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ENFORCEMENT TRENDS TO WATCH IN 2015

INTRODUCTION

Since the inception of the Health Care Fraud and Abuse Control ("HCFAC") Program in 1997, the Medicare Trust Funds have received $25.9 billion in recoveries. A substantial portion of this sum has stemmed from allegations against pharmaceutical manufacturers relating to off-label promotion and the Anti-Kickback Statute ("AKS"). While prosecutors have continued to rely on these theories of liability, 2014 bucked the recent trend of billion dollar settlements resolving such allegations and also marked the lowest annual total of dollars received by the government under the False Claims Act ("FCA") in five years. The evolution of the government's enforcement priorities and focus of the *qui tam* relators' bar cannot be predicted with certainty. However, what is certain is that government and private enforcement targeted at the industry will not soon abate and that both prosecutors and whistleblowers will continue to pursue new potential theories of liability.

Although actions implicating "off-label" and related promotion-based theories are sure to continue, recent court decisions and the Food and Drug Administration's ("FDA's") commitment to reevaluating its policies in light of First Amendment concerns likely will shape a refined enforcement approach to such cases. The AKS, long a driver of significant enforcement activity and substantial settlements, similarly will continue to be a focus of the Department of Justice ("DOJ") and *qui tam* whistleblowers, and may increasingly be driven by the use of Sunshine Act and other data mining efforts. And what of DOJ's recently articulated commitments to add violations of current Good Manufacturing Practice ("GMP") regulations to its enforcement arsenal? Such efforts are likely to be impacted this year by recent judicial decisions rejecting this as a basis of civil FCA liability. A similar question may be asked regarding DOJ's public commitments to pursue charges against individuals, including under the *Park* theory of liability. Despite these statements, we have yet to see the government pursue pure *Park*-based prosecutions of drug or device company executives.

In this article we explore these enforcement trends worth watching in 2015.

ENFORCEMENT FOCUSED ON DRUG PROMOTION UNDER THE SHADOW OF THE FIRST AMENDMENT

Despite the absence of a billion-dollar "off-label" settlement as in years past, settlements to resolve allegations of off-label promotion still represented a substantial portion of last year's healthcare recoveries. For example, both Shire Pharmaceuticals and Endo Pharmaceuticals entered into settlement agreements to resolve allegations solely relating to off-label promotion, while numerous other settlements also touched on off-label promotion. However – and despite some public statements to the contrary – DOJ's approach to such cases necessarily must be impacted by recent court decisions and FDA's own acknowledgement that it is searching for a regulatory framework that can be fully reconciled with the First Amendment.

For years, the pharmaceutical industry has pressed DOJ and FDA on the extent to which enforcement focused on truthful communications about "off-label" uses creates tension with First Amendment freedoms. The Second Circuit's decision in *United States v. Caronia* in late 2012 intensified this discussion. In *Caronia*, the Second Circuit assumed without deciding that speech could be used as evidence of intent to promote a drug for a new, unapproved use. However, the court reversed the defendant sales representative's conviction, ruling that he had been prosecuted solely for his truthful, non-misleading speech about off-label uses, in contravention to his First Amendment rights. In the immediate wake of the *Caronia* decision, both DOJ and FDA at least publicly took the view that it would not change enforcement under the Food, Drug and Cosmetic Act ("FDCA"). For its part, FDA denied that *Caronia* conflicted with its own regulatory interpretations. Shortly after the decision was released, Tom Abrams, the director of the Office of Prescription Drug Promotion ("OPDP") noted in remarks at an industry group meeting that, "The decision does not strike down any provision of the [FDCA] or its implementing regulations, nor does it find a conflict between the Act's misbranding provisions and the First Amendment or call into question the validity of the Act's drug approval framework." Similarly, a number of U.S. Attorneys and DOJ officials went on record that *Caronia* will not impact the pursuit of "off-label" cases against drug makers. Nonetheless, the government elected not to seek review of the Second Circuit's decision.

