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FEATURE

The Compliance-Legal Relationship *A Never-Ending Debate*

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Summary: In the first article of our “Back to Basics” series, we are starting with an examination of the history and ongoing debate surrounding the relationship between the compliance and legal functions.

Ever since the birth of compliance programs within life sciences,² the debate over the reporting and working relationship between the corporate compliance and legal functions has occupied countless industry conference hours and numerous articles. While many pundits and compliance professionals take the position that ethics and compliance cannot report into the legal function but instead must report to both the Board of Directors and the Chief Executive Officer, the debate continues to rage on today.³ Therefore, we thought it would be appropriate to launch our Back-to-Basics series with a review of the history underlying the debate and a discussion of the pros and cons of various models.

In the Beginning: Regulating Marketing Practices

Before we delve into the subject of this first review, it is worth going back in time to the genesis of much of what we will be covering and understand its impact on the current life sciences compliance environment.⁴

Following on earlier efforts dating back to 1973, Senator Edward Kennedy (D-Mass) in 1990 held hearings into the marketing practices of the pharmaceutical industry with a focus on activities, costs, and resulting prices. In what came to be known as the “Kennedy Hearings” great emphasis was put on ‘sham’ continuing medical education (“CME”), gifts, and entertainment.

After the Kennedy Hearings, the American Medical Association (“AMA”) House of Delegates adopted ethical guidelines for their

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INSIDE

FEATURE

- *The Compliance-Legal Relationship* 1
– *A Never-Ending Debate*

ENFORCEMENT

- *Records & Kickbacks are a* 7
Bad Combination for Practice
- *Starting the Year with a Bang* 11
– *Patient Services, Inc. Settles
FCA Suit and Drops First
Amendment Challenge*

OPIOIDS

- *Judge’s Sentencing of Insys* 15
Executives Sends The Wrong Messages

INTERNATIONAL

- *Living Dangerously In A Global World* 20
– *FDA’s International Inspection
Program Makes Progress,
But Problems Linger*

members that covered many practices such as the acceptance of vacations, gifts of substantial value, cash, lavish meals and entertainment.⁵ The Pharmaceutical Manufacturers Association (“PMA”), later re-branded as PhRMA, followed suit by adopting the same guidelines.⁶

In connection with the Kennedy and other hearings into the pharmaceutical industry, the Office of Inspector General (“OIG”) for the Department of Health and Human Services conducted a study “Promotion of Prescription Drugs through Payments and Gifts,”⁷ concluding that “although it is not clear how prevalent illegal or inappropriate promotional activities are the concerns raised by the practices described in this report warrant further monitoring of drug promotion.”⁸ This set in motion future monitoring of pharmaceutical sales and marketing practices, as well as the establishment of significant efforts to curb practices that the OIG deemed illegal and inappropriate.

The Debate Begins

The U.S. Federal Sentencing Guidelines

Since the U.S. Federal Sentencing Guidelines (“FSGs”) are considered the “currency of the realm” or the “gold standard” for effective ethics and compliance programs, the FSGs are an appropriate starting point to the enforcement story.⁹ When the now-infamous seven elements of an effective compliance program were first set out by the U.S. Sentencing Commission in 1991, the FSGs did not specifically address the reporting relationships between the compliance and legal functions.¹⁰ Instead, the Guidelines mandated that “specific individual(s) within high-level personnel of the organization” must have “overall responsibility to oversee compliance.”¹¹

Although the Sentencing Commission substantially modified the compliance program section in 2004, the Guidelines remained silent on the issue of the ethics and compliance reporting relationship.¹² Instead, the 2004 version outlined that high-level personnel are responsible for compliance and their relationship of those involved in day-to-day operational responsibility.¹³

The OIG’s Influence

Unlike the FSGs, the OIG directly influenced the relationship between legal and compliance. The TAP

Pharmaceutical Products Corporate Integrity Agreement (“CIA”) in 2001 started the ball rolling. The TAP CIA, which was the first modern CIA, required that the Compliance Officer must be “a member of [the] senior management of TAP” and he must make at least semi-annual reports “regarding compliance matters directly to the Board of Directors of TAP, or its designated subcommittee.”¹⁴ Although not expressly stated, the implication of requiring the Compliance Officer to be a member of senior management of TAP was that TAP’s Compliance Officer was a direct report of the CEO and not subordinate to the General Counsel and the company’s legal function.

Following the TAP CIA, the OIG, in 2003, published its guidance outlining expectations on what constitutes an effective compliance program for pharmaceutical manufacturers.¹⁵ According to the OIG:

Designating a compliance officer with the appropriate authority is critical to the success of the program, necessitating the appointment of a high-level official with direct access to the company’s president or CEO, the board of directors, all other senior management, and legal counsel.¹⁶

Although the OIG in this section of the Guidance went on to state “[o]ptimal placement of the compliance officer with the organization will vary according to the particular situation of a manufacturer,”¹⁷ the OIG in the endnotes encapsulated its position:

The OIG believes it is generally not advisable for the compliance function to be subordinate to the pharmaceutical manufacturer’s general counsel, or comptroller or similar financial officer. Separation of the compliance function helps to ensure independent and objective legal reviews and financial analysis of the company’s compliance efforts and activities. By separating the compliance function from the key management positions of general counsel or chief financial officer (where the size and structure of the pharmaceutical manufacturer make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.¹⁸

While stopping short of requiring that the Compliance Officer must report directly to the CEO, the OIG in its guidance makes it clear that they viewed compliance being part of legal with skepticism.

By 2009, the OIG's position that the Chief Compliance Officer ("CCO") not report to the General Counsel, but the CEO, was firmly ensconced. Pfizer's \$2.3 billion settlement and CIA mandated that the CCO must be "a member of senior management ... [and] shall report directly to the Chief Executive of Pfizer."¹⁹ The OIG, however, took it a step further, mandating that "[t]he Chief Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer."²⁰

Cooperation and Legal Privilege Lurk in the Background

At the same time that the OIG issued its Compliance Program Guidance, issues surrounding companies using the attorney-client and work-product privileges to protect various compliance activities, including internal investigations, were a major concern of the U.S. Department of Justice ("DOJ"). Therefore, while avoiding attorney-client privilege issues was never expressly discussed in the OIG's Compliance Program Guidance, nevertheless, at the time, it was considered a factor influencing the OIG's position on the separation of the compliance and legal functions.

The Justice Department's concerns about the use of legal privilege were outlined in a 2003 memorandum issued by then-Deputy Attorney General Larry Thompson (the "Thompson Memorandum"). Although the Thompson memorandum was couched in terms of factors, federal prosecutors should consider when deciding to charge a corporation with a crime, the use of legal privilege figured prominently in the document.

One of the nine factors outlined in the Thompson Memorandum was company cooperation with federal investigators and attorneys. As articulated by Justice Department officials at the time:

[T]he term "cooperation" [] mean[s] assistance that discloses all pertinent information sufficient for the government to identify the individuals responsible for criminal conduct and to understand the full

scope of that conduct [which meant] cooperating organizations should enable government investigators to gather facts before they become stale and assist in recovering losses incurred by the victims of wrongdoing.²¹

Therefore, the Thompson Memorandum "allowed prosecutors to consider the corporation's waiver of the corporate attorney-client privilege and work product protections."²²

Although the Thompson Memorandum recognized that waiver of legal privilege was not an absolute requirement, it did not offer prosecutors guidance regarding when a request for waiver was appropriate.²³ As a result, critics argued that "as a practical matter, [] the government was routinely demanding waivers, making it the norm, rather than the exception," a charge the Justice Department vigorously denied.²⁴

Despite the DOJ's denial that legal privilege waivers were being abused, the Justice Department, in 2006, revised the guidelines in the Thompson Memorandum. Under the update, known as the McNulty Memorandum, the Justice Department specified that a waiver of legal privilege should focus on privileged documents containing only facts, and only where there is a "legitimate need."²⁵ Examples of privileged documents containing only facts included: (i) key company documents; (ii) witness statements; (iii) purely factual summaries, (iv) interviews, and (v) reports.²⁶

By requiring the company to position the compliance function outside of the legal function, the OIG reduced or eliminated the need to deal with legal privilege issues. By requiring the compliance function to report into the CEO (i.e., the business), compliance no longer could assert a viable claim that its activities were privileged even if a lawyer was the CCO and headed the department. In short, it became much easier for the Government to obtain key compliance information to support its enforcement actions.

Other Concerns Beyond Legal Privilege

In addition to issues of legal privilege described above, there also is a potential concern not formally discussed in the OIG's guidance and the CIA requirements that the

legal function, because of its daily advisory role to the business may also be implicated by advising on unethical or inappropriate decisions (e.g., activities that were centrally sanctioned and not the result of ‘rogue employee’ actions). In other words, the potential concern is that the legal function could be conflicted on both giving advice to the business while overseeing the compliance program. As we have experienced, a truly effective program sometimes has to give guidance to the legal function.

