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# LIFE SCIENCE COMPLIANCE FROM THE BEGINNING

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This conference marks an important milestone in the development of life science compliance. It is the 20<sup>th</sup> anniversary of the Pharmaceutical and Medical Device Compliance Congress, and so is a fitting time to step back and examine from whence life science compliance and our profession came.

Since the Pharmaceutical Compliance Forum (“PCF”) sponsored the first Congress in 2000 by a small group of dedicated individuals, the original group has grown into a cadre of dedicated and practicing compliance professionals that continues to grow.<sup>2</sup>

## Overview

“THOSE WHO CANNOT REMEMBER THE PAST ARE CONDEMNED TO REPEAT IT”

George Santayana, *The Life of Reason: Reason In Common Sense* (1905)

For some of the more seasoned practitioners at this Conference, the origins of life science compliance are at best murky, while for many new practitioners, it is an unknown. For all attendees at this anniversary Congress, we hope this retrospective is useful.

The history of compliance in the life sciences is an amalgamation of four distinct, but intertwined elements, which are:

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<sup>1</sup> With more than 30 years working in the industry, Dr. Whitelaw started his career in Life Science Compliance in 1993, when he became the Compliance Coordinator for C.R. Bard, Inc. Present since the inception of life science compliance, his career has encompassed a wide variety of roles from in-house compliance officer (C.R. Bard, Inc., SmithKline Beecham NA, GlaxoSmithKline, and Misonix, Inc.) to industry consultant (Deloitte and Whitelaw Compliance Group) to editor (*Policy & Medicine Compliance Update* (formerly *Life Science Compliance Update*)), and finally law professor (Mitchell Hamline School of Law) where he currently teaches students about corporate and life sciences compliance.

<sup>2</sup> At that time, the Congress was known at the *Pharmaceutical Industry Regulatory & Compliance Summit*. Consistent with the fundamental concept that compliance must evolve and adapt to changing times, the *Summit* became

## The Federal Sentencing Guidelines and the “Seven Elements”

While there is no precise date for when the first modern corporate compliance programs were born,<sup>3</sup> the publication of the Federal Sentencing Guidelines for Organizations (“FSGs”) in 1991 and its seven elements of an effective compliance program is perhaps the best place to start for life science programs.

Established by the U.S. Sentencing Commission (“Sentencing Commission”), the Guidelines were a “mechanical structure [that] determines an appropriate monetary fine through means of a mathematical formula: assigning a dollar figure to the seriousness of the offense and multiplying that number by a figure representing the culpability level of the organization.”<sup>4</sup>

Using a “carrot and stick approach,” the Sentencing Commission gave organizations an incentive to implement an effective compliance program. Therefore, the intent of the FSGs was:

not only [to] encourage corporations to exemplify “good corporate citizenship,” but also [to] provide a means to “rehabilitate” corporations that have engaged in criminal conduct . . .<sup>5</sup>

Furthermore, according to the Sentencing Commission, “[t]he hallmark of an effective [compliance] program to prevent and detect violations of law is that the organization exercise due diligence in seeking to prevent and detect criminal conduct by its employees and other agents.”<sup>6</sup>

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<sup>3</sup> Before the 1991 Federal Sentencing Guidelines, the Defense Department under the auspices of its Inspector General, June Gibbs, published the Defense Department Initiative, a set of “voluntary self-regulatory guidelines” for defense industry contractors to combat waste and abuse. See Debbie Troklus, Greg Warner, Emma Wollschlager Schwartz, *Compliance 101 – How to build and maintain an effective compliance program*, 2 (SCCE 2008).

<sup>4</sup> See Lawrence Finder and A. Michael Warnecke, Overview of The Federal Sentencing Guidelines for Organizations and corporate Compliance Programs, 1, ABA Criminal Justice Section (Apr. 12, 2005) at [https://www.americanbar.org/content/dam/aba/publishing/criminal\\_justice\\_section\\_newsletter/crimjust\\_wcc\\_OVERVIEW\\_OF\\_THE\\_FEDERAL\\_SENTENCING\\_GUIDELINES\\_FOR\\_ORGANIZATIONS\\_AND\\_CORPORATE.authcheckdam.pdf](https://www.americanbar.org/content/dam/aba/publishing/criminal_justice_section_newsletter/crimjust_wcc_OVERVIEW_OF_THE_FEDERAL_SENTENCING_GUIDELINES_FOR_ORGANIZATIONS_AND_CORPORATE.authcheckdam.pdf).

