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United States
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Executive Office for
United States Attorneys
Washington, DC
20530

Monty Wilkinson
Director

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Healthcare Fraud 2016

In This Issue

Healthcare Programs and Fighting Healthcare Fraud in the United States of America

Denise O. Simpson
Healthcare Fraud and Affirmative Civil Enforcement Coordinator
Office of Legal Victim Programs
Executive Office for United States Attorneys

I. Introduction

Welcome to the November 2016 United States Bulletin dedicated to the topic of Healthcare Fraud. The last United States Bulletin devoted to this topic was published more than seven years ago in June 2009. Since then, there have been several developments and milestones in the health care arena. For example, the Affordable Care Act was passed in 2010 and upheld in 2012, the Department of Justice increased its efforts to pursue healthcare fraud prosecutions by focusing more on data analytics, and July 30, 2015, marked the 50-year anniversary of the Medicare and Medicaid programs in the United States of America. This USA Bulletin contains a variety of articles reflecting the changes, challenges, and offers practical tips for criminal and civil Assistant United States Attorneys, Department of Justice Attorneys, investigators, auditors, paralegals, and other Department of Justice personnel who handle healthcare fraud matters. Before addressing those topics, we open this issue with a brief history and overview of healthcare programs and a brief introduction to our healthcare fraud enforcement structure in the United States of America.

II. Healthcare Programs in the United States of America

Public and private healthcare programs are nothing new in the United States. For example, in 1798, less than a quarter century after the Constitutional Convention in Philadelphia, Pennsylvania, the first reported public healthcare program was established when President John Adams signed into law the Act for the Relief of Sick and Disabled Seamen. The purpose of this law was to collect funds to "provide for the temporary relief and maintenance of sick or disabled seamen, in the hospitals or other proper institutions...".[1] On the private insurance side, the first company to offer commercial health care was the Health Insurance Company of Philadelphia in 1847, but this venture eventually failed.[2] Since then,

[1] . http://www.forbes.com/sites/rickungar/2011/01/17/congress-passes-socialized-medicine-and-mandates-health-insurance-in-1798/#2b67a71c65cd

[2]https://cuny.edu/site/cc/health-in-america/1800s html

different public and private healthcare programs, outlined in the chart below, have been proposed, with varying results, but all with the intent to provide benefits to those in need of the programs' services:

Proposed Public Law or Private Plan	**Results**
1854 Bill for the Benefit of the Indigent Insane	This bill would have established asylums for the indigent insane, blind, deaf, and mute via land grants to the states. The bill passed both houses of Congress, but it was vetoed by President Franklin Pierce. http://pahealthaccess.org/why-history-health-care-reform-important/.
1915 AALL Bill	The American Association of Labor Legislation (AALL) drafted a standard bill that stipulated a basic health insurance program from which states could vary according to their own interest. Despite having the support of the American Medical Association (AMA), the bill failed after the American Federation of Labor (AFL) and private insurance companies opposed it. https://cuny.edu/site/cc/health-in-america/1900s.html.
1929 Baylor Hospital Health Insurance	Baylor Hospital introduced health insurance as a pilot program for Dallas, Texas public school teachers. This program was ultimately replicated across the country and later became known as Blue Cross. http://www.npr.org/templates/story/story.php?storyId=114045132.
1943 IRS Ruling	The IRS ruled that employer-based health insurance should be tax free, and the tax advantages for employer-based health insurance were expanded in 1954. As a result, employer-based health insurance became the basis of the U.S. healthcare system by the 1960s. *Id.*
1945 Wagner-Murray Dingell Bill	This bill, which was supported by President Harry S. Truman, would have created a national health insurance system financed through social security payroll taxes. However, it failed to pass either house of Congress after it faced vocal opposition from the AMA. http://www.pbs.org/newshour/updates/november-19-1945-harry-truman-calls-national-health-insurance-program/.
1946 Taft-Smith-Ball Bill	This bill would have provided matching grants to states to subsidize private health insurance for the poor. Despite the AMA's support, the bill died after President Harry S. Truman announced his opposition to the bill. *Id.*
1956 Dependents' Medical Care Act	The law provided a statutory basis for the provision of medical care to active and retired members of the military and their dependents. 10 U.S.C. § 1077.

1965 Medicare and Medicaid Acts	In 1965 President Lyndon B. Johnson signed Medicare and Medicaid into law. Medicare provides hospital and medical insurance to all individuals 65 and older. Medicaid provides grants to states to establish public health insurance for low-income families, pregnant women, people with disabilities, and those requiring long-term care. Social Security Act, Title XVIII. *See also*, https://www.cms.gov/About-CMS/Agency-Information/History/index.html?redirect=/History/.
1971 National Health Strategy	President Richard M. Nixon's proposed legislation which would have required all employers to provide basic health insurance to employees, would have required employees to share the cost of insurance up to a set cap, and would have limited the ability of insurance companies to vary benefit packages. It would have also provided federally funded special insurance programs at reasonable rates and replaced Medicaid with a federal plan open to any family below a certain income level. http://ilpi.umich.edu/news/nixoncare-vs-obamacare-u-m-team-compares-rhetoric-reality-two-health-plans. This legislation failed.
1971 Kennedy Healthcare Bill	This ultimately unsuccessful bill introduced by Senator Edward M. Kennedy (D-MA) would have established a national single-payer health insurance system. http://khn.org/news/kennedy-health-care-timeline/
1973 Health Maintenance Organization Act	The law, signed by President Richard M. Nixon, enabled the federal government to assist in the development of Health Maintenance Organizations (HMOs), which became part of the bedrock of the U.S. healthcare system over the next four decades. 42 U.S.C. § 300e.
1974 Comprehensive Health Insurance Plan	President Richard M. Nixon's second proposed healthcare reform bill failed to pass Congress and would have required all employers to insure all full-time employees using federal subsidies, with employee cost-sharing up to a cap, and would have replaced Medicaid with a plan open to anyone not eligible for employee health insurance or Medicare. http://ilpi.umich.edu/news/nixoncare-vs-obamacare-u-m-team-compares-rhetoric-reality-two-health-plans.
1974 Employee Retirement Income Security Act (ERISA)	This law set minimum standards for most voluntarily established pension and health plans in private industry. 29 U.S.C. Ch. 18. *See also*, https://www.dol.gov/general/topic/health-plans/erisa.
1977 Children's Medicaid Expansion	President Jimmy Carter's proposal to expand Medicaid to all children under the age of 6 failed to receive a vote in Congress. http://pahealthaccess.org/why-history-health-care-reform-important/.

1986 Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1986	COBRA, which was signed by President Ronald Reagan, gives workers the option to continue group health benefits provided by the plan under certain circumstances. https://www.shrm.org/ResourcesAndTools/legal-and-compliance/employment-law/Pages/ConsolidatedOmnibusBudgetReconciliationAct(COBRA)of1968.aspx.
1986 Emergency Medical Treatment and Labor Act (EMTALA)	The law, signed by President Ronald Reagan, requires hospital emergency departments to stabilize and treat all patients regardless of their insurance or ability to pay. 42 U.S.C. 1395dd. *See also*, https://www.acep.org/news-media-top-banner/emtala/.
1988 Medicare Catastrophic Coverage Act	The law, signed by President Ronald Reagan, increased Medicare funding for catastrophic care by requiring the 40% highest earners to pay increased Medicare premiums. Subsequent opposition to this law resulted in President George H.W. Bush repealing it in 1989. http://www.nytimes.com/2013/11/18/us/politics/lesson-is-seen-in-failure-of-1989-law-on-medicare.html?pagewanted=all&_r=0.
1993 Clinton Healthcare Plan	President Bill Clinton's proposed healthcare reform which failed to pass Congress. It would have required all individuals to become enrolled in a qualified health plan and provided free coverage to people under a certain income level. S. 1757, 103rd Cong. (1993). *See also*, https://www.govtrack.us/congress/bills/103/s1757/text.
1993 Chafee Healthcare Bill	The Chafee Bill, which would have achieved universal coverage through individual and employer mandates, failed to pass Congress despite support from the AMA and U.S. Chamber of Commerce. Senate Bill 1770 (103rd Congress), Health Equity and Access Reform Today Act of 1993. See also, https://www.govtrack.us/congress/bills/103/s1770/text.
1997 Children's Health Insurance Program (CHIP)	The law, signed by President Bill Clinton, provided health insurance and preventative care to one in seven uninsured children from uninsured families earning too much money to qualify for Medicaid. https://www.cms.gov/About-CMS/Agency-Information/History/index.html?redirect=/History/.
2003 Medicare Prescription Drug Improvement and Modernization Act of 2003	The law expanded Medicare to include an optional prescription benefit known as Medicare Part D and created private health plans approved by Medicare known as Medicare Advantage Plans. *Id.*

The most recent major piece of public healthcare law in the United States is the 2010 Affordable Care Act, which was signed by President Barack Obama and upheld by the U.S. Supreme Court in 2012. The law requires all individuals to obtain health insurance coverage and requires all employers to provide health insurance for full-time employees. The law also prohibits insurers from denying coverage to individuals on the basis of pre-existing conditions and permits children to remain on their parents' health insurance plans until they turn 26. http://www.hhs.gov/healthcare/facts-and-features/key-features-of-

aca/#. The law initially required all states to expand Medicaid, but the United States Supreme Court struck down that requirement as unconstitutional in 2015. *King v. Burwell*, 135 S.Ct. 2480 (2015). All of these enacted or proposed programs had one in thing in common, and that was to provide benefits to those in need of the program's assistance.

III. Enforcement Against Healthcare Fraud

With the advent of any health insurance program or any program designed to distribute benefits, there will always be those who seek to unlawfully take advantage of these programs for their own financial gain. Prosecutors have several federal criminal and civil statutes which specifically address healthcare fraud. For example, 18 USC § 669, theft or embezzlement in connection with healthcare matter, 18 USC § 1035, false statements relating to healthcare matters, 18 USC § 1347, health care fraud, and 31 USC § 3729, the False Claims Act are common statutes used by criminal and civil health care fraud prosecutors. In addition to these statutes, Congress enacted a law to help support prosecutors and investigators handling these matters, and to protect the public and the public fisc from these types of frauds. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191. Most of us are familiar with HIPAA because of its requirements to help protect healthcare information and to provide rights to patients regarding access to their healthcare information. However, as reflected in the title of the law, HIPAA was created to "amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes." H.R. 3103, 104th Cong. (1996). One of these other purposes was the establishment of the Health Care Fraud Abuse Control Program (HCFAC). 42 USC 1320a–7c.

HCFAC was designed to help prosecutors and law enforcement fight fraud in public and private health insurance programs. Under HCFAC the Secretary of the United States Department of Health and Human Services and the United States Attorney General were tasked to establish a program:

> "(A) to coordinate Federal, State, and local law enforcement programs to control fraud and abuse with respect to health plans,
>
> (B) to conduct investigations, audits, evaluations, and inspections relating to the delivery of and payment for health care in the United States,
>
> (C) to facilitate the enforcement of the provisions of sections 1320a–7, 1320a–7a, and 1320a–7b of this title and other statutes applicable to health care fraud and abuse, and
>
> (D) to provide for the modification and establishment of safe harbors and to issue advisory opinions and special fraud alerts pursuant to section 1320a–7d of this title." *Id.*

HCFAC allows prosecutors to maximize coordination efforts in the fight against healthcare fraud. Among its provisions, HCFAC created a trust fund to collect criminal fines, civil monetary penalties, property forfeited, and penalties and damages recovered under the False Claims Act related to healthcare fraud offenses. A portion of these collected funds are used by the United States Department of Health and

Human Services, the Department of Justice, and the Federal Bureau of Investigations to support the hiring of staff and the funding of other needs to investigate, prosecute, educate, and conduct audits and evaluation of healthcare fraud matters. Social Security Act, Section 1817(k).

This funding includes supporting the Centers for Medicare and Medicaid Services' (CMS) Fraud Prevention Systems (FPS), which uses data analytics to help detect patterns of fraud, a practice which the Department of Justice has sought to capitalize on in fighting healthcare fraud. Combining funding with other tools, such as working with the Health and Human Services' Office of the Inspector General in issuing fraud alerts about current schemes, and mandatory and permissive exclusion of certain individuals or entities from providing services under Medicare or any state healthcare program if they have been convicted of certain crimes, HIPAA and HCFAC provide substantial support to prosecutors in the healthcare fraud fight. 42 U.S.C. 1320a–7(a) (Mandatory exclusion include crimes related to providing services to a healthcare program, conviction for patient abuse "relating to a fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct," or a person who has a controlled substance conviction). The collaborative success of the HCFAC Program is reflected in the annual report put out each year by the Department of Justice and the Department of Health and Human Services. THE DEP'T OF HEALTH AND HUMAN SERVICES AND THE DEP'T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FISCAL YEAR 2015 (2016).

IV. Conclusion

All members of the United States Attorney's Offices and the Department of Justice who prosecute healthcare fraud cases either criminally or civilly know that this is important and time-consuming work. We should all continue to coordinate with our state, federal, public and private partners, and fellow Department of Justice and United States Attorney's Offices to continue this work because healthcare fraud affects everyone. I hope that this USA Bulletin will give you a sense of the history of the efforts to provide healthcare insurance, give you guidance on how to address various issues raised in healthcare fraud prosecutions, and encourage you to continue the great work you do for the cause of justice.

ABOUT THE AUTHOR

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The author would like to thank Brad Meisel for his generous assistance and input on this article.

Individual Accountability in Health Care Investigations

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I. Introduction

A pharmaceutical company takes physicians out for lavish dinners and falsifies prior authorizations for drugs that have poor insurance coverage. A medical device company manipulates Medicare Certificates of Medical Necessity, pays kickbacks to high-prescribing physicians, and falsifies medical records to meet insurance coverage standards. Corporate health care investigations are unique because the corporations bear all of the hallmarks of legitimate businesses, and the criminal activity is not always intuitive. Yet the corrosive ramifications of corporate crime have long been recognized by courts and in popular culture. *See, e.g.*, *U.S. v. Benjamin*, 328 F.2d 854, 863 (2d. Cir.) (Friendly, J.), *cert denied*, 377 U.S. 953 (1964) ("In our complex society the accountant's certificate and the lawyer's opinion can be instruments for inflicting pecuniary loss more potent than the chisel or the crowbar"); *see also* Guthrie, W., "The Ballad of Pretty Boy Floyd," Sanga Music Inc. (1940) ("As through this world I wander/I've seen lots of funny men/Some will rob you with a six-gun/And some with a fountain pen."). The Department of Justice recently reaffirmed its commitment to holding individuals responsible in corporate cases. In two recent health care fraud investigations, the Orthofix and Warner Chilcott cases, not only did the corporations plead guilty to felonies and pay large fines, but 14 individuals were charged with crimes, with 12 convictions to date. The purpose of this article is to discuss some of the unique characteristics of corporate health care fraud investigations and to stress the importance of holding individuals responsible for the crimes committed at these organizations.

A. Health Care Spending and Fraud

This country spends an astronomical amount of money on health care. According to the Centers for Medicare & Medicaid Services (CMS), in 2014, spending on health care in the U.S. reached $3 trillion — an increase of 5.3 percent from 2013. Medicare spent $618.7 billion, accounting for 20 percent of all health care spending. The federal government accounted for 28 percent of all health care spending. Health spending made up 17.5 percent of the gross domestic product. *See* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf. At the same time, experts have estimated that tens to hundreds of billions of dollars are lost to fraud each year. *See* https://www.nhcaa.org/resources/health-care-anti-fraud-resources/the-challenge-of-health-care-fraud.aspx; *see also* Donald M. Berwick, MD, MPP; Andrew D. Hackbarth,

MPhil, "Eliminating Waste in US Health Care," JAMA, April 11, 2012, Vol. 307, No. 14 (estimating that fraud and abuse cost Medicare $98 billion and cost the entire health care system $272 billion).

B. The Federal Response to Health Care Fraud

Congress and the Department of Justice have taken a number of steps to attempt to combat the rising tide of health care fraud. Congress included a number of anti-fraud measures in the Affordable Care Act, including increasing the offense level for defendants who cause substantial loss to health care programs. *See* U.S. SENTENCING GUIDELINES § 2B1.1(b)(7) (U.S. SENTENCING COMM'N 2015). In the ACA, Congress also directed the Sentencing Commission to review the Guidelines and policy statements for health care fraud offenses to ensure that they "reflect the serious harms associated with health care fraud and the need for aggressive and appropriate law enforcement action to prevent such fraud" and to provide "increased penalties for persons convicted of health care fraud offenses in appropriate circumstances." *See* Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 10606(a)(C), (3)(a), 124 Stat. 119, 1006-07 (March 23, 2010). Congress also recently strengthened both the Anti-Kickback Statute and the False Claims Act, removing obstacles to their enforcement.

Fighting health care fraud has been a DOJ priority for a number of years. In FY 2015, DOJ health care prosecutions generated $2.4 billion in fines and payments, and health care fraud prosecutions have returned more than $29.4 billion to the Medicare Trust Funds since 1997. Press Release, Dept. of Justice, The Health Care Fraud and Abuse Control Program Protects Consumers and Taxpayers by Combating Health Care Fraud (Feb. 26, 2016). The DOJ primarily fights health care fraud on two fronts. On the first front, the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative has resulted in health care fraud-related charges for more than 2,000 individuals over the last several years, resulting in more than 1,400 guilty pleas and 191 convictions after jury trial. Press Release, Departments of Justice and Health and Human Services announce over $27.8 billion in returns from joint efforts to combat health care fraud (March 19, 2015). HEAT cases utilize sophisticated data analytics to address recurring areas of abuse, such as home health care fraud or durable medical equipment fraud in targeted cities.

This article relates to the second front in the battle against health care fraud, corporate health care fraud. That battle is primarily waged through False Claims Act *qui tam* lawsuits. Corporate health care fraud prosecutions often involve established pharmaceutical and medical device companies, including some of the largest companies in the United States. In recent years, with the assistance of *qui tam* lawsuits, prosecutors have uncovered clear criminal conduct at these companies.

The DOJ has investigated and prosecuted corporate crime for many years. In 2015, Deputy Attorney General Sally Quillian Yates reaffirmed this commitment, while also stressing the importance of holding individuals accountable for fraud, in her memorandum concerning Individual Accountability for Corporate Wrongdoing ("Yates Memo"). Memorandum from Sally Quillian Yates, Deputy Attorney Gen., Dep't. of Justice, to all U.S. Attorneys et al., "Individual Accountability for Corp. Wrongdoing Sept. 9,2015), https://www.justice.gov/dag/file/769036/download (Individual Accountability Policy). The Yates Memo highlighted the importance of holding individuals responsible for corporate crimes and identified six concrete steps that prosecutors must take in connection with corporate criminal investigations, including requiring corporations to provide all relevant facts related to individual responsibility for misconduct as a prerequisite to gaining cooperation credit in a plea, as well as requiring prosecutors to focus on individual accountability from the inception of an investigation.

II. Investigating a Corporate HCF Case

Prosecutors focused on individual accountability right from the beginning in the corporate health care fraud investigations concerning Orthofix, a Texas-based medical device company, and Warner Chilcott, a pharmaceutical company in New Jersey.

A. Qui Tam Lawsuits and the False Claims Act

The Orthofix and Warner Chilcott cases, like many corporate health care fraud cases, were initiated by whistleblower lawsuits. The civil False Claims Act ("FCA") permits a whistleblower ("relator") to file a lawsuit in the name of the government ("qui tam") against a person or corporation. The lawsuit, as well as a written disclosure of information in the relator's possession, is filed in the appropriate judicial district and served on the U.S. Attorney General. The case is filed under seal, providing the government with at least 60 days to investigate the allegations. The government eventually must choose whether or not to proceed with the action ("intervene"). If the government resolves the case with the defendant, the relator is entitled to 15-25 percent of the overall recovery. *See* 31 U.S.C. § 3729, *et seq.*

The *qui tam* action is reviewed by the DOJ Fraud Section, the health care fraud coordinator in the applicable United States Attorney's Office, and, if applicable, the state attorney general's office. The complaint is then typically disseminated to applicable investigative agencies (such as the FBI, HHS-OIG, FDA OI, DCIS), to investigate the allegations. An attorney from DOJ's Civil Fraud section is typically assigned to the case. Counsel from the FDA and DOJ's Office of Consumer Protection will also likely be assigned if the *qui tam* action alleges misbranding violations.

B. Interviewing the Relator and Initial Stages of the Investigation

After a *qui tam* lawsuit is reviewed, the prosecutor should quickly schedule an interview with the relator. The relator is typically represented by an experienced *qui tam* attorney. The *qui tam* attorney's goal is to assemble a compelling case that the prosecutor will find worthy of investigation. The best *qui tam* lawsuits not only contain detailed allegations of wrongdoing, but the relator should be prepared to come to the initial interview armed with hard evidence, such as emails, text messages, and voicemails, that will give prosecutors a head start on the investigation. The relator should also provide names of additional witnesses and other investigative leads.

After the relator's interview, the investigation begins in earnest. Most AUSAs will keep the investigation covert as long as possible. As mentioned above, the FCA provides that a case may remain under seal for 60 days pending an investigation, with additional continuances available for good cause. *See* 31 U.S.C. § 3730(b)(2). Prosecutors should not assume that judges will grant motions to extend the seal in perpetuity. *See, e.g.*, *ACLU v. Holder*, 673 F.3d 245, 257 (4th Cir. 2011) (directing district courts to "weigh carefully any such extension beyond the 60-day [sealing] period"; *see also United States v. Creekside Hospice II, LLC*, 2015 WL 9581743, *7 (D. NV Dec. 30, 2015) ("nothing in the text of the FCA authorizes the government to obtain an indefinite seal of the records").

Of course, there is nothing more powerful than contemporaneous admissions from key company employees. Thus, prosecutors should consider asking the relator to surreptitiously record interactions with

company employees, or recruit others who will. Recording interactions with company insiders raise a variety of legal and ethical issues, including making contact with represented parties. *See* ABA Model R. Prf'l Conduct (Model Rule 4.2). Under rule 4.2, contacts with represented parties are permissible pre-indictment if made for a law enforcement purpose. Courts have found either that Rule 4.2 does not apply or that such contacts are an exception to the rule. *See, e.g.*, *United States v. Binday*, 804 F.3d 558, 592-95 (2d Cir. 2015); *United States v. Carona*, 660 F.3d 360, 364-66 (9th Cir. 2011); *United States v. Sutton*, 801 F.2d 1346, 1366 (D.C. Cir. 1986); see generally Model Rule 4.2 cmt. [5] (Communications authorized by law may also include investigative activities of lawyers representing governmental entities, directly or through investigative agents, prior to the commencement of criminal or civil enforcement."). When in doubt, it is always best to contact your internal ethics advisor and/or PRAO for guidance. Thus, in the Warner Chilcott case, which involved allegations of taking physicians out to dinner and signing them up to bogus "speaker" contracts to leverage prescriptions, the government obtained recordings of Warner Chilcott employees making the following admissions, among others:

- Sales representatives bragged that, after taking physicians out to dinner, they returned to the physician's office the next day and told them, "You're eating my fucking steaks . . . You haven't written shit . . . There's no such thing as a free lunch . . . how many times have I taken you out . . . I just bring in the receipt the next day. No, I'm serious. I leave that shit on the desk. That shit was $800, doc."

- At a regional sales meeting, an aggressive sales representative discussed the direct conversations he had with physicians who were speakers, bragging that he had "business conversations" with them and told physicians who forgot to prescribe his drug "What do you mean you forgot, you know? I just spent like a couple hundred bucks on you . . .you promised me that you're going to give me this . . . you've got to really hold them accountable."

- At a sales meeting, in the presence of the company's president, a regional director instructed sales representatives that, if a physician was filling out prior authorizations for a drug with poor insurance coverage, the representatives should tell the physician, "let me take you and your staff out to dinner and thank you for doing those prior auths" and praised a sales representative for "paying a lot of attention" to physicians who prepared prior authorizations, including "bringing them coffee, taking them to dinner."

- A physician, who had written $100 checks to a sales representative in return for speaking engagements, instructed the sales representative to lie to investigators about the purpose of the checks, suggesting that he "tell 'em I needed you to cash some checks for me, like an ATM" and reassuring the sales representative that "I'll make up something that's reasonable" if asked.

Similarly, in the Orthofix investigation, the government obtained recordings of company insiders, including:

- A sales representative assured a medical device distributor that the company does not actually collect copayments from patients, and that patients could throw the bills "in the trash";

- A physician who allowed a sales representative to alter patient medical records in order to satisfy insurance coverage criteria, upon learning that the government was investigating the

> conduct, warned the sales representative, "if you guys take me out you are never going to live to hear the end of it; if I roll on this, I am serious, heads are going to roll, heads are absolutely gonna roll;" and later instructed the sales representative that, if anyone asked, "you and I have not talked."

These recordings were crucial in corroborating the allegations in the *qui tam* complaints, disciplining witnesses to tell the truth and, in some instances, in obtaining convictions.

C. The Overt Stage of the Investigation

1. Subpoenas and Documents

At some point, the AUSA will determine that the covert stage of the investigation is exhausted and will take the investigation overt. This typically involves some combination of subpoenas and search warrants. In a joint civil/criminal investigation, a "HIPAA subpoena" is usually preferable to launching a grand jury investigation in the early stages to ensure that the civil AUSA is not boxed out of the investigation. *See* 18 U.S.C. § 3486. Initial corporate subpoenas frequently request voluminous categories of records, but the AUSA should consider limiting the initial subpoena to a handful of targeted requests to avoid getting deluged by the production of unhelpful documents.

Typically, an agent will serve the initial corporate subpoena on the target corporation, and outside counsel will quickly materialize. In many cases, literal compliance with the corporate subpoena could result in the production of millions of pages of documents. The AUSA and corporate counsel may agree on search terms or production from certain individuals (custodians), with the AUSA reserving the right to request additional terms or documents. The subpoena will typically specify which documents should be produced in an electronic format (such as emails) and which documents must be produced as hard copies (such as personal or desk folders). For electronic documents, the subpoena should specify a production format that is compatible with the litigation technology platform available at the AUSA's office.

