving executives and employees of those defendants, which will continue operating in the aftermath of the opioid settlements, trials, and appeals. While complex, the goal of establishing truly effective controls to curb these unwanted behaviors, decisions, and actions is achievable. But it is imperative that the work begins now while the actual litigation is ongoing. There simply is no time to waste.

References:

1 *Dr. Whitelaw serves as the Editor of the Policy & Medicine Compliance Update. He also is the President and Chief Executive Officer of the Whitelaw Compliance Group, LLC. and holds the position of Senior Fellow & Adjunct Professor, Life Sciences Compliance with Mitchell Hamline School of Law. The views expressed in this article are solely those of the author.*

2 *See R. Wilkey, Opioid Case Test the Boundaries of Liability: Oklahoma, J&J and the "Mutant Poppy Strain", 5.9 POLICY & MEDICINE COMPLIANCE UPDATE, 1 (2019); K. Wildoner, An Insys Update – Settlement of Civil and Criminal Allegations, 5.9 POLICY & MEDICINE COMPLIANCE UPDATE, 17 (2019); C. Greene, Transcending the Opioid Crisis: Insys as a Compliance Cautionary Tale, 5.7 POLICY & MEDICINE COMPLIANCE UPDATE, 9 (2019); R. Wilkey, Transcending the Opioid Crisis II: Indivior Another Case Study, 5.7 POLICY & MEDICINE COMPLIANCE UPDATE, 16 (2019); C. Greene, Renewed Focus on the Importance of compliance – Analyzing the Recent Rochester Drug Co-Operative Case and DOJ Updated Compliance Program Guidance, 5.6 POLICY & MEDICINE COMPLIANCE UPDATE, 1 (2019).*

3 *See U.S. House Energy & Commerce Committee Report, Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia, 115th Cong., 4 (Dec. 19, 2018).*

4 *Id. (quoting information provided the by Centers for Disease Control, citations omitted).*

5 *Id.*

6 *See Centers for Disease Control and Prevention, Vital Signs; Today's Heroin Epidemic (Jul. 2015).*

7 *See Int'l Narcotics Control Bd., Narcotic Drugs: Estimated World Requirements for 2018; Statistics for 2016, 36 (2017).*

8 *Id. at 37.*

9 *See David F. Musto, The American Experience with Stimulants and Opiates, 2 Persp. on Crime & Just., 51, 56 (1998) (In 1898, the Bayer Company introduced heroin as a powerful cough suppressant).*

10 *In re: National Prescription Opiate Litigation, MDL No. 2804 (N.D. Ohio, E.D.)*

11 *See Amanda Bronstad, Opioid Judge Refuses to Dismiss Claims That Drug Companies Caused 'Man-Made Plague,' LAW.COM (Dec. 20, 2018 at 04:35 P.M.), https://www.law.com/2018/12/20/opioid-judge-refuses-to-dismiss-claims-that-drug-companies-caused-man-made-plague/ .*

12 *See Oxycontin: Its Use and Abuse, Hearing Before the House Subcomm. on Oversight and Investigations, H. Comm. on Energy and Commerce, 107 Cong., (Aug. 28, 2001), https://www.govinfo.gov/content/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm*

13 *See Oxycontin: Its Use and Abuse, Hearing Before the House Subcomm. on Oversight and Investigations, H. Comm. on Energy and Commerce, 107 Cong., (Aug. 28, 2001), https://www.govinfo.gov/content/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm; see also U.S. Gen'l Accounting Office, Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem, GAO-04-110 (Dec. 2003), https://www.gao.gov/new.items/d04110.pdf.*

14 *See, e.g., U.S. House Energy & Commerce Committee Report, Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia, 115th Cong., 4 (Dec. 19, 2018).*

15 *See Andrew Sullivan, The Poison We Pick, INTELLIGENCER - NEW YORK MAGAZINE (Feb. 2018), http://nymag.com/intelligencer/2018/02/americas-opioid-epidemic.html.*