More recently, however, FDA has acknowledged that its existing regulatory approach cannot remain static in light of *Caronia* and the Supreme Court's earlier decision in *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011). In April 2014, FDA's Chief Counsel, Liz Dickinson, remarked at an industry conference that FDA's "own evolving scientific and medical policy views and changes in how information is conveyed and healthcare is delivered are driving a new commitment at the highest levels of the agency to align FDA's regulatory posture" with First Amendment considerations. At the same conference, Center for Drug Evaluation and Research ("CDER") Director Janet Woodcock more explicitly made the same announcement, stating "We are currently carefully evaluating our policies in light of court decisions on 1st Amendment issues." Two months later, FDA granted a pair of citizen petitions submitted by the Medical Information Working Group ("MIWG") in 2011, which requested that FDA clarify its regulations and policies on selected topics relating to the dissemination of information by manufacturers, including related to off-label uses of drugs. FDA explained it was granting the request for clarity as "part of FDA's more comprehensive review of its regulations and guidance documents in an effort to harmonize the goal of protecting the public health with First Amendment interests." FDA, Re: Docket Nos. FDA-2011-P-0512 and FDA-2013-P-1079, at 8 (June 6, 2014). If FDA finalizes promised guidance in this area in 2015 it may significantly shape the landscape at least of criminal enforcement of the FDCA for "off-label" and "out of label" communications by manufacturers.

Not surprisingly, DOJ has tried to limit the impact of *Caronia*. One way in which it has done this is by staking out the position that it does not apply to claims asserted under the False Claims Act. In a statement of interest filed in a case proceeding against drug maker Cephalon for alleged off-label promotion of its cancer and cancer-related treatments Treanda® and Fentora®, DOJ argued that *Caronia* "is inapposite to [a] False Claims Act matter." *See* Statement of Interest of the United States, *United States ex rel. Matthew Cestra v. Cephalon, Inc.*, No. 10-cv-6457 (S.D.N.Y. Nov. 7, 2013). DOJ went on to distinguish criminal prosecutions for off-label promotion under the FDCA from civil claims under the FCA in two respects: "the FCA does not prohibit off-label promotion of prescription drugs; rather, the FCA prohibits conduct that causes the submission of false claims to the Government for payment. The First Amendment is, thus, not implicated in the context of an FCA claim, such as this one, where a defendant causes others to submit false claims for payment to the Government for non-reimbursable prescription drugs. Moreover, false and misleading speech, to the extent it is alleged in the [complaint], is not protected under the First Amendment." *Id.*

Whether the government can pursue claims against drug manufacturers based on truthful, non-misleading speech is currently a subject of hotly contested amicus briefs in *United States ex rel. Solis v. Millennium Pharmaceuticals, Inc.* In that *qui tam* suit relator alleges that defendants' dissemination of truthful journal articles discussing off-label uses caused physicians to submit false claims. The government did not intervene in the case, but submitted an amicus brief to address, among other points, the defendants' contention that they could only be liable under the FCA if their statements about off-label uses were false or misleading. DOJ argued that even if promotional messages are truthful, the First Amendment is not implicated in the FCA context, because off-label promotion can be evidence of a pharmaceutical company causing physicians to submit false claims. United States' Statement of Interest Regarding Certain Issues Raised in Defs.' Mtns. to Dismiss the Relator's Second Amended Compl. 11, *U.S. ex rel. Solis v. Millennium Pharms., Inc.*, No. 09-cv-3010 (N.D. Cal. June 4, 2014). In response, the Pharmaceutical Research and Manufacturers of America ("PhRMA") submitted an amicus brief highlighting the First Amendment consequences were the court to adopt a speaker-based restriction and rule that manufacturers cannot circulate truthful journal submissions. PhRMA urged the court to adopt a position of constitutional avoidance and either hold that the FDCA only prohibits false or misleading speech, or that violations of the FDCA cannot serve as a predicate for FCA liability because "truthful and non-misleading speech about unapproved uses cannot be a violation of any requirement that is a condition of payment under any federal healthcare program." PhRMA's Amicus Brief 4, *U.S. ex rel. Solis v. Millennium Pharms., Inc.*, No. 09-cv-3010 (N.D. Cal. Sept. 18, 2014). How the courts will resolve the application of the First Amendment to claims asserted under the FCA remains a key open question post-*Caronia*.