In health care investigations, subpoenas often request personally identifiable information ("PII"), such as patient medical records. AUSAs frequently execute a protective order to allow the defendant to have access to PII for the purposes of the litigation only. In addition, many districts have local rules that require AUSAs to redact PII from trial exhibits.

By the time the AUSA is ready to serve a corporate subpoena, potential individual targets or subjects have likely been identified. Thus, at the same time that the corporate subpoena is served, agents should serve subpoenas on individuals as well. This is especially important to preserve information on witnesses' phones—which prosecutors may not yet have probable cause to search. Moreover, individuals often possess incriminating evidence that would not appear on a corporate server. In the Orthofix investigation, one of the issues under investigation was the company's manipulation of Medicare Certificates of Medical Necessity ("CMNs")—forms that were required by Medicare but that doctors frequently were too busy to prepare. In response to a subpoena, one witness appeared at the U.S. Attorney's Office with a box full of fake physician's signatures and phony CMNs that he kept in his car and prepared each time he received a prescription. The prosecutors would not have received these records absent a separate subpoena to the witness.

In addition to serving subpoenas on targets and employees, any substantial investigation will involve subpoenas to a wide range of third parties. In the Warner Chilcott case, prosecutors were investigating the company's manipulation of prior authorization medical forms for a drug that was not covered by many insurance companies. Through third party subpoenas, the government obtained both prior authorization forms (PA) from insurance companies and medical records from physicians in order to test the medical justifications contained in the PAs. Prosecutors discovered that: (1) many of the justifications in the PAs were not supported by the patients' medical records; and (2) insurance companies had received PAs for Warner Chilcott's drugs from separate physicians that contained identical medical rationales—compelling evidence that the PAs had been manipulated by the company. The Warner Chilcott case also involved allegations of illegal remuneration to physicians in the form of lavish dinners and improper "speaker" arrangements. In addition to subpoenaing records from the vendor who operated the "speaker" bureau, the government obtained receipts from "medical education" dinners from high-end Manhattan restaurants, complete with hundreds of dollars of alcohol and suckling pig entrees.

The Orthofix investigation involved allegations that sales representatives falsified patient medical records to match insurance coverage requirements. Medicare required that device manufacturers like Orthofix maintain patient medical records that supported each claim. Prosecutors used third party subpoenas to physician's offices to compare original medical records with the medical records in Orthofix's files. Many of the records in Orthofix's files were inconsistent with the original records with respect to coverage criteria—clear evidence of fraud. This was critical evidence in securing four individual health care fraud pleas in this investigation.

Some information is best obtained by a search warrant rather than a subpoena. For instance, if the AUSA is concerned about spoliation of evidence, or does not trust that the target will faithfully respond to a subpoena, a search warrant is the better practice. Moreover, some categories of evidence, such as electronic medical records, are better suited to capture in a search warrant rather than a subpoena. However, if there is any risk that agents will seize information protected by the attorney-client privilege, the prosecution team should establish a taint review team staffed by agents and/or AUSAs not on the case team in order to identify and remove from the seized records any privileged materials. Of course, agents must handle all seized materials with care, carefully documenting the chain of custody each time materials are removed from the evidence room no matter how many records are seized or how "routine" the materials appear to be.

In health care cases, federal agencies that are impacted by the allegations can be an extremely helpful resource. In a false claims case, the Department of Health and Human Services Office of Inspector General (HHS-OIG) can assist in running analyses and accumulating information on a target, such as claims data or prescription usage. HHS-OIG also maintains a public database of guidance and memoranda it has issued on a wide range of topics. Chances are HHS-OIG has provided public guidance on at least one issue raised in a *qui tam* complaint. Similarly, in a misbranding investigation, the Food & Drug Administration (FDA) will invariably have expertise on the approved and unapproved uses of a product, and the agency may have issued warning letters to the corporation as well. In cases where HHS or FDA regulations are at issue, prosecutors will want to search agency files for any communications with the target corporation. It is not unusual for a corporation to present to a prosecutor correspondence between the corporation and the agency, sometimes several years old, which, on its face, authorizes the corporation's practice, providing the company with a good faith defense.

Having obtained all of these records via subpoena and search warrant, the records must be reviewed. This can be a monumental task in health care cases, but there is simply no substitute for hours

and hours of document review. A well-financed target will review every single page that is produced in discovery, and no AUSA wants to have a government witness confronted at trial with a document that the government produced in discovery but that has never reviewed. Sophisticated document review platforms are available today to help reviewers identify key documents, such as Relativity and Eclipse. AUSAs with document-heavy cases should contact Automated Litigation Support ("ALS") Services for assistance.

2. Interviews and Testimony

After weeks or months of document review, agents and prosecutors will be anxious to interview witnesses. Former employees of a target corporation are usually a rich source of information, and they frequently have relevant materials, emails, and text messages as well. Agents may also interview current employees as long as they are not represented by counsel in the investigation. *See* Model Rule 4.2. Frequently, of course, witnesses are represented by counsel. Defense lawyers' practices vary concerning access to their clients; some will readily allow their client to be interviewed, sometimes without counsel present, while other cases involve protracted negotiations preceding the interview, with counsel demanding a preview of the questions to be asked, documents to be shown, and demanding various protections for their client. Counsel often requests a "proffer" or "queen for a day" letter to protect their client from direct use of incriminating statements at trial.

Counsel for the target company will frequently retain separate counsel for witnesses. Even though these witnesses have separate counsel, they often enter into a joint defense or common interest agreement with the company and other witnesses in order to exchange information about the investigation and protect work product from disclosure. *See, e.g.*, *United States v. Almeida*, 341 F.3d 1318, 1324 (11th Cir. 2003); *United States v. Schwimmer*, 892 F.2d 237 (2d Cir. 1989). Prosecutors should inquire if witnesses have joined a joint defense agreement, not only so they know if the witness is sharing information with other targets, but also to ensure that the witness's testimony is based on personal knowledge, rather than matters learned during debriefings from counsel for other witnesses in the joint defense agreement.

A single lawyer frequently represents multiple witnesses in an investigation. Problems arise, however, if one client is charged and other clients are potential witnesses. Faced with conflicted loyalties, counsel should find new counsel either for the target or the other clients—unless the conflict is waived.

For the most important witnesses in the case, AUSAs will want to lock in their evidence with testimony under oath. In a joint civil/criminal investigation, prosecutors may use Civil Investigative Demands (CID) to obtain documents, answers to interrogatories, or oral testimony. *See* 31 USC 3733(a)(1). Unlike a grand jury appearance, defense counsel can attend a CID and state objections, where appropriate.

When an investigation has yielded clear evidence of criminal activity, the prosecutor will convene a grand jury. While the grand jury is one of the most powerful tools available to prosecutors, it is rife with potential pitfalls and should be used with care. In a joint investigation, the civil AUSA can be cross-designated to the criminal investigation. Otherwise, the civil AUSA cannot participate in the grand jury investigation, and information obtained by the grand jury (testimony or documents) may not be used by the government in its civil False Claims Act complaint after intervening in the *qui tam* action. *See* Attorney General's Memorandum Concerning Coordination of Parallel Criminal, Civil, Regulatory, and Administrative Proceedings (2012) for further discussion.

Witnesses called before the grand jury often request use immunity. In most offices, prosecutors have the option of offering an immunity agreement with the U.S. Attorney (which only binds that district) or obtaining an immunity order. *See* 18 U.S.C. § 6001, *et seq.* The latter requires authorization from the DOJ Policy and Statutory Enforcement Unit (PSEU) and an order from a district judge. While it is often necessary to immunize witnesses in health care investigations, ultimately, the decision to immunize a witness is a trial decision. Jurors may view an immunized witness with suspicion. Moreover, the witness will be subjected to vigorous cross-examination concerning his or her immunity deal with the government, and the judge will likely instruct the jury to consider an immunized witness's testimony with particular care.

It is not unusual for the grand jury stage of a health care investigation to last for years. The prosecutor should take this into account at the inception of the grand jury phase of an investigation. A grand jury sits for 18 months, with a six-month extension available upon request of the prosecutor if the grand jury agrees. *See* Fed. R. Crim. P. 6(g). In lengthy investigations, it is optimal for a prosecutor to complete the investigation before the grand jury that heard all of the evidence in the case rather than present the case to a new grand jury.

D. Resolution and Charging

1. Corporate Resolution

After reviewing thousands of documents, interviewing dozens and sometimes hundreds of individuals, and taking sworn testimony from the most important witnesses, the prosecutor must determine how to resolve the investigation and which criminal charges are appropriate. Negotiating a civil or criminal resolution with a corporation usually involves protracted negotiations, with exhaustive presentations from counsel on the evidence and damages. If the corporation wishes to resolve the entire criminal and civil investigation, to avoid the appearance of the government using a criminal investigation to leverage a civil settlement, counsel must send a letter to prosecutors expressing this desire.

If the AUSA determines that a criminal resolution with the corporation is appropriate, a number of steps must be followed. Of course, the prosecutor must consult the *Principles of Federal Prosecution of Business Organizations*, U.S. Attorneys' Manual § 9-28.000 to weigh the various considerations involved in prosecuting a corporate entity. In a corporate case, the prosecutor must obtain authority from the Assistant Attorney General of the Criminal Division to enter into a global plea agreement. Defense counsel will also likely request a release from criminal liability for all other conduct known to the USAO in the plea agreement. The prosecutor must contact EOUSA to consult with health care fraud coordinators in other districts to ensure that no other investigation exists concerning the corporation.

Prosecutors must also consider the collateral consequences of corporate guilty pleas. Exclusion from federal health care programs is a collateral consequence that arises frequently in corporate health care cases. The Secretary of HHS must exclude from any federal health care program any individual or entity convicted of a felony health care fraud conviction. *See* 42 U.S.C. § 1320a-7(a) (2010). In addition, the Secretary has "permissive" authority—or discretion—to exclude from any federal health care program any individual or entity involved in a wide range of separate criminal activity. *See* 42 U.S.C. § 1320a-7(b) (2010). Exclusion from the Medicare program is a matter of utmost importance to corporate health care targets and is frequently the subject of intensive discussions amongst HHS counsel, the prosecutor, and defense counsel.

Consistent with the Yates Memo, prosecutors should include a cooperation clause in the corporate plea agreement. Indeed, obtaining cooperation in the government's ongoing investigation of individuals is a crucial component of any corporate plea. The importance of corporate cooperation cannot be overstated. No matter how thorough the investigation has been, a corporation will be able to assist the ongoing investigation in a number of ways. For instance, a corporation can supply the prosecutor with information such as "hot documents" to prepare for witness interviews. The corporation can supply the prosecutor with records of corporate expenses in a kickback case, or claims data and medical records in a fraud case, or compensation information concerning a target. Even better, the cooperating corporation must provide this information on demand, without a subpoena. In some cases, the prosecutor has a direct line to the corporation's general counsel, who may prefer to respond directly to the prosecutor rather than incur the expenses of working through outside counsel. In short, the prosecutor should leverage the pleading corporation's resources in the ongoing investigation against culpable individuals. Indeed, consistent with the Yates Memo, prosecutors cannot resolve a case with a corporation without a clear plan to resolve individual cases.

2. Charging Individuals

Corporations do not break the law in the abstract. If a corporation is pleading guilty to a crime, human beings within the corporation caused the criminal conduct. In a large corporation, it can be extremely difficult determining which individuals: (1) acted with criminal intent; and (2) warrant criminal prosecution. While a sales representative may have paid a kickback or falsified a document, did the representative act alone or at the direction of a supervisor? Was the representative trained on compliance with health care laws, or was compliance not emphasized and enforced at the company? How pervasive was the misconduct at the company? These are just some of the questions that the prosecutor must ask in determining who should be held responsible for corporate criminal misconduct.

Lower-level employees acting in accordance with company directions or expectations may be less attractive criminal targets. On the other hand, lower-level employees acting unlawfully on their own, or in contravention of compliance policies, may well be appropriate for prosecution.

For example, as mentioned above, in the Warner Chilcott investigation, the company launched a new drug without securing favorable insurance coverage, and many insurers only paid for the drug upon receiving a prior authorization from the patient's physician requesting the non-covered drug. While Warner Chilcott initially instructed the sales force to become involved with and push through PAs for the new drug, shortly after launch, the company issued clear guidance in a memorandum to sales personnel to *refrain* from involvement with PAs due to patient privacy concerns. Notwithstanding this guidance, the government learned, after an exhaustive investigation involving many of the techniques described above, that certain Warner Chilcott sales managers continued to instruct their sales representatives to manipulate and falsify PAs, causing insurance companies to pay for the drug under false pretenses. There was limited evidence that senior sales management was involved in the PA manipulation scheme after the memorandum was issued. Therefore, the prosecutors determined that four managers merited prosecution, three for conspiracy to commit health care fraud, and a fourth for a criminal HIPAA violation. (One culpable manager was diagnosed with terminal cancer after agreeing to plead guilty. The prosecutors agreed to not charge this defendant. Instead, they preserved his testimony against a Warner Chilcott executive in a trial deposition.); *see* Fed. R. Crim. P. 15.

Similarly, in the Orthofix investigation, a handful of sales representatives falsified patient medical records to support claims for a medical device that otherwise would not have satisfied insurance guidelines. Prosecutors attempted to determine if these sales representatives acted on their own or at the direction of supervisors. The sales representatives claimed that their supervisors were aware of their conduct, but this could not be corroborated, and the prosecutors determined that the misconduct was egregious enough to warrant prosecution. Four sales representatives were charged with health care fraud (one was also charged with paying kickbacks).

In both investigations, the prosecutors had to choose whether to proceed by indictment or information. While the *qui tam* lawsuits were filed in Massachusetts, none of the defendants committed crimes in the Commonwealth. These defendants could only be charged in an indictment in Massachusetts with a conspiracy charge (alleging at least one overt act in Massachusetts). Otherwise, the cases would have to be referred to AUSAs in the targets' home districts (Prosecutors who uncover criminal conduct in another district should contact the health care fraud point of contact in the district where the conduct occurred. In the Orthofix case, prosecutors referred one defendant to the Eastern District of Pennsylvania, where the defendant pleaded guilty to health care fraud.). On the other hand, the defendants could waive venue and plead guilty to an information in Massachusetts. A putative defendant faced with overwhelming evidence of guilt may well agree to plead guilty to an information, not only to garner credit for accepting responsibility, but also, where appropriate, to gain further consideration for cooperating with the government's ongoing investigation into more culpable individuals. In the Orthofix and Warner Chilcott cases, many of the lower-level defendants cooperated; as a result, prosecutors moved for departures from their guideline sentencing range based on their substantial assistance with the prosecution of others. U.S. SENTENCING GUIDELINES § 5K1.1 (U.S. SENTENCING COMM'N 2015).

It is not unusual in a large corporate case that criminal activity attracts the attention of multiple districts. A prosecutor in one district may learn that a physician is taking kickbacks from a sales representative and only later realize that a prosecutor in a separate district is already investigating the representative's employer—and possibly the same representative and/or physician. If all targets cannot be charged in the same district because of venue or other reasons, the prosecutors should at least consult frequently to ensure consistency in charging, plea, and sentencing decisions.

Most of the lower-level defendants in the Warner Chilcott and Orthofix investigations cooperated with the government's investigation of higher-level, more culpable executives. In the Orthofix case, the government discovered, through testimony from cooperating witnesses and exhaustive document review, that the Vice President of Sales was involved with a number of kickback schemes with high-prescribing physicians. For example, the defendant authorized bogus consulting payments to a high-prescribing physician in New York. Moreover, the government discovered from the sales representative, the physician, and various documents, that the defendant authorized the sales representative to falsify timesheets reflecting supposed work that the physician was performing in exchange for the consulting payments in order to conceal from Orthofix's compliance department that the physician was actually doing nothing at all (except prescribing Orthofix's products). As another example, the defendant authorized consulting payments to a physician's assistant who chose the medical devices used by a high prescribing physician in Rhode Island. When Orthofix announced that it was canceling such arrangements, the defendant ordered from a separate vendor, who relied exclusively on Orthofix for business, to assume the payments to the physician's assistant. The defendant ultimately pleaded guilty to violating the Anti-Kickback Law. The Rhode Island physician's assistant also pleaded guilty to accepting kickbacks. The New York doctor was not charged.

In the Warner Chilcott investigation, the relators alleged in the *qui tam* complaint, and the prosecutors quickly corroborated, that the company's primary sales strategy was to take out physicians for lavish meals and sign them up as paid "speakers" in order to generate prescriptions. The investigation revealed countless instances of egregious kickbacks, such as sales representatives giving physicians restaurant gift cards, allowing physicians to go out to dinner on their own using the corporate credit card, and paying for a physician's anniversary dinner (reminding the physician via text message that they no longer had any excuse not to prescribe their drug). However, the practices were so widespread and ingrained within the corporation that it made more sense to charge the executive responsible for promulgating the sales strategy than the sales representatives who were merely executing the plan. Numerous witnesses, including the cooperating district manager defendants, testified that Warner Chilcott's president had directed the kickback scheme. Prosecutors corroborated their accounts by obtaining recordings of his direction, as well as developing evidence that he ignored the company's compliance department and emphasized sales at any cost. After a multi-year investigation, the former president was indicted for conspiracy to pay kickbacks to physicians. In addition, a Massachusetts physician was indicted for accepting kickbacks, obstruction of justice, and violating HIPAA by allowing a Warner Chilcott sales representative to manipulate prior authorizations for her patients. (The former president was acquitted after a five-week trial. The case against the physician has not yet been scheduled for trial.).

III. Conclusion

Health care fraud prosecutors around the country increasingly are holding individuals responsible for fraud committed at corporations. The Orthofix and Warner Chilcott investigations represent two examples of this trend. These cases were resolved not only with felony pleas against the corporations, complete with substantial civil payments and criminal fines, but also, after lengthy investigations assisted by corporate cooperation, with charges brought against 14 individuals, including executives from each company. To date, 12 individuals have been convicted, and one is pending.

ABOUT THE AUTHOR

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What is "Use" After Medlock?: The Challenges of Charging 1028A in the Health Care Fraud Context

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I. Introduction

Aggravated Identity Theft, 18 U.S.C. § 1028A, is an effective tool in health care fraud prosecutions. However, prosecutors should consider the challenges facing them when charging the statute and should be particularly mindful of the Sixth Circuit's recent decision in *Medlock* concerning the interpretation of the word "use" in the context of health care fraud cases. *United States v. Medlock*, 645 F. App'x 810 (10th Cir. 2016).

The Identity Theft Penalty Enhancement Act of 2004 established a new federal offense, 18 U.S.C. § 1028A, Aggravated Identity Theft. This statute offered federal prosecutors an effective new tool in the fight against fraud and other serious federal crimes. The statute makes it a crime for anyone during, or in relation to, any felony violation enumerated in 18 U.S.C. § 1028A(c), to knowingly transfer, possess, or use, without lawful authority, a means of identification of another person.

With 18 U.S.C. § 1028A, Aggravated Identity Theft, Congress created a crime which carries a mandatory consecutive sentence of two years under 18 U.S.C. § 1028A (a)(1), in addition to the sentence for the underlying felony. In passing the law, Congress was responding to the drastic upsurge in "identity theft" and "identity fraud," including "all types of crimes in which someone wrongfully obtains or uses another person's personal data in some way that involves fraud or deception, typically for economic or other gain…" H.R. REP. 108-528, at 4, (2004) *reprinted in* 2004 U.S.C.C.A.N. 779, 780. The statute itself demonstrates how serious Congress was about increasing the mandatory sentence. Section 1028A(b) expressly cuts off most of the mechanisms through which such a sentence could be reduced, namely by: (1) prohibiting a court from placing on probation a person convicted of a violation of the section; (2) requiring a term of imprisonment to be imposed consecutively to a conviction for the underlying felony; and (3) prohibiting the court from reducing the term of imprisonment for the underlying felony to compensate or account for the term of imprisonment resulting from the 18 U.S.C. § 1028A violation.

At its signing, President George W. Bush touted the law as one that would "dramatically strengthen the fight against identity theft and fraud." Press Release, Office of the Press Sec'y, Identity Theft Penalty Enhancement Act of 2004 (July 15, 2004). He also signaled that the law should raise "the standard of conduct for people who have access to personal records through their work" and ensure that "those convicted of abusing and stealing from their customers serve a sentence equal to their crimes." *Id.*

Challenges

A. Defining the Scope of Predicate Felonies

In the twelve years since it was enacted, circuit courts have been confronted with a number of challenges to the Aggravated Identity Theft statute. The first reported challenge concerned the scope of cognizable predicate felonies under 18 U.S.C. § 1028A. Specifically, the defendants argued that 18 U.S.C. § 1347, health care fraud, could not serve as the underlying offense for aggravated identify theft because it is not "[a] felony violation enumerated in subsection (c)." 18 U.S.C. § 1028A(a)(1). *United States v. Diaz*, No. 07-20398-CR, 2008 WL 686961, at *1 (S.D. Fla. Mar. 12, 2008) (rejecting the defendants' argument), *report and recommendation adopted*, No. 07-20398-CR, 2008 WL 2178135 (S.D. Fla. May 22, 2008).

The same challenge was raised before the Second Circuit in *United States v. Abdur-Rahman*. 708 F.3d 98, 99 (2d Cir. 2013). There, the court held that health care fraud was a cognizable predicate felony to aggravated identity theft. *Id*. at 102. In doing so, it noted that while other circuit courts had not directly confronted an argument related to the scope of cognizable predicate felonies under 18 U.S.C. § 1028A, the Fourth, Ninth, and Eleventh Circuits, as well as several district courts, had upheld convictions of aggravated identity theft when health care fraud served as the predicate felony. *Id.* at 102 & n.1 (citing *United States v. Abdelshafi*, 592 F.3d 602, 607 (4th Cir. 2010) (noting that "health care fraud qualified as [a] predicate felony offense under 18 U.S.C. § 1028A(c)(1)"); *United States v. Bradshaw*, 433 F. App'x. 618, 619-20 (9th Cir. 2011) (summary grant); *United States v. Silvio*, No. 10-14792, 2012 WL 5373537 (11th Cir. Nov. 2, 2012) (granting a motion pursuant to *Anders v. California*, 386 U.S. 738 (1967), when a similar argument was raised on proceedings below); *United States v. Estrada-Sanchez*, 558 F. Supp. 2d 129, 131 (D. Me. 2008)).

This series of opinions validated the position of many health care fraud prosecutors who viewed the statute as an effective tool in health care fraud prosecutions.

B. The Defendant Must Know that the Identification Belongs to Another Person

The next significant challenge to the statute concerned the government's required proof regarding the defendant's knowledge surrounding the means of identification in question. In contrast with the issue of scope, circuit courts were split on the question of whether the government was required to show that the defendant *knew* that the "means of identification" which he or she unlawfully transferred, possessed, or used, in fact, belonged to "another person." *Compare United States v. Godin*, 534 F.3d 51 (1st Cir. 2008) (knowledge requirement applies to "of another person"); *United States v. Miranda-Lopez*, 532 F.3d 1034 (9th Cir. 2008) (same); *United States v. Villanueva-Sotelo*, 515 F.3d 1234 (D.C. Cir. 2008) (same), *with United States v. Mendoza-Gonzalez*, 520 F.3d 912 (8th Cir. 2008) (knowledge requirement does not apply to "of another person"); *United States v. Hurtado*, 508 F.3d 608 (11th Cir. 2007) (*per curiam*) (same); *United States v. Montejo*, 442 F.3d 213 (4th Cir. 2006) (same).

The Supreme Court resolved the issue in *Flores-Figueroa v. United States*. 556 U.S. 646 (2009). Flores-Figueroa, a citizen of Mexico, gave his employer a false name, birth date, and Social Security number, along with a counterfeit alien registration card. The Social Security number and the number on the alien registration card were not those of a real person. On appeal, Flores-Figueroa argued that the government could not prove that he *knew* that the numbers on the counterfeit documents were numbers assigned to other people. The Court concluded 18 U.S.C. § 1028A required the government to show that the defendant knew that the means of identification at issue belonged to another person. *Id*. at 657.

In classic cases of identity theft, "intent is generally not difficult to prove." *Id*. at 656. "For example, where a defendant has used another person's identification information to get access to that person's bank account, the Government can prove knowledge with little difficulty." *Id*. "Both the circumstances in which an offender obtained a victim's identity and the offender's later misuse of that identity can shed light on the offender's knowledge about that identity." *United States v. Gomez-Castro*, 605 F.3d 1245, 1248 (11th Cir. 2010).

The Court's decision in *Flores-Figueroa* did not meaningfully impact the use of 18 U.S.C. § 1028A in health care fraud prosecutions for obvious reasons. Medicare does not issue Medicare numbers or provide Medicare benefits to individuals who are not Medicare-eligible. The purpose of submitting claims using the names of Medicare beneficiaries is to obtain payment from Medicare. For Medicare to reimburse a provider, the beneficiaries identified in the claims would need to be actual Medicare beneficiaries. It would be fruitless to submit a bill for a non-existent person, much less a person who is not Medicare-eligible. *See United States v. Essien*, 530 F. App'x 291, 300 (5th Cir. 2013) (unpublished).

C. "Without Lawful Authority" Does Not Require Proof of Theft or Misappropriation

Every circuit court, save the Second and Tenth, has been confronted with a challenge to the "without lawful authority" element. Each court to address the issue has uniformly concluded that proof of theft or misappropriation is not required to show that the defendant used a means of identification without lawful authority.

The aggravated identity theft statute requires that the transfer, possession, or use of the means of identification of another person be "without lawful authority." The plain language of the phrase "without lawful authority" indicates Congress's intent to prohibit more than just the transfer, possession, or use of identification that was obtained by theft. *United States v. Hurtado*, 508 F.3d 603, 607 (11th Cir. 2007). The element "without lawful authority" does not require proof of theft, or any other illicit method of procurement, of the means of identification. *United States v. Ozuna-Cabrera*, 663 F.3d 496, 501 (1st Cir. 2011).