<sup>5</sup> 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).

<sup>6</sup> See *id.* (Quoting from the U.S. Sentencing Guidelines Manual at ch. 8).

The Sentencing Commission, in a comment to the applications section, outlined seven criteria for a compliance program to qualify as “effective” and receive mitigation credits and with that comment, the now-famous “Seven Elements,” were born.<sup>7</sup>

The elements outlined in the Sentencing Guidelines were not industry-specific but rather were intended to apply to corporations across industries.<sup>8</sup> Even though their origin in 1991 through 2010, the Seven Elements were not legally or regulatorily mandated,<sup>9</sup> the “primary impact has been the creation or enhancement of compliance or ethics programs by thousands of companies across the United States, and even outside the U.S.”<sup>10</sup>

Therefore, despite their general nature, “[w]hat makes the Guidelines critically important ... is that ... their framework for effective compliance has become a universal ... in compliance circles.”<sup>11</sup> Thus, the Seven Elements are “the currency of the realm” and remain to this day, “the gold standard.”<sup>12</sup>

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<sup>7</sup> See U.S. Sentencing Commission, Guidelines Manual, § 8A.1.2, comment. (n. 3k) (Nov. 1991).

<sup>8</sup> See *id.*

<sup>9</sup> That changed in 2010 with the passage of the Affordable Care Act. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6401(a)(7), 124 Stat. 119, 689 (codified as amended at 42 U.S.C. § 1320a-7h) (amending Part A of title XI of the Social Security Act by adding section 1128G) (2010). The ACA made having a corporate compliance program a legal requirement in order to be eligible to participate in and receive reimbursement from federal health care programs (e.g., Medicare, Medicaid and the Children’s Health Insurance Program (“CHIP”)). *Id.* at §§ 6401(a)(7)(A), (b)(5) and (c)(2). Under section 6401(a)(7) in order to participate in the Medicare program (e.g., receive reimbursement), “a provider of medical or other items or services or supplier within a particular industry sector or category shall, as a condition of enrollment in the program under this title, title XIX, or title XXI, establish a compliance program that contains the core elements established under subparagraph (B) with respect to that provider or supplier and industry or category.”

<sup>10</sup> See 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); see also U.S. Sentencing Commission Proceedings, *Corporate Crime in America: Strengthening the “Good Citizen” Corporation*, Second Symposium on Crime and Punishment in the United States (Sept. 7-8, 1995).

<sup>11</sup> See 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 ¶ 30,245 (Al Joseph, John Falcetano, Roy Snell, Debbie Troklus, eds. 2016).

<sup>12</sup> *Id.* at ¶¶ ¶ 30,180 and 30,245.

## The Formative Years – A Slow Start

Even though the “Seven Elements” were published in 1991, for the pharmaceutical and medical device industries, the appearance of life sciences compliance programs did not occur until several years later. In addition, the period from 1994 to 2002 marks the formative period for life science compliance, as companies started to recognize the need for dedicated compliance programs and compliance officers. In addition to semi-annual members-only meetings, the PCF

### The Case of C.R. Bard, Inc. (1994)

The first appearance of a compliance program came as a result of the *U.S. v. C.R. Bard, Inc.* settlement in 1994.<sup>13</sup> The *Bard* case, an enforcement action against a medical device company, was brought by the U.S. Attorney’s Office in Boston for 391 felony counts including various violations of the Federal Food, Drug, and Cosmetic Act (“FFDCA”).<sup>14</sup> In accepting Bard’s settlement and guilty plea, District Court Judge Wolf condemned the company’s actions writing that “[i]n the view of this court ... the officers and directors of Bard ... are morally responsible for a corporate culture which placed potential profit above the value of human life.”<sup>15</sup>

From the perspective of life sciences compliance, Bard, as part of the settlement, was required through its plea agreement to implement a compliance program. Although many of the provisions appear rudimentary by today’s compliance program standards, it marked the first time that a life science company was required to implement a compliance program embodying the “Seven Elements.”<sup>16</sup> Therefore, Bard’s settlement helped motivate both pharmaceutical and medical devices companies to view corporate compliance as a priority.