In the meantime, the government remains on its firmest footing when pursuing promotion-based claims that are actually false or misleading in some way, as it did in connection with the 2014 resolution of claims against Shire Pharmaceuticals. Such allegations may therefore continue to be at the fore of government enforcement efforts focused on promotional statements in 2015, at least until FDA issues final guidance on the communication of scientific information.

DATA MINING AND THE AKS

2014 continued the decade-long trend of prosecutors vigorously pursuing claims under the AKS to battle healthcare fraud and abuse. The basic theories and alleged schemes at issue in the cases resolved are familiar to the industry. For example, in November 2014 the United States intervened in a *qui tam* suit filed against Daiichi Sankyo Inc., alleging that the company paid physicians inflated speaker fees and compensated physicians for serving on advisory boards and participating in round table discussions, despite not having a bona fide need for such feedback. *See* Compl., *U.S. ex rel. Fragoules v. Daiichi Sankyo, Inc.*, No. 10-10420 (D. Mass. Mar. 10, 2010). The company settled the matter shortly thereafter. In the same time period, Biotronik Inc. settled similar allegations regarding its physician advisory board program. Earlier in the year, the United States also intervened in a *qui tam* suit filed against Carefusion Corp., alleging that the company paid above fair market value to one of its clinical investigators, in exchange for his conversion of VA hospitals to Carefusion products. Second Amended Compl., *U.S. ex rel. Kirk v. CareFusion et al.*, No. 10-2492 (D. Kan. July 15, 2011). DOJ's press release further alleged that Carefusion paid kickbacks through sham service arrangements to a physician who served in the National Quality Forum, a non-profit organization that makes endorsements about standardized healthcare performance measures and practices.

The inaugural releases last year of two major databases by the Centers for Medicare and Medicaid Services ("CMS") promises new tools for prosecutors to analyze manufacturer-physician relationships and additional scrutiny by the relators' bar of such arrangements. In April 2014, CMS released the Medicare Provider Utilization and Payment Data, which sets forth physician-specific inpatient and outpatient claims submitted to Medicare in Calendar Year 2012, and the resulting reimbursement received by more than 880,000 providers. In September, CMS released data from the Open Payments Database reflecting payments and other transfers of value from manufacturers to physicians. In conjunction, these databases permit data mining that whistleblowers may argue link increased utilization by physicians to payments received from manufacturers.

Whether the impact of these datasets will be limited to prospectively altering conduct, or whether they can contribute to enforcement actions related to past conduct, is an open question. As an initial matter, discerning meaningful statistical relationships from these data is fraught with challenges. For example, the Medicare Provider database fails to delineate the portion of each payment attributable to the cost of purchasing physician-administered drugs, which can lead to apples-to-oranges comparisons. CMS received widespread complaints from physicians frustrated by the system's failure to permit them to review the accuracy of the payment reports prior to release. Furthermore, CMS held back a third of the Open Payments data during the initial release due to flaws in the data, causing some to call into question the integrity of the database as a whole. Yet in spite of the potential pitfalls, journalistic outlets such as ProPublica quickly wrote about the initial results of their efforts to find patterns, and doubtless would-be relators have been performing their own analyses.

However, while data mining may reveal relationships implicating AKS concerns, *qui tam* relators' ability successfully to use these data to support FCA claims could be hamstrung by the public disclosure bar, which mandates dismissal of *qui tam* suits premised on information previously made publicly available unless the relator is an original source. While some relators may argue that the databases do not meaningfully place knowledge of supposed kickback relationships in the public domain, there is case law support for the proposition that so long as the essential elements of the financial relationships are released, even in a disorganized form, the public disclosure bar can be triggered. *See*, e.g., *U.S. ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 36 ITRD 697, 2014 WL 4375638 at *10 (E.D. Pa. Sept. 4, 2014); *U.S. ex rel. Doe v. Staples, Inc.*, 932 F. Supp. 2d 34, 40–41 (D.D.C. 2013) ***aff'd***, 773 F.3d 83 (D.C. Cir. 2014). As a result, the most material impact of the datasets may be to allow relators who are otherwise "original sources" with information that "materially adds" to the payments data to file complaints that are more detailed and well-founded, increasing the likelihood that *qui tam* suits survive challenges under Rule 9(b) at the motion to dismiss stage.