Every circuit court which has confronted the issue has held that theft of the means of identification is not required to trigger criminal liability under § 1028A(a)(1). *See, e.g.*, *United States v. Lumbard*, 706 F.3d 716, 724-25 (6th Cir. 2013) (the crime may be committed where the defendant purchases or otherwise obtains the identification from the legitimate holder or where the defendant obtains the permission of the person whose information the defendant misused); *United States v. Reynolds*, 710 F.3d 434, 436 (D.C. Cir. 2013) ("use . . . without lawful authority" easily encompasses situations in which a defendant gains access to identity information legitimately but then uses it illegitimately—in excess of the authority granted); *United States v. Retana*, 641 F.3d 272, 273-75 (8th Cir. 2011) (father's permission to use his social security number does not amount to "lawful authority" to excuse defendant's fraudulent use of the information to commit other crimes); *United States v. Mobley*, 618 F.3d 539, 547-48 (6th Cir. 2010) (finding a 18 U.S.C. § 1028A violation for credit card conspiracy where victims willingly provided their social security numbers); *United States v. Carrion-Brito*, 362 F. App'x 267, 273 (3d Cir. 2010) (unpublished) (permission or payment to use another's identity does not

bestow "lawful authority" on the perpetrator); *United States v. Hurtado*, 508 F.3d 603, 608 (11th Cir. 2007) (concluding that proof of theft not required for conviction).

In *United States v. Osuna-Alvarez*, the defendant urged the Ninth Circuit to construe literally the section's title, "Aggravated Identity Theft," so as to require actual theft or misappropriation of the means of identification. The court rejected the argument:

> Our sister circuits have universally rejected this argument. *See United States v. Reynolds*, 710 F.3d 434, 404 (D.C. Cir. 2013); *United States v. Lumbard*, 706 F.3d 716 (6th Cir. 2013); *United States v. Spears*, 697 F.3d 592 (7th Cir. 2012), *vacated*, 729 F.3d 753 (7th Cir. 2013) (en banc); *United States v. Ozuna-Cabrera*, 663 F.3d 496 (1st Cir. 2011); *United States v. Retana*, 641 F.3d 272 (8th Cir. 2011); *United States v. Abdelshafi*, 592 F.3d 602 (4th Cir. 2010); *United States v. Carrion-Brito*, 362 Fed. App'x 267 (3d Cir. 2010); *United States v. Hurtado*, 508 F.3d 603 (11th Cir. 2007), *abrogated in part on other grounds by Flores-Figueroa v. United States*, 556 U.S. 646, 129 S. Ct. 1886, 173 L. Ed. 2d 853 (2009); *United States v. Hines*, 472 F.3d 1038 (8th Cir. 2007). We agree with this authority and now hold that, despite its title, 18 U.S.C. § 1028A does not require theft as an element of the offense.

788 F.3d 1183, 1185 (9th Cir. 2015).

The statute simply requires the unlawful use of a means of identification during or in relation to an enumerated felony. As the Fourth Circuit aptly summarized in *United States v. Otuya*:

> [I]t is obvious that, with or without permission from its rightful owner, a defendant who uses the means of identification of another 'during and in relation to any felony violation enumerated' in the statute necessarily lacks a form of authorization recognized by law. Our holding as much places us in accord with every circuit to have addressed the question.

720 F.3d 183, 189 (4th Cir. 2013).

The Fourth and Fifth Circuits, in *Abdelshafi* and *Mahmood* respectively, have confronted this issue in the health care fraud context. *United States v. Abdelshafi* involved the owner of a medical transportation service who at times up-coded claims and at other times submitted claims for services which were not rendered. 592 F.3d 602, 605 (4th Cir. 2010). *United States v. Mahmood* involved the physician-owner of several Texas hospitals who manipulated diagnosis codes for inpatient hospital treatments without regard to the patients' actual diagnoses in order to increase reimbursements. 820 F.3d 177, 182 (5th Cir. 2016). In both cases, the defendants were charged with health care fraud and aggravated identity theft. The aggravated identity theft charges at issue were premised upon the use of the patients' information (names and health insurance numbers) to submit the fraudulent health care claims.

According to the Fourth Circuit in *Abdelshafi*, a defendant need not steal identifying information in order to be found guilty of violating the statute: "While Abdelshafi had authority to possess the Medicaid identification numbers, he had no authority to use them unlawfully so as to perpetuate a fraud." 592 F.3d at 609. The court also rejected the defendant's contention that to use another person's identifying information "without lawful authority" there must be no authority for the basic, underlying use to which it is put. The court explained that 18 U.S.C. § 1028A (a)(1) does not distinguish between "basic uses" and "excessive uses" of another person's identifying information. *Id.* at 609, n.5. Indeed, the

statute applies to *any knowing use* of another's identifying information performed without a form of authorization recognized by law. *Id*.

Like Abdelshafi, Mahmood argued that the "without lawful authority" element of 18 U.S.C. § 1028A required the government to prove that he actually stole patients' identifying information. *Mahmood*, 820 F.3d at 187. Seemingly impervious to the overwhelming circuit law opposing his position, Mahmood mistakenly relied on *United States v. Spears*, 729 F.3d 753, 758 (7th Cir. 2013) (en banc) (*Spears II*) for support. But *Spears II* did *not* decide whether "without lawful authority" requires an actual theft. *United States v. Spears*, 697 F.3d 592, 599 (7th Cir. 2012) (*Spears I*), *reinstated in part on reh'g*, *Spears II*, 729 F.3d at 755. *Spears II* is silent on the "lawful authority" element because the defendant "acknowledge[d] that he lacked 'lawful authority' to sell counterfeit permits." *Spears II*, 729 F.3d at 758. (The First Circuit in *United States v. Soto-Mateo* did not make the distinction between the Seventh Circuit's analysis in *Spears I* and *Spears II* and thus reasoned that the issue has engendered a circuit split. 799 F.3d 117, 123 (1st Cir. 2015), *cert. denied*, 136 S. Ct. 1236 (2016).)

At trial, both the government and Mahmood offered patient consent forms into evidence demonstrating that patients granted Mahmood authority to use their personal information in the course of their treatment. The patient consent forms were notable, however, for what they lacked. The consent forms did not grant Mahmood authority to use the patients' information to commit fraud. The government argued, consistent with *Abdelshafi*, that while Mahmood had authority to possess the patient's means of identification, he had no authority to use them unlawfully or in excess of the authority granted so as to perpetuate a fraud.

The Fifth Circuit agreed, joining the "circuit trend" and holding that "18 U.S.C. § 1028A does not require actual theft or misappropriation of a person's means of identification as an element of aggravated identity theft." *Mahmood*, 820 F.3d at 187. The court explained that the statute plainly criminalizes situations where a defendant gains access to a patients' identifying information lawfully, but then proceeds to use that identification unlawfully and in excess of his patients' permission. *Id*. at 187, 189.

As each court that has addressed the matter held, proof of theft or misappropriation is not required to show that a defendant used a means of identification without lawful authority. *Abdelshafi* and *Mahmood* resolved the issue in the health care fraud context, confirming that the use of a patient's means of identification in the commission of a health care fraud scheme constitutes use without lawful authority.

D. *Medlock*: The Problem of the False Premise

Woody and Kathy Medlock were the owners and operators of a non-emergency ambulance company that transported Medicare patients to scheduled kidney-dialysis appointments. *United States v. Medlock*, 792 F.3d 700, 703 (6th Cir. 2015). The Medlocks were convicted of health care fraud, aggravated identity theft, and other related crimes. *Id*. The aggravated identity theft convictions were premised upon the Medlock's use of the patients' information (names and Medicare numbers) to submit the fraudulent health care claims based upon medically-unnecessary transports. *Id*. at 705.

On appeal, the Medlocks argued that their aggravated identity theft convictions must be reversed because they did not "use" a means of identification within the meaning of 18 U.S.C. § 1028A(a)(1). The Medlocks noted that they were not alleged to have "illegitimately obtained the patients' names or

Medicare Identification Numbers, impersonated them, or otherwise stolen their identity." *Brief of Defendant-Appellant*, *United States v. Medlock*, No. 3:10-cr-0004, at *51 (6th Cir. 2014). Rather, they submitted claims to Medicare that stated that a beneficiary was transported via stretcher or draw sheet when such beneficiary had been transported in the front seat of the ambulance. *Id.* According to the Medlocks, the only allegedly unlawful "use" of the Medicare beneficiaries' means of identification was the misrepresentation of some of the factual circumstances regarding their physical location within the ambulance on the two occasions identified in charged counts. *Id.* at *56. Accordingly, they argued that the court should hold that the submission of claims to Medicare containing misrepresentations regarding the beneficiaries' physical location in the ambulance during transportation did not constitute the "use" of the means of identification of another within the meaning of 18 U.S.C. § 1028A(a)(1). *Id.* at *58-9.

The government argued that the Medlocks "used" the means of identification when they caused the submission of claims to Medicare which contained false information. *Medlock*, 792 F.3d at 705.

The court sided with the Medlocks, holding that "the Medlocks' misrepresentation that certain beneficiaries were transported by stretchers does not constitute a 'use' of those beneficiaries' *identification* under the federal aggravated-identity-theft statute, 18 U.S.C. § 1028A, because their company really did transport them." *Id.* at 708. The court reasoned that the statutory definition of "use" was narrow and contemplated the "active employment of the means of identification during and in relation to the crime charged." Id. at 706.

The basic flaw in the court's holding is that it is based upon a demonstrably false premise, namely that the rendering of services, in this case the provision of transportation, negates the use of patients' identifications under 18 U.S.C. § 1028A. According to the court's analysis:

- If the Medlocks transported the patients, then the Medlocks did not "use" the patients' identifications.
- The Medlocks transported the patients.
- Therefore, the Medlocks did not "use" the patients' identifications.

Id. at 708.

If the court is right and the Medlocks did not "use" the patients' identification, then it begs the question, how did the Medlocks manage to submit claims to Medicare without using the very pieces of information that are indispensable to a Medicare claim, specifically a patient's name and Medicare number? The court is silent on this point.

Medicare payment for an ambulance service furnished to a Medicare beneficiary is available *only if*, among other requirements, the transportation by ambulance is medically necessary, i.e., the beneficiary's medical condition is such that other forms of transportation are medically contraindicated. MEDICARE CLAIMS PROCESSING MANUAL, Chapter 15 § 10.2 (Rev. 3481, March 25, 2016). Setting this aside, the Medicare claims process requires the active employment of a patient's name and Medicare number as well as other information. If a Medicare claim is submitted without a patient's name *or* Medicare Health Insurance Claim Number (HICN), the claim will be considered incomplete and will be returned as "unprocessable." MEDICARE CLAIMS PROCESSING MANUAL, Chapter 26 § 10.1 (Rev. 3547, June 22, 2016). According to Chapter 26 of the Medicare Claims Processing Manual, the first three items which must be identified when submitting a claim are as follows:

- Item 1 - Shows the type of health insurance coverage applicable to this claim by the appropriately checked box; check the Medicare box.
- Item 1a - Enter the patient's Medicare Health Insurance Claim Number (HICN) whether Medicare is the primary or secondary payer. This is a required field.
- Item 2 - Enter the patient's last name, first name, and middle initial, if any, as shown on the patient's Medicare card. This is a required field.

Id. The Medlocks did, in fact, actively employ the means of identification in relation to and for the purpose of helping commit the crime of health care fraud when they included the means of identification in the Medicare claims.

The court offers a "simple hypothetical" that according to the court "exemplifies the flaw in the government's logic." *Medlock*, 792 F.3d at 707. In the court's hypothetical, a defendant bills his patient (or the patient's insurer) in the patient's actual name, stating that the medical service, which the defendant provided, costs $200, when it really costs $100. *Id*. According to the court, "on the government's logic, that lie would constitute a *use* of the patient's name, and so would be aggravated identity theft." *Id*.

On this point, the court is precisely correct. The health care fraud violation committed by the court's hypothetical defendant would also constitute an aggravated identity theft violation. 18 U.S.C. § 1028A(a)(1) does not distinguish between "basic uses" and "excessive uses" of another person's identifying information, nor does it distinguish between the applicability of the aggravated identity theft statute to a health care fraud scheme involving up-coding versus a health care fraud scheme involving services not rendered. *Id*. at 609, n.5. Indeed, the statute applies to *any knowing use* of another's identifying information performed without a form of authorization recognized by law. *See Abdelshafi*, 592 F.3d at 609, n.5. The statute certainly proscribes any knowing use of identifying information obtained by individuals who have access to such records in the course of their employment and who subsequently use such identifications unlawfully during or in relation to a fraud scheme, irrespective of whether or not some services are provided incidental to the fraud scheme itself.

Surprisingly, the court affirmed the substantive health care fraud convictions upon which the aggravated identity theft convictions were based. *Medlock*, 792 F.3d at 711. Counts 40 and 41, the aggravated identity theft counts, were based upon violations charged in Counts 12 and 16, health care fraud counts. In Counts 40 and 41, the government specifically alleged that the patients' information was used during and in relation to the specific health care fraud violations charged in Counts 12 and 16.

If the Medlocks did not "use" the patients' information during or in relation to the health care fraud violations charged in Counts 12 and 16, then how did the Medlocks commit health care fraud? Put another way, how could the Medlocks, or anyone else for that matter, commit health care fraud if they do not "use" a patient's identification?

At bottom, the only conclusion the court could have reached based upon the evidence and Medicare claims regulations is summarized by the following:

- If the Medlocks submitted Medicare claims, then the Medlocks "used" the patients' identifications.
- The Medlocks submitted Medicare claims.

- Therefore, the Medlocks "used" the patients' identifications.

Whether or not services were rendered—specifically, whether or not the Medlocks transported the patients, should not have had any bearing upon the court's analysis.

E. What is "Use" After *Medlock*?

Health care fraud prosecutors outside of the Sixth Circuit should continue to charge 18 U.S.C. § 1028A in appropriate cases consistent with the case law of their circuit. Health care fraud prosecutors in the Sixth Circuit will likely be limited to charging 18 U.S.C. § 1028A in cases where services are not rendered or in cases where defendants steal beneficiaries' identifications. Section 1028A charges in the *Abdelshafi* or *Mahmood* settings, where a health care provider gains access to his patients' identifying information lawfully but then proceeds to use that information unlawfully and in excess of his patients' permission, may be appropriate, particularly in the Fourth, Fifth, and D.C. Circuits. *See Reynolds*, 710 F.3d at 436.

Prosecutors may also charge 18 U.S.C. § 1028A in appropriate cases where sufficient proof exists that the defendant transferred or possessed a means of identification without lawful authority during or in relation to an enumerated felony. Prosecutors should, however, exercise caution when considering the appropriate case for a "possession" charge. Based upon the development of the case law, it is unlikely that a "possession" charge would be appropriate in the case of an otherwise legitimate provider who submits fraudulent claims using information which belongs to patients with whom he has a physician-patient relationship or for whom he provides services. Rather, a "possession" charge should ordinarily be limited to those instances when a health care provider purchases quantities of patient information belonging to patients he does not know in order to submit fraudulent claims. ("Transfer" is a term of art defined in 18 U.S.C. § 1028(d)(10) which has limited applicability in the traditional health care fraud context.)

Arguments may be made that the *Medlock* decision precludes charging 18 U.S.C. § 1028A in two distinct situations: (1) where the defendant misrepresents a patient's eligibility for the service rendered, or (2) where the defendant up-codes claims for services actually rendered. As explained above, courts should be appropriately educated on the applicable Medicare regulations and brought to the fundamental understanding that a patient's HICN and name are indispensable to a Medicare claim. In other words, every valid Medicare claim submitted requires the "use" of the patient's HICN and the patient's name.

In any case, eliminating the use of 18 U.S.C. § 1028A in the situations identified in the preceding paragraph would be a mistake. These types of cases, particularly those involving up-coding, are in the heartland of health care fraud cases involving otherwise legitimate providers like Abdelshafi, Mahmood, and the Medlocks.

The statute proscribes *any* knowing use of identifying information during or in relation to a fraud scheme, even use of that information that is obtained by individuals who have access to such records in the course of their employment, irrespective of whether or not some services are provided incidental to the fraud scheme. The statute does not make exceptions for situations involving misrepresenting eligibility for services or up-coding claims for services rendered. To the contrary, when President Bush signed the bill into law he signaled that the law should ensure that "those convicted of abusing and stealing from their customers serve a sentence equal to their crimes." Press Release, Office of the Press Sec'y, Identity Theft Penalty Enhancement Act of 2004 (July 15, 2004). This surely includes health care providers who lawfully possess identifying information but use it unlawfully so as to perpetuate a fraud.

II. Conclusion

In 2011, then-Attorney General Eric Holder called health care fraud "a problem that has reached crisis proportions." Eric Holder, Detroit Health Care Fraud Prevention Summit (March 15, 2011), https://www.justice.gov/opa/speech/attorney-general-eric-holder-speaks-detroit-health-care-fraud-prevention-summit. Since then, the Department of Justice has made notable progress in the fight against health care fraud, but much work remains. After more than twelve years, 18 U.S.C. § 1028A is still a highly effective tool in health care fraud prosecutions. Prosecutors should carefully consider the challenges facing them when making charging decisions and should be particularly mindful of the Sixth Circuit's recent decision in *Medlock*. It is inevitable that similar challenges will be raised in other circuits, but these challenges can be overcome by capable prosecutors who are versed in the law, the applicable Medicare regulations, and the specific facts of their cases.

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Recent Developments Governing "Reverse False Claims" Under the False Claims Act

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I. Introduction

The federal False Claims Act (FCA) is a powerful weapon for recovering money from health care providers and others who, among other things, submit false claims. The FCA's treble damages and penalties provisions also serve as a powerful deterrent to providers contemplating schemes to get more than they are due from the government.

The FCA has its roots in Civil War fraud but it has since been significantly strengthened and expanded in scope. Assistant United States Attorneys and other federal government attorneys around the country have taken full advantage of the FCA to pursue *qui tams* brought by whistleblower relators and cases initiated through other means. The Department of Justice obtained more than $3.5 billion in FCA settlements and judgments in fiscal year 2015. Total FCA recoveries from January 2009 to September 2015 were $26.4 billion. Federal health care programs, such as Medicare, Medicaid, and TRICARE, have proven to be fertile grounds for FCA recoveries. In fiscal year 2015, nearly two billion dollars was recovered for the U.S. Department of Health and Human Services.

The most basic example of a health care FCA case is when a provider, such as a doctor, submits an "upcoded" claim to a federal program. "Upcoding" means submitting a claim for a more expensive service or procedure than was actually done or submitting a claim for a service or procedure that was not done at all. However, submitting a "reverse false claim" is another basis of FCA liability. The name suggests how it works: the health care provider does not submit a false claim to the federal government; rather, the provider is paid something to which it is not entitled. If the provider does not timely investigate this overpayment and return it to the government, FCA liability— with its treble damages and penalties— can attach. As explained below, government attorneys now can use a reverse false claims theory increasingly more than in the past.

II. The evolution of section 3729(a)(1)(G) in the False Claims Act

The federal FCA, 31 U.S.C. § 3729, *et seq*., dates back to a time when our sixteenth president, Abraham Lincoln, occupied the White House, and it has been referred to as the "Lincoln Law". The American Civil War revealed a treasury depleted by defense contractors billing the union government for nonexistent or worthless goods and charging exorbitant prices. *United States v. McNinch*, 356 U.S. 595, 599 (1958) (citing H.R. REP. NO. 2, Part 2, 37th Cong., 2d Sess.; CONG. GLOBE, 37TH CONG., 3D SESS. 952-58). In response to this widespread fraud, Congress enacted the FCA. *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 692 (2d Cir. 2001). In its most basic application, the FCA penalizes any person who fraudulently makes a monetary claim against the federal government or deprives the government of money or property. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537, 551-52 (1943). The common understanding of liability incurred under the FCA occurs when a government payee knowingly submits either a legally or factually false request for payment. *See* 31 U.S.C. § 3729(a)(1)(A) (2016). But the FCA is far more encompassing and generally covers all fraudulent attempts to cause the government to pay out sums of money. *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008) (citation omitted).

One particular provision governs "reverse false claims." This type of claim differs from the traditional FCA claim in that it involves fraudulent action designed to *avoid* refunding *overpayments* to the government rather than fraudulently *presenting* a false claim to the government for payment. *See Si v. Laogai Research Found*., 71 F. Supp. 3d 73, 88 (D.D.C. 2014). For example, an entity has a statutory duty to pay the government back for overpayments it has received from Medicaid. *See* 42 U.S.C. § 1320a-7k(d)(1)(A) (2016) (when a person "has received an overpayment, the person shall—(A) report and return the overpayment to the Secretary, the State, ...").

The reverse false claims provision (§ 3729(a)(1)(G)) was added to the FCA when the statute was substantially amended in 1986 to combat fraud in the areas of defense and health care. *See* S. REP. NO. 99-345, at 2-4, 8 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5280; *see also Kane ex rel. United States v. Healthfirst, Inc.*, 120 F. Supp. 3d 370, 379 (S.D.N.Y. 2015). Liability arises under the reverse false claim provision when a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to an *obligation* to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an *obligation* to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G) (2016) (emphasis added). The prohibited conduct is known as a reverse false claim because "the action of the defendant results *not* in improper payment to the defendant from the Government, but rather no payment to the Government when payment is otherwise *obligated*." *United States ex rel. Branch Consultants, L.L.C. v. Allstate Ins. Co.*, 668 F. Supp. 2d 780, 811 (E.D. La. 2009) (emphasis added) (citation omitted); *see also United States ex rel. Grynberg v. Praxair, Inc*., 389 F.3d 1038, 1041 n.2 (10th Cir. 2004) ("A reverse false claim is documentation resulting in an underpayment to the Government, as opposed to a false claim, generally referring to an inflated or false bill for payment from the Government."); *United States ex rel. Atkinson v. Pennsylvania Shipbuilding Co.*, 473 F.3d 506, 513 n.12 (3d Cir. 2007) (the reverse false claims provision imposes liability for "an alleged fraudulent effort to reduce a liability owed to the government rather than to get a false or fraudulent claim allowed or paid").

The year 2009 marked a major shift in reverse false claims matters. For liability to attach, there must be a "clear" *obligation* or liability to the government. *United States ex rel. Petratos v. Genentech,*

Inc., 141 F. Supp. 3d 311, 322 (D.N.J. 2015) (citations omitted). Prior to 2009, the reverse false claims provision (then codified at 31 U.S.C. § 3729(a)(7)) stated that a person violates the FCA when he or she "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7) (1994). Under this version, the United States or a relator was required to prove that "the defendant made or used (or caused someone else to make or use) a false record [or statement] in order to avoid or decrease an obligation to the federal government." *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004) (citation omitted). "Obligation" was an undefined term and, thus, led to conflicting definitions of the term "obligation" as applied to the false claims provision. *See Kane*, 120 F. Supp. 3d at 380; *see also United States ex rel. Landis v. Tailwind Sports Corp.*, 51 F. Supp. 3d 9, 56 (D.D.C. 2014); *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, No. 13-2983, 2015 U.S. Dist. LEXIS 46929, at *41 n.10 (E.D. Pa. Apr. 10, 2015) (citing *American Textile Mfg. Inst., Inc. v. Limited, Inc.*, 190 F.3d 729, 738 (6th Cir. 1999); *United States ex rel. Hoyte v. American Nat'l Red Cross*, 518 F.3d 61, 67 (D.C. Cir. 2008); *United States ex rel. Bain v. Georgia Gulf Corp.*, 386 F.3d 648, 657 (5th Cir. 2004)). Therefore, "the reverse claims provision left a 'loophole' that excused from liability the concealment, avoidance, or decreasing of an obligation to return to the Government 'money or property that is knowingly retained by a person even though they have no right to it.'" *Kane*, 120 F. Supp. 3d at 380 (quoting S. REP. NO. 111-10, at 13-14 (2009), *reprinted in* 2009 U.S.C.C.A.N. 430, 441).

But with the enactment by Congress of the Fraud Enforcement and Recovery Act (FERA), which went into effect on May 20, 2009, the FCA's scope was modified in two significant respects. First, FERA added the specifically defined term "obligation" to the FCA. Pub. L. No. 111-21, 123 Stat. 1617, 1625 (2009) ("The amendments made by [FERA] shall . . . apply to all claims under the False Claims Act . . . ."). Under the FCA, an "obligation" is defined as "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." 31 U.S.C. § 3729(b)(3) (2016).

Second, in addition to broadening the term "obligation," FERA also eliminated the requirement that a person make or use a false record or statement to avoid, conceal, or decrease an obligation to the United States. An individual can also be liable when he or she "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government." 31 U.S.C. § 3729(a)(1)(G) (2016). "The scienter element is 'critical' to establishing liability under the False Claims Act." *United States ex rel. Ruhe v. Masimo Corp.*, 977 F. Supp. 2d 981, 991 (C.D. Cal. 2013) (citing *United States ex rel. Hochman v. Nackman*, 145 F.3d 1069, 1073 (9th Cir. 1998)). The United States or a relator can establish the scienter required for liability by either: (a) proving that the defendant made or used a false record or statement that was "material to" an obligation to pay the government; or (b) proving that the defendant "knowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G) (2016). This alternative ground exposes an individual to liability when he or she is aware of a potential obligation but knowingly elects to do nothing or take steps to avoid payment. *See* 31 U.S.C. § 3729(b)(1) (2016) (defining "knowing" and "knowingly").