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<sup>13</sup> 848 F. Supp. 287 (D. Mass. 1994).

<sup>14</sup> *Id.* at 288.

<sup>15</sup> *Id.* at 291.

<sup>16</sup> As a side note, the plea agreement did not use the term “Compliance Officer,” but rather referred to that position as “Compliance Coordinator.” Although the title “Compliance Coordinator” did not have the same gravitas as “Compliance Officer,” given the role that Compliance Officers play in oversee and coordinating a company’s compliance efforts, it perhaps was a better descriptor of the role.

### The PCF is Born (1999)

The Pharmaceutical Compliance Forum was formed by a small group of pharmaceutical compliance professionals as a forum for companies to share their knowledge and explore solutions to solve common compliance challenges. Launched in 1999 at a meeting hosted by SmithKline Beecham in Philadelphia, initial members included SmithKline, Merck, and Pfizer amongst others, mainly large pharmaceutical companies. PwC, through the auspices of Brent Saunders and his team, provided a coordinating function. In addition to holding semi-annual members-only meetings, the PCF in 2000 sponsored the Pharmaceutical Industry Regulatory & Compliance Summit, the first industry-wide compliance conference.

### The TAP Settlement (2001)

The next major milestone in the development of life sciences compliance occurred in 2001 with a settlement involving TAP Pharmaceutical Products, Inc.<sup>17</sup> While there were other life sciences case or settlements between 1994 and 2001, none had the significance of TAP.<sup>18</sup> The TAP case simply was in a class by itself.

The impact of the TAP case can be attributed to several factors. First, the case originated as a whistleblower claim, which at the time was relatively rare. Second, the size of the fine was unprecedented. At \$875 million, more than 2.5 times the size of the fine in the SmithKline Beecham clinical laboratories case, it quickly grabbed the attention of industry Boards of Directors. Third, and perhaps most importantly for our profession, TAP ushered in the era of the modern Corporate Integrity Agreement (“CIA”).

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<sup>17</sup> See *U.S. v. TAP Pharmaceutical Products, Inc.*, 1:01-cr-10354 (D. Mass. 2001).

<sup>18</sup> See, e.g., *U.S. ex rel. Merena v. SmithKline Beecham Corp*, 52 F. Supp.2d 420 (E.D. Pa. 1998) (\$325 million to settle allegations of providing inducements to physicians to refer patients for clinical testing services and improper bundling of services); GENENTECH PRESS RELEASE, Genentech Confirms Settlement Agreement with U.S. Government, <https://www.gene.com/media/press-releases/4871/1999-04-14/genentech-confirms-settlement-agreement-> (Apr. 14, 1999) (\$50 million in fines and restitution for improper marketing of its human growth hormone).

With the TAP CIA came many of the requirements, we view as standard in today's CIAs and compliance programs.<sup>19</sup> For example, the TAP CIA introduced the concepts of the "Compliance Committee," Independent Review Organizations ("IROs"), and "reportable events." It also expressly mandated that the Chief Compliance Officer be part of the company's senior management and have access to the Board of Directors to make regular reports.

In addition, the TAP CIA introduced the conjoined concepts of the "covered person" and "certain covered persons" targeting various groups of employees for additional scrutiny and training. Thus, for the first time, instead of just "one size fits all" compliance, compliance departments now were required to establish specific detailed training and certifications tailored to individual groups of employees.

The impact of the TAP settlement on our profession cannot be overemphasized, and many of the provisions outlined in the CIA would later be incorporated into guidance issued by the Office of Inspector General ("OIG") for Health and Human Services two years later.

## The Industry Gets Specific Guidance

Prior to 2002, there was little guidance from Government regulators on how to construct and operate compliance programs specifically for life sciences. Therefore, industry compliance professionals often were forced to rely on the experience and guidance from other industries such as defense contractors or financial services.<sup>20</sup> There also was the Ethics Officer Association formed in 1992 to "bring together ethics and compliance professionals and academics from all over the world to share techniques, research and, most of all, exciting new ideas."<sup>21</sup>

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<sup>19</sup> See Corporate Integrity Agreement between DHHS OIG and TAP Pharmaceutical Products, Inc., (2001), [https://www.oig.hhs.gov/fraud/cia/agreements/tap\\_pharmaceutical\\_products\\_92801.pdf](https://www.oig.hhs.gov/fraud/cia/agreements/tap_pharmaceutical_products_92801.pdf).