Fast Forward to Today

It has now been more than 15 years since the OIG issued its Compliance Program Guidance articulating the Government’s position that the CCO and the compliance function be independent of the company’s legal function. That position has become well enshrined. For example, in 2019, the Justice Department’s Criminal Division updated the prior 2017 guidance on compliance entitled “Evaluation of Corporate Compliance Programs” stating that “[a]s a threshold matter, prosecutors should evaluate how the compliance program is structured.”²⁷

Speaking directly to the separation issue, the guidance provided that as part of the determination, prosecutors should establish “[w]here within the company is the compliance function housed (e.g., within the legal department, under a business function, or as an independent function reporting to the CEO and/or board).”²⁸ Likewise, the OIG’s recent CIAs have continued the trend seen in the Pfizer CIA, and mandating compliance be an independent function.²⁹

The Debate Continues

Given that both the Justice Department and the OIG have stated a clear preference that life science compliance functions be independent of the company’s legal function, why does the debate and reporting structures that are contrary to government recommendation persist? We believe there are several reasons.

First, and perhaps foremost, the enforced separation of the compliance and legal functions, while recommended, is not mandatory except for the OIG CIAs. As the DOJ highlighted in the 2019 program evaluation guidance, it “does not use any rigid formula to assess the

effectiveness of corporate compliance programs,” thus it makes “an individualized determination in each case.”³⁰ Thus, while the separation of compliance from legal may be the current standard industry approach, and preferred by the Government, there is no formulaic requirement to do so. Rather ensuring “the program is adequately designed for maximum effectiveness in preventing or detecting wrongdoing by employees” remains the threshold.³¹

Second, in the past 25 years, the thinking about what background is ideal for compliance leadership has come full circle. In the mid-1990s and early 2000s, lawyers dominated most life science compliance programs. We believe this was due, in part, to the fact that the FSGs are primarily a legal construct utilized in criminal litigation, a lawyer’s traditional purview.

The thinking that the best background for compliance professionals was a legal one began to shift in the mid-2000s in conjunction with the idea that compliance should be a “business partner.” The impact of this approach is undeniable, given the highly-operational component of compliance programs. Let’s face it, most attorneys were not trained for or have a desire to handle: information and accounting systems, marketing training programs, business processes and the like, which are essential elements of an effective compliance program. Therefore, during that period, many companies pursued compliance leaders with hands-on experience operational experience as opposed to a more traditional legal background.

However, recently with the increasing number and complexity of federal and state health care laws and the use of new enforcement tools (e.g., the RICO statute) to address poor company behaviors, plus the prominence of whistleblower complaints and resulting investigations, the question is back in vogue.

Third, resistance to separating compliance from legal continues to persist because large market cap companies no longer dominate the life sciences industry, and it now operates in a more dynamic and fragmented marketplace populated by numerous smaller, highly focused, and in many cases virtual, players. These smaller companies with limited funding often cannot afford single-purpose

functions but must employ a matrixed approach with employees having multiple roles. Given the obvious overlap in roles, combining compliance and legal is an obvious focal point.

Furthermore, some companies are too small to afford additional structures and reporting lines. In some of these cases, the legal function is better equipped and qualified to design, build and oversee the compliance program. In others, the CEO is too busy to manage the minutia of a program outside of giving broad direction and resolving major issues, especially now that so much of effective compliance program management is systems and operations. However, just because they are busy, the CEO cannot divorce themselves from their compliance responsibilities. In other words, they need to be aware of compliance issues and concerns.

Our Take

At the risk of committing compliance heresy, we believe that to some extent, the functional separation debate is a bit of a “red herring” and resolving it can squander both focus and time from more important compliance considerations. We believe that the right answer lies not in reporting lines but in having the right people, the right processes, clear accountabilities, and robust lines of communication. Regardless of the chosen structure, the compliance function must work, and that has not changed. Furthermore, depending on the organization and the individuals involved, either approach (i.e., functional separation or combined) can work effectively.

That said, before deciding to combine the compliance and legal functions, there are some important considerations to keep in mind. First, as noted in this article, the Government has and continues to maintain a strong preference for compliance and legal to be separate functions. Thus, if the functions are combined, senior company leadership should discuss this approach with the board and develop a written record of why that approach was selected that reflects careful and thoughtful deliberations. In other words, if the functions are combined, it should not appear to be a random or accidental choice. Furthermore, it is important to ensure the compliance function is enabled to function independently. Therefore, the legal function cannot and

should not “filter” messages and communications that compliance believes to be appropriate for Senior Leadership, including Boards of Directors. Therefore when the compliance officer reports to the General Counsel, who attempts to play the organizational hierarchy card, issues can arise.

Second, cost should not be the sole determiner of whether compliance and legal are combined or not. While cost certainly is a factor in the decision, there should be other pragmatic reasons supporting the combination as well. For example, combining the compliance and legal functions may provide the compliance function with the required “authority and stature” to implement the program effectively. Properly designed, it should also allow compliance to take advantage of specialized and technical expertise and resources.

Third, having legal training does not always translate into effective compliance leadership. While having legal training is helpful, especially when addressing complex or unsettled legal and regulatory principles, it is not essential. We believe other attributes are at least as important, and below are some of those attributes: Here are some of the other attributes we believe define good compliance leadership:

Belief: Strong compliance leaders need to believe in the ultimate objective. Those who do not believe cannot be an effective cheerleader, motivating reluctant peers. It is not blind faith, but passion tempered with practical wisdom. Knowing that the task is difficult and likely to be unpopular, the compliance leaders must have persistence in the face of the company’s skepticism of the program’s value and the ability to stand up to the General Counsel, no matter the consequences.

Understanding: A deep and preferably hands-on understanding of business activities can be very helpful not only in setting policy and direction but for understanding and assessing business processes, SOPs, reports, and the like. With this deep understanding comes credibility.

Diplomacy: Compliance leaders also need experience in diplomacy. Frequently, the compliance function will need to deliver critical information

that is unwelcome. Therefore, whether key information is heard and acted upon, even if unpopular, depends on the diplomatic skills of the company's compliance leaders, and in some instances, their ability to navigate around General Counsels attempting to dissuade difficult conversations or in the worst case, attempting to penalize compliance personnel for making waves when difficult business conversations or decisions need to occur.

Judgment & Integrity: As the primary enforcer of the company's policies and procedures, compliance leadership has an internal enforcement role. However, as with all enforcement, the difficult part is employing the right amount of authority at the right time. Also, compliance leaders need an enormous amount of personal integrity when challenged to look the other way. It is not easy to stand up to the pressure that senior executives can bring to bear, especially when an issue involves one of their own, or when their employment or compensation is decided by the head of legal who may want to ensure the executive management is always happy.

Scholarship: Compliance leaders also need to be quick studies. The breadth and complexity of the topics involved in working with complex and highly regulated products mean that one individual cannot be an expert in all facets. However, compliance leaders must have a working knowledge of the topics, the ability to see the interconnections, and have the experience to know when to bring in the precise subject matter experts to assist. They must be able to assimilate highly detailed information quickly.

Curiosity: Compliance leaders also need to be innately curious. They to be comfortable asking "why" when things either don't look or feel right. Good compliance leaders also need to remain skeptical and never accept the answer "because we've always done it this way" as the sole reason for taking a course of action.

Finally, regardless of whether a separate or combined structure is selected, the pragmatic reality is that the compliance and legal teams need to have a strong,

transparent, and mutually respectful relationship. Although the roles and responsibilities of the compliance and legal functions are different, they share the same goal of protecting the company and its employees by mitigating the ethical, legal, and compliance risks inherent in the development, manufacture, and sale of life science products.

However, because the roles and responsibilities are different, we recommend developing a framework that makes it clear what the responsibility of each function is. This type of thoughtful planning will help avoid contentious misunderstandings and infighting that only serve to diminish the credibility of both functions to others in the company. In short, while they may disagree at times, legal and compliance always should be on the same side in the end.

Conclusion

Although the Government might wish it were otherwise, the debate on how to structure the compliance function and its relationship with the legal function likely will continue as an effective compliance program is highly individualistic. Furthermore, these decisions need thoughtful vetting and careful documentation to demonstrate that the underlying goal of effectiveness was ever-present and top of mind.

References

- 1 *Ms. Rand is the former Vice President and Chief Compliance Officer for Seattle Genetics. Mr. Davidovic is President and Founder of pathForward Strategic Consulting. Ms. Rand and Mr. Davidovic also serves as Policy & Medicine Compliance Update Editorial Board Members. 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 teaches compliance as a Senior Fellow & Adjunct Professor, Life Sciences Compliance with Mitchell Hamline School of Law.*
- 2 *For a history of corporate ethics and compliance in life sciences, see S. Whitelaw & N. Fiorentino, Turning 20 – A Retrospective Look at Life Science Compliance, 5.12 Policy & Medicine Compliance Update 1 (2019).*
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Records & Kickbacks are a Bad Combination for Practice Fusion

By Kaitlin Fallon Wildoner, Esq., Senior Staff Writer

Summary: In January 2020, the Justice Department announced an agreement with electronic health records vendor Practice Fusion, Inc., for its involvement in a kickback scheme aimed at increasing opioid prescriptions. Before the agreement, an EHR vendor implicated in a kickback scheme was uncharted waters. This article outlines the agreement and how the different facets of the agreement will impact both electronic health records providers and the life science industry.