III. Recent developments in the law

In 2010, Congress passed the Patient Protection and Affordable Care Act (commonly referred to as the Affordable Care Act), which included a provision obligating a person who "has received an overpayment" to "report *and return* the overpayment to the Secretary [of the Department of Health and Human Services], the State, an intermediary, a carrier, or a contractor, as appropriate . . . [within] 60 days after the date on which the overpayment was identified" or by the date on which a corresponding cost report is due. 42 U.S.C. § 1320a-7k(d)(1)-(2) (2016) (commonly referred to as the "60-day overpayment rule") (emphasis added). The failure to timely return an overpayment exposes the person, including health care providers, to liability under the FCA because any overpayment retained beyond the 60-day period constitutes an "obligation" carrying liability under the FCA. 42 U.S.C. § 1320a-7k(d)(3) (2016).

Overpayments received from Medicare and Medicaid can take many forms, such as duplicate payments, payments in excess of the allowable amount for a covered service, payments for non-covered services, and payments made by another payer with primary responsibility for the payment. The critical question becomes when has the person or provider "identified" the overpayment and, thus, triggered the 60-day period to report and return the overpayment. Congress, however, did not define the term "identify" or "identified" in the Affordable Care Act.

The meaning of "identify" and "identified" became the subject of litigation in the first action enforcing the 60-day overpayment rule for failing to return Medicaid overpayments. In 2011, a *qui tam* action was filed in the Southern District of New York alleging causes of action under the FCA and related New York state law. *Kane ex rel. United States v. Healthfirst, Inc.*, 120 F. Supp. 3d 370, 375 (S.D.N.Y. 2015). After investigating the allegations made by the relator (Robert Kane), the government and the State of New York elected to intervene as plaintiffs. *Id.*

The plaintiffs in *Kane* alleged that Beth Israel Medical Center and St. Luke's-Roosevelt Hospital Center (which both belong to a network of non-profit hospitals operated by Continuum Health Partners (Continuum)) knowingly failed to return overpayments owed to Medicaid in violation of the 60-day overpayment rule provided in 42 U.S.C. § 1320a-7k(d). *Id.* at 375-76. The government asserted that, as a result of a computer glitch, the defendants billed a private, non-profit insurance program (Healthfirst, Inc.) for services rendered to patients enrolled in Healthfirst, Inc.'s Medicaid managed-care plan and then also sought reimbursement from Medicaid for the same services. *Id.* at 375-77. Kane, an employee of Continuum, conducted an internal investigation in late 2010 and early 2011 regarding the potentially improper billings submitted to Medicaid and then he reported the findings to his managers in February 2011. *Id.* at 377. Kane identified over 900 potentially improper billings, totaling approximately one million dollars in Medicaid reimbursements. *Kane*, 120 F. Supp. 3d at 377. Continuum returned some overpayments to the New York State Department of Health beginning in April 2011, but it did not return all of the overpayments until March 2013. *Id.* at 377-78. According to the Intervenors' Complaints, Continuum violated the FCA by failing to repay all of the overpayments within 60 days after identifying the improper claims. The defendants moved to dismiss the complaints arguing, in part, the complaints failed to allege that the defendants had an "obligation" in that they were only provided notice of potential overpayments and did not identify any actual overpayments to trigger the 60-day clock. *Id.* at 384.

In this case of first impression, the district court rejected the defendants' assertion that Congress intended the term "identified" to mean "conclusively proven to be an overpayment." *Id.* at 387. The court

analyzed the term's plain meaning, the Affordable Care Act's legislative history and purpose, and the interpretation provided by the Centers for Medicare and Medicaid Services (CMS), which is the executive agency within the Department of Health and Human Services responsible for administering the Medicaid program, 42 U.S.C. § § 1395-96. The Court then determined that the 60-day period ran from the date on which the defendants were "put on notice that a certain claim may have been overpaid." *Id*. at 388. In the *Kane* litigation, the United States and the State of New York filed a stipulation and order of settlement and partial dismissal resolving the government's claims against the defendants on August 23, 2016; the litigation between the defendants and the relator remains pending. *See Kane ex rel. United States v. Healthfirst, Inc., et al.*, No. 1:11-CV-02325 (S.D.N.Y.).

On August 4, 2015, one day after the court rendered its opinion in the *Kane* litigation, the Department of Justice announced its first settlement under the FCA involving a health care provider's failure to investigate in violation of the 60-day overpayment rule. Press Release, U.S. Attorney's Office for the Southern District of Georgia (Aug. 4, 2015). In addition to agreeing to pay over $6.88 million to resolve the allegations, the provider of home nursing services entered into a corporate integrity agreement with the Department of Health and Human Services, Office of Inspector General. *Id*.

Following the court's holding in *Kane*, concerns arose that the court's interpretation of the 60-day overpayment rule would support the position that the 60-day period begins as soon as a health care provider is notified of a potential overpayment. On February 12, 2016, CMS released a final rule (RIN 0938-AQ58, CMS-6037-F) defining how the 60-day overpayment rule will be applied to Medicare Parts A and B health care providers and clarifying that "identification" of an overpayment occurs when a provider verifies an overpayment has been received, after exercising due diligence. Medicare Program; Reporting and Returning Overpayments, 81 Fed. Reg. 7653-84 (Feb. 12, 2016) (codified at 42 C.F.R. § 401.305(a)(2)). Overpayment identification includes both determining that a provider has "received an overpayment and quantified the amount of the overpayment" based on reasonable diligence. 81 Fed. Reg. 7660-61 (codified at 42 C.F.R. § 401.305(a)(2)).

Therefore, health care providers have an obligation to use "reasonable diligence" to ascertain the fact and amount of an overpayment. A six-month time frame will serve as a benchmark for how long the reasonably diligent inquiry should take absent extraordinary circumstances. 81 Fed. Reg. 7662 (codified at 42 C.F.R. § 401.305(a)(2)). But if the provider fails to exercise reasonable diligence, then the 60-day period starts running on the date the provider received information about the potential overpayment. 81 Fed. Reg. 7661 (codified at 42 C.F.R. § 401.305(a)(2)). CMS defines "reasonable diligence" to include "both proactive compliance activities to monitor claims and reactive investigative activities undertaken in response to receiving credible information about a potential overpayment." *Id.* The final rule also clarified that the length of the "lookback period" for when an overpayment must be reported and returned is six years, rather than ten years, of the date the overpayment was received. 81 Fed. Reg. 7671-74 (codified at 42 C.F.R. § 401.305(f)). Overall, the final rule solidifies the high expectations for health care providers to exercise reasonable diligence and timely return any overpayments.

IV. Conclusion

Federal government attorneys who handle FCA matters have an opportunity and an obligation to recover funds for taxpayers and to deter those tempted by upcoding schemes. With recent changes in the law governing reverse false claims, they are now even better equipped and have the tools necessary to recover from providers who receive overpayments from federal programs but fail to timely investigate and return those payments.

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Effective Plea Negotiations in Health Care Fraud Cases

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I. Introduction

There are few things more frustrating, in my opinion, than having the defendant in any significant fraud or white collar crime case plead guilty right before the scheduled trial. You and your agents have worked together for months (and probably a lot longer) to investigate and develop a solid case, and you have accomplished the most important goal that you set for the prosecution—your defendant has accepted responsibility for his or her crime. In the process, though, you and your agents probably spent hundreds of hours in trial preparation, almost all of which suddenly feels like a waste of time. This is just about the least efficient use of our resources, especially in a small district like mine, where trial preparation necessarily diverts attorneys, support staff, and agency personnel away from other work.

National data may suggest that the defendants in fraud and white collar crime cases (including health care fraud) plead guilty *slightly* less often than defendants overall. (*See* Figure 1 below.) But health care fraud defendants do plead guilty, the vast majority of the time, and the conviction rate in fraud and health care fraud cases are comparable to the rates in many other case types. (*See* Figure 2 below.)

Figure 1.

Defendants Who Pled Guilty as a Percent of Total Guilty—By Program Category[3]	
Average, 2012—2016	
Program Category	Percentage
Immigration	99.6
OVERALL	97.6
Regulatory Offenses	96.3

[3] All data and program category descriptions, for both Figure 1 and Figure 2, taken from the Administrative Office of the U.S. Courts, *Statistical Tables for the Federal Judiciary*, Table D-4 ("U.S. District Courts—Criminal Defendants Disposed of, by Type of Disposition and Offense"), for the calendar years 2012 through 2015.

Property Offenses	96.2
Drugs (Overall)	95.8
Firearms & Explosives	95.8
Fraud (Overall)	95.7
General Offenses	95.4
Violent Offenses	93.5
Health Care Fraud	87.6

Figure 2.

Conviction Rate	
Average, 2012—2016	
Program Category	Percentage
Immigration	97.1
Firearms & Explosives	92.2
Fraud (Overall)	92.4
Drugs (Overall)	91.8
OVERALL	91.0
Health Care Fraud	88.5
Property Offenses	88.4
Violent Offenses	88.2
General Offenses	81.2
Regulatory Offenses	81.2

Now, let me be absolutely clear. I fully recognize that in some cases, there may simply be nothing you (or anyone else) can do to reach an acceptable resolution prior to the morning of trial. In many cases, the sides are just too far apart, and trial is a necessity. But, again, nearly all of the cases end in a guilty plea. I am most interested in cases in which the defendant eventually decides to accept responsibility and plead guilty, but waits to do so until just prior to trial. For several years I have been interested—some of my colleagues might say obsessed—with figuring out ways to reduce this inefficiency.

In the article below, I offer some of the things we have learned in our district and some of the ideas I have tried in the cases in which I have been involved, either as the assigned prosecutor or as counsel to other prosecutors handling the cases. We are fortunate to have a Medicare Fraud Strike Force in our district, which since approximately 2010, has been a valuable resource in our effort to investigate and prosecute health care fraud cases. Our cases have ranged from straightforward prosecutions of small durable medical equipment-supply companies to our district's recent prosecution of seventeen defendants who operated a group of community mental health centers and submitted more than $258 million in Medicare claims, with numerous one- or two-defendant cases involving a variety of schemes as well. Some of these ideas may already be standard practice in your districts, or they may be impractical. But I hope that you will find at least one or two of them helpful.

II. Be Proactive About Explaining Your Case and Evidence to The Defense.

Health care fraud cases are not the type of case where you can dump your discovery materials on the defense counsel and then forget about the case for a month, or until the substantive motion filing deadline set by the Court. In fact, well before you charge the case, I think one key step to take is to begin thinking about how you will organize your discovery. As I was thinking about how to put together this article, I reached out for input from a number of experienced defense attorneys in my district who handle these types of cases and who have been able to successfully and efficiently work with prosecutors in my district (and others) to reach pleas. Across the board, they unanimously cited a logical, user-friendly discovery production as one of the most valuable steps we as prosecutors can take to move our cases forward. Depending upon the case, this may mean that the discovery is organized by defendant, searchable or electronically "bookmarked," and/or accompanied by a clear index.

As part of this effort, we often identify our key documents—and not a box full of 5-inch binders—but the very best documents that most clearly prove the case. Of course, you will probably have a good idea of what these documents are by the time you charge the case; so an even better practice may be to have these documents identified before discovery begins and then to segregate them from the rest of your discovery and produce them to defense counsel separately. Assuming that you do not want to do that, however—and in some situations, there are good reasons why that may be the case—I also think you are making a mistake if you do not begin identifying and organizing them until it is time to assemble your trial exhibits.

Moreover, we typically offer to meet with defense counsel, with or without the defendants, very early in the litigation to discuss the key documents and other issues in the case. If you do not believe that defense counsel has a genuine interest in working with you to explore a reasonable resolution, then, of course, this step may be one to skip. But in most cases I am not sure there is any disadvantage to being willing to outline the strengths of your case early on. Some may have the impression that defense attorneys like to try to sandbag the prosecution—expressing just enough interest in a meeting to persuade us to reveal our best evidence, without any real interest in a plea, and attempting to gain some tactical advantage for the trial that they are anticipating all along.

I am not so naïve as to believe that this never happens, but I do believe that it is incredibly rare. Assuming that we have a strong case, which we should and usually do, few reputable defense attorneys should want to take a weak case to trial, when the likelihood of a conviction is very high. The most probable result—a conviction after trial—is not just bad for the defendant but also bad for defense counsel. The defense attorney not only failed to secure a good result for his client, but he may also have invested significant time for which the client did not pay, re-scheduled other court hearings and/or trials, and lost out on new business and new clients. As one very experienced defense attorney (and former federal prosecutor) told me, "my main message to a prosecutor would be that I do not want to get whipped in court." No defense lawyer has ever told me that there was any upside or benefit to him in taking a weak case to trial and losing.

There are potential advantages to assembling and disclosing your key documents in the early stages of discovery. You may be required to disclose your exhibits before trial anyway and, if so, you will have eliminated a project that can take a lot of time in the last few weeks before trial. Moreover, if the case ultimately heads to trial, the fact that you have already disclosed your key documents may help you defeat a last-minute defense "motion to continue" filed at the late stages of the litigation.

Some will try to tell you that you are doing the defense attorney's work for him. I think this is short-sighted. I also think that we, as prosecutors, sometimes operate under the impression that our practice is a lot more like the practice of our colleagues in the defense bar than it really is. Some of the data that I have seen reflects that, generally speaking, AUSAs who handle white collar matters may be assigned a few dozen matters at a time. Of course, some of these matters may be in the very early stages of the investigation or awaiting sentencing, where there may not be as much work for the AUSA to really do. In my district, at least, caseloads among the defense bar are much, much higher. I conducted a primitive, unscientific poll, for purposes of this article, of a handful of experienced defense attorneys who handle health care fraud cases in my district: their caseloads ranged from 30 to well over 100 matters at a time. All of these attorneys handle cases in both federal and state court. A few try to focus on cases in the same metropolitan area—*i.e.*, the federal district court where my office is located and the state courthouses located in our parish, or county, and the neighboring areas—but this still involves at least four or five different courthouses. Most of the attorneys routinely have court appearance in several different courthouses on the same day. Some of the attorneys also practice in neighboring federal judicial districts and in other states as well. If you can help defense counsel focus on the most important evidence early in the case and save them time by avoiding less-important evidence you may also have produced, chances are you will be saving yourself time later, too.

Finally, do not underestimate the significant advantage that we derive from our access to information from our agents. I cannot count the number of times I have been stuck wading through documents and unable to locate the information I need; a quick phone call to the case agent usually gets me the answer within minutes. Defense counsel's go-to source for information is often the defendant, however, whose answers may not be consistent with the evidence, but which defense counsel may or may not recognize at the time. (Of course, if the defendant is in custody, it may also take the defense counsel a lot longer to get the answers in the first place.) This, too, fosters inefficiency.

In one recent case (though it was an environmental case, not health care fraud), I agreed to be on "stand-by," essentially as defense counsel met with his client to discuss a proposed plea agreement. I worked on other matters in my office but periodically received calls throughout the afternoon during which I fielded questions about the agreement and tried to point defense counsel to the evidence that undermined whatever story on which the defendant had hoped to rely. Of course, I could have dismissed

the idea, scheduled my own meeting with defense counsel to discuss all of the questions that came up in his session with his client, and then waited for defense counsel and the defendant to meet again, days (or weeks) later, to review what I had discussed with the defense counsel. In that scenario, however, I would likely have wasted dozens of hours in trial preparation as I waited to hear back. Compressing the time that it takes to answer defense counsel's questions and get his or her resulting advice to the client can be one way to save significant time.

III. Run The Guidelines Over and Over Until You Have A Good Sense Of How They May Apply In Your Case.

Hopefully, this will seem obvious to most. But projecting how the guidelines may apply to your case involves a lot more than simply circling the total amount of the defendant's Medicare claims, circling a few specific offense characteristics, and then looking at the total offense level with and without acceptance.

A. Start With Loss: Give Some Early Thought To The Range of Potential Loss Amounts and Whether You Will Need Additional Evidence to Prove The Loss You Believe Is Appropriate.

In many cases the loss figure will be the largest piece of the guidelines range. This part of a health care fraud case has changed significantly over the past five years, at least in my view. When I was handed my first health care fraud case back in 2009, a garden-variety case involving fraudulent claims for power wheelchairs, the loss seemed easy. All the case agents and I had to do was open the claims database, isolate the billing codes that our evidence proved had been fraudulently used, and note the total amount of money that the defendant billed using those codes.

These days, the analysis is different. Estimating the loss figure for guidelines purposes became more difficult, at least in the Fifth Circuit, after *United States v. Isiwele*, 635 F.3d 196 (5th Cir. 2011). In that case, the court narrowed the concept of intended loss, holding that the amount fraudulently billed to Medicare/Medicaid is "prima facie evidence of the amount of loss [the defendant] intended to cause," but noting that the parties may introduce additional evidence that the amount billed "either exaggerates or understates" the defendant's intent. *Id.* at 203. This "fact-specific, case-by-case inquiry into the defendant's intent," *Id.*, will likely mean that the loss figure ultimately accepted in these cases will run the spectrum between the actual amount paid by Medicare, *see, e.g.*, *United States v. Turner*, 620 Fed. Appx. 249, 257 (5th Cir. 2015) (explaining that the PSR "calculated the actual loss . . . to be the total amount of the fraudulent claims *paid* by Medicare to all three home-health agencies involved in the scheme"), to the total amount billed, *see, e.g.*, *United States v. Imo*, 739 F.3d 226, 241 (5th Cir. 2014) (affirming the district court's finding that the defendant intended to cause a loss equal to the entire amount billed to Medicare). Many cases may land somewhere in between. *See, e.g.*, *United States v. Alaniz*, 569 Fed. Appx. 219 (5th Cir. 2014) (affirming the district court's finding that intended loss was "equal to only 80 percent of the billed amount").

Another recent case, *United States v. Mahmood*, 820 F.3d 177 (5th Cir. 2016), may further complicate the loss determination. In that case, based largely on a comment to U.S. SENTENCING

GUIDELINES § 2B1.1 3(E)(i) (U.S. SENTENCING COMM'N 2015), the court held that the defendant is entitled to a credit against the loss figure equal to the fair market value of services rendered to the beneficiaries if Medicare "would have paid for the services . . . but for [the defendant's] fraudulent billing." *Id* at 193. In *Mahmood*, the defendant fraudulently billed for services related to medications provided at his hospitals, but "neither party disputed that the patients needed those medications or that the insurance companies would have had to pay for the medications had the defendant not fraudulently billed them." *Id.* On one hand, the court agreed that if Medicare "would not have paid for the services . . . then [the defendant] is entitled to no such credit." *Id.* at 194 (citing *United States v. Jones*, 664 F.3d 966, 984 (5th Cir. 2011)). Where the defendant actually provided a service that *would* have been covered by Medicare, absent the fraudulent billing, the loss calculation under Section 2B1.1 must account for the fair market value of the service. *Mahmood*, 820 F.3d at 193 (citing *United States v. Klein*, 543 F.3d 206, 213-14 (5th Cir. 2008)).

In short, figuring out your loss theory early is probably wise for several reasons. If you intend to argue that the intended loss figure is the entire amount billed to Medicare (either overall or across a set of billing or procedure codes), you may want to take a few extra steps during the investigative phase, or shortly after the case is charged, so that you will be prepared to rebut any defense argument that your figure exaggerates the defendant's subjective intent. Then, once you believe you have that evidence lined up, it is probably wise to make sure that defense counsel is aware of the loss theory you intend to pursue and the evidence that supports your theory.

B. Research The Specific Offense Characteristics and Enhancements to Identify Those That Are Likely to Apply.

Analyzing the loss figure is just one step. There are also several specific offense characteristics that can apply, depending upon the facts of your case. Collectively, these characteristics and enhancements have the potential to have just as much of an impact on the guidelines range as the loss amount. The better you are able to predict, based on current law in your circuit, which enhancements are likely to apply, the more informed your plea discussions will be, and the less uncertainty you will face as you (hopefully) approach the sentencing date.

In the Fifth Circuit, the offense level adjustment for offenses that involve "sophisticated means,", usually applies. U.S. SENTENCING GUIDELINES § 2B1.1(b)(10) (U.S. SENTENCING COMM'N 2015). *See, e.g.*, 620 Fed Appx. 249, 259-60 (2015) (where the defendant, a registered nurse, was convicted of health care fraud and conspiracy to commit health care fraud arising out of a scheme to purchase stolen personal information, used the information to recruit patients for home health companies, and then submitted false Medicare claims in the patients' names, affirming the court's finding that the defendant's scheme employed "sophisticated means," rejecting the defendant's argument that there was "nothing complex or intricate about" her crime and comparing the defendant's conduct to several examples discussed in the comments to U.S. SENTENCING GUIDELINES § 2B1.1 (U.S. SENTENCING COMM'N 2015); *United States v. Alaniz*, 569 Fed. Appx. 219, 220 (5th Cir. 2014) (where the defendant pled guilty to conspiracy to commit health care fraud based on his involvement with a company that submitted false Medicare and Medicaid claims for power wheelchair claims and accessories, affirming the sophisticated means enhancement based on the fact that the defendant "created multiple false documents" to support the claims).

This provision was narrowed slightly in 2015. Previously, the enhancement applied whenever the "the offense otherwise involved sophisticated means," but since November of 2015, it only applies where "the offense otherwise involved sophisticated means *and* the defendant intentionally engaged in or caused

the conduct constituting sophisticated means." U.S. SENTENCING GUIDELINES § 2B1.1(B)(10) (U.S. SENTENCING COMM'N 2015) (emphasis added). I have yet to see any cases in which the amendment made any difference, but it seems like it should make a difference, and the case law may bear this out over time.

Similarly, for defendants who owned, operated, or managed the health care company at issue, the Fifth Circuit has consistently held that the "position of trust" enhancement found at U.S. SENTENCING GUIDELINES § 3B1.3 (U.S. SENTENCING COMM'N 2015) applies. *See, e.g.*, *United States v. Nowlin*, 640 Fed. Appx. 337, 2016 U.S. App. LEXIS 3398 (5th Cir. Tex. Feb. 25, 2016), (affirming the district court's application of the position-of-trust enhancement to the defendant, the owner and operator of a durable medical equipment supply company); *United States v. Njoku*, 737 F.3d 55, 78 (5th Cir. 2013) (affirming the position-of-trust enhancement where the defendant, a supervisory nurse at a home health company, occupied a position of trust under Medicare, which relies on RNs to accurately complete patient questionnaires and certify and re-certify plans of care); *United States v. Read*, 710 F.3d 219, 233-34 (5th Cir. 2012) (where the defendants were convicted of health care fraud and other offenses arising out of fraudulent claims they submitted through their ambulance business, affirming the district court's application of the position-of-trust enhancement, noting "clear and longstanding precedent" that supports the enhancement's application "to Medicare and Medicaid providers when sufficient evidence supported a finding that they had substantial discretion to submit claims that they knew would not be scrutinized"); *United States v. Miller*, 607 F.3d 144 (5th Cir. 2010) (holding that the defendant's "position and authority as owner of a licensed DME [durable medical equipment] provider 'involve[d] the type of complex, situation-specific decision-making that is given considerable deference precisely because it cannot be dictated entirely by, or monitored against, established protocol" and further explaining that "by granting [the defendant] a license to provide durable medical equipment, the government entrusted her to provide good faith, accurate information in seeking reimbursement from Medicare and Medicaid"); *see also United States v. Gieger*, 190 F.3d 661, 665 (5th Cir. 1999) (upholding the district court's application of the enhancement to defendants who operated a transportation service for Medicare beneficiaries, explaining that the defendants "carried out their fraud by abusing a . . . position of trust with medical insurers").

Many of the defendants in these cases occupy an aggravating role within the fraudulent scheme and qualify for an enhancement under U.S. SENTENCING GUIDELINES MANUAL § 3B1.1 (U.S. SENTENCING COMM'N 2015). *See United States v. St. Junius*, 739 F.3d 193, 208-09 (5th Cir. 2013) (affirming the court's application of a 3-level enhancement under Section 3B1.1(b), where the defendant was not the "true leader" of the criminal enterprise, but "played a significant role in the functioning" of the medical supply company and profited more than nearly anyone else; noting that the defendant "knowingly and willingly led others to believe" that she owned the company and "signed Medicare documents, signed and issued paychecks, and sent correspondence"); *United States v. Mauskar*, 557 F.3d 219, 235 (5th Cir. 2009) (affirming the district court's 3-level enhancement under Section 3B1.1(b) to the defendant, who was convicted of Medicare and Medicaid fraud and directed and supervised other employees); *see also United States v. Nowlin*, 640 Fed. Appx. 337, 2016 U.S. App. LEXIS 3398 (5th Cir. Tex. 2016); *Turner*, 620 Fed Appx. at 258-59.

Other offense level adjustments and enhancements that may apply include the following:

- U.S. SENTENCING GUIDELINES MANUAL § 2B1.1 (b)(2) (U.S. SENTENCING COMM'N 2015), based on the number of victims (*see, e.g. United States v. Nowlin*, 640 Fed. Appx. 337, 2016 U.S. App. LEXIS 3398 (5th Cir. Tex. 2016));
- U.S. SENTENCING GUIDELINES MANUAL § 2B1.1 (b)(7) (U.S. SENTENCING COMM'N 2015), which applies to certain health care offenses;
- U.S. SENTENCING GUIDELINES MANUAL § 2B1.1 (U.S. SENTENCING COMM'N 2015), which can apply to the use of one "means of identification" to obtain another "means of identification" (*See United States v. Gonzalez*, 644 F. App'x 456 (6th Cir. 2016).
- U.S. SENTENCING GUIDELINES MANUAL § 3A1.1 (U.S. SENTENCING COMM'N 2015), based on offenses targeting "vulnerable victims" (*see United States v. Patel*, 485 Fed. Appx. 718, 718-719 (5th Cir. 2012) (affirming the vulnerable victim enhancement where some of the beneficiaries were "uniquely vulnerable," and noting that the enhancement does not require the defendant to have "targeted" the victims because of their vulnerability but only to have knowledge of their status); and
- U.S. SENTENCING GUIDELINES MANUAL § 3C1.1 (U.S. SENTENCING COMM'N 2015) enhancement for obstruction of justice. *See Alaniz*, 569 Fed. Appx. at 220.