POLICING COMPLIANCE WITH GMPs

In 2013 a top DOJ official announced that compliance with GMP regulations would be "one of [DOJ's] top areas of focus. … We appreciate that achieving GMP compliance is not easy given that safety is not a simple black and white issue. Rather, it is a continuous process of assessing and eliminating and minimizing risks. … We know, of course, that there are enormous pressures on all parts of the industry to produce drugs more quickly, cheaply, and efficiently, and our message to you is that you cannot sacrifice drug safety in service of these pressures. … You want to make sure that there are strong … incentives for people to see problems, report problems, and fix problems." Maame Ewusi-Mensah Frimpong, Deputy Assistant Attorney General, U.S. Department of Justice, CBI

Pharmaceutical Compliance Congress (Jan. 29, 2013). Subsequently, generic drug manufacturer Ranbaxy pled guilty to felony charges in connection with GMP violations and paid $500 million in criminal fines and a civil settlement. The U.S. Attorney in Boston announced that her office would make the pursuit of similar cases a priority, and a number of manufacturers announced investigations related to alleged GMP violations. Although similar enforcement actions in the device industry based on Quality System Regulation ("QSR") violations have not yet generated large settlements, DOJ's expressions of concern can be extended equally to device manufacturers.

Since these statements, however, two courts have rejected GMP violations as a basis of FCA liability, calling into question the viability of continued government enforcement efforts—at least in the civil context. In 2012, the District of Maryland became the first court to make a dispositive ruling on a *qui tam* suit premised on violations of GMPs. Relator Barry Rostholder alleged that his former employer, Heartland Repack, and its parent company, Omnicare, violated GMPs requiring penicillin and non-penicillin drugs to be packaged in separate facilities. *U.S. ex rel. Rostholder v. Omnicare, Inc.*, No. CIV. CCB-07-1283, 2012 WL 3399789, at *5 (D. Md. Aug. 14, 2012) *aff'd*, 745 F.3d 694 (4th Cir. 2014). At the time of the opinion, the Fourth Circuit had not yet adopted the implied certification theory of FCA liability (it has since done so, *see United States ex rel. Badr v. Triple Canopy, Inc.*, No. 13-2190 (4th Cir. Jan. 8, 2015)), and the relator advanced only an express certification theory. *Rostholder*, 2012 WL 3399789, at *14. As the relator argued, any claim for payment for an item provided in violation of a statute or regulation constituted fraudulent conduct, and thus could support FCA liability. *Id.* However, the district court held that failure to affirmatively disclose regulatory violations does not necessarily rise to the level of fraudulent conduct, and that the relator had failed otherwise to plead fraud. *Id.* In a strong opinion issued in 2014, the Fourth Circuit affirmed the district court's dismissal, ruling that even assuming that the violation of GMPs was material to the government's decision to pay, the relator had failed to plead an independent false statement or fraudulent course of conduct, because compliance with GMPs is not a condition for payment by Medicare or Medicaid. *U.S. ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 701–02 (4th Cir.) cert. denied, 135 S. Ct. 85, 190 L. Ed. 2d 38 (2014).