When it comes to drug company kickbacks, there appears to be no shortage of creativity. Also, as we discussed in December, we believe third-party conduit arrangements with drug manufacturers appear destined to become the next major kickback and false claims issue facing the industry.¹ It seems the U.S. Department of Justice (“DOJ”) agrees.

In January 2020, the Justice Department announced a \$145 million settlement and deferred prosecution agreement (“DPA”) with Practice Fusion, Inc. to resolve criminal and civil investigations of alleged kickbacks. While pharmaceutical kickback arrangements are nothing new, this case stands alone because, for the first time, the alleged kickback scheme involves an electronic health record (“EHR”) software supplier.²

Background

This new scheme involved allegations that Practice Fusion received unlawful kickbacks from pharmaceutical companies in exchange for implementing clinical decision support (“CDS”) alerts in its EHR software. CDS alerts help medical providers by providing evidence-based clinical decision support interventions within their EHR technology.³

Practice Fusion, in exchange for “sponsorship payments” was accused of allowing pharmaceutical companies to participate in the CDS alerts, including selecting the guidelines used to develop the alerts, setting the criteria that would determine when a healthcare provider received an alert, and in some cases, even drafting the language used in the alert itself.⁴ The net result, according to the Government, was that by doing so, Practice Fusion allowed the participating drug companies to increase sales of their products. Drug company involvement also potentially harmed patients because in some cases, the CDS did not always reflect current medical standards.⁵ Thus, from 2014 and 2019, health care providers using Practice Fusion’s EHR software wrote numerous prescriptions after receiving the pharma designed CDS alerts. As further evidence of the impropriety of these arrangements, Practice Fusion allegedly touted the anticipated financial benefits drug companies would see from increased sales resulting from custom-tailored CDS alerts.

Breaking Down the Settlement

Although Practice Fusion agreed to pay approximately \$26.4 million in criminal fines and forfeiture, the bulk of the settlement (approximately \$118.6 million) was intended to resolve the civil allegations that through taking kickbacks from the opioid company (and other pharmaceutical companies), Practice Fusion caused users of its system to submit false claims for federal incentive payments by misrepresenting the capabilities of its EHR software.⁶ Furthermore, as part of the settlement, Practice Fusion agreed to a deferred prosecution agreement (“DPA”) with enhanced compliance provisions.

Settlement Agreement and Criminal Information Provide Details of the New Scheme

According to the Settlement Agreement, Practice Fusion knew that for healthcare providers to receive incentive payments under the Centers for Medicare and Medicaid Services (“CMS”) EHR Incentive Payment Programs, they were required to use certified EHR software. The DOJ contends that despite knowing that its EHR software would not satisfy the 2014 Edition criteria for certification under the Office of National Coordinator’s (“ONC’s”) Health IT Certification program, Practice Fusion falsely represented to its ONC Authorized Certification Body (“ONC-ACB”) that its EHR software did comply with all requirements under the criteria. This background forms the basis of the allegation that Practice Fusion knowingly caused eligible healthcare providers who used certain versions of its EHR software to attest to compliance with CMS requirements falsely, and in turn, received Medicare incentive payments from 2014 through 2016 and Medicaid incentive payments from 2014 through 2017.⁷

According to the criminal information that was released at the time of settlement, Practice Fusion solicited a payment of almost \$1 million from an unnamed opioid company (“Pharma Co. X”) to create a CDS alert in its EHR that would prompt doctors to prescribe more extended-release opioids.⁸ In soliciting the payment, Practice Fusion employees modeled the estimated return on investment for Pharma Co. X (increased extended-release opioid (“ERO”)prescriptions from the pain CDS) and justified the \$1 million price tag based upon that ROI calculation.

Believing that the CDS would influence doctors’ prescriptions of extended-release opioids and that Pharma Co. X would have the anticipated increase in ERO prescriptions as outlined by Practice Fusion, the parties signed a contract, and the opioid company’s marketing department made the payment.⁹

As a result, Company X’s employees helped design the CDS. During the development phase, employees of both companies “regularly communicated in order to collaborate on the design, approval, and execution of the Pain CDS.”¹⁰ They also worked together to develop the pain CDS *without* incorporating the most recent CDC guidelines or other mitigating measures recommended by recent medical literature to reduce addiction and abuse risk.¹¹ In fact, in one instance, Practice Fusion’s legal department noted that the guidance used to develop the alert was “not the gold standard.”¹²

The CDS was developed to present EROs as a treatment option on equal footing with other pain treatment irrespective of whether EROs were medically appropriate for patients. It was also designed to direct providers to prepare a pain treatment plan only for some patients (and not only when pain is present) in contrast to the QOM upon which the CDS was purported to be based.¹³

Practice Fusion offered its EHR system to healthcare providers free of charge, with the costs being covered by sponsoring drug companies, who saw the clinical functionality of the system and paid for the privilege of creating the custom-tailored CDS alerts.¹⁴ This arrangement was the essence of the scheme.

From approximately July 2016 to April 2019, when the CDS was pulled from the EHR, it is estimated that it alerted practitioners using Practice Fusion’s system during more than 230,000,000 patient visits.¹⁵ The Government contends these prompts likely caused doctors to focus on the treatment of pain and to suggest opioids as a treatment of choice when there may have been other medically-appropriate options available.

The Anti-Kickback Statute (“AKS”) prohibits companies from knowingly and willfully soliciting or receiving remuneration in return for “arranging or recommending” any good or item for which payment may be made – in whole or in part – under a Federal health care program.¹⁶

The AKS also prohibits conspiracies, stating that, if “two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.”¹⁷

Consequently, Practice Fusion was charged with two felony counts. One count of outright violating the AKS and one count of conspiring with drug companies to violate the AKS.¹⁸ Practice Fusion acknowledged and agreed that it conspired with Pharma Co. X to receive “remuneration in return for arranging for or recommending purchasing or ordering of a good or item for which the payment may be made in whole or in part under a Federal health care program” and that it “knowingly and willfully solicit[ed] and receiv[ed] remuneration from Pharma Co. X in return for arranging for or recommending purchasing or ordering of a good or item for which payment may be made in whole or in part under a Federal health care program.”¹⁹

Deferred Prosecution Agreement Breaks New Ground

Since this case is the first-ever criminal action against an EHR vendor, the DPA contains unique provisions intended to address the EHR area. In general, the DPA imposes strict requirements on Practice Fusion to ensure transparency as to its underlying conduct and to invest heavily in compliance and an independent oversight organization.²⁰

Enhanced Compliance

The DPA outlines the compliance measures Practice Fusion must take to be compliant, including engaging its ONC-ACB to review and re-test its compliance with the data export functionality required for certification under the 2015 Edition of electronic health record certification criteria under 45 C.F.R. § 170.315(b)(6).²¹

First, Practice Fusion is required to maintain a current and comprehensive version of its software “bug list” on its customer portal. The bug list will include bugs relating to any certification capabilities, patient safety,

interoperability, and data portability and shall specify the nature of the bug and the date the bug was first reported to/identified by Practice Fusion.²²

Second, Practice Fusion agreed to “maintain and implement a Sponsored Clinical Decision Support Compliance Program to apply to any sponsored Clinical Decision Support (‘Sponsored CDS’) to be designed or implemented. This compliance program applies to current Practice Fusion employees, as well as former Practice Fusion employees currently employed by an affiliate.²³ Practice Fusion must begin implementing the Sponsored CDS Compliance Program procedures and systems to review all current (and future) Sponsored CDSs within 90 days of the effective date.”²⁴

Third, Practice Fusion also must review - and enhance - its methodology for reviewing and approving Sponsored CDS programs to ensure they are medically appropriate and not influenced or directed by its sponsors’ commercial interests (i.e., “commercially neutral”). Such a medical review of any Sponsored CDS must include consultation with medical professionals with expertise in the area of medicine relating to the Sponsored CDS at issue.²⁵

Fourth, Practice Fusion cannot enter into any Sponsored CDS without conducting a thorough and diligent review to determine whether the CDS is clinically appropriate, commercially neutral, and consistent with any applicable Clinical Quality Measures (“CQM”) and Guidelines. Therefore, all Sponsored CDS must receive written approval by the Practice Fusion Compliance Officer before launch. The Compliance Officer’s written approval must confirm that Practice Fusion took reasonable steps to ensure that Sponsors’ sales, marketing, or brand personnel were not involved – either directly or indirectly – in designing, creating, or financing the CDS.²⁶

Finally, the DPA requires that “Practice Fusion shall not knowingly, or with reckless disregard, accept remuneration, including but not limited to sponsorship money, in connection with any Sponsored CDS from any Sponsors’ sales, marketing, or brand budget, and knowingly, or with reckless disregard, permit any Sponsors’ sales, marketing or brand personnel to have any input or influence on the design or implementation of any Sponsored CDS.”²⁷ To

demonstrate compliance with this provision, Practice Fusion must implement a randomized monitoring program to ensure personnel are not violating either the Compliance Addendum or the AKS.²⁸

Continuing Cooperation

The DPA also requires that Practice Fusion cooperates in any ongoing investigations of the kickback arrangement. Additionally, Practice Fusion must make documents relating to its unlawful conduct available to the public through a website and must retain an independent oversight organization that reviews and approves any sponsored CDS before Practice Fusion implements it, and create a comprehensive compliance program designed to ensure such abuses are not repeated.