<sup>20</sup> See, e.g., The Defense Department Initiative.

<sup>21</sup> See ETHICS & COMPLIANCE INITIATIVE, *About ECI*, <https://www.ethics.org/about/>, (last visited Jul. 16, 2019). Now known as ECI, the Ethics Officer Association ("EOA") and later the Ethics & Compliance Officer's Association ("ECO") was initially supported by the Center for Business at Bentley College, but later split from the College to become a stand-alone organization. See ETHICS & COMPLIANCE INITIATIVE, *The EOA*, <https://www.ethics.org/the-eoa/> (last visited Jul. 16, 2019).

### The Pharma Code (2002)

Although often overshadowed by the OIG's Compliance Program Guidance issued in 2003, it is worth remembering that the Pharmaceutical Research and Manufacturers of America ("PhRMA") issued a voluntary code for its members that took effect on July 1, 2002, almost a year before the OIG issued its guidance.<sup>22</sup> Developed largely as an effort address the pharmaceutical industry's increasingly negative compliance image, the Code on Interactions with Healthcare Professionals (the "PhRMA Code") has been updated periodically, and in the cases of Massachusetts and Nevada, pharmaceutical manufacturers registered with those states are required to certify compliance with it.

### OIG's Compliance Program Guidance (2003)

After the Federal Sentencing Guidelines, perhaps the second most influential guidance for our profession, came in 2003 when the OIG issued its compliance program guidance document for pharmaceutical manufacturers.<sup>23</sup> According to the OIG, "[t]he purpose of the compliance program guidance is to encourage the use of internal controls to efficiently monitor adherence to applicable statutes, regulations, and program requirements."<sup>24</sup>

### Federal Sentencing Guidelines II (2004)

A year after the introduction of the OIG compliance program guidance, the U.S. Federal Sentencing Commission once more updated the Sentencing Guidelines.<sup>25</sup> At the outset, the Sentencing Commission elevated the corporate compliance discussion from a comment

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<sup>22</sup> See PhRMA, *Code on Interactions with Healthcare Professionals*, (2008) at <https://www.phrma.org/codes-and-guidelines/code-on-interactions-with-health-care-professionals>. In 2003, the Advanced Medical Technology Association ("AdvaMed") revised its code for medical device and technology companies making it similar to the PhRMA Code. See THE NATIONAL LAW REVIEW, *Revised Advamed Code Reflects an Evolving Industry*, <https://www.natlawreview.com/article/revised-advamed-code-reflects-evolving-industry> (Mar. 18, 2019).

<sup>23</sup> See Department of Health and Human Services, Office of Inspector General, *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731 (May 5, 2003) ("OIG Pharma Guidance").

<sup>24</sup> See OIG Pharma Guidance at 23731.

<sup>25</sup> While § 8B.2.1 was amended in 2010, 2011 and 2013, those amendments were technical in nature and did not affect the overall requirements set out in that section. See U.S. Sentencing Commission, *Guidelines Manual*, Appendix C and Supplement to Appendix C (Nov. 2018) (Amendments 744, 758 and 778).

to its own new chapter and section.<sup>26</sup> This change was a clear signal of vital importance the Sentencing Commission placed on corporate compliance programs.

The 2004 update also included three other major changes. The first involved the addition of “ethics” to the program name. With the name change came an expanded role beyond just detecting and preventing criminal conduct. An effective ethics and compliance program also now had a role in promoting “an organizational culture that [encouraged] ethical conduct and a commitment to compliance with the law.”<sup>27</sup>

With the second change, the now-famous “Seven Elements” became eight with the formal inclusion of risk assessments as an essential element. Although the risk assessment element was implied in the original 1991 Guidelines comment,<sup>28</sup> now with the 2004 changes, it was explicitly highlighted. As described by the Commission, “[i]n implementing subsection (b), the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement set forth in subsection (b) to reduce the risk of criminal conduct identified through this process.”<sup>29</sup>

The final significant change specifically provided that courts and judges could apply industry practice, as well as the standards in government regulations when determining whether a compliance program was effective. Taking it a step further, the Commission commented that:

- (A) **In General.**—Each of the requirements set forth in this guideline shall be met by an organization; however, in determining what specific actions are necessary to meet those requirements, factors that shall be considered include: (i) applicable industry practice or the standards called for by any applicable governmental regulation; (ii) the size of the organization; and (iii) similar misconduct.