C. Run Guidelines Scenarios to Estimate the Defendant's Potential Exposure.

Once you have an idea as to which enhancements might apply in your case, I think it makes sense to run a number of different scenarios, including: (1) a "best case" scenario for the defendant (in the event of a timely plea by the defendant, full cooperation, and, perhaps just as importantly, no additional investigation by the case agents); (2) a reasonable projection of what the defendant may face if he waits until just before trial to plead; and then (3) a couple of different trial-based scenarios that may vary based on the specific evidence that may be admitted, whether the defendant testifies and is found to have obstructed justice, etc. The chart below (Figure 3) provides an example:

Figure 3.

		Plea Scenario A	Plea Scenario B	Plea Scenario C	Trial Scenario A	Trial Scenario B
1	Base offense level (2B1.1(a)(2))	6	6	6	6	6
2	Loss (2B1.1(b)(1))	+16 (>$1.5M)	+16 (>$1.5M)	+18 (>$3.5M)	+18 (>$3.5M)	+20 (>$9.5M)
3	HC offense (2B1.1(b)(7))	+2	+2	+2	+2	+2
4	Sophisticated means (2B1.1(b)(10))	0	+2	+2	+2	+2
5	Vulnerable victims (3A1.1)	0	0	0	+2	+2

6	Aggravating role (3B1.1)	0	0	+4	+4	+4
7	Position of Trust (3B1.3)	+2	+2	+2	+2	+2
8	Timely plea and acceptance (3E1.1)	-3	-3	-3	0	0
9	Obstruction (3C1.1)	0	0	0	0	+2
10	Final offense level	23	25	31	36	40
11	Guidelines range	XXX	XXX	XXX	XXX	XXX

U.S. SENTENCING GUIDELINES MANUAL §§ 2B1.1, 3B.1, 3C1.1, 3E1.1 (U.S. SENTENCING COMM'N 2015).

You can create a similar table with as many additional rows and columns as you believe would be helpful. Depending upon the facts of your particular case, there may be additional Chapter 2 specific offense characteristics and Chapter 3 adjustments that could arguably apply. However you conduct the analysis, I think one of the purposes of the exercise is to be able to divide the enhancements and adjustments into the following three general categories: (1) those that are likely to apply; (2) those that are likely to not apply; and (3) those that are unclear, and which may or may not apply, based on additional investigation.

With respect to the loss amount, my agents and I spend time performing a kind-of "stress test" on our loss assumptions. That is, we will look at what we believe may be the loss figure in a couple of different ways—by billing code, by date range, by defendant—to make sure we recognize as many of the potential outcomes as possible. In some cases, we also adjust the figure that we use as the percentage of claims that we believe we can prove to be fraudulent. For instance, we may be fairly confident that we can establish the fraudulent nature of 100 percent of the claims for a particular code, or 100 percent of the claims within any particular subset of the claims data. If we spot some weakness in our position, however, we will re-run our loss figures using 90 percent, 75 percent, and so on, to see if the resulting changes to the dollar amount make any difference under the loss table.

The overarching objective is to make sure that you can have an informed, educated discussion about a plea if the defendant and his attorney express an interest in such a discussion. More specifically, though, this analysis may tell you that the loss figure is not likely to make much of a difference in the case. It may be that the defendant is going to be in the same loss range or within a range or two no matter how many beneficiaries you interview and no matter how you slice the data. In that case, you can save a lot of time by moving onto other issues in the case.

Moreover, like some of the other ideas discussed here, this work can be helpful even if it does not lead to a plea. You may find that there are outstanding questions that you want to shift resources toward answering in anticipation of trial and/or sentencing. You may realize, for instance, that all of your loss estimates come in at just under $3.5 million, but by conducting a few additional interviews, you may be able to reach the "more than $3.5 million" threshold at U.S. SENTENCING GUIDELINES § 2B1.1(b)(1)(J) (U.S. SENTENCING COMM'N 2015) and capture two more offense levels. Spotting that issue early in the case gives you the most opportunity to address it, as opposed to waiting until the Pre-Sentence Investigation Report is released, realizing how close you are to the next threshold, and then scrambling to see if you have sufficient evidence in-hand to support an objection to the Pre-Sentencing Report (PSR).

IV. Have a Candid Conversation with Defense Counsel About the Guidelines.

It is not unreasonable to suspect that there are cases in which the defendant might have pled guilty, or might have pled guilty earlier, had he had an accurate projection of the guidelines range he would likely face. There are also cases, I believe, in which the defendant pled guilty based on an unrealistic projection of the range.

The first situation is obviously undesirable. You, your agents, defense counsel, and the Court have invested resources that could have been saved if the defendant had the information that mattered to him most.

But I would argue that the second situation is almost as bad. In some cases, you may be tempted in your plea discussions to undersell the potential sentence; I would argue that doing so is a mistake in the long run for a number of reasons, and probably not advisable in the short-term either. My anecdotal guess is that a defendant who pleads guilty and then receives a sentence far longer than what he was expecting to receive when he decided to plead is far more likely to tie up you and your colleagues with appeals, ineffective assistance claims, and other post-conviction motions. More importantly, your professional reputation is at stake, particularly if you practice in a small district or a district, such as mine, where you are very likely to have future cases with the same defense attorney.

Accordingly, once I have done the guidelines analysis above, I offer to discuss my analysis in detail with defense counsel. I generally do not let defense counsel retain copies of my notes, but I do let them see my notes, if they would like. Depending upon your relationship and level of trust with the defense attorney, you will either know that he will understand (and convey to his client) that your projections are just your own, non-binding estimates for discussion purposes, or you may have to consider making that point more formally and expressly, ahead of time.

Of course, your projections will not always be accurate. I have run the guidelines in hundreds of cases, and the PSR rarely matches my notes exactly. I often miscalculate the defendant's criminal history category, and it is not uncommon that I miss an offense characteristic or cross-reference or two. But, in general, you want to minimize the number of big surprises contained in your PSRs.

In one recent case (though not a health care fraud case), the PSR, when released, reflected a guidelines range about twice as high as what I had envisioned. The most significant surprise was that the Probation Office applied a 6-level enhancement (U.S. SENTENCING GUIDELINES § 3A1.2 (U.S.

SENTENCING COMM'N 2015)) that neither I nor the defendant's lawyer had ever considered. After doing some research, I was comfortable that the Probation Office had gotten it right, and the defendant's lawyer and I had just missed the issue entirely. And, to be clear, this was not an unwelcome development for the United States; the PSR, if adopted by the court, would help keep the defendant, a dangerous offender, in custody for significantly longer than I originally envisioned. But one of my first calls was to the defendant's lawyer, to make sure he understood why I thought it was that I never considered the enhancement at issue. This was not our first case together, and I knew it would not be our last, and trying to "sneak" a plea agreement through based on incomplete information is not something I recommend you ever try to do.

V. Be Flexible.

Years ago, transitioning into health care fraud from firearms and narcotics cases and other types of white collar work, I think I had fallen into a pattern of thinking that drafting the factual basis was an afterthought. In my mind, I had already described the crime quite well in the indictment, and since the defendant had decided to accept responsibility and plead guilty (or was seriously considering doing so), surely the description I used in the indictment was 100 percent accurate in all respects and would be perfect to use as the factual basis to support the guilty plea. A few dicey re-arraignments later, I began to appreciate the need for more flexibility.

Besides, you can waste a lot of time going back and forth with defense counsel (and, in between those conversations, waiting for him to go back and forth with his client) over language or details that are just not very important. We need to prepare an "adequate factual basis" that assures against a conviction of someone who is not guilty. *See* U.S. ATTORNEYS' MANUAL § 9-27.430(B)(2) (2009). We do not need to write novels. There is no need to include every minor detail that appeared in the indictment, which can be a hard habit to break, especially if you are used to working from the indictment as your source document when you sit down to draft the factual basis. Depending upon your relationship with the defense lawyer on your case, the most efficient way to prepare a suitable factual basis may be to sit down with the lawyer, fire up a laptop computer, and put together something that both of you can live with in one session.

Finally, when it comes to sentencing enhancements (and even the loss figure), you should consider agreeing to concede in your plea agreement issues that you will likely have to concede at sentencing anyway. There is no significant downside, in my view. Defense attorneys will tell you that any additional certainty that they can provide to their clients—or any reduction of the uncertainty—has value to them. Besides, in those rare instances where you are wrong—if, for instance, the Probation Office identifies facts that would support an enhancement that you were not aware of—the court is not going to be bound by your stipulation anyway.

VI. Conclusion

When you proceed to trial, you lose sleep, miss family events, and the progress you and your agents may have been making on other investigations probably grinds to a halt. In those cases, where a trial is necessary, we all understand those sacrifices and stand ready to make them. In the event that you

are not already trying some of the ideas discussed above, though, I hope you will consider them going forward. If they work for you, you may just be able to charge one of your other cases that would otherwise have had to wait.

ABOUT THE AUTHOR

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Parallel Investigations and Prosecutions in Anti-Kickback Cases Involving Healthcare Providers

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I. Introduction

In 2014, pursuant to a global resolution involving civil and criminal forfeiture, as well as various State claims, DaVita Healthcare Partners Inc. (DaVita) paid $400,000,000.00 to resolve allegations of violations of the federal Anti-Kickback statute that were investigated, in parallel investigations, by the Civil Division and Criminal Division of the United States Attorney's office for the District of Colorado and the Department of Justice Civil Frauds Section. Additionally, the HHS Office of Counsel to the Inspector General (OCIG) negotiated a Corporate Integrity Agreement requiring, among other things, monitoring of DaVita's business practices by independent auditors. The resolution was the largest-ever resolution that involved only Anti-Kickback allegations. This article will identify considerations that investigators and prosecutors must take into account as they conduct parallel investigations involving the federal health care Anti-Kickback Statute (AKS). Because the AKS has such broad application to numerous business arrangements and transactions, this article will only address those issues that are common to these sorts of investigations.

II. The Federal Anti-Kickback Statute

The federal Anti-Kickback Statute (AKS) criminalizes the payment of benefits or remuneration, direct or indirect, in exchange for a referral relating to a federal healthcare program:

1. Title 42, United States Code, Section 1320a-7b(b)(1)(A) and (B) prohibits health care providers from knowingly and willfully soliciting or receiving any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

2. Title 42, United States Code, Section 1320a-7b(b)(2)(A) and (B) prohibits health care providers from knowingly and willfully offering or paying any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

Federal Healthcare Programs include the Medicare and Medicaid programs which are administered by the Center for Medicare and Medicaid Services ("CMS") within the Department of Health and Human Services on the federal level. Medicare provides health insurance for, among others, persons aged 65 and older, certain younger people with disabilities, and people with end-stage renal disease. The Medicare program was established by Congress in 1965 when it enacted Title XVIII of the Social Security Act.

A person who offers or pays remuneration to another person violates the Anti-Kickback Act so long as one purpose of the offer or payment is to induce federal healthcare program patient referrals; it is not necessary to show that this was the primary purpose. *United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000); *See* also *United States v. Greber*, 760 F.2d 68, 69 (3rd Cir. 1985). Individuals need only solicit or receive payments as an inducement, that is, as encouragement, to refer patients to be liable under the AKS. *See United States v. Picciotti*, 40 F.Supp.2d 242 (D.N.J. 1999). The concept of remuneration is broad. “Cash payments” paid by a physician and nurse employed by a medical facility for referral of Medicare cardiac patients are an obvious form of remuneration in violation of the AKS. *United States v. Polin*, 194 F.3d 863 (7th Cir. 1999). “Rebates” may constitute an offer to pay a bribe or kickback for referrals of federal healthcare benefit program business. *See United States v. Duz-mor Diagnostic Laboratory, Inc.*, 650 F.2d 223 (9th Cir. 1999). “Consulting contracts” used to camouflage underlying agreement to give remuneration for patient referrals violate the AKS. *United States v. LaHue*, 261 F.3d 993 (10th Cir. 2001). Similarly, a “services contract” used to facilitate payments by hospitals to physicians for ostensible services when they performed little or no services violates the AKS. *United States v. Anderson*, 85 F.Supp. 1047, 1057 (D.Kan. 1999).

A violation of the AKS also creates civil liability under the Federal False Claims Act, 31 U.S.C. §§ 3729-33 (FCA). *See* also, 42 U.S.C. 1320a-7b(g). The FCA provides for civil damages of three times the amount of any false claim submitted to the United States, as well as penalties of $10,781 to $21,563 for each false claim submitted. A defendant liable under the AKS has exposure under the FCA for three times the amount of all claims tainted by the payment of a kickback. For those businesses that structure their referral networks under a cloud of kickbacks, litigation under the FCA can be a "bet the company" proposition.

In addition, several other statutes provide criminal liability in association with the AKS, including Title 18 Conspiracy (18 U.S.C. § 371); the Money Laundering Statutes (18 U.S.C. §§ 1956 and 1957); and even the Mail Fraud Statute (18 U.S.C. § 1341). Title 18 United States Code §§ 371 and 2 prohibit conspiracy to commit federal offenses and aiding and abetting, including the objects of violating the AKS by conspiring to knowingly and willfully violate Title 42, United States Code §§ 1320(b)(1) and (2) by offering, paying, soliciting or receiving remuneration, directly and indirectly, overtly and covertly, in cash or in kind. *McClatchey*, 217 F.3d at 834. Also, Title 18 U.S.C. § 1956(c)(7)(F) provides that "specified unlawful activity" as a predicate to money laundering includes any act or activity constituting an offense involving a Federal health care offense. Title 18 § 24(a) provides that, as used in Title 18, the term "Federal health care offense" includes, among other things, a violation of the AKS, section 1128B of the Social Security Act, 42 U.S.C. § 1320a–7b. Finally, violations of the AKS may support criminal liability for mail fraud and, presumably, wire fraud. *See United States v. Carroll*, 320 F.Supp.2d 748 (S.D. Ill. 2004).

III. Parallel Investigations - Policy of the Department

In January 2012, the Attorney General issued a mandate to criminal prosecutors and affirmative civil enforcement attorneys to consider parallel proceedings between criminal, civil, administrative, and regulatory investigations at every stage of the investigation and prosecution, whenever practicable. *See* U.S. Attorneys' Manual § 1-12.000 (Coordination of Parallel Criminal, Civil, Regulatory, and Administrative Proceedings). Notably, "[e]very United States Attorney's Office and Department litigating component should have policies and procedures for early and appropriate coordination" of all government remedies.

This directive dovetails with the more recent memorandum from the Deputy Attorney General on September 9, 2015, to address Individual Accountability for Corporate Wrongdoing (the "Yates Memorandum"). In general, a parallel proceeding is naturally well suited to address both the liability of a corporation through civil proceedings, as well as to address the culpability of individuals through criminal prosecutions.

Successful implementation of Departmental policies requires close coordination by both criminal prosecutors and affirmative civil enforcement attorneys. Both the criminal prosecutor and the affirmative civil enforcement attorney must understand and appreciate the unique obligations of each practice. Discovery practice points that seem routine for the civil or criminal practitioner may be unfamiliar for their counterpart.

Accordingly, before beginning a parallel proceeding, an affirmative civil enforcement attorney will find it helpful to review the Department's guidance on the discovery obligations of criminal prosecutors. Criminal discovery obligations have several important differences from the obligations of civil discovery. Notably, criminal discovery obligations are constitutional in nature, and the failure to adhere to them (especially the failure to adhere to the Supreme Court holdings in *Brady v. Maryland*, 373 U.S. 83 (1963), *Giglio v. United States*, 405 U.S. 150 (1972) and their progeny) can result in severe sanctions. Online training is available through the National Advocacy Center, as well as annual in-person trainings in most United States Attorney's Offices. Similarly, criminal prosecutors should be aware of the broad obligations that can flow from civil discovery (*See* generally Fed. R. Civ. P. 26). It is important for both the criminal prosecutor and the civil affirmative enforcement attorney to meet and discuss how these obligations will be addressed before embarking on any of the steps below.

A. Joint Intake of the Cases

The joint intake of cases, including *Qui Tam* cases, is specifically considered in the Attorney General's Memorandum. This is consistent with the concept that coordination begins at the earliest possible moment. *See* U.S. Attorneys' Manual § 1-12.000. Coordination includes a realistic assessment of the potential of both cases, as well as consideration of the best application of government resources. It may be the case that during a joint intake, issues or obstacles to one type of prosecution or case makes it clear that the matter should be pursued primarily by the criminal or civil division. No two cases are alike, and your office's approach to such matters can vary.

1. *Qui Tam* Relators and Cooperating Witnesses. Under the Federal False Claims Act (31 U.S.C. §§ 3739-33), the government is often provided with information from private individuals about fraud on the government. The individuals who bring these claims are known as *relators*, and they have special legal standing in civil cases under the False Claims Act in that relators stand to receive a portion of any civil recovery in any successful criminal action. Such matters are filed initially under seal, and during this time affirmative civil enforcement attorneys consider relators as confidential sources of information. Criminal prosecutors view these same individuals as potential cooperating witnesses in their criminal investigation. Quite often, these witnesses will have personal knowledge of underlying wrongdoings that can form the bases of criminal, as well as civil liability. Accordingly, under Department policy, civil and criminal attorneys are encouraged to communicate and share evidence, where permitted by law, at the earliest stages of the investigation. Because the AKS creates both criminal and civil liability (through the False Claims Act) for individuals and business entities, cases involving the AKS will be of interest to both the civil and criminal components of the Department. Likewise, cooperating witnesses that reach out to criminal prosecutors may be of interest to civil counterparts in the Department.

2. Referrals from Agencies. Quite often, agencies like the FBI or the Office of Inspector General for the Department of Health and Human Services, as well as other state and other federal agencies, will receive citizen complaints or anonymous tips regarding potential violations of law, including the AKS. If the referring agency determines there is a credible criminal or civil complaint, the initial intake at the United States Attorney's Office should include representatives from both the civil and criminal components of the office. Further, information derived from interviews should be shared as early as possible in the process. Often, cases that are not of interest to a criminal prosecutor may be attractive to a civil attorney because the burden of proof is lower in a civil case

or because certain evidence may be more easily admitted in a civil case, for example, statistical sampling.

3. Referrals from Industry Competitors. Although industry competitors may have an incentive to report about wrongdoings by competitors, they are often in the best position to detect questionable business practices. These referrals may include the identification of specific illegal practices and the witnesses necessary for the government to prosecute. Obviously, whenever an individual or entity provides evidence, the government must be wary of the motivation for providing such information and be prepared to meets its *Brady* and *Giglio* obligations as the case proceeds. Consistent with Department policy, these witnesses can be jointly interviewed by the civil and criminal attorneys, and in the alternative, interview reports can be shared.

4. Individuals and Media. Disgruntled or offended employees and professionals often vent about wrongdoing to the media. Media stories have been the source of a number of investigations and prosecutions. A prosecutor or affirmative civil enforcement attorney needs to be aware of special considerations with regard to utilizing the media as a source of information. *See* U.S. Attorneys' Manual § 9-13.400 . However, the media stories themselves may be a fruitful source of information at the outset of a case. Because of the public nature of this source of information, the leads generated can be shared among criminal, civil, administrative, and regulatory agencies, as mandated by Department policy.

5. Sharing Investigative Materials. While sharing of information between criminal and civil components is encouraged where allowed, there are bright lines where sharing is prohibited. Before embarking on a parallel prosecution, both criminal and civil personnel must familiarize themselves with the following guidelines thoroughly. The most obvious example is the use of a grand jury, which can only be used by criminal prosecutors. *See* Fed. R. Crim. P. 6(e)(2)(b); *United States v. Sells Engineering,* Inc. 463 U.S. 418 (1983) (Civil Division of the Justice Department and their assistants and staff may not obtain automatic disclosure of grand jury materials); U.S. Attorneys' Manual, Crim. Resource Manual, § CRM 156 (Disclosure of matters occurring before the grand jury to Department of Justice attorneys and Assistant United States Attorneys). Once initiated, absent a Court Order, prosecutors may not disclose "a matter occurring before the grand jury." Fed. R. Crim. P. 6(e)(2)(B). There can be disagreement over the precise application of this secrecy restriction. Universally, prosecutors understand this to apply to grand jury testimony, which must occur before the grand jury. But various views exist about the nature of pre-existing business records obtained by grand jury subpoena. While the subpoena itself is restricted, various Districts may or may not contend that the pre-existing documents are matters "occurring before the grand jury." Caution is the watchword in this area, however, and any concern should be closely considered with supervisors.

In sum, there is no doubt that grand jury investigations will limit what information can be shared with affirmative civil enforcement attorneys, their agents, investigators, and auditors. Thus, when conducting a parallel proceeding, Department policy strongly suggests the grand jury process be utilized after other alternatives are considered. *See* U.S. Attorneys' Manual § 1-12.000. Should a grand jury investigation be anticipated, best practice recommends that two investigative teams be created: one for the criminal investigation and one for the civil investigation. Only the criminal investigation team should

have access to grand jury information. Information sharing between the two teams – if allowed from that point forward -- should be coordinated by the attorneys running the two investigations. Investigating agencies working both investigations should ensure the information derived from each investigation is "walled off" internally and that the agents be cautioned about sharing information. Such a procedure will necessarily add complexity to any parallel proceeding. However, the Rules of Criminal Procedure require carefully protecting grand jury information. *See* Federal Rules of Criminal Procedure, Rules 6e(2)(B)(vi) and 6(e)(3)(E)(i). Matters occurring before the grand jury cannot be disclosed by an attorney for the government outside the criminal investigation without a Court order "preliminary to or in connection with a judicial proceeding." While there are some statutory exceptions, caution in this area is strongly advised, as well as strict adherence to your local standards of practice, which may create additional expectations for your Court.

B. The Civil Investigation

1. The Federal False Claims Act and AKS

Case law over the past 20 years has clearly established civil liability under the Federal False Claims Act (FCA) for AKS violations. In sum, compliance with the AKS is a condition of payment under a federal healthcare benefit plan. Thus, the submission of a claim for payment is rendered materially false if it violates the AKS.

The law in this area has developed substantially since 1997, when the Fifth Circuit found that liability under the FCA could arise if the government's payment of health care claims was conditioned on defendant's certifications of compliance with health care laws and regulations, including the AKS provisions. *United States ex rel. Thompson v. Columbia/HCA* Healthcare Corp., 125 F.3d 899 (5th Cir. 1997). The Supreme Court recently reaffirmed a basic element of liability under the FCA in *United States Health Service v. U.S. ex rel. Escobar*, finding that to violate the FCA the defendant must be found to *knowingly* violate a condition that is material to the government's payment decision. *Id.*, 136 S.Ct. 1989 (2016). "Knowingly" is separately defined under the FCA to include deliberate ignorance and reckless disregard of truth or falsity. 31 U.S.C. 3729(b)(1)(A). No specific intent to defraud is required. 31 U.S.C. § 3729(b)(1)(B).

Given both the framework of the AKS, and the numerous cases that have defined and explained the interrelationship between the FCA, the AKS, and the related prohibitions under the so-called "Stark Act" (42 U.S.C. § 1395nn, prohibiting physicians from referring to an entity where they have an ownership interest), it is clear that compliance with the AKS is material to the government's payment decision. *See, generally*, *United States v. Rogan*, 517 F.3d 449 (7th Cir. 2008) (finding materiality as a matter of law).

In 2010, the Affordable Care Act, made plain within the AKS itself what affirmative civil enforcement attorneys convincingly argued for decades: "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31." By adding this language directly into the AKS (42 U.S.C. 1320a-7b(g)), Congress made clear what the majority of Courts had already found. The new language squarely addressed arguments advanced by those few Courts that had previously expressed concern about this application of the FCA. *See e.g.*, *Mikes v. Strauss*, 274 F.3d. 687, 700 (2d. Cir. 2001) (requiring statute or regulations to expressly require compliance). Given the complex history around this fairly nuanced point, affirmative

civil enforcement attorneys will do well to spend some time studying the evolution of the case law in this area.

Disagreement will often focus on a peculiar aspect of AKS jurisprudence. AKS violations are most clear when health care claims are factually false – for example when no medical service was provided, or where the services provided were medically unnecessary, but performed because a health care provider received a kickback. *See, generally, United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295 (3d Cir. 2011) ("A claim is factually false when the claimant misrepresents what goods or services that it provided to the government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for government payment."). In those circumstances when the health care service was otherwise necessary, and valuable medical care was provided to a needy patient, liability can attach under a theory of legal falsity. *Id.*

AKS violations are established under both theories – of factual or legal falsity. Patient harm can be a focus of the former theory, while the nature of the illegal business arrangement and the context of the challenged remuneration is the subject of the latter. Generally, the AKS is designed to protect patients and help ensure that medical judgments are not tainted by secret monetary incentives. The Office of Inspector General for the Department of Health and Human Services has found that kickbacks lead to: (1) overutilization: (2) increased program costs; (3) corruption of medical decision making; (4) patient steering; and (5) unfair competition. (https://oig.hhs.gov/compliance/physician-education/01laws.asp, last accessed on 10/12/2016).

While an expansive treatment of the variety of such violations is not the purpose of this article, it is important to note the wide variety of prohibited remuneration and businesses practices:

- Medical device manufacturers who provide remuneration to doctors to use certain devices in surgeries can violate the AKS. *United States ex rel. Hutcheson v. Blackstone Medical,* Inc., 647 F.3d 377 (1st Cir. 2011). Diabetes treatment centers can violate the AKS by making payments to physicians in return for patient referrals. *United States ex rel. Pogue v. Diabetes Treatment Centers of America*, 565 F.Supp.2d 153 (D.D.C. 2008).
- Providing testing at below cost in exchange for referrals of non-routine tests can create liability under both the FCA and AKS. *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F.Supp.2d 35 (D. Mass. 2000).
- Off-label marketing of drugs, including the publication and marketing of false and inflated average wholesale prices, can violate AKS. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F.Supp.2d 12 (D. Mass. 2007).
- Kickbacks camouflaged as rental payments and commissions to pharmacists violate the AKS. *United States ex rel. McNutt v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005).