Finally, in a rather unusual that signals the Justice Department may widen its investigation of electronic health records, Practice Fusion must report any evidence of kickback violations it observes concerning other EHR vendors.

Conclusion

Christina E. Nolan, United States Attorney for the District of Vermont, did not mince words in announcing the settlement:

Practice Fusion's conduct is abhorrent. During the height of the opioid crisis, the company took a million-dollar kickback to allow an opioid company to inject itself in the sacred doctor-patient relationship so that it could peddle even more of its highly addictive and dangerous opioids. The companies illegally conspired to allow the drug company to have its thumb on the scale at precisely the moment a doctor was making incredibly intimate, personal, and important decisions about a patient's medical care, including the need for pain medication and prescription amounts.... We can not—and will not—tolerate technology companies influencing patient treatment merely because a pharmaceutical company provided a kickback.²⁹

Taking Nolan's words to heart, life science compliance professionals need to take a hard look at any arrangement that can suggest that a company's business

partners are conduits for otherwise inappropriate conduct, whether they be charities or technology partners.

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Starting the Year with a Bang

Patient Services, Inc. Settles FCA Suit and Drops First Amendment Challenge

By Carolyn Greene, Staff Writer

Summary: As Congress looks for solutions to spiraling drug prices, the DOJ has heightened its scrutiny of AKS issues relating to drug manufacturers and third-party conduits, such as patient advocacy organizations. The DOJ just announced a settlement with the non-profit Patient Services for alleged FCA violations.

While Congress looks for solutions to contain upwardly spiraling drug prices, the relationships between independent co-pay charities and the Government continue a downward spiral. Looking closer, however, this trajectory was no surprise. Independent co-pay charities have been a favorite enforcement target of the Justice Department for some time now, and in December, we reported on how third-party conduit arrangements with drug manufacturers appeared destined to become the next major false claims issue facing the industry.¹

It seems we were correct. As if on cue, the U.S. Department of Justice (“DOJ”) in January announced the first major settlement of the year with Patient Services, Inc., (“PSI”). As an alleged conduit for pharmaceutical manufacturers, PSI, while not admitting fault, agreed to pay \$3 million to resolve charges that the company

provided kickbacks to Medicare patients by paying their copayments.² PSI also entered into a three-year Corporate Integrity Agreement (“CIA”).³

“Coordinating” With Drug Companies

Headquartered in Midlothian, Virginia, Patient Services is a not-for-profit premium and copay assistance foundation for patients with a wide variety of diseases ranging from bleeding disorders, various cancers and infectious diseases, to connective tissue, digestive, urinary and endocrine conditions.⁴ Charging that PSI was a conduit for illegal drug company activities, U.S. Attorney for the District of Massachusetts, Andrew Lelling, noted “[p]harmaceutical companies cannot use foundations to funnel drug co-payments disguised as routine charitable donations, all to prop up excessive drug prices.”⁵ The alleged scheme was uncovered by whistleblowers working for the companies, who previously settled with the DOJ for their roles in the scheme.⁶

According to the Justice Department, PSI allegedly coordinated with three pharmaceutical companies (Insys Therapeutics, Aegerion Pharmaceuticals, and Alexion Pharmaceuticals) to operate “as a vehicle for specific pharmaceutical companies essentially to pay kickbacks at the ultimate expense of the American taxpayers who support the Medicare program.” According to the DOJ, PSI did so by working with the three companies to “design and operate certain funds that funneled money from the companies to patients,” and that the “schemes minimized the possibility that the companies’ contributions to the funds would go to patients taking competing drugs.”⁷ As a result, any contributions paid to PSI by these companies could not be considered as bona fide donations.

PSI & Insys

PSI allegedly worked closely with Insys to create the “Breakthrough Cancer Pain” fund, which was intended to provide copay assistance for its sublingual fentanyl product, Subsys. Since Insys was the only donor to that fund, PSI also allegedly allowed Insys to see the status of each patient it referred to PSI, including whether the patient had received copay assistance.

Furthermore, PSI allegedly knew that Insys was referring patients to the fund who did not, in fact, have cancer.

Thus, Insys was referring patients who were using Subsys for off-label conditions, “but PSI stated that it would only prevent ‘off-label use ... if the Donor wants us to.’” Clearly that was something Insys and its executives did not want.⁹

PSI & Aegerion

In the situation with Aegerion Pharmaceuticals, the DOJ alleged that PSI created a fund for homozygous familial hypercholesterolemia, which can be treated by Aegerion’s product, Juxtapid. With Aegerion, PSI allegedly allowed Aegerion to participate in establishing patient eligibility criteria for copay assistance. It also allowed Aegerion to pay for Medicare patients’ copays to reduce or eliminate price sensitivity physicians and patients might have to prescribing or using the drug.¹⁰

PSI & Alexion

Finally, in the case of Alexion Pharmaceuticals, the Justice Department alleged that PSI created a Complement Mediated Diseases Fund to provide copay assistance to patients with diseases that can be treated by Alexion’s drug Soliris. In addition to copay assistance, the fund also paid other medical expenses for those patients. The DOJ alleged that PSI provided financial assistance from the fund only to patients taking Soliris, and PSI detailed to Alexion which Soliris patients were approved for assistance, as well as details of those payments.¹¹

PSI & the First Amendment

The FCA enforcement actions, however, were not the only contentious litigation that PSI was involved in with the Government. Since 2018, the PSI was embroiled in a first amendment case with the Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”).¹² At issue in the case was PSI’s contention that advisory opinions provided by the OIG unconstitutionally infringed on PSI’s rights of commercial free speech and its communications with potential and existing donors.

The OIG provides two distinct forms of advisory opinions. General advisory opinions, including special bulletins, are intended as guidance for an entire area of regulated entities. The OIG, upon request, also will issue specific advisory opinions “regarding the application of specific facts, relating to an existing or proposed

arrangement, to certain specified topics, including ... whether any activity or proposed activity constitutes grounds for sanctions under AKS or other fraud and abuse civil sanction provisions.”¹³

The OIG’s 2002 Advisory Opinion

In 2002, the OIG provided specific guidance to PSI about what the Agency considered appropriate program communications. The OIG issued this advisory opinion in part to ensure that communications made by PSI about its programs did not “interfere with patient and provider choices of treatments.”¹⁴

The OIG Changes Its Mind & PSI Sues

Later in 2017, the OIG updated that advisory opinion to address “certain features that we [the OIG] have since determined are problematic.”¹⁵ According to the updated opinion, a charity, such as PSI, which provides grants to defray medical expenses for patients who meet specific financial need criteria and suffer from specific chronic illnesses or rare disorders, can continue operating as long as it does not define its disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states. Furthermore, the charity may not limit any disease fund to only provide copayment assistance for just one drug or therapeutic device, or only one drug or therapeutic device manufacturer and its affiliates.¹⁶ This was a primary issue in the *United Therapeutics* case.¹⁷

The OIG updated opinion also stipulated that charities are not permitted to limit assistance simply to high-cost or specialty drugs. Instead charities must make assistance available to all products, including generic or bioequivalent products when prescribed for the treatment of the disease state(s) covered by the fund. It also prescribes that charities are not permitted to determine eligibility other than through a “reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.”¹⁸

PSI, however, contended that the 2017 updated opinion imposed new restrictions on PSI prohibiting it from asking donors and potential donors about a wide range of issues, including diseases, drugs and patient

populations.¹⁹ Thus, PSI specifically challenged the following restrictions:

1. PSI will not solicit suggestions from donors regarding the identification or delineation of disease funds.
2. No donor can directly or indirectly influence the identification or delineation of any of PSI's disease funds.
3. PSI will not establish or modify funds for specific diseases at the request of donors that manufacture drugs or devices for the treatment of such diseases, or that otherwise have a financial interest in establishing or modifying such funds.²⁰

As a result, PSI asserted that OIG's updated opinion effectively prevented the company from communicating with experts about:

1. The available treatments for a disease, including new treatments either on the market or in the developmental pipeline,
2. The costs of the new or evolving treatments,
3. The manner in which treatments are administered, including where they are administered and whether there are significant diagnostic, transportation, or other costs associated with obtaining treatment, and
4. The burdens faced by patients receiving treatment, including associated conditions, complications, or side effects and the costs associated with managing those issues, all of which is essential to PSI's ability to maintain and develop its charitable efforts.²¹

PSI contended that having this information is critical to create programs that help patients, and further that only corporate donors would possess such information. Consequently, PSI alleged that restricting its ability to ask for and to receive this type of information impinged on their First Amendment rights, and asked the U.S. District Court for the Eastern District of Virginia to order OIG to rescind its restrictions and allow PSI to obtain this information.²²

PSI's Suit Is Dead

As a condition of its settlement agreement resolving the FCA allegations discussed above, PSI agreed to drop and

not renew its the First Amendment suit against the OIG, which it did on January 22, 2020. Had PSI not filed for dismissal the Justice Department and the OIG could have rescinded the settlement agreement.²³

PSI's CIA Embodies the Updated OIG Advisory Opinion

PSI did not comment on why it agreed to drop its suit against the OIG, although the threat of potential treble damages likely was a powerful motivator. PSI, however did comment that the "OIG has recognized the importance of a variety of communications between manufacturers and charitable assistance programs about patient needs and clarified that a number of these communications are permitted under OIG guidance."²⁴ However, it is not clear what constitutes permitted communications.

The Government, when commenting on the settlement and CIA, struck a less conciliatory tone. U.S. Attorney for the District of Massachusetts noted that "[p]harmaceutical companies cannot use foundations to funnel drug co-payments disguised as routine charitable donations, all to prop up excessive drug prices."²⁵ This was echoed by Gregory Demske, OIG Chief Counsel, who noted that "[f]oundations operating patient assistance programs should operate with integrity and act independently from their donors."²⁶

However, Joseph Bonavolonta, Special Agent in Charge of the Federal Bureau of Investigation's Boston Division was even more pointed, commenting:

Few things undermine public confidence quite like finding out the pharmaceutical companies and non-profits they entrust with their health and financial peace of mind have been playing fast and loose with the law. Schemes like these, and the individuals and organizations who perpetrate them, are an affliction on our health care systems.²⁷

General Requirements

PSI's CIA requires the company to "implement measures designed to ensure that it operates independently and that its arrangement and interactions with pharmaceutical manufacturer donors are compliant with the law," including making periodic reports regarding compliance

matters to the PSI Board of Directors, and to monitor the day-to-day compliance activities.²⁸

The CIA also requires PSI to establish and maintain a Compliance Program that includes the following elements typically seen in current OIG CIAs:

1. PSI must appoint a Compliance Officer, who is an employee and member of PSI senior management with responsibility for “developing and implementing policies, procedures, and practices to ensure compliance with the [CIA] and with Federal health care program requirements.”²⁹
2. PSI’s Board of Directors must meet at least quarterly to review the Compliance Program and must submit to OIG a description of the documents it reviewed, as well as any additional steps taken, such as engaging an independent advisor or other third-party resources. The Board also must describe its oversight of the Compliance Program during the reporting period.³⁰
3. PSI shall implement policies and procedures which are designed to ensure that PSI interactions with donors comply with Federal health care program requirements, and with all OIG guidance relating to the support and funding of patient assistance programs. PSI also must implement policies and procedures to ensure that PSI interactions with third parties that participate in patient assistance functions, for example, vendors, hubs, pharmacies, and other entities, comply with Federal health care program requirements.³¹
2. PSI will establish and maintain disease funds in accordance with widely recognized clinical standards and will cover a broad spectrum of products. It shall not define any disease fund by reference to specific symptoms, or severity of symptoms, or in a manner that narrows a widely recognized disease as a patient eligibility criterion. PSI shall not limit its assistance to high-cost or specialty drugs.³³
3. PSI will not establish or modify a disease fund at the request of a donor. In addition, PSI will not provide any donor with data that would enable the donor to correlate its donations with the use of its products. PSI will also not provide any donor with any data related to patient identity, or to the amount or nature of products for which assistance is provided through the fund. PSI will also not request specific donation amounts from any donor and will not permit donors to earmark any donations to any specific drug or disease state within a fund.³⁴
4. PSI will assist all eligible patients on a first-come, first-served basis, and will establish a uniform process for screening applicants for compliance with a fund’s designated financial eligibility and medical criteria. PSI shall sever any link between donors and patients, and PSI will not inform patients of the identity of the donor to the fund from which they receive assistance.³⁵

Thus, the specific PAP requirements in PSI’s CIA included all the issues that PSI disputed in its suit with the OIG.

Conclusion

Patient co-pay charities and PAPs have long been the subject of enhanced scrutiny by the OIG and now the Justice Department. Given the continued scrutiny and indications that the DOJ intends to broaden the scope of its attention to include other financial relationships between drug manufacturers and third-party conduits, pharmaceutical companies should remain wary of entering into these relationships without conducting a thorough compliance review.

References

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Specific Patient Assistance Program Requirements

In addition to the general requirements, the OIG required PSI to undertake a long list of obligations specific to the operations of Patient Assistance Programs (“PAPs”). These include requirements that:

1. PSI will operate independently from donors. PSI shall operate with “absolute, independent and autonomous discretion” as to establishing disease funds and using donor contributions. PSI alone will determine the diseases it supports through its funds.³²

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Judge’s Sentencing of Insys Executives Sends the Wrong Messages

By Dr. Seth B. Whitelaw, Editor, and Nicodemo Fiorentino, Associate Editor, of Policy & Medicine Compliance Update

Summary: Commentators, pharmaceutical executives, and compliance professionals have closely followed the Insys saga. Some, including this publication, believe it was a cautionary tale that others should heed. However, now that the Court has sentenced John Kapoor and the other individual defendants, we believe that the outcome sends the wrong messages about individual accountability and cooperation.

Beyond the actual parties in a case, the sentencing of criminal defendants by a Federal judge does not typically provoke much commentary or criticism. However, U.S. District Court Judge Allison Burroughs managed to garner both when she imposed sentences, that in some cases, were 75% less than the Government’s recommendation, on the group of Insys former executives and managers, including the company’s founder, John Kapoor. Even Andrew Lelling, the U.S. Attorney for the District of Massachusetts, issued a rare public rebuke stating:

My view is that the public interest demanded higher sentences for these defendants ... [because] [t]hese guys basically took a publicly-traded pharma company and turned it into an engine for corrupting doctors and jeopardizing the health of men and women nationwide.¹

We are inclined to agree, as we believe the sentences imposed by the Court ultimately send messages that are extremely unhelpful for compliance professionals who work every day to ensure their companies do not stray into the swamp of unethical or illegal behaviors.

Setting the Stage

Comparing Insys to a “street-level drug dealer,”² in April 2018, the “United States intervened in five *qui tam* lawsuits accusing Insys of violating the civil False Claims Act.”³ The cases claimed that Insys “paid kickbacks to

induce physicians and nurse practitioners to prescribe Subsys for their patients,” including “payments for sham speaker program speeches,” and “jobs for the prescribers’ relatives and friends, [together with] lavish meals and entertainment.”⁴ Besides, the complaints alleged that “Insys improperly encouraged physicians to prescribe Subsys for patients who did not have cancer and lied to insurers about patients’ diagnoses to obtain reimbursement for Subsys prescriptions that had been written for Medicare and TRICARE beneficiaries.”⁶

Specifically, the Justice Department concluded that:

1. Insys paid bribes to healthcare providers to induce them to write unnecessary Subsys prescriptions. Insys targeted providers that prescribed large volumes of rapid-onset opioids, as identified by pharmacy data provided by third parties.
2. Insys paid bribes to healthcare providers through a sham Speaker Program, in which events often did not involve any educational programs about Subsys, did not include attendees who could prescribe Subsys, and sometimes had no attendees at all.
3. Insys “high-level officers, directors, executives, managers, and the executive chairman of Insys’s Board of Directors” expressly required healthcare practitioners “to write a minimum number of Subsys prescriptions, write prescriptions at a minimum dosage, and write prescriptions for a minimum number” of Subsys units to continue receiving the bribes.
4. Insys tracked its “return on investment” for the sham Speaker Programs; that is, it tracked the effect of the bribes on practitioners’ prescribing habits, and it calculated “the effect of the bribes on the revenue that each bribed speaker generated for it.” If a practitioner failed to meet return on investment requirements, Insys stopped paying the bribes to that practitioner.