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<sup>26</sup> See U.S. Sentencing Commission, *Guidelines Manual*, § 8B.2.1 (Nov. 2004) Therefore, the 2004 Sentencing Guidelines contain the last major substantive update to the compliance program section.

<sup>27</sup> See *id.* at § 8B.2.1(a)(2).

<sup>28</sup> Although this concept was noted in the 1991 version, it was the very last sentence of the comment. See U.S. Sentencing Commission, *Guidelines Manual*, § 8A.1.2, comment. (n. 3k) (Nov. 1991).

<sup>29</sup> See U.S. Sentencing Commission, *Guidelines Manual* at § 8B.2.1(c) (2004).



- (B) **Applicable Governmental Regulation and Industry Practice.** —An organization’s failure to incorporate and follow applicable industry practice or the standards called for by any applicable governmental regulation weighs against a finding of an effective compliance and ethics program.<sup>30</sup>

## The Era of Big Fines & Health Care Reform

After the 2004 Federal Sentencing Guideline update, life science compliance settled into a steady pattern of ever-increasing fines and penalties for violations of the Anti-Kickback Statute (“AKS”) and False Claims Act (“FCA”), especially as it related to the off-label promotion of pharmaceutical products. Therefore, we can view the years from 2004 to 2012 as the period that transformed life science compliance into the format used today.

### The Pfizer and GSK Settlements (2009 and 2012)

With Pfizer’s settlement in 2009 and GlaxoSmithKline’s (“GSK”) in 2012, we see a dramatic increase in the number and types of baseline requirements included in CIAs.<sup>31</sup> Notwithstanding the new CIA provisions, both the Pfizer and GSK settlements represent that largest monetary fines and penalties) ever assessed against the pharmaceutical industry (Pfizer at \$2.3 billion and GSK at \$3 billion): fines and penalties that were more than two and even three times the fines in TAP.

With Pfizer CIA, the OIG added several new provisions, including mandates for:

1. Detailed the compliance obligations of the Board Audit Committee including adopting an annual resolution that Pfizer ‘has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements and the requirements of the CIA’;
2. Required detailed management certifications that appropriate oversight has occurred;

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<sup>30</sup> See *id.* at § 8B.2.1, comment. (n. 2) (emphasis added).

<sup>31</sup> See Corporate Integrity Agreement between DHHS OIG and Pfizer, Inc., [https://oig.hhs.gov/fraud/cia/agreements/pfizer\\_inc.pdf](https://oig.hhs.gov/fraud/cia/agreements/pfizer_inc.pdf) (2009) (The Pfizer 2009 CIA was a continuation of the 2004 CIA that Pfizer entered into settle another matter) (hereinafter “Pfizer CIA”); see also Corporate Integrity Agreement between DHHS OIG and GlaxoSmithKline LLC., <https://www.justice.gov/sites/default/files/opa/legacy/2012/07/02/hhs-oig-corp-integrity-agreement.pdf> (2012) (hereinafter “GSK CIA”).

3. Maintaining a formal Risk Assessment and Mitigation Process (“RAMP”);
4. Defined and required “self-disclosure” of certain non-compliance situations to the OIG (“reportable events”);
5. Required Pfizer to implement a detailed monitoring program of various activities including speaker programs, sales representative customer calls, grants, and publications; and
6. Tracking of payments to customers (a forerunner to the Physician Payment Sunshine Act).<sup>32</sup>

Following the normal OIG pattern, GSK’s Corporate Integrity Agreement three years later built upon the provisions contained in the Pfizer CIA. Within GSK’s agreement, the OIG added the following new enhancements requiring:

1. Establishment of an executive financial recoupment (i.e., “clawback”) program to recoup performance pay and incentives of senior company executives in the event of wrongdoing;
2. Compliance reports must be submitted directly to the Health Care Fraud Unit of the U.S. Attorney’s Office for the District of Massachusetts and the Department of Justice’s (“DOJ”) Consumer Protection Branch; and
3. GSK to continue to maintain a system of Deputy Compliance Officers assigned to each U.S. commercial business units and Medical Affairs.<sup>33</sup>