While *Rostholder* was an important victory for the industry, in many ways the holding was limited, as the relator had not advanced theories of either implied certification, fraud by omission, or worthless services, and had not alleged any patient harm. But the intersection of GMP compliance and FCA liability garnered renewed attention earlier this year when the Northern District of California granted defendant Gilead's motion to dismiss a *qui tam* suit alleging even more widespread GMP violations. *U.S. ex rel. Campie v. Gilead Sciences, Inc.*, No. 11-cv-00941, 2015 WL 106255 (N.D. Cal. Jan. 7, 2015). Like the *Rostholder* court, the *Campie* court rejected relators' explicit certification theory (along with promissory fraud), although in doing so, articulated a holding reaching well beyond the sphere of GMP compliance. FCA liability, the court explained, cannot stand on fraudulent statements made to one regulatory agency where there have been no misrepresentations to the payor agency and payment is not otherwise conditioned on regulatory compliance. *Campie*, 2015 WL 106255, at *11. Disputing the extent to which agency separation is meaningful for FCA suits, relators had argued in supplemental briefing that FDA served as a "gatekeeper" for CMS, with both entities standing as "two arms of the same federal department." Accordingly, fraudulent conduct directed toward one arm and a request for payment directed toward another arm could be synthesized so as to have a sufficiently direct nexus. Plaintiff-Relators' Supplemental Submission 1, *U.S. ex rel. Campie v. Gilead Sciences, Inc.*, No. 11-cv-00941 (N.D. Cal. Nov. 12, 2014). The court disagreed, viewing the causal chain too attenuated. The court further rejected the claim that Gilead had implicitly certified to CMS that it had complied with GMP regulations, because CMS only required FDA approval of a drug (and not adherence to GMPs) as a condition for payment.

The court granted Gilead's motion to dismiss, but offered the relators an opportunity to amend their complaint, either to set forth a direct misrepresentation to the payor agency, or to better elucidate their final theory of "worthless services." To survive a motion to dismiss, the *Campie* relators likely face an uphill battle. The relators conceded at oral argument that Gilead never made any direct misrepresentations to a payor, and rather than attempt to articulate a worthless services theory, the Second Amended Complaint rebuilds the relators' express certification arguments. The government, however, has expressed an interest in liability under a worthless services theory, arguing in statements of interest in both *Campie* and *Rostholder* that some GMP violations may so affect a drug "that the drug is essentially 'worthless' and not eligible for payment by the government." However, many other courts have viewed "worthless services" allegations with skepticism. For example, last year in *U.S. ex rel. Absher v. Momence Meadows Nursing Center, Inc.*, the Seventh Circuit reinforced the importance of the distinction between products and services with a diminished value that are "worth less," and truly "worthless" items and services. 764 F.3d 699, 710 (7th Cir. 2014). The *Campie* court also reiterated the narrow nature of this

theory. *See Campie*, 2015 WL 106255, at *11 (quoting the government's statement of interest, which remains under seal); United States' Statement of Interest as to Defendants' Motion to Dismiss 4, *U.S. ex rel. Rostholder v. Omnicare, Inc.*, No. 07-cv-01283 (D. Md. Nov. 18, 2011). Nonetheless, the *Rostholder* district court expressly left open the possibility of liability under this theory, observing in a footnote that its "opinion should not be taken to suggest that a violation of the CGMP may never result in FCA liability." *Rostholder*, 2012 WL 3399789, at *15 n.9. This remains an undeveloped area of caselaw within GMP suits, and, particularly for drugs that are allegedly defective in a manner that risks patient safety or in fact did cause patient harm, a court may rule that a worthless services theory is viable.

Courts have persistently rejected efforts to leverage the FCA into a tool for addressing mere regulatory non-compliance, and in this respect, *Campie* reiterated the rulings of its predecessors. However, by also drawing a strong dichotomy between the agency on the receiving end of fraudulent statements or conduct, and the agency making the payment decision, the court set forth a far-reaching limitation on FCA theories of liability. Whether this holding has a spillover effect into other FCA cases premised on alleged violations of the FDCA will be a trend to watch in 2015, as will whether the government shifts its focus and pursues GMP violations as criminal enforcement matters.

INDIVIDUAL LIABILITY AND THE PARK DOCTRINE

For years, the FDA and DOJ have expressed an intent to expand their use of the so-called *Park* doctrine to hold company officers criminally liable for corporate violations of the FDCA even where they did not know of the problematic conduct but were in a position to stop it. Government rhetoric around individual liability gained significant traction in the early 2010s. For example, in a March 2010 letter in response to an inquiry from a congressional committee, FDA Commissioner Margaret Hamburg noted that the Agency was considering an internal recommendation to "increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable." Letter from Margaret Hamburg, M.D., FDA Commissioner to Senator Charles E. Grassley, Ranking Member, Senate Committee on Finance (Mar. 4, 2010). In an interview later that year, Robert DeConti, chief of the administrative and civil remedies branch of the OIG, reiterated "[t]hat [there] is definitely a renewed emphasis, maybe a new emphasis, on holding individuals accountable."