Pursuing the Company

On June 5, 2019, the Justice Department announced a “global resolution to settle the government’s separate criminal and civil investigations” into Insys.⁷ This global resolution is a multi-faceted settlement that includes:

- The resolution of the criminal allegations via a deferred prosecution agreement (“DPA”),⁸
- A company guilty plea to five counts of mail fraud,⁹ and
- A \$2 million fine and \$28 million in forfeiture.¹⁰

Finally, as part of the civil resolution, Insys will pay \$195 million to settle allegations it violated the False Claims Act.¹¹

Insys also entered into a five-year Corporate Integrity Agreement (“CIA”) and Conditional Exclusion Release with the Office of Inspector General of the United States Department of Health and Human Services (HHS-OIG).¹² As part of the Conditional Exclusion Release, Insys admitted the HHS-OIG had a basis for permissive exclusion from participating in federal healthcare programs by the OIG. The coup de grâce came when Insys filed for Chapter 11 bankruptcy protection just a few days after the announcement of the global settlement.¹³

Pursuing the Individuals

In addition to pursuing the company, the Justice Department also pursued several former executives and managers of Insys, including:

- Michael L. Babich, the former CEO and President of the company;
- Alec Burlakoff, former Vice President of Sales;
- Richard M. Simon, former National Director of Sales;
- Sunrise Lee and Joseph A. Rowan former Regional Sales Directors; and
- Michael J. Gurry, former Vice President of Managed Markets.¹⁴

On October 24, 2017, a superseding indictment was filed and added the founder and owner of Insys, John N. Kapoor.¹⁵ All defendants were charged with conspiracy to violate the Racketeering Influenced and Corrupt Organizations (“RICO”) Act.

The Government alleged that:

- Sales representatives’ bonuses were tied to the number of dosages of Subsys prescribed by the practitioners in their areas, as well as the amount of each dose, with higher doses generating higher bonuses.

- The higher doses of Subsys cost more than lower doses, and patients were more likely to become dependent when treated with higher doses.¹⁶
- Two sales representatives created a rap video, which included the former Vice President of Sales, Alec Burlakoff, dressed in a Fentanyl Spray costume.¹⁷ In the video, Insys representatives joked about how Subsys titration, which is the process used to increase a patient's dose, leads to a lot of new patients.
- Finally, there was the “Insys Reimbursement Center,” in which Insys employees posed as healthcare providers and deceived insurers to obtain insurance coverage for off-label uses of Subsys.¹⁸

Under the RICO Act, it is “unlawful for anyone employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity.”¹⁹ Here, the “pattern of racketeering activity” involved the illegal distribution of controlled substances, mail fraud, wire fraud, honest services mail fraud, and honest services wire fraud. If convicted, the individuals faced penalties including fines, forfeiture, as well as a possible prison sentence of not more than twenty (20) years.²⁰

Two Executives Plead Guilty

Before the start of the trial, in November 2018, Burlakoff pled guilty to one count of racketeering conspiracy and agreed to cooperate with the Government.²¹ In January 2019, Babich pled guilty to one count of conspiracy to commit mail fraud and wire fraud and one count of mail fraud, and also agreed to cooperate with the Government.²² With their guilty pleas and cooperation, Babich and Burlakoff hoped for leniency.

Rolling the Dice

The remaining defendants took their chances before a jury. However, in less than 30 days from the trial’s beginning, a Boston jury, on May 2, 2019, found the four remaining defendants guilty of engaging in a racketeering conspiracy by running a nationwide bribery scheme, representing the highest-ranking pharmaceutical executives to face trial amid a national opioid epidemic.²³

However, at the trial’s conclusion, the defendants moved for acquittal and a new trial on a variety of grounds. These included arguments that:

1. The jury was tainted by “spillover” prejudice, where many of the charges against Defendants had common legal predicates and acts.²⁴
2. The Government made improper statements in its rebuttal argument.²⁵
3. The trial court erred in making several evidentiary rulings that contributed to the verdict.²⁶
4. The DOJ, in the case of defendants and Kapoor, had failed to demonstrate all elements of the RICO conspiracy charges, specifically that he “knowingly and willfully agreed to be a member of the criminal conspiracy alleged in the indictment.”²⁷

On November 26, 2019, the Court upheld the wire and mail fraud predicates but overturned the verdicts for the illegal distribution of controlled substances, honest services mail fraud, and honest services wire fraud predicates.²⁸ According to Judge Burroughs, while “the conduct of Insys and the Defendants, in this case, was reprehensible and designed to financially incentivize healthcare practitioners to prescribe Subsys without regard for the best interests of their patients” that the in the case of the Controlled Substances Act and honest services fraud allegations, the “Government did not prove the requisite intent on the part of Defendants, that is, an intent that healthcare practitioners prescribe the drug to people that did not need it or in unnecessarily high doses.”²⁹ She also criticized the Justice Department’s handling of the case, noting that “the Government could have easily proved bribery, but it elected not to charge bribes or kickbacks and now must live with that decision.”³⁰

The Sentencing

When imposing sentences in federal causes, Federal District Court judges follow the guidelines established by the U.S. Sentencing Commission.³¹ A key component of which is the directive that judges should “take into account both the seriousness of the offense and the offender’s criminal⁴¹ history.”

In the memorandum outlining its sentencing recommendations for all the defendants (e.g., Kapoor, Gurry, Simon, Rowan, Lee, Babich, and Burlakoff), to Judge Burroughs, the Government began by arguing:

Sheer greed caused each of the defendants in this case not only to participate in a massive campaign of bribery and fraud but to ignore the dangers of a drug that is 70 to 100 times more potent than morphine. The criminal agreement at the heart of this case was driven by that greed, and it destroyed the health and safety of patients throughout the United States.³²

The Government also cautioned the Court that other pharmaceutical companies, including their executives, were watching the outcome of their sentencing. Therefore, the Government concluded the “Court should send a strong message to those companies and individuals by sentencing each of these defendants to significant terms of incarceration.”³³ As a result, the Government recommended prison sentences for the defendants that ranged between 60 months to 180 months.³⁴

While judges are not bound to follow Government sentencing recommendations, they often do so. But in this case, Judge Burroughs ignored the recommendations, imposing significant lighter sentences for Kapoor, Gurry, Simon, Rowan, and Lee.

By contrast, Judge Burroughs, again ignoring the Government’s recommendations, imposed heavier sentences for Burlakoff and Babich, the two cooperating executives, who testified against their colleagues.³⁵ In

Burlakoff’s case, he received a sentence of 26 months versus the recommended 20 months, and Babich received 30 months versus 24. Rejecting the fact that Burlakoff and Babich ultimately cooperated, Judge Burroughs in imposing the harsher sentences concluded that both men were “co-architects” of the scheme, along with the other defendants, and warranted no cooperation credit.³⁶

Of all the sentences imposed by Judge Burroughs, John Kapoor’s sentence was perhaps the most troubling. Kapoor was the founder and owner of Insys, making him, in many ways, the centerpiece of the criminal conduct. For Kapoor, the Government requested the Court to impose 180 months or 15 years in prison. Judge Burroughs disagreed sentencing Kapoor to 66 months or just 5.5 years. To support her sentence, Judge Burroughs cited Kapoor’s age (he is 76), and his philanthropy work in developing treatments for AIDs patients and those with heart problems.³⁷

Our Take - Maybe Crime Does Pay, But Cooperation Does Not

Judge Burroughs actions disregarding all of the sentencing recommendations put forth by the Justice Department are both troubling and disheartening. It also sends the wrong signals to executives contemplating illegal activity and to those employees who might ultimately cooperate with company compliance officials, regulators, or prosecutors.

Insys’s conduct, and that of its executives and managers, was not merely wrong; it was egregious. Even Judge

TABLE 1: Sentencing Recommended vs. Sentencing Imposed

Defendant	Sentences Recommended ³⁸	Sentences Imposed
Kapoor	180 months	66 months ³⁹
Gurry	132 months	33 months ⁴⁰
Simon	132 months	33 months ⁴¹
Rowan	120 months	27 months ⁴²
Lee	72 months	366 days ⁴³
Babich	66 months (Government asked for 24 months at the sentencing hearing) ⁴⁴	30 months ⁴⁵
Burlakoff	60 months (Government asked for 20 months at the sentencing hearing) ⁴⁶	26 months ⁴⁷

Burroughs, herself, labeled it “reprehensible.” Furthermore, it involved a product, that by virtue of its Schedule II classification, the regulators had determined was even more dangerous if used improperly than most drugs.

Insys and its employees, by recklessly aiding and abetting the medical community’s misuse of Subsys, became rich through their illegal activities. At its pinnacle, Insys traded at \$641.95 per share in 2000, but slowly declined to \$45 a share in 2015, and \$3.60 a share in May 2019.⁴⁸ Following the announcement the company was considering bankruptcy, the stock plunged further to under \$1 a share.⁴⁹ The Justice Department was correct when it noted the defendants’ “sheer greed” lead them to engage in a massive campaign of bribery and fraud,” while ignoring the harm they caused.

The Government also was correct that other pharmaceutical executives and companies were watching the case closely. However, with her relatively lenient sentences, Judge Burroughs has encouraged those companies and executives to continue considering the fall-out of engaging in unethical and illegal conduct as just “a cost of doing business.” Kapoor’s sentence, in particular, will continue to eviscerate Government enforcement as a deterrent to bad behavior. These are the wrong signals to send.