### The Affordable Care Act (2010)

Perhaps the most significant change for corporate compliance programs during this period occurred with the passage of the Affordable Care Act (“ACA”) in 2010.<sup>34</sup> While the standards detailing what constitutes the make-up of an effective compliance program existed since 1991 and were widely adopted by most large pharmaceutical manufacturers and other prudent life sciences companies, not to mention being included in various Government guidance documents and settlements, application of the “Eight Elements” was not mandatory.<sup>35</sup>

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<sup>32</sup> See generally, Pfizer CIA.

<sup>33</sup> See generally, GSK CIA.

<sup>34</sup> See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6401(a)(7), 124 Stat. 119, 689 (codified as amended at 42 U.S.C. § 1320a-7h) (amending Part A of title XI of the Social Security Act by adding section 1128G) (2010) (hereinafter “ACA”).

<sup>35</sup> In 2005, the U.S. Supreme Court in a complex opinion concluded that the Sentencing Guidelines violated a defendant’s Sixth Amendment right to a jury, but also found that courts could still use them, provided the court was able to tailor the final sentencing to address the specific facts of the case. See Lawrence

That changed under the ACA. The ACA now required that as a condition for participating in or receiving reimbursement from Medicare, state Medicaid programs, and the Children’s Health Insurance Program (“CHIP”), “providers of medical or other items or services or supplier[s]” have a corporate compliance program.”<sup>36</sup> Furthermore, through the use of the concept of “core elements,” the Act tied previous corporate compliance guidelines and standards into this new requirement by requiring the Secretary of Health and Human Services:

in consultation with the Inspector General of the Department of Health and Human Services, [to] establish core elements for a compliance program ... for providers or suppliers within a particular industry or category.<sup>37</sup>

Thus, with the passage of the ACA, compliance officers now had an express, statutory mandate to implement effective programs.

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Finder and A. Michael Warnecke, *Overview of The Federal Sentencing Guidelines for Organizations and Corporate Compliance Programs*, 2-3, ABA Criminal Justice Section (Apr. 12, 2005) (Discussing *United States v. Booker*, 123 S. Ct. 785 (2005)), [https://www.americanbar.org/content/dam/aba/publishing/criminal\\_justice\\_section\\_newsletter/crimjust\\_wcc\\_OVERVIEW\\_OF\\_THE\\_FEDERAL\\_SENTENCING\\_GUIDELINES\\_FOR\\_ORGANIZATIONS\\_AND\\_CORPORATE.authcheckdam.pdf](https://www.americanbar.org/content/dam/aba/publishing/criminal_justice_section_newsletter/crimjust_wcc_OVERVIEW_OF_THE_FEDERAL_SENTENCING_GUIDELINES_FOR_ORGANIZATIONS_AND_CORPORATE.authcheckdam.pdf).

Following the *Booker* decision, the Justice Department responded by issuing a memorandum to all federal prosecutors instructing them that they were required to use the Sentencing Guidelines and ranges in all but the extraordinary case. See Memorandum from James B. Comey, Dep. Atty. Gen. To All Fed. Prosecutors, *Department Policies and Procedures Concerning Sentencing* (Jan. 28, 2005), [http://sentencing.typepad.com/sentencing\\_law\\_and\\_policy/files/dag\\_jan\\_28\\_comey\\_memo\\_on\\_booker.pdf](http://sentencing.typepad.com/sentencing_law_and_policy/files/dag_jan_28_comey_memo_on_booker.pdf). The net result is that despite *Booker’s* holding, the Sentencing Guidelines continued to define the elements of an effective ethics and compliance program by the courts, the regulators and the life sciences industry

<sup>36</sup> See ACA at §§ 6401(a)(7)(A) , 6401(b)(5), 6401(c)(2).

<sup>37</sup> *Id.* at § 6401(a)(7)(B).

The ACA also codified the Sunshine Act (a/k/a “Open Payments”)<sup>38</sup> that requires the disclosure of certain transfers of values to certain healthcare professionals and entities by applicable group purchasing organizations and applicable manufacturers.<sup>39</sup> Although the provisions of the Sunshine Act are not reviewed in detail here, nevertheless, Open Payments has had a significant impact on life sciences compliance programs, and it continues to absorb a significant amount of compliance resources.