However, the feared onslaught of individual prosecutions has not arrived, and instead, individual prosecutions remain narrowly limited to circumstances where individual defendants were alleged to have at least some level of direct involvement in the misconduct, and where the company was indifferent to patient safety. For example, in March 2011, Marc Hermelin, the former chief executive officer of KV Pharmaceutical Co., was charged with two counts of misdemeanor misbranding because Hermelin "had the power, authority, and responsibility to prevent drug manufacturing problems in the first instance and promptly correct any drug manufacturing problems that did occur," but failed to do so. Sentencing Memorandum, *United States v. Hermelin*, No. 4:11-cr-00085 (E.D. Mo.). However, the prosecution was more than a mere failure to correct noncompliance, as the government had also alleged that Hermelin instructed employees to minimize written communications about manufacturing problems and to limit distribution and discussion of such communications within the company. *See* Information, *United States v. Hermelin*, No. 4:11-cr-00085 (E.D. Mo.). Similarly, the individual Synthes executives who were indicted had allegedly been aware of patient deaths in the unauthorized clinical trials the company had been conducting, in addition to making false and fraudulent statements to FDA investigators. Indictment, *United States v. Norian Corp.*, No. 2:09-cr-00403 (E.D. Pa. June 16, 2009). Furthermore, when the government has held corporate officers liable, including in each of the foregoing examples, it has done so where the company's conduct implicated serious patient safety concerns.

In contrast, after Forest Laboratories pled guilty in 2010 to misdemeanor violations of the FDCA for off-label promotion, the government initially indicated its intent to exclude CEO Howard Solomon from participation in federal healthcare programs. However, as Solomon's lawyers argued to the OIG, Solomon had limited involvement in the misconduct at issue and had promoted compliance at Forest. In addition, the off-label promotion was not tied to any patient harm. The OIG ultimately reversed course and elected not to exclude Solomon.

The government continued to take action against individuals with direct responsibility for problematic conduct in 2014, when two device company CEOs were indicted based on their companies' sales of products that had failed to receive FDA approval. On November 13, 2014, DOJ announced a criminal indictment against Vascular

Solutions Inc. ("VSI") and its CEO, Howard Root. Earlier in the year, VSI had paid $520,000 to resolve allegations that the company promoted its varicose vein treatment device for a use that had failed to obtain FDA approval, due to poor clinical trial results. The indictment charges Root with approving sales training materials promoting the device for an uncleared use, and otherwise encouraging the sales campaign. Indictment, *United States v. Vascular Solutions Inc.*, No. 14-cr-00926 (W.D. Tex. Nov. 13, 2014). Patient safety was also at issue here, as FDA had harbored safety concerns and warned the company not to promote the device outside of its cleared indication. Similarly, in December 2014, OtisMed and its CEO, Charlie Chi, pled guilty to violating the FDCA by distributing replacement surgery cutting guides, despite the rejection of their 510(k) submission for these products. Chi was charged with having ordered shipments of the cutting guides, even after the company had received a "not substantially equivalent" letter from FDA and the Board of Directors (including Chi) had been warned by outside counsel that subsequent shipment of the device would violate the law. *See* Indictment, *United States v. Chi*, No. 14-cr-687 (D.N.J. Dec. 8, 2014).