Likewise, we believe her sentences for Burlakoff and Babich create a powerful disincentive for employees contemplating cooperation. Granted, Burlakoff and Babich were participants and should not be absolved of their crimes, but completely ignoring their cooperation also sends the wrong message. It is not by accident that Lady Justice holds a scale since finding the right balance is a crucial component of holding individuals accountable for their misdeeds.

Finally, although we may never know all the reasons Judge Burroughs completely ignored the Government’s sentencing recommendations, we believe that her actions could create the appearance that her negative views towards the Justice Department’s handling of the case, which she expressed in her order on the defendants’ motion for acquittal and a new trial, factored into her decision. Regardless of whether it did or did not, we

believe that the results, in this case, may further erode confidence in judicial impartiality. Consequently, we would not be surprised to see increased challenges to perceived judicial bias by emboldened defense counsel. At the very least, we believe that these sentences make holding individuals accountable even more difficult.⁴⁹

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Living Dangerously in a Global World

FDA's International Inspection Program Makes Progress, but Problems Linger

By Gwendolyn A. Ball, Staff Writer

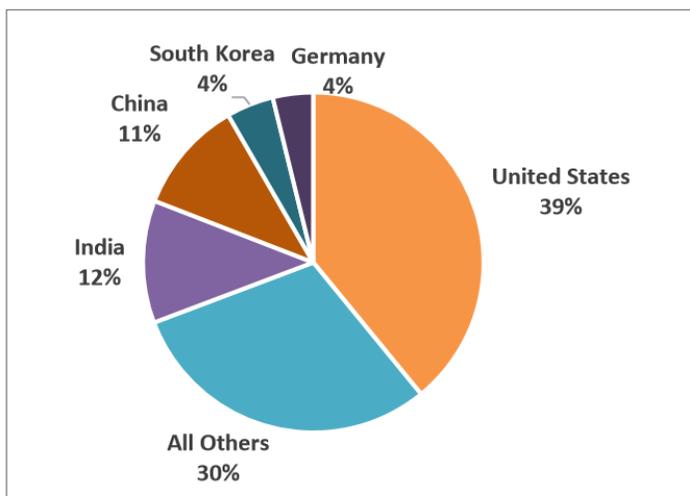
Summary: Over the past forty years conducting foreign establishment inspections, the FDA has scored several notable successes. However, substantial challenges remain, and since the global pharmaceutical supply chain remains a reality, the FDA's job in assuring the safety of the U.S. drug supply will continue to be a difficult one.

The reality is that we live and work in a highly interconnected world. Products are no longer designed, produced, and marketed in a single country. However, globalization, which has reshaped both markets and industries, is a double-edged sword. On the one hand, it has produced economic prosperity and lower consumer prices. On the other, globalization has created enormous compliance and quality challenges, many of which remain unresolved.

U.S. Market Supplied by Overseas Manufacturers

The pharmaceutical industry and the U.S. Food and Drug Administration (“FDA”) are no strangers to this duality. In 2016, the U.S. Government Accountability Office (“GAO”) reported that the FDA estimated that nearly 40 percent of finished drugs and approximately 80 percent of active ingredients are manufactured overseas.¹ By 2019, the GAO noted that more than 80 percent of the facilities manufacturing drugs for the U.S. market (including brand name, generics, and their active ingredients), were located overseas (Figure 1).²

FIGURE 1: All drug manufacturing sites for the U.S. market by country for FY2018



Source: FDA REPORT ON THE STATE OF PHARMACEUTICAL QUALITY, 2019

Recent High-Profile Cases Raise Concerns

High profile cases, such as Ranbaxy’s Abbreviated New Drug Application (“ANDA”) withdrawals in 2012 and most recently the recalls of valsartan, highlight the continuing vulnerability of the U.S. drug supply.³ In the case of valsartan, three U.S. companies that marketed the generic blood pressure drug, voluntarily recalled it after the FDA found it might be contaminated with N-nitrosodimethylamine (“NDMA”), a probable human carcinogen.⁴ All three companies used the same Chinese manufacturer for their products’ active ingredients.⁵ Other firms supplying the same drug in the U.S. market used a different manufacturer and were found to be free of the contamination.⁶ The valsartan incident highlights

the growing challenge for firms and regulators working to preserve the safety of drug products through adherence to the Current Good Manufacturing Practices (“CGMPs”) standards in a market dominated by international supply chains because most drugs sold in the U.S. market are produced by foreign manufacturers that are inherently more difficult to oversee or inspect.

The inherent challenges in overseeing and inspecting foreign manufacturers, and the FDA’s inability to comprehensively do so, are something that Congress, the GAO and healthcare analysts have expressed concern about, and some independent researchers have suggested that foreign drug manufacturers have more frequent and more serious problems complying with components of CGMP such as data integrity.⁷

In 2009, the GAO added the FDA’s inability to adequately inspect inspection of foreign facilities to its government-wide “high risk” series.⁸ Today, the issue remains on the list, even though the GAO acknowledges that the Agency has made progress dealing with the issue.⁹ Recent Congressional hearings and an updated and GAO review confirm that the FDA has made progress over the past decade, but new problems are emerging that the Agency will need to address.

A Problem 40 Years in the Making

While the recent valsartan recalls and the GAO’s “high risk” designation makes it appear that the FDA’s foreign inspection and compliance deficiencies somehow are new developments, in actuality, the problems with the FDA’s oversight of foreign manufacturers of drugs and active pharmaceutical ingredients (“APIs”) go back over forty years.¹⁰

The Same Requirements for Foreign and Domestic Establishments

Whether a prescription and over-the-counter drug is manufactured in the U.S. or abroad, manufacturers, including API suppliers, who sell pharmaceutical products in the U.S. must meet the same statutory and regulatory requirements. These requirements include complying with the U.S. standards for safety, quality, and effectiveness,¹¹ as well as CGMPs.¹²

Furthermore, establishments in foreign countries

engaged in the manufacture, preparation, propagation, compounding, or processing of drugs for importation into the U.S. are required to register annually with the FDA.¹³ The same is true for domestic establishments. Registration information for both foreign and domestic establishments is maintained in the FDA's drug registration database.¹⁴

GAO Reports Highlight the Problems

More than 20 years ago, the GAO issued a report detailing the FDA's foreign inspection program.¹⁵ Ever since that report in 1998, the GAO periodically has reevaluated the program. Thus, the GAO reports provide a detailed record of the FDA's progress, or in some cases, lack of progress in ensuring foreign establishments meet U.S. standards.

As a result of its 1998 review, the GAO determined that inspections of foreign pharmaceutical manufacturers in China and India occurred on average every four to five years, which was far less frequently than the two-year interval required for domestic manufacturers.¹⁶ The GAO also noted that most foreign inspections occurred in the context of FDA's approving new drug applications ("NDAs"). For example, in FY 1995, routine inspections of foreign manufacturers with approved products marketed in the U.S. accounted for only 20 percent of all FDA's foreign inspections.¹⁷ Thus, the GAO concluded that the FDA:

1. Did not deal effectively when in foreign facilities;
2. Was slow to react when concerns were raised;
3. Often downgraded problems found during inspections; and
4. Failed to conduct sufficient follow-up after problems were uncovered.¹⁸

The GAO also highlighted problems with the method the FDA used to identify and track foreign manufacturers. Specifically, the GAO found that information on foreign facilities was recorded on fifteen different computer systems. Over time the FDA has worked to remediate this situation and improve its database systems.¹⁹ As a result of these efforts, the GAO, in 2016, concluded that the Agency had improved the "accuracy and

completeness" of its catalog of manufacturing facilities by improving its database management practices.²⁰

However, the fragmented storage of foreign inspection data across multiple platforms was not the only data problem that the GAO has uncovered. Data quality also was a problem.