2. The Investigative Team-Investigative Stakeholders

The primary investigative partner for AKS violations is the Office of Inspector General for the Department of Health and Human Services (HHS-OIG). HHS-OIG expertise and guidance is critical to any successful AKS investigation. Attorneys wishing to practice in this area should consult closely with

HHS-OIG special agents, as well as with counsel to HHS-OIG to ensure that they are acquainted with the most relevant and recent guidance in this area. HHS-OIG has agents located around the country with access to important Medicare and Medicaid data. HHS-OIG conducts audits and inspections and issues advisory opinions to health care providers. The agency also publishes a substantial amount of industry guidance that identifies which business practices are suspect, and which are of less regulatory concern. Importantly, the agency administers both permissive and mandatory exclusion authority, which can exclude a provider from participating in federal health care programs. *See, e.g.*, HHS Exclusion Database (https://exclusions.oig.hhs.gov/, last accessed on October 10, 2016). In lieu of pursuing exclusion, HHS-OIG may negotiate a Corporate Integrity Agreement, which provides certain legally enforceable conditions to a health care provider's conduct. (https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp, last accessed on October 10, 2016). Thus, affirmative civil enforcement attorneys should be prepared to work closely with HHS-OIG, as that agency will investigate the allegations to assess whether exclusion should be pursued against any particular provider.

The Centers of Medicare and Medicaid Services (CMS) is often an important stakeholder in AKS investigations. Specific involvement of this agency will be case dependent. If necessary, contacts within CMS can be identified by HHS-OIG.

Other federal law enforcement partners can play an important role in AKS investigations, depending on the facts of any particular scheme. The Federal Bureau of Investigations (FBI) has broad investigatory authority, including criminal and civil violations of law. The Defense Criminal Investigative Service investigates health care fraud, especially in those instances involving TRICARE (formerly CHAMPUS). The Drug Enforcement Agency (DEA), Food and Drug Administration Office of Criminal Investigations (FDA-OCI), and the Internal Revenue Service (IRS-CI) often are investigative partners depending on the nuances of the AKS scheme utilized by a potential defendant.

Medicaid Fraud Control Units (MFCUs) are important stake holders in any case in which Medicaid pays claims. These units obtain part of their funding from the Department of Health and Human Services, and are able partners in fraud matters. Most MFCUs are located within the State Attorney General's Office, although there are a few instances in which the MFCU is a separate agency with state jurisdiction. It is possible to locate relevant MFCU offices through the National Association website. (http://www.namfcu.net/medicaid-fraud-control-unit1.php, last accessed October 10, 2016).

Other state agencies can also be important sources of information. In particular, licensing agencies such as state medical boards investigate allegations of professional misconduct and can be helpful sources of information in certain matters.

State False Claims Acts. Many states have enacted their own state false claims acts, which have similar provisions to the federal statute. *See, generally*, Taxpayers Against Fraud (webpage: http://www.taf.org/states-false-claims-acts, last accessed October 10, 2016). States that have such statutes will often have their own separate and independent theories of liability for AKS violations in those instances when claims are paid in whole or in part by Medicare, which is funded by both state and federal funds.

Civil Investigative Tools. An affirmative civil enforcement attorney has two primary investigative tools to deploy in AKS cases: administrative subpoenas and civil investigative demands.

Administrative Subpoenas. Traditionally, affirmative civil enforcement attorneys relied upon their investigative partners for assistance in issuing subpoenas for documents. For example, HHS-OIG, as established by the Inspector General Act of 1978, has authority to issue subpoenas for documents. 5

U.S.C. app. 3 §§ 1-12. A court's scope of inquiry into enforcement is narrow, provided certain safeguards are followed. *See FDIC v. Garner*, 126 F.3d 1138. 1142 (9th Cir. 1997) (outlining the scope of inquiry in enforcement of an investigatory subpoena). Inspector General subpoenas are especially useful because information obtained through such a subpoena is not restricted to civil, criminal, or administrative enforcement purposes. (*But see* caution below, regarding "stalking horse" concerns).

Civil Investigative Demands. More recently, after the 2009 amendments to the False Claims Act, the Department has expanded authority to issue Civil Investigative Demands, which can now be authorized by the Attorney General, or her designee, pursuant to 31 U.S.C. § 3733(a)(1); *see also United States v. Markwood*, 48 F.3d 969, 976-77 (6th Cir. 1995) (finding Court's role in enforcement of CID is limited). Importantly, either the United States Attorney or the Assistant Attorney General for the Civil Division can authorize such subpoenas for documents, interrogatories, and/or testimony. The ability to obtain testimony in such investigations has proven especially helpful in some investigations.

Practice Caution: Beware the "Stalking Horse." Once parallel proceedings are begun, both criminal prosecutors and civil affirmative enforcement attorneys should be mindful of representations that are made about the existence of both types of proceedings. Beware the stalking horse—or the false pretext concealing true intent. [Merriam Webster defines a "stalking horse" as a horse or a figure like a horse behind which a hunter stalks game or something used to mask a purpose. (http://www.merriam-webster.com/dictionary/stalking%20horse, last accessed October 12, 2016)].

Specifically, a government attorney can become subject to scrutiny when declining to affirmatively disclose the existence of a criminal investigation at the beginning of compelled testimony in a civil investigation. In one instance, the result was years of litigation, although it was ultimately resolved in the government's favor. *See United States v. Stringer*, 521 F.3d 1189 (9th Cir. 2008) (reversing suppression of evidence).

To guard against such scrutiny, attorneys are advised to ensure that accurate representations are made about the existence of parallel proceedings. Further, being mindful of the 5th Amendment right against self-incrimination, affirmative civil enforcement attorneys should consider giving warnings that such testimony could be used in a criminal proceeding. Department attorneys are further encouraged to consult with their supervisors and office management on these issues, especially as local bar rules may pose additional requirements in various jurisdictions.

Burdens of Proof and Persuasion in Civil Case. While still subject to some disagreement, it is generally accepted that a civil burden of proof – preponderance of evidence -- applies to any case brought under the FCA. This includes establishing the elements of the underlying criminal AKS violation, as well as the FCA itself. The FCA provides, specifically, that "[i] n any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence." 31 U.S.C. § 3731(d). By extension, in a FCA case predicated on a violation of the AKS, the burden of proof that Congress has provided for an FCA violation should also apply to all elements, including the elements of the AKS violation.

Not many Courts have yet opined on this issue, and some have arrived at a contrary view. In dicta contained in a footnote, the Court in Northern District of Mississippi suggested that were it to consider the issue, the proper course would likely be to use a criminal intent standard to prove a civil AKS

violation. *See United States ex rel. Jamison v. McKesson Corp.*, 900 F.Supp.2d 683, 698 n. 7 (N.D. Miss. 2012) (citing *Gonzalez v. Fresenius Medical Care North America*, 689 F.3d 470 (5th Cir. 2012).

Safe Harbors/Defenses in Civil Cases. There are numerous defenses that can be employed in AKS matters. Of primary interest are the so-called "Safe Harbors." (https://oig.hhs.gov/fraud/docs /safeharbor- regulations/safefs.htm) These are business practices which ostensibly fall within the ambit of the AKS, but have been excluded from offenses under the statute because of important societal benefits such business practices can serve. In 1991, 13 original safe harbors were identified. These have grown over time and are found at 42 C.F.R. 1001.952, (*See* also https://oig.hhs.gov/compliance/safe-harbor-regulations/index.asp, last accessed October 10, 2016). There are numerous safe harbors including: investment interests, space rental, equipment rentals, personal services and management contracts, sales of practice, referral services, warranties, employees, waivers of coinsurance and deductible amounts, increased coverage, reduced cost sharing amounts, reduced premium amounts in health plans, among other items. To qualify for a safe harbor, a provider must meet all the criteria found in the regulation. As can be imagined, there is much litigation about the meaning of the safe harbors, and the regulatory definitions have been clarified by HHS-OIG guidance on various disputed points, which can be found on its website. *See* https://oig.hhs.gov/compliance/compliance-guidance/index.asp. Thus, before beginning an AKS investigation, it is appropriate to assess whether a particular practice is subject to the protections of the Safe Harbors. *See*, e.g., *U.S. ex rel. Villafane v. Solinger*, 543 F.Supp.2d 678 (W.D.Ky.2008) (referring physicians qualified for the Academic Medical Center (AMC) exception to prohibition on self-referrals).

C. The Criminal Case

The U.S. Attorneys' Manual § 9-27.220 establishes the threshold for prosecution of individuals: "The attorney for the government should commence or recommend Federal prosecution if he/she believes that the person's conduct constitutes a Federal offense and that the admissible evidence will probably be sufficient to obtain and sustain a conviction, unless, in his/her judgment, prosecution should be declined because: (1) no substantial Federal interest would be served by prosecution; (2) the person is subject to effective prosecution in another jurisdiction; or (3) there exists an adequate non-criminal alternative to prosecution." In 2015, Department policy was augmented to focus on individual liability for wrongdoing. *See* U.S. Attorneys' Manual § 9-28.210. Thus, the investigative and prosecution team should focus on obtaining the necessary admissible evidence for purposes of its analysis, which includes both individual and corporate liability.

1. The Criminal Investigation and Prosecution: The Criminal Investigative Team

The participants on the investigative team are largely determined by the interests of the agencies involved in the investigation, regardless of whether the agencies are state or federal agencies. For example, AKS investigations involving Medicaid will almost always include the Medicaid Fraud Control Unit (MFCU) as a state investigatory agency and the Department of Health and Human Services, Office of the Inspector General (HHS-OIG), as the investigating agency on the federal side. Additionally, because the Federal Bureau of Investigations (FBI) has wide authority in large scale investigations, and provides much needed resources and expertise in complex white collar investigations, they should be considered as potential partners in the criminal investigation.

2. Elements of Pertinent Crimes

At a minimum, offenses involving the AKS have the following elements, derived from the statute itself:

> 42 U.S.C. §§1320a-7b(b)(2)(A) and (B)- Illegal Remunerations Involving Federal Health Care Programs (Violation of Anti-Kickback Statute)-
>
> (1) the defendant knowingly and willfully offered or paid any remuneration directly or indirectly, overtly or covertly;
>
> (2) the remuneration was offered or paid (a) in order to induce or in exchange for the referral of patients insured by Medicare or Medicaid, federal health care programs, or (b) to arrange for, order or recommend ordering any good, service or item;
>
> (3) the patient's services, or any good, service or item were covered in whole or in part by Medicare or Medicaid, federal health care programs.

Notes: (a) Medicare and Medicaid are federal health care programs; (b) a defendant acts willfully if he knew his conduct was wrongful or unlawful; (c) the government need only prove that "one purpose" of the remuneration was to violate the law. *United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000); USA Book 6.42.1320 Soliciting or Receiving Kickbacks in Connection with Medicare or Federal Health Care Program Payments; Eighth Circuit Model Criminal Jury Instruction 6.42; and, 42, United States Code, Sections 1320a-7b(b)(2)(A) and (B).

If more than one individual was involved in the AKS violations, the prosecution should consider whether the general conspiracy statute, in conjunction with the AKS, is an appropriate charge. 18 U.S.C. § 371, which describes a Conspiracy to Defraud the United States or Violate the Laws of the United States, is proven based upon the following elements:

(1) First, beginning on or about [date], and ending on or about [date], there was an agreement between two or more persons to defraud the United States by obstructing the lawful functions of [The United States Department of Health and Human Services] by deceitful or dishonest means as charged in the indictment; or there was an agreement between two or more persons to violate a law of the United States, more particularly the Anti-Kickback Statute;

(2) Second, the defendant became a member of the conspiracy knowing of at least one of its objects and intending to help accomplish it; and

(3) Third, one of the members of the conspiracy performed at least one overt act for the purpose of carrying out the conspiracy, with all of you agreeing on a particular overt act that you find was committed.

See, 9th Circuit Pattern Jury Instructions; *See* also 3rd Circuit Pattern Jury Instructions.

Multiple individuals involved in the violation of the AKS may have criminal exposure as aiders and abettors to the conduct. Aiding and Abetting, 18 U.S.C. § 2(a), is proven when the evidence supports the following elements:

First: someone else committed the charged crime,

Second: the defendant intentionally associated himself in some way with the crime and intentionally participated in it as he would in something he wished to bring about. This means that the government must prove that the defendant consciously shared the other person's knowledge of the underlying criminal act and intended to help him.

See, 10th Circuit Pattern Jury Instructions, 2.06 (2011).

3. The Investigation

Undercover Investigations. In a proactive case, undercover operations are a critical tool used to investigate AKS violations. A defendant could be convicted of offering a bribe or kickback for referring persons to a provider of federal healthcare benefit programs even though the alleged offer was made to a Federal Bureau of Investigation informant who could not in fact refer to defendant services reimbursable from federal funds. *United States v. Duz-Mor Diagnostic Laboratory, Inc.*, 650 F.2d 223 (9th Cir. 1981). Of course, in a purely reactive case, undercover operations might not be available to further the investigation. Both civil and criminal attorneys should be cognizant of bar rules and rules of professional conduct in their respective jurisdictions that may affect how undercover investigations, including the use of "deception," are conducted. A few jurisdictions may prohibit this practice, and attorneys should consult with their Professional Responsibility Officer prior to proceeding.

Search Warrants. Regardless of whether the case involves a proactive or reactive investigation, search warrants are necessary to gather evidence necessary to prosecute a case. If the case involves medical providers, a search warrant may yield documents associated with patient care, agreements and contracts with referral sources, solicitations for kickbacks, patient files, contracts and policies defining the relationships between individuals and entities, and financial information, including payment information. If the investigation is covert, execution of the search warrant will disclose its existence. In order to maximize the potential recovery of evidence, the investigatory team should be prepared to conduct interviews at the time the search warrant is executed. Quite often, this is the moment when support employees and staff can be approached overtly for interviews that will ultimately aid in the prosecution.

Subpoena Practice: Administrative, HIPAA and Grand Jury Subpoenas. Of course, subpoena practice might also cause an investigation to become known to the subjects. Thus, this concern should be balanced against the desired sharing of information derived in the subpoena practice with the civil investigative team. Administrative and HIPAA subpoenas for documents are not restricted in terms of their use to the criminal investigation and should be considered over grand jury subpoenas for that reason. Another advantage associated with HIPAA subpoenas relative to grand jury subpoenas lies in the fact that HIPAA subpoenas can issue even after indictment. Grand jury subpoenas are critical to the investigation if other process is ineffective or if candid testimony can only be secured through the secretive grand jury process.

Proffer Letters and Use Immunity Agreements. Proffer agreements that provide a level of "use" immunity to potential witnesses are valuable in gaining the cooperation of witnesses who may perceive they have criminal exposure. However, often these tools are overused and create trial issues for the case if they are given gratuitously. For example, the giving of use immunity to a witness triggers *Brady* and *Giglio* obligations and might result in a cautionary instruction regarding that witness at trial. Some Courts recognize that such use immunity agreements may be coextensive to the statutory immunity available to the Court. *See* 18 U.S.C. § 6002, which provides, in part: "…no testimony or other information compelled under the order (or any information directly or indirectly derived from such testimony or other

information) may be used against the witness in any criminal case, except a prosecution for perjury, giving a false statement, or otherwise failing to comply with the order." *See also, United States v. Anderson,* 778 F.2d 602, 606 (10th Cir. 1985).

Assertion of Attorney-Client and Attorney Work Product Privileges to Conceal Transactions. Because many complex transactions involve legitimate assertion of attorney-client and attorney work product privileges, prosecutors and attorneys for the government should be wary about the possibility that those privileges are misused to conceal illicit conduct. "Many courts fear that businesses will immunize internal communications from discovery by placing legal counsel in strategic corporate positions and funneling documents through counsel (*viz*, addressing documents to the lawyers with copies being sent to the employees with whom communications were primarily intended). As a result, courts require a clear showing that the attorney was acting in his professional legal capacity before cloaking documents in the privilege's protection." *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 789, 797 (E.D. La. 2007). "It is settled law that the party claiming the privilege bears the burden of proving that the communications are protected." *In re Lindsey,* 158 F.3d 1263, 1270 (D.C. Cir. 1998). "Because it is an exception to the general rule, courts narrowly construe the privilege and place the onus of proving its applicability on the proponent." *United States v. Halifax Hosp. Med. Ctr.*, 2012 U.S. Dist. LEXIS 158944, *6 (M.D. Fla. Nov. 6, 2012) (herein *Halifax Hosp.*).

The law on attorney-client privilege, particularly its basic concepts, has been stable for quite a long time. *Hickman v. Taylor,* 329 U.S. 495 (1947). The attorney-client privilege protects confidential communications by a client to an attorney made in order to obtain legal assistance from the attorney in his capacity as a legal advisor. The attorney-client privilege applies if: (1) the asserted holder of the privilege is or sought to become a client; (2) the person to whom the communication was made, (a) is a member of the bar of a court, or his subordinate, and (b) in connection with this communication, is acting as a lawyer; (3) the communication relates to a fact of which the attorney was informed, (a) by his client, (b) without the presence of strangers, (c) for the purpose of securing primarily either, (i) an opinion on law, or (ii) legal services, or (iii) assistance in some legal proceeding and not, (d) for the purpose of committing a crime or tort; and (4) the privilege has been, (a) claimed, and (b) not waived by the client. *United States ex rel. Stone v. Rockwell Int'l Corp.*, 144 F.R.D. 396, 399 (D. Colo. 1992) (*emphasis added*) (quoting *United States v. United Shoe Machine Corp.*, 89 F.Supp. 357, 358-59 (D.Mass. 1950)).

The mere fact that an attorney was involved in a communication does not automatically render the communication subject to the attorney-client privilege; rather, the communication between a lawyer and client must relate to legal advice or strategy sought by the client. *In re Grand Jury Proceedings,* 616 F.3d 1172, 1182 (10th Cir. 2010). "The mere act of copying an attorney in a communication between non-attorneys does not protect the communications between the non-attorneys." *In re CFS-Related Securities Fraud Litig.*, 223 F.R.D. 631, 635 (N. D. Okla. 2004). "Simply funneling non-privileged information through an attorney does not automatically encase the document in the privilege." *Halifax Hosp.*, 2012 U.S. Dist. LEXIS 158944 at *9 (citation omitted). "Where business and legal advice are intertwined, the legal advice must predominate for the communication to be protected." *Coleman v. ABC,* 106 F.R.D. 201, 206 (D.D.C. 1985). "Business advice, unrelated to legal advice, is not protected by the privilege even though conveyed by an attorney to the client." *CFS-Related Securities Fraud,* 223 F.R.D. at 635. "Federal

law extends the privilege to communications about legal subjects, and it is hard to see why a business evaluation meets that description." *Burden-Meeks v. Welch,* 319 F.3d 897, 899 (7th Cir. Ill. 2003).

The Crime-Fraud Exception. Under the right circumstances, this exception may prove fruitful to the discovery of documents at the core of an AKS violation. "[T]he attorney-client privilege does not apply where the client consults an attorney to further a crime or fraud." *Motley v. Marathon Oil Co*., 71 F.3d 1547, 1551 (10th Cir. 1995). "The crime/fraud exception has been applied … to the work product privilege as well as the attorney/client privilege." *Lifewise Master Funding v. Telebank,* 206 F.R.D. 298, 304 (D. Utah 2002), citing *Vargas,* 723 F.2d at 1467.

Waiver Because of Delays in Assertion of the Privilege and Production. A delay in asserting the privilege might waive a proponent's ability to later claim its applicability: "Inordinate delay in claiming the privilege can prejudice the adversary and may be deemed a waiver." *Bank Brussels Lambert v. Credit Lyonnais (Suisse) S.A.,* 160 F.R.D. 437, 445 (S.D.N.Y. 1995). Also, "a presumption of regularity attaches to a grand jury subpoena, and those challenging its regularity have the burden of showing irregularity[.]" *First Nat'l Bank v. U.S. Dep't. of Justice,* 865 F.2d 217, 219 (10th Cir. 1989) (citation omitted). Failure to make a timely objection could amount to waiver.

4. The Prosecution

***Burdens of Proof*.** Parallel investigations allow the government to seamlessly and efficiently optimize its resources, including prosecutorial resources. The complex nature of some AKS transactions lend themselves to civil or administrative resolutions that have lower burdens of proof than criminal prosecutions.

Statute of Limitations on AKS and Conspiracy and "Running out the clock." Government attorneys must always be concerned about the applicable statute of limitations. Because of the complexity involved in many AKS cases, and the fact that the illegality is not discovered until many years have passed, the timing of an investigation and subsequent prosecution must be watched closely. The statute of limitations associated with both the AKS and general conspiracy statute is 5 years. *See* 18 U.S.C. § 3282. Clever defense counsel, cognizant of the limitations issue, may exercise dilatory tactics to run the clock out on the investigation. For example, providing privilege logs that fail to disclose anything about the underlying document, or attempting to provide "rolling production" of documents rather than comply with production dates of subpoenas. Government counsel should be prepared to press for the timely disclosure of subpoenaed documents through motions to compel or motions to show cause.

5. Common Defenses, both Legal and Factual

Statutory Exceptions and Safe Harbors. The AKS, by its very terms, explicitly lists conduct that is excepted from liability, including provisions that authorizes the Secretary of Health and Human Services to promulgate safe harbors by regulation. *See* 42 U.S.C. § 1320(b)(3)(A)-(H). Effective enforcement of the AKS must take into consideration regulations promulgated by HHS that, if met, provide a safe harbor for conduct that is otherwise a violation of the AKS. However, in order to qualify for protection under the safe harbor regulations, the conduct must meet all the applicable regulations. Discussed *supra*.; *see* also, *Nursing Home Consultants, Inc. v. Quantum Health Services, Inc.*, 926 F.Supp. 835 (E.D. Ark. 1996). For example, under the "discount exception," both buyer-providers and seller-suppliers are required to "properly disclose and appropriately reflect" the reduction in price offered or received for Medicare or Medicaid reimbursable goods or services in order to avoid criminal liability

under AKS. *United States v. Shaw*, 106 F.Supp.2d 103 (D. Mass. 2000); *See* also 42 U.S.C § 1320(b)(3)(A).

Advisory Opinions and Application of the Anti-Kickback Statute. Although advisory opinions issued by the HHS Office of Inspector General provide specific guidance regarding the legality of specific conduct by specific parties relative to the AKS, and limit its applicability to those facts and parties, those opinions are often relied upon by industry and legal counsel in advising healthcare providers about the legality of conduct. As such, prosecutors and others can expect defensive arguments rooted in advisory opinions and which may rise to buttress a good faith or advice of counsel defense for criminal and civil liability. *Zimmer, Inc. v. Nu Tech Medical Inc.*, 54 F. Supp.2d 850 (N.D. Ind. 1999) (Advisory opinion of Office of Inspector General of Department of Health and Human Services regarding legality, under the AKS, of contract between manufacturer of orthopedic products and independent contractor to sell products was entitled to deference as informed judgment to which courts and litigants may properly resort for guidance). It is very important that the prosecutor and Department attorneys engage with counsel for HHS to stay abreast of advisory opinions that may impact prosecutorial decisions.

Paying Fair Market Value for Assets. The concept of paying only fair market value in good faith for assets, goods, and services is inconsistent with illicit remuneration to influence a healthcare provider's judgment. If there is no economic inducement for a referral because fair market value is paid for assets, the AKS, which regulates referrals between physicians and hospitals who participate in federal health care programs, does not prohibit hospitals from acquiring medical practices, nor does it preclude seller-physician from making future referrals to buyer-hospital. *See United States ex rel. Obert-Hong v. Advocate Health Care*, 211 F.Supp.2d 1045 (N.D.Ill. 2002).

***Good Faith as a defense*.** The good faith defense will almost always loom in an AKS case because these cases often involve complex transactions. If the evidence supports its submission, a failure to give a good faith instruction, when properly requested, is error. *See United States v. Goss*, 650 F.2d 1336 (5th Cir. 1981). The term "willfully," as that term is used in the AKS, means unjustifiably and wrongfully, known to be such by defendant; because the *mens rea* of the offense includes "willful" conduct, an instruction that good faith is a defense to an AKS charge is appropriate if it is raised by the evidence. *See United States v. Jain*, 93 F.3d 436 (8th Cir. 1996). The defense, once raised by the evidence, negates the *mens rea* of "willfulness" or "intent to defraud."

***Advice of Counsel as a defense*.** "Advice of Counsel" is often a defense asserted by sophisticated defendants in AKS cases. This defense is a sub-specie of the good faith defense and requires that the advice provided by counsel was provided after all the relevant facts were provided to counsel to get an opinion that supports the defense: "If a defendant, before taking any action, sought the advice of an attorney whom he considered competent, in good faith and for the purpose of securing advice on the lawfulness of his possible future conduct, *and made a full and accurate report to his attorney of all material facts which he knew and acted strictly in accordance with the material advice of his attorneys who had been given a full report*, then the defendant would not be knowingly and willfully doing wrong in doing something the law forbids." *See United States v. McClatchey*, *cited supra*.; *United States v. Condon*, 132 F.3d 653 (11th Cir. 1998).

D. Additional Prosecutorial Considerations: Corporate Liability

Corporate criminal exposure is subject to the *Principles of Federal Prosecution of Business Organizations*, U.S. Attorneys' Manual § 9-28.000 (2008). Section 9-28-300 of the United States Attorneys' Manual enumerates a non-exhaustive list of considerations for prosecutors of business entities:

1. The nature and seriousness of the offense, including the risk of harm to the public, and applicable policies and priorities, if any, governing the prosecution of corporations for particular categories of crime;
2. The pervasiveness of wrongdoing within the corporation, including the complicity in, or the condoning of, the wrongdoing by corporate management;
3. The corporation's history of similar misconduct, including prior criminal, civil, and regulatory enforcement actions against it;
4. The corporation's timely and voluntary disclosure of wrongdoing and its willingness to cooperate in the investigation of its agents;
5. The existence and effectiveness of the corporation's pre-existing compliance program;
6. The corporation's remedial actions, including any efforts to implement an effective corporate compliance program or to improve an existing one, to replace responsible management, to discipline or terminate wrongdoers, to pay restitution, and to cooperate with the relevant government agencies;
7. Collateral consequences, including whether there is disproportionate harm to shareholders, pension holders, employees, and others not proven personally culpable, as well as impact on the public arising from the prosecution;
8. The adequacy of the prosecution of individuals responsible for the corporation's malfeasance;
9. The adequacy of remedies such as civil or regulatory enforcement actions.