However, 2014 brought a potential exception to this trend as the government pursued criminal misdemeanor charges against compounding pharmacy Main Street Family Pharmacy, LLC, and one of its co-owners, David Newbaker. In June 2013, following a series of adverse event reports, FDA isolated certain Main Street products as the source of a string of patient infections; investigation revealed bacterial contamination. On December 4, 2014, both the pharmacy and Newbaker pled guilty, in Newbaker's case, because he "was responsible for, and actively directed," the pharmacy's compounding activities, in addition to having "oversight of employee training and the quality control of sterile drugs compounded" by the pharmacy. Neither DOJ nor FDA press releases set forth any allegations that Newbaker had been personally involved in the misconduct, and the case stands in stark contrast to the indictment of fourteen New England Compounding Center employees, alleging that they knowingly produced medication in unsanitary conditions. It remains an open question whether the government will more vigorously pursue *Park* prosecutions of responsible corporate officers in similar cases, which raise significant patient safety concerns, or even more broadly, or whether it will instead continue to pursue charges against executives who are directly responsible for misconduct.

CONCLUSION

Whether 2015 marks the second year of decreasing recoveries by the government against the industry or is marked by increased enforcement driven by these or other trends remains to be seen. Indeed, the settlements that became public in the last year resolved enforcement actions that had been pending for some time, focused on conduct that occurred sometimes many years ago. Thus, it is difficult to draw many conclusions about the government's current enforcement priorities on this basis. What is clear is that as drug manufacturers have increased compliance efforts over the last decade so too have the government and relators' bar increased their focus on the industry. This suggests that recoveries from manufacturers may stem from new or evolved theories of liability but will continue to be significant.

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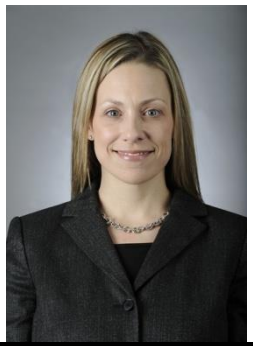

JAIME L.M. JONES represents leading pharmaceutical and device manufacturers and institutional providers in healthcare fraud and abuse and food and drug enforcement and litigation matters. She has defended numerous civil, criminal, and administrative enforcement actions involving allegations of healthcare fraud and abuse and off-label promotion and other violations of the Food, Drug, and Cosmetic Act. She has handled the defense of such matters conducted by the Department of Justice's Consumer Protection Branch and Civil Fraud Section, FDA Office of Criminal Investigations, the Department of Health and Human Services Office of Inspector General, various U.S. Attorneys' Offices, and State Attorneys General. She has negotiated significant Corporate Integrity Agreements with HHS-OIG and has substantial experience counseling clients on compliance and CIA-related issues.

Jaime also has significant experience defending civil litigation in both state and federal courts, with an emphasis on False Claims Act cases and whistleblower retaliation claims. She has successfully defended *qui tam* claims brought against pharmaceutical and device manufacturers and institutional healthcare providers, in both federal and state courts.

Jaime leverages her experiences in enforcement and litigation matters to effectively and efficiently conduct confidential internal investigations and compliance audits concerning, among other things, drug and device promotional practices, including potential off-label promotion and pre-selling, and anti-kickback, pricing and reimbursement, and Good Manufacturing Practices (GMP) and Quality System Regulation (QSR) issues and compliance program effectiveness. She routinely counsels life sciences companies on these and other compliance issues.

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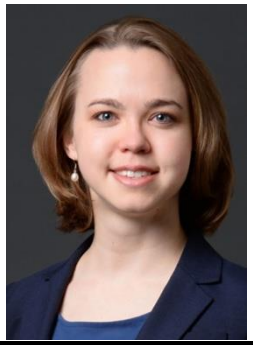

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Her practice includes advising FDA-regulated companies and large provider groups on a range of regulatory and compliance matters, with an emphasis on government enforcement actions. In addition to counseling clients on issues relating to coverage and reimbursement and compliance with fraud and abuse laws, Brenna has experience in assisting clients with both internal investigations and responding to government subpoenas.

In a joint degree program, Brenna received her J.D., *cum laude*, from Harvard Law School, and her M.P.H. from Harvard School of Public Health. During that time, Brenna served as Managing Editor of the *Harvard Journal of Law & Public Policy* and the Recent Developments Editor of the *Journal of Law, Medicine & Ethics*. Prior to joining the firm, Brenna clerked on the Eighth Circuit Court of Appeals.