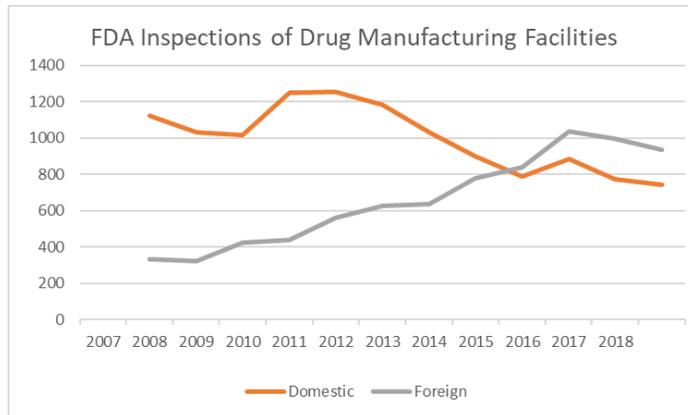
The GAO in its 2008 report found that inaccurate information in FDA's databases caused the Agency not to know how many foreign drug establishments were subject to inspection.²¹ For example, in some cases establishments included in FDA's registration database ceased doing business, without informing the FDA, and in others the establishments did not actually manufacture drugs for the U.S. market.²²

The GAO also found that the FDA registration was being abused. For example, many sites on in the Agency's registry were not producing human drugs for the U.S. market, but instead were producing other products (e.g., veterinary medicines).²³ In other cases, facilities registered in the mistaken belief that doing so gave the impression that the facility has some form of "endorsement" from the FDA.²⁴ Compounding these data quality issues, was the fact that the FDA failed to enforce the requirement that facilities re-register annually, and so facility changes went undetected.²⁵

As a result of these findings, the FDA, beginning in 2010, moved to address these issues. For example, the FDA began using outside contractors to conduct site visits to verify the existence of registered foreign establishments, as well as to confirm that the registered facilities manufactured the products recorded in U.S. import records.²⁶

However, the GAO expressed concerns about the pace of foreign inspections. Using a "prioritized list" of facilities, the GAO estimated that FDA visited on average only eight percent of foreign registered sites per year between 2002 and 2007, and from there extrapolated that it would take the Agency 13 years to visit all registered foreign sites while all domestic sites were visited every 2.7 years.²⁷

Between 2008 and 2012, FDA slowly began increasing the number of its foreign inspections (Figure 2). According to FDA's own estimates, it visited 11% of all actual sites in 2009.²⁸ However, the Agency did not markedly improve

FIGURE 2: FDA Inspections of Drug Manufacturing Facilities

Source: GAO, 2016; GAO 2019

the ratio of NDA preapproval inspections to routine surveillance inspections. Thus in 2009, 83% of foreign drug inspections conducted were associated with a preapproval application with less than 20% purely based on routine surveillance.²⁹

Thus, as of 2010, although the number of foreign inspections had increased, many registered foreign facilities still had never been inspected.³⁰ As the U.S. was becoming more reliant on foreign drug manufacturers, the FDA inspection program was falling further behind.

Congress Steps Up

To address the continuing downward trajectory, Congress finally stepped up to help the FDA cope with the burden of foreign inspections through both statutory changes and increased appropriations.³¹ These new changes freed the Agency from unrealistic statutory deadlines and provided additional resources to conduct more inspections.

In 2012, Congress passed the Food and Drug Administration Safety and Innovation Act (“FDASIA”).³² FDASIA addressed the statutory issue that the FDA was required to inspect domestic facilities on a two year cycle, but the prior statute provided no corresponding timeframe for inspecting foreign facilities.³³

Rather than creating an arbitrary fixed inspection cycle, under FDASIA, the Agency was allowed to schedule inspections according to a public health risk algorithm based on the facility score, product score and time since last inspection.³⁴ This new rationalized work program allowed the FDA to finally address the GAO’s standing

recommendation from 2008 that foreign facilities be inspected with the same frequency as domestic.³⁵ As a result, the number of foreign inspections increased and, beginning in 2015, the number of foreign inspections even exceeded the domestic ones (See Figure 2).³⁶

The statutory improvements were reinforced by Congressional appropriations and user fees, which increased Agency resources dedicated to conducting foreign inspections. Thus, funding for the FDA’s foreign inspections essentially doubled from \$53 million in FY 2010 to \$92 million in FY 2016.³⁷

While the FDA back in 2009 had established a cadre of U.S.-based inspectors dedicated exclusively to foreign inspection,³⁸ an increase in the user fees charged to generic drug manufacturers³⁹ helped finance the hiring of 80 new inspectors largely dedicated to foreign inspections.⁴⁰ The FDA beginning in 2008 created foreign field offices in countries of particular importance,⁴¹ and after 2016 the staff of these offices provided meaningful assistance with foreign inspections.⁴²

The Changes Bring Results

The statutory changes and additional resources had a predictable result by dramatically improving the FDA’s foreign inspections performance. The number of inspections increased from 8% in 2008 to 11% in 2010 to 21% by 2016.⁴³ Likewise, the ratio of pre-approval to routine surveillance inspections also improved. While only 17% of FDA’s foreign inspections in 2008 were solely routine surveillance inspections, from 2010-2016, that percentage increase to 55%.⁴⁴

Furthermore, as part of its risk-based strategy, FDA focused on inspecting facilities with no inspection history. As of 2016, approximately 1,000 foreign facilities, or about one-third of FDA’s “catalogue” (i.e., the “inventory”) of foreign manufacturing facilities fell into this category. The FDA announced plans to visit all facilities lacking an inspection history between 2017 and 2020 and as of November 2019, all these establishments had either been inspected or were eliminated from the catalogue because they were not producing drugs for the U.S. market.⁴⁶

With Improvement Comes New Challenges

While FDA’s program to increase the number and quality of its foreign inspections had notable successes, the expanded program quickly disclosed new issues.

The Total Number of Inspections Drops

Overall, the total number of both foreign and domestic inspections has decreased. Between 2016 to 2019, the total number of FDA foreign and domestic inspections decreased 10% and 13% respectively.⁴⁷ The reduction in domestic inspections is attributable to the FDA’s risk-based inspection approach.

In the case of foreign inspections, the decline is a partially a product of the FDA’s previous success. After focusing on previously uninspected foreign establishments, the FDA discovered that many did not need inspection particularly in China (Figure 3).⁴⁸ After removing these establishments from the list, the highest priority facilities based on risk assessment were domestic establishments, and so the FDA began dedicating more resources to domestic inspections, resulting in a corresponding decline in foreign inspections.⁴⁹

Lack of Qualified Personnel

However, the number of foreign inspections also fell for a more pernicious reason: an overall shortage of qualified inspectors. Approximately 75% of FDA’s foreign inspections are conducted by experienced U.S.-based staff who perform both domestic and foreign inspections.⁵⁰

As of November 2019, there were 190 investigators eligible to conduct foreign inspections, but 58 vacancies in this group.⁵¹ Thus, nearly a third of the FDA’s needed inspections posts were vacant. While the hiring of new

investigators is financially supported by the generic drug user fees, the FDA is finding it increasingly difficult to recruit a sufficient number of qualified individuals, both for administrative reasons and the fact the FDA is competing for resources in a strong economy with historically low employment.⁵² These factors have an even greater effect on the international cadre, since the most experienced investigators are used for foreign inspections.⁵³

Even greater problems exist filling positions dedicated to foreign inspections. The foreign inspections “cadre,” which conducts about 15% of all foreign inspections, only has 12 dedicated investigators, but 20 unfilled positions.⁵⁴

A similar problem exists with staffing the overseas offices. The foreign offices in the India and China had a 30% vacancy rate amongst inspectors.⁵⁵ These posts are particularly difficult to fill, since they involve medical and background checks and security clearances,⁵⁶ so only the most experienced individuals are considered for such posts.⁵⁷

The Difficulty of Operating Overseas

Further complicating the FDA’s efforts to sustain an effective foreign inspections program are the unique operational challenges of working internationally. For example, the FDA must coordinate logistics, including safety of its personnel, with various local, regional, and national governments.⁵⁸ It also needs to confirm that the target facilities are currently manufacturing finished drugs or APIs for the U.S. marketplace.⁵⁹ Thus, unlike

many domestic inspections, FDA foreign inspections are announced events, giving the target facilities the opportunity to “clean up their act” before the inspectors arrive.⁶⁰ Logistical issues can make the inspection team’s task more difficult, forcing them to visit multiple sites on the same trip and making it difficult to extend a trip when problems with an individual sites’ operations are encountered.⁶¹

Language often is another barrier. Since U.S.-based personnel conduct most of the foreign inspections, there is a need for

FIGURE 3: Total Number of FDA Foreign Drug Inspections, by Country, Fiscal Years 2012 through 2018

Country	2012	2013	2014	2015	2016	2017	2018
India	140	110	114	204	207	219	252
China	59	74	113	127	173	165	153
Germany	59	60	72	68	72	69	68
Canada	49	51	39	52	56	72	48
Italy	38	45	50	41	69	46	45
Japan	49	28	47	31	65	46	43
South Korea	4	7	8	5	13	56	40
France	25	37	44	45	55	42	36
Switzerland	23	23	37	31	37	25	32
United Kingdom	29	27	33	43	41	40	12
All other countries	150	175	222	193	247	213	206
Total foreign	625	637	779	840	1,035	993	935
Total domestic	1,184	1,030	897	784	882	772	742

Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-20-262T
 Note: The total number of inspections includes those conducted for preapproval, surveillance, and for-cause purposes.

Source: GAO 2019 at 13.

translators to assist with document review and interviews.⁶² In many cases, the inspection team is forced to rely on translators provided by the target establishment, raising concerns about the completeness and accuracy of the translations.⁶³

Conclusion

Over the past forty years conducting foreign establishment inspections, the FDA has scored several notable successes. However, substantial challenges remain, and the global pharmaceutical supply chain remains a reality, the FDA's job in assuring the safety of the U.S. drug supply will continue to be a difficult one.

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