16 *See The 'Oxy Express': Florida's Drug Abuse Epidemic, NPR (Mar. 2, 2011), https://www.npr.org/2011/03/02/134143813/the-oxy-express-floridas-drug-abuse-epidemic; Pat Beall, Florida cuts of oxy: Death, Devastation follow, THE PALM BEACH POST, https://heroin.palmbeachpost.com/florida-cuts-off-oxycodone-death-devastation-follow/?ref=lowerTeases, (last visited Apr. 4, 2019).*

17 *See Amanda Bronstad, MDL Panel Orders All Federal Opioid Cases to Ohio, LAW.COM (Dec. 5, 2017 at 07:50 P.M.), https://www.law.com/nationallawjournal/sites/nationallawjournal/2017/12/05/mdl-panel-orders-all-federal-opioid-cases-to-ohio/?slreturn=20190814210602*

18 *See Lenny Bernstein, Purdue Pharma reaches tentative deal in federal, state opioid lawsuits, THE WASHINGTON POST (Sept. 11, 2019, 1:50 p.m. EDT), https://beta.washingtonpost.com/health/purdue-pharma-reaches-tentative-settlement-in-federal-lawsuit-and-some-state-litigation/2019/09/11/ce6cb942-d4b8-11e9-9343-40db57cf6abd_story.html.*

19 *See C. Greene, Transcending the Opioid Crisis: Insys as a Compliance Cautionary Tale, 5.7 POLICY & MEDICINE COMPLIANCE UPDATE, 9 (2019); R. Wilkey, Transcending the Opioid Crisis II: Indivior Another Case Study, 5.7 POLICY & MEDICINE COMPLIANCE UPDATE, 16 (2019). Both cases involved a major Federal False Claims Act component.*

20 *See, e.g., William Rashbaum, For First Time, Pharmaceutical Distributor Faces Federal Criminal Charges, THE NEW YORK TIMES (Apr. 23, 2019)(company, CEO and Chief Compliance Officer indicted with conspiring to distribute drugs, conspiracy to defraud the United States, and company also was indicted for failure to file suspicious orders under the DEA requirements) https://www.nytimes.com/2019/04/23/nyregion/opioid-crisis-drug-trafficking-rochester.html; Jeff Overley, DOJ Indicts Opioid Distributor, Execs Over Pain Killer Sales, LAW360 (Jul. 18, 2019) (indictment of company, former CEO and former Compliance Officer on conspiracy to distribute and dispense a controlled substance).*

21 *See id.*

22 *See Thomas Sullivan, Purdue Pharma Agrees to Pay $270 Million to Oklahoma to Settle Case Involving Deceptive Marketing Practices of Opioid Painkillers*

Representing 1.2% of the Total Potential State Liability, Policy & Medicine (Apr. 26, 2019), https://www.policymed.com/2019/04/purdue-pharma-agrees-to-pay-270-million-to-oklahoma-to-settle-case-involving-deceptive-marketing-practices-of-opioid-painkillers-representing-1-2-of-the-total-potential-state-liability.html.

23 See Vanessa Romo, Insys Files For Chapter 11, Days After Landmark Opioid Settlement of $225 Million, NATIONAL PUBLIC RADIO (June 10, 2019), https://www.npr.org/2019/06/10/731363225/insys-files-for-chapter-11-days-after-landmark-opioid-settlement-of-225-million; Thomas Sullivan, Indivior Indicted in Alleged Multibillion-Dollar Fraud Scheme, Policy and Medicine, April 24, 2019, https://www.policymed.com/2019/04/indivior-indicted-in-alleged-multibillion-dollar-fraud-scheme.html; Sumeet Sigh, Miami-Luken to Begin Winding Down Operations, Five Rivers Rx (May 10, 2018), https://www.fiveriversrx.com/single-post/2018/05/10/Miami-Luken-to-Begin-Winding-Down-Operations; Lenny Bernstein, Purdue Pharma reaches tentative deal in federal, state opioid lawsuits, THE WASHINGTON POST (Sept. 11, 2019, 1:50 p.m. EDT), https://beta.washingtonpost.com/health/purdue-pharma-reaches-tentative-settlement-in-federal-lawsuit-and-some-state-litigation/2019/09/11/ce6cb942-d4b8-11e9-9343-40db57cf6abd_story.html.

24 See PHARMAEXEC.COM, Pharm Exec's Top 50 Companies, http://www.pharmexec.com/pharm-execs-top-50-companies-2019 (last visited Sep. 9, 2019).