E. The *Sentencing Guidelines:* Individual and Corporate Exposure in AKS Cases

Individuals convicted under the AKS may face serious sentencing ranges pursuant to the *Sentencing Guidelines* calculations before application of the 18 U.S.C. § 3553(a) factors. *See Gall v. United States*, 552 U.S. 38 (2007) (the guidelines remain the "initial benchmark" for sentencing); *see also Kimbrough v. United States*, 552 U.S. 85 (2007); *see* also, *United States v. Booker*, 543 U.S. 220 (2005) (making the guidelines advisory). Application of the *Sentencing Guidelines* begins with a consideration as to what constitutes "relevant conduct." U.S. SENTENCING GUIDELINES MANUAL § 1B1.3. (U.S. SENTENCING COMM'N 2015). U.S. SENTENCING GUIDELINES MANUAL §3b1.3(A)(2) (U.S. SENTENCING COMM'N 2015) indicates the relevant conduct includes conduct which is ". . . the same course of conduct or common scheme or plan" even if it's outside the offenses of conviction. The base offense level is thereafter determined by examining U.S. SENTENCING GUIDELINES MANUAL § 2B4.1 (U.S. SENTENCING COMM'N 2015) which begins the offense at a level 8, but if the offense involves an "improper benefit" exceeding $6500.00, there is an increase associated with the fraud tables of U.S. SENTENCING GUIDELINES MANUAL § 2B1.1 (U.S. SENTENCING COMM'N 2015). Thus, the base offense level applicable to individual defendants is quickly propelled upward by the application of the fraud *Guideline*; for example, if the improper benefit exceeded $20,000,000.00, the base offense level is raised by 22

levels to a level 30. *Id.* In addition, the court can consider a role adjustment, if appropriate, which could result in a reduction up to four levels for a mitigating role, or an increase of up to four levels for an aggravating role. U.S. SENTENCING GUIDELINES MANUAL §§ 3b1.1 and 3B1.2(U.S. SENTENCING COMM'N 2015) . Pursuant to U.S. SENTENCING GUIDELINES MANUAL § 3b1.3 (U.S. SENTENCING COMM'N 2015), the court can consider an additional two-level adjustment for the use of a "special skill" if the defendant used a special skill or professional ability. Assuming no adjustments to the base offense level for role in the offense or "special skill," and a minimal criminal history, which is often the case in an AKS case, the resulting applicable range is a sentence of 97-121 month's imprisonment and a fine range of $30,000.00 to $300,000.00. *See* U.S. SENTENCING GUIDELINES MANUAL § 5E1.2 (U.S. SENTENCING COMM'N 2015).

Similarly, business entities convicted of AKS violations face serious financial consequences. Once the amount of "relevant conduct" is established, the applicable *Sentencing Guideline* analysis begins at U.S. SENTENCING GUIDELINES MANUAL § 2b4.1(C)(1) (U.S. SENTENCING COMM'N 2015), which provides special instructions for fines of organizations: "In lieu of the pecuniary loss under subsection (a)(3) of § 8C2.4 (Base fine), use the greatest of: (A) the value of the unlawful payment; (B) the value of the benefit received or to be received in return for the unlawful payment; or (C) the consequential damages resulting from the unlawful payment." Thereafter, Chapter 8 of the *Sentencing Guidelines* are applied for business organizations. Chapter 8 will address matters such as appropriate "Fines," "Remedying Harm of Criminal Conduct," "Criminal Purpose Organizations," "Culpability," "Disgorgement," and "Restitution," among other factors in setting an appropriate sentence. To illustrate the magnitude of fines possible under Chapter 8, assuming the same conduct described above, and the improper benefit is $20,000,000.00 which represents the highest base fine contemplated by U.S. SENTENCING GUIDELINES MANUAL § 2B4.1(c)(1) (U.S. SENTENCING COMM'N 2015), U.S. SENTENCING GUIDELINES MANUAL §§ 8C2.2-8C2.9 (U.S. SENTENCING COMM'N 2015) are applicable. Significantly, a "culpability score" pursuant to U.S. SENTENCING GUIDELINES MANUAL § 8c2.5 (U.S. SENTENCING COMM'N 2015) may generate a maximum multiplier of up to 4 times the applicable fine amount. U.S. SENTENCING GUIDELINES MANUAL § 8c2.6-8c2.8 (U.S. SENTENCING COMM'N 2015). Additionally, the Court must consider disgorgement of any gain to the organization from the offense that has not and will not be paid as restitution or by way of other remedial measures. U.S. SENTENCING GUIDELINES MANUAL § 8c2.9 (U.S. SENTENCING COMM'N 2015). Part D of Chapter 8 also contemplates the imposition of probation and conditions of probation. U.S. SENTENCING GUIDELINES MANUAL § 8D1.1-8D1.4 (U.S. SENTENCING COMM'N 2015). As illustrated, the financial consequences to a business organization could be severe.

Once the proper calculation of the *Sentencing Guidelines* produces a sentencing range, the court must apply the factors designated in 18 U.S.C. § 3553(a). In *Gall*, cited *supra*, the Supreme Court determined that sentences are reviewed for reasonableness under an abuse of discretion standard. *See also United States v. Reinhart*, 442 F.3d 857, 862 (5th Cir. 2006) (the abuse of discretion standard applies to both guideline and non-guideline sentences). The court may impose concurrent or consecutive sentences after considering the factors in 18 U.S.C. § 3553(a). *See* 18 U.S.C. § 3584 (a) and (b). Ultimately, pursuant to *Gall*, *Kimbrough*, and their progeny, the sentencing judge may consider the 18 U.S.C. § 3553(a) factors in fashioning a reasonable sentence, including the following:

"(2) the need for the sentence imposed--

(A) to reflect the seriousness of the offense, to promote respect for the law and provide a just punishment for the offense;

(B) to afford adequate deterrence to criminal conduct;

(C) to protect the public from further crimes of the defendant; and

(D) to provide the defendant with the needed educational or vocational training, medical care, or other correctional treatment in the most effective manner;

. . .

(7) the need to provide restitution to victims."

18 U.S.C. 3553(a).

F. Alternatives and Coextensive Remedies to Prosecution

Administrative Remedies. The Department of Health and Human Services, Office of Counsel to the Inspector General (HHS-OCIG), has wide latitude in exercising administrative remedies against violators of the AKS and other healthcare statutes, from suspension to debarment or exclusion. Individuals and entities convicted of healthcare related offenses are subject to mandatory and permissible exclusion from participating in the Medicare and Medicaid programs. 42 U.S.C. §§ 1320a-7(a) and (b). Exclusion from federal programs could effectively mean a "death sentence" for some business organizations and could severely impact other healthcare professionals. It is important to consult with HHS-OCIG counsel to understand the ramifications of safe-harbors or advisory opinions that may impact the prosecution. Likewise, counsel must understand the impact a particular resolution will have on individuals and entities in crafting a just result. Also, HHS-OCIG has expertise in crafting corporate integrity agreements to prevent future violations.

Pretrial Diversion. In the appropriate case, pretrial diversion may be considered by the prosecution in lieu of criminal sanctions. *See* U.S. Attorneys' Manual § 9-2.022.

Prosecutorial Recommendations to HHS-OCIG. Prosecutors may make recommendations to HHS-OCIG regarding the disposition of the administrative case involving individual and entity defendants; however, they are not permitted to commit "…to forego or restrict administrative remedies, which the HHS may elect to pursue…and are made only after obtaining prior explicit approval from the Criminal Division." *See* U.S. Attorneys' Manual § 9-42.451. Such recommendations are not binding on HHS-OCIG as their administrative authority and action are independent of the criminal case.

State Licensing Considerations. Most healthcare professionals are governed by state licensing agencies. Quite often, conviction of a criminal offense could result in suspension or revocation of a license to practice in a given profession. For example, doctors and nurses are normally licensed by state authorities. Consideration must be given to the potential impact of a resolution on the subject and the state licensing interests.

Global Resolutions involving federal Healthcare Providers and State Stakeholders. Usually, AKS cases draw sophisticated defense counsel that understand the responsibilities of each stakeholder to proceed independently. It often behooves defense counsel to resolve all matters with all stakeholders at the same time rather than conduct litigation after litigation with numerous different agencies. It is important to note that global resolution should not be considered until it is requested by the defense.

Absent such a request, the specter of a "stalking horse" argument by the defense might present an issue. Once global resolution is requested by the defense, the stakeholders should consult regarding a just resolution of their various cases globally. A resolution might involve criminal dispositions, civil dispositions, administrative resolutions, corporate integrity agreements, and forfeiture on both the state and federal levels.

IV. Forfeiture Investigation and Allegations

Criminal Forfeiture. Bringing a forfeiture count in an indictment can be an efficient way to achieve forfeiture, as it alleviates the need for a civil forfeiture action. FED. R. CRIM. P. 32.2 and 21 U.S.C. § 853 give crucial information about procedures depending upon timing as well as the property that is sought to be forfeited. A criminal forfeiture count is most likely to be successful when there are identifiable assets which constitute proceeds of the crime, although substitute assets or monetary amounts for the amount of proceeds of the crime can also be obtained after a conviction. There is no right to a jury determination of monetary damages in a criminal case, although third parties with ownership rights can contest the forfeiture in ancillary proceedings.

Criminal forfeitures are available for violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), as long as the violation occurred **after** March 23, 2010. Title 18 § 981(a)(1)(C) of the U.S.C. provides that any property, real or personal, which constitutes or is derived from proceeds traceable to any offense constituting "specified unlawful activity" as defined in 18 U.S.C. § 1956(c)(7) is subject to forfeiture to the United States. 18 U.S.C. § 1956(c)(7)(F) provides that "specified unlawful activity" includes any act or activity constituting an offense involving a Federal health care offense. 18 U.S.C. § 24(a) provides that, as used in Title 18, the term "Federal health care offense" includes, among other things, a violation of the AKS, section 1128B of the Social Security Act, 42 U.S.C. § 1320a–7b. Forfeiture based on violations of the AKS are limited to proceeds of the crime and do not include property which has facilitated commission of the crime, as many other criminal statutes provide. Often a charge of money laundering, pursuant to 18 U.S.C. § 1956, is also appropriate in a case with an AKS charge. This charge expands the class of assets available for forfeiture to those involved in or facilitating the money laundering. Like other criminal forfeitures, those based on the AKS require a Motion for Preliminary Order of Forfeiture to be entered prior to sentencing and regardless of any third party claims which are considered after the defendant's interest is terminated.

Civil Forfeiture. A civil forfeiture action is an *in rem* action against the property sought to be forfeited. A complaint, verified by the (federal) case agent, names the item sought as defendant and sets forth the details of why the property is believed to be subject to forfeiture under the AKS, or whichever criminal statute is the basis for the action. After the complaint is filed and a warrant for the property is issued by the court, notice must be given as widely as possible to anyone who might have an ownership interest in the property. The notice must be sent to anyone whom it is known might have a claim to it, and counsel, if known. A proper notice must also give information about the necessity of filing a claim with the court that has jurisdiction over the property and the mandatory timing for doing so. It must also inform a potential claimant of the necessity of filing an Answer with the court within 21 days after the filing of the claim. Finally, the item sought to be forfeited must be listed on a government website

(forfeiture.gov) for thirty consecutive days, giving sixty days from the first date of publication for anyone to file a claim.

Administrative Forfeiture. Administrative forfeitures are done by federal agencies that have been given that power by Congress. It is a process by which property may be forfeited without the involvement of a court and makes up the vast majority of forfeitures. Certain seizures can be made without a warrant through exceptions to the Fourth Amendment. These include the automobile exception, exigent circumstances, as incident to arrest, or with consent. Other forfeitures start with a request for a seizure warrant submitted through the U.S. Attorney's office to the U.S. District Court. The warrant application includes a sworn statement from a federal agent explaining the factual basis for seizure of the property, along with the statutory authority added by the Assistant U.S. Attorney who submits it to the court. 28 U.S.C. § 1355 states that seizure warrants can be issued in any district. The warrants can be executed in any district in which the property is found. With proper substantiation, these motions can be filed under seal so that notice need not be given at that point. Generally, the basis for this is concern about the destruction of evidence by the wrongdoer who knows their property has been taken but not why. Use of a seizure warrant is helpful for bringing assets under government control before an indictment has been obtained.

Most assets that are subject to civil forfeiture actions have had an attempted administrative forfeiture action before the judicial filing. Unless a warrant has been sealed, the administrative agency must give notice to the party from whom the property was taken, within 60 days of the seizure, as well as anyone else who is known to have a possible ownership interest in the property. If no claim is filed with the agency on the property within the appropriate period of time, the item may be administratively forfeited with no further proceedings. It is only if a claim is filed within the time limit, that the property is referred to the U.S Attorney's Office for the filing of a civil action. There is no obligation of that office to file a civil action if it is believed, for example, the agency lacked probable cause for the seizure, or the value of the item is not within the thresholds set by the applicable agency. Real property cannot be administratively seized.

V. Conclusion

The AKS ensures quality healthcare will be provided in federal healthcare programs without financial self-interest clouding medical decisions. It is imperative that federal and state stakeholders use every available legal remedy to enforce our healthcare laws and protect the public health.

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Medicaid, the MFCU, and You

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As is true in the Medicare arena, Medicaid fraud costs the American taxpayers a staggering amount of money annually. Medicaid is the second-largest federal health care program, and for that reason alone, the Department of Justice should be pursuing Medicaid fraud investigations. The fact that we have additional resources available through state Medicaid Fraud Control Units makes the inclusion of Medicaid in health care fraud investigations even more obvious. In fiscal year 2015, Medicaid Fraud Control Units were responsible for over 1,500 criminal convictions, nearly 800 civil settlements, and judgments totaling nearly $750 million in recoveries. Additionally, in the most recent national health care fraud takedown, 24 Medicaid Fraud Units were actively involved across the country.

I. Background

Medicaid was created in 1965 as a jointly funded federal and state health care program tasked with providing health services to low-income individuals and families. There are broad federal guidelines in place in the form of statutes, regulations, and policies, but each state is tasked with administering its Medicaid program and determines eligibility thresholds, services to be provided, and the rates of payment. The federal government sets the baseline for Medicaid services, but the states may offer services that go beyond those minimum requirements.

Until 1975, Medicaid operated without any agency tasked with investigating potential criminal activity within the program and no controls in place to prevent fraud. The first effort to curtail Medicaid fraud came in the form of a special prosecutor in New York who investigated and prosecuted crime in the state's nursing home industry. The special prosecutor, Charles J. Hynes, testified before Congress in 1976 and proposed state fraud control units. Congress passed the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977, P.L. 95-142, in response to Hynes's proposal, and President Jimmy Carter signed the legislation in October 1977. The objective of the amendments was to "strengthen the capability of the government to detect, prosecute, and punish fraudulent activities under the Medicare and Medicaid programs." The law provided 90 percent federal funding to each state for three years to establish a Medicaid Fraud Unit. In 1978 the federal government certified 17 units. Permanent federal funding, at the rate of 75 percent after the first three years, was approved in the Omnibus Reconciliation Act of 1980, P.L. 96-499. As of 1995, federal law requires each state to have a Medicaid Fraud Control Unit unless the state can demonstrate that there is a minimum amount of Medicaid fraud and that Medicaid beneficiaries are protected from abuse and neglect.

Medicaid Fraud Control Units (MFCUs) are state entities charged with investigating Medicaid provider fraud. There are currently 50 MFCUs; every state, with the exception of North Dakota, as well as the District of Columbia, have staffed MFCUs. The Office of Inspector General conducts an annual

recertification of each MFCU to ensure compliance with federally mandated requirements, assess performance, and administer federal grant money to help cover operational costs. All but six of the MFCUs are located in the office of the state Attorney General. MFCUs employ approximately 2,000 people across the nation.

In substance Medicaid fraud does not vary significantly from Medicare fraud. MFCUs have prosecuted individual providers in virtually every segment of health care—hospitals, nursing homes, home health agencies, durable medical equipment companies, medical transportation companies, and pharmacies. The types of Medicaid fraud include the laundry list of schemes familiar to health care fraud AUSAs — billing for services not provided or not medically necessary, double billing, upcoding, and kickbacks to name a few.

II. Resources

MFCUs are intended to follow a multi-disciplinary "strike force" model utilizing a team of investigators and auditors working with an attorney. All three disciplines add value to health care fraud cases through their collective expertise and experience.

A. Investigators

MFCU investigators are counterparts to the federal investigative agents working on health care matters. They can participate and assist with interviews, search warrants, trial preparation, and most other tasks HHS OIG, FBI, and other federal agents handle or facilitate. MFCU agents bring specialized knowledge of Medicaid fraud, and many have previous law enforcement experience. Like federal agents, they memorialize their work on the investigation in written reports. In some districts, MFCU investigators share office space with HHS OIG agents and are co-case agents on every case. MFCU investigators and federal agents routinely share investigative information, but the sharing of information and resources varies greatly across the country.

B. Auditors

Auditors work in conjunction with investigators and attorneys to evaluate allegations of fraud and develop investigation strategies. Auditors can analyze claims data for patterns of fraud; examine and schedule financial records; interview potential witnesses, Medicaid recipients, and others with knowledge of fraudulent activities; prepare memorandums and summaries to synthesize the evidence; and testify in court proceedings regarding their findings. By querying and analyzing Medicaid claims data and applying statistical sampling techniques, MFCU auditors identify Medicaid overpayment. In addition, auditors work with medical, billing, and statistical experts and are proficient in navigating numerous databases. In sum, auditors working at MFCUs analyze complex financial records, healthcare billing data, and other relevant information to provide evidence in the investigation and prosecution of healthcare fraud.

C. Attorneys

Like the investigators and auditors, MFCU attorneys have specialized knowledge and are typically more informed about the inner workings of the state Medicaid program than AUSAs. Many districts deputize MFCU attorneys as SAUSAs to enable them to more easily work on federal cases. The health care expertise and experience of these attorneys is a valuable resource, especially for AUSAs who handle many types of cases in addition to health care fraud.

III. Teamwork

The reasons USAO's should be working alongside MFCUs are obvious. Chief among them are the additional resources that can be put to use in health care fraud investigations. Unfortunately, there is more fraud in Medicare and Medicaid than federal law enforcement and prosecutors can tackle. Sharing intelligence and resources with our state MFCU partners promotes efficiency, allows us to combat more of the fraud, and results in larger recoveries. Because the fraud perpetrators do not discriminate between government health care programs, opting not to include Medicaid inevitably means missing out on a sizable portion of the loss.

If working together means better cases, faster turnaround, and larger loss amounts, are there any reasons for not working with MFCUs? The answer is no, but as with any multi-agency case, there are challenges to working as partners. Coordination, communication, and organization are all essential for successful collaboration.

Effective coordination includes delegating tasks to members of the investigative team based on their relative strengths, as well as practical considerations such as level of experience, location, and assigned caseloads. Coordination between the federal agencies and MFCUs avoids duplication of effort; jointly investigating fraud saves both time and resources for everyone. Coordination is easier where MFCU investigators are sharing space with HHS OIG agents or are co-case agents in every case; it presents more of a challenge where several hundred miles separate the two agencies. Having regularly scheduled conference calls and/or task force meetings assists in coordinating efforts when the MFCU is in a different location from the USAO and the federal agents.

Clearly communicating expectations and deadlines also becomes more important as the size of any prosecution team grows. Keeping an antenna up for any personality issues, and dealing with interpersonal difficulties directly and professionally, is necessary for a successful long-term relationship. As with any covert investigation, communication between the attorneys and investigators is imperative to ensure that everyone has the same understanding and expectations before any operation. Concerns about joint state and federal investigations go both ways, and an often repeated criticism directed from state agencies is that federal prosecutors' cherry pick only the best cases. Part of working together is realizing that some cases are better suited for state adjudication, even after a joint investigation. Communication and a good working relationship between AUSAs and MFCU attorneys can help foster a give-and-take relationship.

Organization is also key, especially in the area of discovery. Health care fraud is no different from other types of multi-agency white collar investigations in that discovery is voluminous and document-intensive with each partner agency responsible for some of the intake, inventory, and eventual disclosure. Discussing discovery obligations clearly, early, and often is key to organizing discovery as well as evidence for trial.

IV. Conclusion

The enormity of health care fraud is one of the chief challenges in fighting the problem. We should be using every tool and resource available to combat this pervasive problem that erodes confidence in government health care programs and has the potential to harm patients. Working closely

with the MFCUs around the country is an obvious way to multiply the resources directed at health care fraud. Tackling the problem together will result in better investigations, more complete evidence and loss analysis, and larger recoveries.

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Searching for Bright-Lines in the Darkness: Enforcing Quality of Care Standards Using the False Claims Act

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I. The False Claims Act

The False Claims Act (FCA), 31 U.S.C. §§ 3729–3733, has long been the federal government's primary litigation tool for combating fraud in federal government programs. The FCA applies to all fraudulent efforts to lure the government into paying out sums of money. *United States ex rel. Loughren v. Unum Group*, 613 F.3d 300 (1st Cir. 2010); *United States ex rel. Siewick v. Jamieson Science and Engineering, Inc.*, 214 F.3d 1372 (D.C. Cir. 2000). Liability under the FCA attaches when a false or fraudulent claim to the government is presented for payment or approval. 31 U.S.C. § 3729(a)(1). The mere submission of a claim, however, is insufficient. Some degree of scienter is required. The claim must be presented knowingly, with deliberate ignorance for its truth or falsity, or with reckless disregard for its truth or falsity. *Id.* at § 3729(b)(1)-(3).

Although the FCA dates back to the Civil War and has been applied in a wide array of contexts, beginning in the 1980s the FCA was used heavily to combat health care fraud. A wide variety of fraudulent schemes, arising in an even wider variety of contexts, have been litigated pursuant to the FCA. *See, e.g.*, *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377 (1st Cir. 2011) (kickbacks); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004) (false certifications); *United States v. Applied Pharmacy Consultants, Inc.*, 182 F.3d 603 (8th Cir. 1999) (unjust enrichment).

II. The Regulation of Nursing Facilities

One area where the FCA has been applied is in the context of Medicare and Medicaid claims for the care of residents in skilled nursing facilities. It is in this context that the bright-lines between federal litigation under the FCA, on one hand, and state regulation, on the other, begin to blur.

Nursing facilities are regulated by both federal and state governments. In 1987, in response to reports of widespread neglect and abuse, Congress enacted the Nursing Home Reform Act. Pursuant to the NHRA, nursing facilities are obligated to "provide services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with a written plan of care." 42 U.S.C. § 1396r(b)(2).

In addition, to participate in Medicare and Medicaid, nursing facilities must comply with an enumerated list of requirements that run the gamut from minimum staffing levels, to recordkeeping requirements, to care planning. Among other requirements, facilities are obligated to provide care "of a quality which meets professionally recognized standards of health care." 42 U.S.C. § 1320c-5(a).

Each state is responsible for conducting unannounced surveys of the nursing facilities within that state. The state must then report each nursing facility's compliance or noncompliance to the federal government. The state may recommend appropriate enforcement actions by state and federal governments. States may also have their own regulatory scheme and may impose even stricter requirements than those required by the federal government.

An interesting interplay between state regulation and federal FCA litigation arises in cases where a nursing facility's care does not meet the regulatory requirements. The question, in such a case, is whether only a regulatory violation lies or whether the federal government may also pursue FCA claims.

In cases where the nursing facility has billed for services that were not provided, inarguably, FCA liability may attach. *See United States v. Bornstein*, 96 S. Ct. 523, 46 L. Ed. 2d 514 (1976). Seeking payment for unperformed services is fraud. The more challenging case involves circumstances where some care was provided, but that care was so poor that the government contends it would not have paid if it would have known of such substandard care. These cases, known as "quality of care" cases, often take two forms: first, cases where the provided services were arguably worthless; or second, cases where the nursing facility falsely certified (either expressly or impliedly) that it complied with the applicable standard of care.

III. Worthless Services

Worthless service claims are based on the theory that even if services are provided, those services can be so deficient as to be valueless. *See In re: Genesis Health Ventures*, 112 F.App'x 140, 143 (3d Cir. 2004); *United States ex rel. Lee v. Smithkline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001). In a worthless service claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all. *United States ex rel. Mikes v. Strauss*, 274 F.3d 687, 703 (2d Cir. 2001). These claims are "effectively derivative of an allegation that a claim is factually false" because these claims seek reimbursement for a service that was not provided. *United States v. Cathedral Rock Corp.*, No. 03-1090, (E.D. Mo. Nov. 30, 2007).

Courts have recognized this theory as a basis for a FCA claim. See, e.g., *United States v. Covenant Care, Inc.*, 279 F.Supp.2d 1212, 1216 (E.D. Cal. 2002), *United States v. NHC Health Care Corp.*, 163 F.Supp.2d 1051, 1056 (W.D. Mo. 2001). No certification is required. See *Mikes*, 274 F.3d at 702. Such recognition validates the reality that the government does not intend Medicare "simply to reimburse for treatment," but rather that the program is designed to "maintain a certain level of quality medical care . . . " *Fisher v. United States*, 529 U.S. 667, 679 (2000).