## A Renewed Emphasis on Corporate Compliance

After the GSK settlement in 2012, life sciences compliance once more settled into a predictable pattern where new compliance concepts primarily were driven by the Open Payments program and various enforcement actions (e.g., cases and settlements). Since compliance and compliance programs are constantly evolving, that pattern was upended once again in 2017 with a renewed emphasis on compliance generally.

### DOJ & OIG Effectiveness Guidance

In early 2017, both the OIG and DOJ published guidance on the elements that they consider when ascertaining whether a Corporate Compliance Program is effective.<sup>40</sup> The OIG guidance was developed in conjunction with the Health Care Compliance Association (“HCCA”) after meeting between a group of compliance professionals and OIG staff. Although structured differently (the DOJ guidance is formulated as a list of questions, while the OIG document examines things to measure and how to accomplish it), both guidance documents stress that they should be used not as a wholesale checklist, but a list of common elements and attributes to consider.

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<sup>38</sup> “The Sunshine Act” is an abbreviation of “Physician Payments Sunshine Act,” The legislation was later absorbed into and became section 6002 of the Patient Protection and Affordable Care Act, it continues to be commonly referred to as “the Sunshine Act.” CMS uses “Open Payments,” a name CMS created, to refer to its program implementing the Sunshine Act. Consistent with popular usage, this article uses “the Sunshine Act.”

<sup>39</sup> 42 U.S.C. § 1320a-7h(a); 42 C.F.R. §§ 403.904, .906. These reporting requirements are subject to various exemptions in the Sunshine Act and its implementing regulation. See, e.g., 42 U.S.C. § 1320a-7h(e)(10)(B); 42 C.F.R. § 403.904(i).

<sup>40</sup> See U.S. Dep’t. of Just., Criminal Division- Fraud Section, “*Evaluation of Corporate Compliance Programs*,” <https://www.justice.gov/criminal-fraud/page/file/937501/download>; see also HCCA-OIG Compliance Effectiveness Roundtable, *Measuring Compliance Program Effectiveness: A Resource Guide* (Mar. 27, 2017) at <https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf>; see also S. Foroughi and K. Wildoner, *Effectiveness, The Holy Grail of Compliance - Both the DOJ & OIG Weigh In*, 3.7 Life Science Compliance Update 7 (2017), available at <https://complianceupdate.policymed.com/>.

## Conclusion

Over the past 25 years, life sciences compliance, although a relatively new profession, has grown tremendously and continues to make an impact on how the life science industry operates and is perceived. However, as recent cases, which are fueled in part by the opioid public health crisis, clearly demonstrate, there is much left to accomplish, and the need for experienced, trained compliance professionals is even more important in today's environment.<sup>41</sup>

It is the same point that the Justice Department continues to make. To quote from remarks made by 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 ....”<sup>42</sup>

Therefore, it appears that life sciences compliance has a bright future ahead, but it is up to us to make it happen.

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<sup>41</sup> See, e.g., *U.S. v. Rochester Drug Co-Operative*, 19 C.r. (S.D. N.Y. 2019); U.S. Dep't. of Just., Press Release: Opioid Manufacturer Insys Therapeutics Agrees to Enter \$225 Million Global Resolution of Criminal and Civil Investigations, (Jun. 5, 2019), <https://www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal>; U.S. Dep't. of Just., Press Release: Founder and Four Executives of Insys Therapeutics Convicted of Racketeering Conspiracy, (May 2, 2019), <https://www.justice.gov/usao-ma/pr/founder-and-four-executives-insys-therapeutics-convicted-racketeering-conspiracy>; see also C. Greene, *Transcending the Opioid Crisis – Insys as a Cautionary Tale*, 5.7 POLICY & MEDICINE COMPLIANCE UPDATE 9 (2019); C. Greene, *Renewed Focus on the Importance of Effective Compliance, Analyzing the Recent Rochester Drug Co-Operative Case and DOJ Updated Compliance Guidance*, 5.6 POLICY & MEDICINE COMPLIANCE UPDATE 1 (2019). Both articles are available at <https://complianceupdate.policymed.com/>.

<sup>42</sup> 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>.