25 See U.S. House Energy & Commerce Committee Report, Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia, 115th Cong., 9 (Dec. 19, 2018).

26 See STATISTA, Top U.S. pharmacies ranked by prescription drug market share in 2018, https://www.statista.com/statistics/734171/pharmacies-ranked-by-rx-market-share-in-us/ (last visited Sep. 9, 2019).

27 Written Statement of Steven H. Collis Chairman, President, and Chief Executive Officer AmerisourceBergen Corporation Before the Subcommittee on Oversight and Investigations Committee on Energy and Commerce U.S. House of Representatives at (May 8, 2018), https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Wstate-CollisS-20180508.pdf.

28 See, Milton Friedman, The Social Responsibility of Business Is to Increase Its Profits, The New York Times, 379 (Sept. 13, 1970) ("What does it mean to say 'business' has responsibilities? Businessmen who talk this way are unwitting puppets of the intellectual forces that have been undermining the basis of a free society these past decades."); see also Andrew Ross Sorkin, How Shareholder Democracy Failed the People, The New York Times (updated Aug. 21, 2019) ("For nearly a half-century, corporate America has prioritized, almost manically, profits for its shareholders … [which] overran nearly every other constituent, pushing aside the interests of customers, employees, and communities."), https://www.nytimes.com/2019/08/20/business/dealbook/business-roundtable-corporate-responsibility.html.

29 As used in this article, court documents include pleadings, expert reports, settlement documents, as well as original company documents released by various courts to the media.

30 See Sari Horwitz, et al., Newly unsealed exhibits in opioid case reveal inner workings of the drug industry, THE WASHINGTON POST (Jul. 23, 2019), https://www.washingtonpost.com/investigations/newly-unsealed-exhibits-in-opioid-case-reveal-inner-workings-of-the-drug-industry/2019/07/23/acf3bf64-abe5-11e9-8e77-03b30bc29f64_story.html.

31 Id.

32 See Nolan Clay, Opioid Trial moves closer to the end, THE OKLAHOMAN (Jul. 7, 2019, 5:00 a.m.), https://oklahoman.com/article/5635558/opioid-trial-moves-closer-to-end.

33 THE WASHINGTON POST, The Records Revealed (Updated Jul. 25, 2019), https://www.washingtonpost.com/graphics/2019/investigations/opioid-drug-company-documents/.

34 See U.S. Sentencing Commission, Guidelines Manual at § 8B.2.1.

35 See, e.g., Gabriel Imperato and Anne Novick Brannan, The Federal Sentencing Guidelines: A Practical Overview of Their Background, Intent, and Implications, in HEALTH CARE COMPLIANCE PROFESSIONAL'S MANUAL ¶ 30,180 (Al Joseph, John Falcetano, Roy Snell, Debbie Troklus, eds. 2016); Debbie Troklus, Greg Warner, Emma Wollschlager Schwartz, Compliance 101 – How to build and maintain an effective compliance program, (SCCE 2008); Dove Izraeli and Mark S. Schwartz, What Can We Learn from the U.S. Federal Sentencing Guidelines for Organizational Ethics?, 17 JOURNAL OF BUSINESS ETHICS, 1045-1055 (1998).

36 See U.S. Sentencing Commission, Guidelines Manual at § 8B.2.1.

37 See Diane Murphy, The Federal Sentencing Guidelines for Organizations: A Decade of Promoting Compliance and Ethics, 87 IOWA L. REV. 697, 703 (2002) (citations omitted).

38 U.S. Dep't. of Just., Press Release: Criminal Division Announces Publication of Guidance on Evaluating Corporate Compliance Programs (Apr. 30, 2019), https://www.complianceweek.com/regulatory-enforcement/justice-department-revises-the-evaluation-of-corporate-compliance-programs/26985.article.

39 See U.S. Department of Justice, Criminal Division, Evaluation of Corporate Compliance Programs, 9 (updated Apr. 2019) (citations to the Justice Manual omitted), https://assets.documentcloud.org/documents/5983840/DOJ-Evaluation-of-Corporate-Compliance-Programs.pdf.

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