In egregious cases, the line between a worthless case and simply deficient care is easy to draw. In *United States v. NHC Health Care Corporation*, 163 F.Supp.2d 1051 (W.D. Mo. 2001), it was alleged that nursing facility patients were allowed to develop pressure sores and were found lying in feces-ridden bedsheets. It was further alleged that although these conditions were documented, and although the nursing facility knowingly maintained inadequate staffing levels, it nonetheless billed the government for care. The Court concluded that such care was worthless, reasoning that:

> [the facility] agreed to provide 'the quality of care which promotes the maintenance and enhancement of the quality of life.' At some very blurry point, a provider of care can cease to maintain this standard by failing to perform the minimum necessary care activities required to promote the patient's quality of life. When the provider reaches that point, and still presents claims for reimbursement to Medicare, the provider has simply committed fraud against the United States.
>
> *Id*. at 1055-56.

Where the care is so clearly deficient, some courts conclude that the government would not have paid. See, e.g., *United States v. Health Care Mgmt. Partners., LTD*, No. 04-cv-02340-REB-BNB, (D. Colo. August 17, 2006), (holding that if services are so deficient as to be medically worthless, then the submission of a bill for those services may constitute a FCA violation). Where the care is unquestionably worthless, the government has a straightforward argument.

The argument is less straightforward where the performance was simply deficient. Some courts have drawn a line between completely worthless services and those which are deficient in a lesser manner. *See, e.g., United States ex rel. Absher v. Momence Meadows Nursing Center, Inc.*, 764 F.3d 699 (7th Cir. 2014) (holding that there is no FCA violation if a healthcare facility provides deficient services with some arguable worth but declining to decide whether entirely worthless services violate the FCA); *United States ex rel. Chesbrough v. VPA, P.C.*, 655 F.3d 461 (6th Cir. 2011) (holding that billing for merely defective services does not violate the FCA unless the services are so bad as to have no value).

The *Absher* court held that FCA liability does not lie where services are less valuable or "worth less"; the services must be wholly deficient or "worthless." *Absher*, 764 F.3d at 710. Although the *Absher* court declined to address the validity of the theory in general, the court nonetheless set a high bar for actionable deficiencies. Some courts have read the *Absher* decision as casting doubt on the validity of the worthless services theory of FCA liability, at least in certain cases. *See, e.g., United States ex rel. Soodavar v. Unisys Corp.*, No. 1:14-cv-1217, (E.D. Va. Apr. 5, 2016).

As these cases illustrate, a worthless service claim is not an automatic win for the government. It remains, however, a viable theory in many circuits and contexts. Although courts have not universally concluded that care must meet professionally recognized standards of health care to be billable, worthless services cases have nonetheless been successfully litigated in a variety of circuits. *Compare Mikes*, 274 F.3d at 687 (holding that the Medicare statute does not expressly condition payment upon compliance with 42 U.S.C. § 1320c-5(a)) with *United States v. Villaspring Health Care Ctr*., Inc., No. 3:11-43-DCR, (E.D. Ky. Dec. 19, 2011) (holding that it is not necessary that the government demonstrate that the services were completely lacking, the government must simply show that residents were not provided with the quality of care required under the statutory standard).

In many cases, the facts in a worthless service case demonstrate far more deficiencies in performance than a handful of technical regulatory violations. As the *NHC Health Care* case illustrates, litigating worthless care claims pursuant to the FCA in these types of cases is fundamentally different than enforcing regulatory compliance. At issue in these types of worthless care cases is not whether specific, individual requirements have been met. At issue in these cases is whether, taken in total, the care fell below a threshold that was tantamount to non-performance.

In a less egregious case, the line may be harder to draw. Even if it is hard to draw, however, the line is not set by the boundaries of regulatory compliance. To the contrary, the line marks the difference between care that is equivalent to performance, even if imperfect, and care that is tantamount to no performance at all. Although the line may be hard to draw, and may be fact-specific, the fundamental difference between a worthless care case pursuant to the FCA and an accusation of regulatory non-compliance is the holistic effect of the nursing facility's failures. Where the failures do not equate to non-performance, FCA litigation may be inapt. Where, however, the failures in aggregate render the performance so poor that it is equivalent to non-performance—FCA litigation is appropriate.

IV. False Certification

False certification claims originate from situations where a provider fails to comply with regulations, but nonetheless certifies its compliance to the government. *Chesbrough*, 655 F.3d at 467. In some cases, the false certification is express, i.e. in its application for payment, the provider has explicitly represented that the claim complies with applicable laws and regulations. If the claim does not comply with those regulations, then the certification is false.

Recently, the Supreme Court has approved the theory of "implied certification." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S.Ct. 1989 (2016). Pursuant to this theory, liability attaches "if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned." *United States ex rel. Connor v. Saline Reg'l Health Ctr.*, 543 F.3d 1211, 1218 (10th Cir. 2008); *United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 415 (6th Cir. 2002). Under this theory, the certification does not have to appear on the face of the claim.

In certain cases, false certification may be egregious. For example, in *United States ex rel. Scharber v. Golden Gate National Senior Care LLC*, 135 F.Supp.3d 944 (D. Minn. 2015), it was alleged that the nursing facility falsified documents in advance of government surveys to falsely depict the facility as being in compliance with mandated regulations notwithstanding that the facility was well aware of its non-compliance. In addition to manipulating the surveys, the facility billed for care where staff levels fell below regulatory guidelines. *Id*. at 951-53.

The nursing facility argued that FCA liability did not attach, but the *Scharber* court disagreed. The court concluded that what matters is whether the wrongdoing was material to payment, noting that:

> The FCA is not concerned with regulatory noncompliance. The FCA attaches liability, not to the underlying fraudulent activity, but to the claim for payment. The scope of regulatory requirements and sanctions may affect the fact-intensive issue of whether a specific type of regulatory non-compliance resulted in a materially false claim for a specific government payment. The issue is often complex and may require inquiry into whether a regulatory requirement was a precondition to the government payment or merely a condition of continuing participation in a government program.

Id. at 963 (citing United States ex rel. Onnen v. Sioux Falls Indep. Sch. Dist. No. 49-5, 688 F.3d 410, 414-15 (8th Cir. 2012)).

As the Scharber case illustrates, litigating false certification claims pursuant to the FCA is fundamentally different than enforcing regulatory compliance. At issue in a false certification care case is not whether specific individual requirements have been met, but rather whether certification of

compliance was a material misrepresentation that would have resulted in non-payment had the government known.

V. Opposition to Quality of Care Litigation Pursuant to the FCA

Over the past several years, the government has increasingly pursued worthless service and false certification claims in the context of nursing facilities. Such cases involve not only false claims and losses to the government, but often devastating consequences for the vulnerable elderly and disabled residents.

Opponents of such application of the FCA raise numerous arguments, all of which can be countered. First, they argue that through these cases, the government is inappropriately using the FCA to regulate nursing facilities. While arguing that such regulation is better left to the state, opponents further posit that the government is attempting to engage in administrative or judicial expansion of federal regulation of health care.

Such an argument is misplaced in the case of worthless services or false certification cases, even in the context of state-regulated facilities. Regardless of how such facilities are regulated, the FCA applies where the level of care provided is below the threshold that the government would fund. That threshold may be fact-specific in the case of a worthless care claim, or it may be based on material misrepresentations in the case of a false certification case.

The government should not be estopped from pursuing fraud claims simply because a state regulatory system exists. Yet, this would be a consequence of the opponents' argument. There is nothing contrary to public policy about holding a nursing facility liable under the FCA, even where alternative administrative remedies exist.

Second, opponents argue that the FCA was never intended to encompass worthless services or false certification claims in the health care context. To the contrary, these claims are consistent with the text and legislative history of the FCA. Congress intended that the FCA be the government's primary fraud fighting tool. The Senate Report states that a false claim under the FCA "may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specifications, statute or regulation." S. Rep. No. 99-345 at 9, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274. As the legislative history makes abundantly clear, a violation of a statute or regulation in the nursing home context, that renders a provider ineligible for payment, is squarely the type of conduct that Congress intended to make actionable under the FCA.

As the Supreme Court has observed, in enacting the FCA, Congress was expansive in its desire "to reach all types of fraud, without qualification, that might result in financial loss to the government." *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968); *see also Cook Cnty. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003). Indeed, recovery from persons who knowingly provide substandard and deficient products to the United States was the very impetus for enactment of the FCA. *See United States v. McNinch*, 356 U.S. 595, 599 (1958) (impetus for the FCA was sales of "provisions and munitions to the War Department [during the Civil War]" of "nonexistent or worthless goods").

Third, opponents argue that, as a matter of public policy, the federal government should not be involved in setting health care standards. As noted herein, however, liability under the FCA for worthless

services and false certification claims is not equivalent to an assertion of a claim for regulatory violations or violations of professional standards. To the contrary, although such standards may play a role in the fact-specific inquiry as to whether the claims that were submitted to the government were worthless or constituted false certifications, only care well-below any established standard is actionable.

Although the standard for payment under Medicare and Medicaid is not perfect compliance, and the FCA is not intended to be a vehicle to coerce general regulatory compliance, "the standard of care is indeed at the heart of the agreement between the parties." *NHC Health Care Corp.*, 163 F.Supp.2d *at* 1055. Therefore, it is not inappropriate for the government to use statutory and regulatory standards as a "measuring stick" to help the fact-finder determine whether the services provided sufficient value to support a bill for payment or to determine whether certifications were materially false.

The quality of care in nursing facilities is a matter of significant interest to the federal government. Although federal and state oversight has positively influenced nursing facility quality, problems nonetheless persist. Some problems may amount to mere regulatory violations, but others should be litigated as fraud pursuant to the FCA. When payment is conditioned upon certain statutory requirements, and those requirements are unmet, the government does not get what it bargained for. This basic principle is not changed simply because the bargain arose in the health care context or in the context where state regulation and federal litigation may at times overlap.

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More Money, More Problems: Considerations for the Resolution of Parallel Health Care Fraud Cases

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The published literature on parallel proceedings has focused, in large part, on parallel investigations. As it pertains to parallel resolutions, the available guidance emphasizes certain core principles, including that: (1) the request for a global resolution must come from the defendant, not the government; and (2) the criminal aspects of a global negotiation should be handled by the criminal AUSA, while the civil aspects of a global negotiation should be handled by the civil AUSA. Resolving a parallel health care fraud case, however, involves complex questions and several actors, including the Criminal and Civil Divisions of the U.S. Attorney's Office, *qui tam* relators, victims, and defendants—who are guided by different rules, regulations, and incentives. Defendants, for example, may seek to limit the scope of their conduct in the criminal case while maximizing the scope of the covered conduct and the corresponding liability releases in the parallel civil case. *Qui tam* relators, for their part, may seek to have all recoveries collected through the civil case, where they can claim a statutory share of the proceeds under the False Claims Act, 31 U.S.C. § 3729, *et seq.* (the "FCA"). These dynamics lead to two common questions for civil and criminal AUSAs resolving parallel health care fraud cases:

- Under what circumstances can civil settlement payments be used to offset restitution in the parallel criminal case?
- Are *qui tam* relators entitled to a share of criminal restitution or the proceeds of assets that have been seized and are subject to forfeiture?

I. Using Civil Settlement Payments to Offset Criminal Restitution

Each of the parties to a parallel health care fraud resolution has an independent interest in how the financial aspects of the final agreements are handled. In this way, resolving a parallel case is an exercise in consensus-building that involves maximizing the utility of a defendant's limited resources across the spectrum of civil and criminal obligations. We therefore advocate exploring, early in global settlement negotiations, whether the civil settlement payments can or will be used to offset restitution in the related criminal case. Certainly, the offset analysis can flow in the other direction, as restitution can be used to offset compensatory damages in the parallel civil case. *See, e.g.*, *United States ex rel. Schaefer v. Conti Med. Concepts, Inc.*, 2010 WL 1485660, at * 3 (W.D. Ky. Apr. 12, 2010). We find, though, that defendants and *qui tam* relators prefer the certainty of having the civil settlement executed and paid—a benefit to all

parties—before criminal sentencing where the court independently calculates and orders restitution. In any event, the considerations outlined below apply to both offset scenarios.

Criminal restitution is mandatory in most health care fraud cases under the Mandatory Victim Restitution Act (the "MVRA"), which includes, in its ambit, "offense[s] against property. . . including any offense committed by fraud or deceit" where "an identifiable victim or victims has suffered a physical injury or pecuniary loss." 18 U.S.C. § 3663A(a)(1), (c)(1)(A)–(B). The MVRA further provides that:

> [a]ny amount paid to a victim under an order of restitution shall be reduced by any amount later recovered as compensatory damages for the same loss by the victim in—
>
> (A) any Federal civil proceeding; and
>
> (B) any State civil proceeding, to the extent provided by the law of the State.

18 U.S.C. § 3664(j)(2) (emphases added). The purpose of Section 3664(j)(2) "is to prevent double recovery by a victim." *United States v. Stanley*, 309 F.3d 611, 613 (9th Cir. 2002). Section 3664(j)(2) thus reflects the general principle that restitution should not result in double recoveries by a victim. *See United States v. Fore*, 169 F.3d 104, 110 (2d Cir. 1999); *United States v. Hamburger*, 414 F. Supp. 2d 219, 224 (E.D.N.Y. 2006); *United States v. Anderson*, 85 F. Supp. 2d 1084, 1102 (D. Kan. 1999). Whether civil settlement payments can offset criminal restitution depends on whether the civil recoveries qualify as compensatory damages for the same loss in the criminal case.

Whether the parties proceed under Section 3664(j)(2) or the general rule against double recoveries, civil settlement payments only qualify as offsets to the extent that such recoveries constitute "compensatory damages for the same loss by the victim." 18 U.S.C. § 3664(j)(2); *see also United States v. Manzer*, 69 F.3d 222, 230 (8th Cir. 1995) (noting that a reduction to the initial restitution calculation is appropriate only to avoid a "double recovery for the same loss through both a restitution order and a civil judgment") (emphasis added). Calculating compensatory damages, simple in theory, is complicated in the application. To begin, FCA settlements, by their nature, present challenges because the FCA's damages multiplier has both compensatory and punitive functions. *See Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 131 (2003). As the Supreme Court noted in *Chandler*, "the tipping point between payback and punishment" in categorizing FCA recoveries "defies general formulation, being dependent upon the workings of a particular statute and the course of particular litigation." *Id.* at 130. Civil AUSAs, moreover, are instructed to remain neutral on the characterization of settlement proceeds in settlement agreements, and silent as to whether such proceeds constitute single, double, or treble damages (or some variation thereof) under the FCA.

To further complicate the quantification of compensatory damages, it is the rare case in which a civil FCA settlement is perfectly coextensive with a parallel criminal resolution. Civil settlements may involve longer loss periods (due to the more generous FCA limitations period), additional misconduct, and different theories of liability. For example, the affirmative submission of a false Medicare claim in violation of the FCA, 31 U.S.C. § 3730(a)(1)(A), typically leads to a failure to refund the resulting overpayment in violation of the statute, *id.* § 3730(a)(1)(G). Defendants thus have every incentive to broaden the scope of the covered conduct, legal theories, and the attendant releases in civil cases. At the same time, defendants, eyeing the Sentencing Guidelines, are motivated to limit the scope of the illegal conduct and loss in the parallel criminal case. This can result in parallel civil and criminal health care fraud resolutions that only partially overlap in terms of covered conduct. Several courts have declined to offset restitution in these circumstances, particularly when the civil settlement does not clearly apportion recoveries to specific claims. *See, e.g.*, *United States v. Parsons*, 141 F.3d 386, 393 (1st Cir. 1998) (refusing to offset criminal

restitution when the civil settlement satisfied a broader universe of claims in addition to the one for which the defendant was paying restitution); *United States v. All Star Indus.*, 962 F.2d 465, 477 (5th Cir. 1992) (declining to offset criminal restitution when (1) the civil settlement addressed a broader class of victims and conduct; and (2) "the [defendant] . . . offered no accounting to show how the victims of its criminal conspiracy received restitution through that civil conspiracy settlement").

United States v. Arguin, No. 00-10383, 2010 WL 2893515 (D. Mass. July 26, 2010) illustrates the complexity involved in calculating offsets to criminal restitution. In *Arguin*, the defendant advised the United States Air Force to purchase goods and services from third-party contractors who, in turn, paid the defendant to provide certain of those goods and services in violation of contractual and regulatory conflict-of-interest rules. *Id.* at 1. After the defendant pled guilty to twenty-four counts of a criminal indictment, the court apportioned liability and imposed $3,200,000.00 of the total restitution obligation (over $9,000,000.00) on the defendant. *Id.* The Government subsequently brought a civil FCA suit against the defendant's employer based on the same underlying facts. *Id.* The civil case was settled for $15,000,000.00, plus interest, after the Government obtained summary judgment on FCA liability. *Id.* at 3. At the time, the Government had previously recovered $6,230,000.00 from parties in the criminal case. *Id.* at *5.

The defendant, citing 18 U.S.C. § 3664(j)(2), moved the court in the criminal case for an order declaring that his restitution obligation was satisfied by the Government's recovery of over $15,000,000.00 in the related civil case. *Arguin*, 2010 WL 2893515, at *1. The court, recognizing that "whether to offset a settlement agreement against restitution sometimes is a judgment call," held that the civil FCA recoveries offset the defendant's restitution obligation in its entirety. *Id.* at *4. The court reasoned as follows:

First, on summary judgment in the civil case, the Government quantified its damages as "$30,106,121.73 (treble damages)," which the court noted equated to $10,035,373.91 in single damages. *Id.* at *2.

Second, citing *United States v. Bornstein*, 423 U.S. 303 (1976), the court found that double damages under the FCA serve a compensatory purpose. *See Bornstein*, 423 U.S. at 314–17 (referencing "the congressional judgment that double damages are necessary to compensate the Government completely for the costs, delays and inconveniences occasioned by fraudulent claims"). The court calculated that the Government was therefore owed $20,070,747.82 in compensatory (double) damages in the civil case, less the $6,230,000.00 the Government collected in the criminal case, leaving an outstanding balance of $13,840,747.82. Because the Government collected $15,000,000.00 in the civil settlement, the Government was "fully compensate[d] for the FCA loss" and, under 18 U.S.C. § 3664(j)(2), the related criminal restitution. *Arguin*, 2010 WL 2893515, at *5.

The court supported its conclusion by citing a press release announcing the civil settlement in which the Government stated that "[t]he $15 million recovered in the settlement agreement is more than the restitution figures from the criminal cases. The United States' total recovery in these actions exceeds by approximately $10 million the losses it estimated as a result of the misconduct." *Id.* at *3.

The court was not persuaded by the Government's argument that offsetting was inappropriate because the civil settlement resolved claims and damages theories beyond those at issue in the criminal case. *Id.* at *5. The court noted that the Government, in its summary judgment brief, "did not explain [those theories] or seem to press a claim for these additional damages." *Id.* The court concluded, from the record

in the civil case, that "it is unlikely the government relied on those monies for its theory of damages in the [civil] litigation." *Id.*

Arguin, of course, was not a true parallel case insofar as the civil case followed a completed criminal prosecution. The parties in that case were therefore not in a position to address the offset issue as part of a global resolution. This left the court to decide the issue, to include referencing and divining the Government's intent from pleadings and press releases in the civil case. *Arguin* nonetheless demonstrates the utility of analyzing and reaching agreements on offsets during global settlement negotiations in parallel cases. Where the parties reach such an agreement, it is advisable to raise that issue with the court during the criminal proceedings, whether in a plea agreement, presentence investigation report, or at sentencing. This not only avoids potentially unnecessary litigation, but absolves civil AUSAs of having to characterize recoveries in the civil case.

In cases where offsets are feasible, and where assets have been seized but not forfeited in the criminal case, criminal AUSAs can, subject to certain thresholds, secure the release of assets subject to forfeiture to apply toward the civil settlement—and, by extension, criminal restitution—without resort to the remission and restoration processes outlined at 28 C.F.R. Part 9. *See* Asset Forfeiture Policy Manual at 81–82, 2016, U.S. DEP'T OF JUSTICE, http://www.justice.gov/sites/default/criminalafmls/file/839521/download (providing that U.S. Attorneys have the authority to settle civil or criminal forfeiture cases in which: (1) the amount involved does not exceed $1 million, regardless of the amount to be released to the claimant or defendant; or (2) the amount involved is between $1 million and $5 million, if the amount to be released to the claimant or defendant does not exceed 15 percent of the original claim). In those cases, the parties can file a joint motion to release and/or allow the sale of seized property in order to apply the proceeds toward the civil settlement and criminal restitution. These motions afford the parties another opportunity to outline, for the court, any agreements on offsets to criminal restitution.

Finally, the parties to a global resolution should be aware that several courts have concluded that, to qualify as an offset under the MVRA, 18 U.S.C. § 3664(j)(2), the victim must receive civil proceeds after an order of restitution has been entered in the criminal case. *See, e.g.*, *United States v. Joseph*, 743 F.3d 1350, 1355 (11th Cir. 2014) ("[T]he MVRA . . . specifically prohibits the court from reducing [the restitution] amount by the value of any other compensation received by the victim before entry of the restitution order."); *United States v. Banks*, 62 F. Supp. 3d 125, 132 (D.D.C. 2014) (declining to offset restitution where the defendant "settled with, and paid [the victim] for the same loss months before the Court entered the restitution order") (emphasis in original). If the parties proceed under 18 U.S.C. § 3664(j)(2), defendants should: (1) escrow the civil settlement amount in an interest-bearing account during settlement negotiations pursuant to the terms of an escrow agreement with the government; and (2) further agree, in the civil settlement agreement, to release the escrowed funds toward payment of the civil settlement amount within a prescribed number of days following entry of the criminal restitution order. Defendants then have the burden of moving the court, under Section 3664(j)(2), to modify their restitution obligations.

II. *Qui Tam* Relators and Criminal Recoveries

Qui tam relators in civil health care fraud cases may assert that the "proceeds of the action" in which relators are entitled to participate under the FCA, 31 U.S.C. § 3730(d), include criminal restitution and the assets, or value of any assets, seized in a parallel criminal case. To that end, relators may argue that the related criminal case constitutes an alternate remedy under the FCA, *id.* § 3730(c)(5). That provision of the FCA provides, in relevant part, that

> the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have if the action had continued under this section.

31 U.S.C. § 3730(c)(5). Relators must clear a number of hurdles before even reaching the ultimate question of whether criminal or asset forfeiture proceedings constitute alternate remedies under the FCA.

First, the *qui tam* action must have been pending at the time the government pursued criminal or asset forfeiture proceedings; otherwise, the government cannot have made an "election" within the meaning of the FCA, 31 U.S.C. § 3730(c)(5). *See United States ex rel. Babalola, et al. v. Sharma, et al.*, 746 F.3d 157, 162 (5th Cir. 2014) ("[F]or a remedy to be 'alternate' to the qui tam proceeding, there must have been two proceedings from which to choose. Accordingly, we hold that the *qui tam* proceeding must have been in existence at the time of the Government's election of the alternate remedy."). Note that the court in *United States v. Dyck* extended this principle, finding that while the Government filed criminal charges three years after the pending *qui tam* action, the government made no "election" under § 3730(c)(5) because: (1) the government (*i.e.*, HHS-OIG) initiated the criminal investigation before the relators filed the civil case; and (2) the relators could not establish that the information they provided to the government was new or prompted the criminal investigation. *See* Order Denying Relators' Motion to Intervene, *United States v. Van Dyck*, No. 2:15-cr-00200 (E.D. Cal. Mar. 30, 2016).

Second, the government must have declined to intervene in the *qui tam* action. The government does not elect an alternate remedy under the FCA when it intervenes in a *qui tam* action. *See United States ex rel. Bledsoe v. Comm'y Health Sys., Inc.*, 342 F.3d 634, 649 (6th Cir. 2003) ("[A] settlement pursued by the government in lieu of intervening in a *qui tam* action asserting the same FCA claims constitutes an 'alternate remedy' for purposes of 31 U.S.C. § 3730(c)(5)."") (emphasis added); *United States ex rel. Barajas v. Northrop Corp.*, 258 F.3d 1004, 1010 (9th Cir. 2001) ("An alternate remedy under § 3730(c)(5) is a remedy achieved through the government's pursuit of a claim after it has chosen not to intervene in a qui tam relator's FCA action.") (emphasis added) (citing *United States ex rel. LaCorte v. Wagner*, 185 F.3d 188, 192 (4th Cir. 1999) and *United States ex rel. Dunleavy v. County of Delaware*, 123 F.3d 734, 739 (3d Cir. 1997)). If a parallel health care fraud case involves an intervened civil *qui tam* case, or if the government has yet to make an intervention decision in the *qui tam* case (because the case has been stayed pending resolution of the criminal case, for example), there will be no election of an alternate remedy within the meaning of the FCA.

Third, relators must establish that they could have recovered the proceeds of criminal restitution or the seized assets if the action had continued under the FCA. *See* 31 U.S.C. § 3730(c)(5) (stating, in relevant part, that "the person initiating the action shall have the same rights in such proceeding as such person would have if the action had continued under this section"); *United States v. Kurlander*, 24 F. Supp. 3d 417, 425 (3d Cir. 2014) (denying relators' motion to intervene in criminal proceedings because, in part, there was no "showing that the criminal pleas . . . actually implicate[d] any federal dollars or monies recoverable under their FCA action"). This becomes an issue if relators seek to share in criminal restitution related to private insurance reimbursements. In *United States v. Rathod*, No. 1:12-cr-17, 2012 U.S. Dist. LEXIS 158951 (W.D. Mich. Oct. 17, 2012), a parallel health care fraud case in the Western District of

Michigan, the lead defendant paid a civil settlement of $1,000,000.00 related to Medicare and Medicaid reimbursements and $50,000.00 in additional criminal restitution related to upcoded claims that were submitted to Blue Cross Blue Shield of Michigan ("BCBSM"). While the relator claimed entitlement to a share of the $50,000.00 relating to BCBSM losses, she was not entitled to share in that criminal restitution under § 3730(c)(5) because: (1) the Government intervened in the *qui tam* case and did not elect an alternate remedy; and (2) the relator had no right to recover private insurance reimbursements under the FCA or its state-law analogue. *Id.*

Even if relators clear these hurdles, the majority of courts hold that criminal and asset forfeiture proceedings do not constitute alternate remedies under the FCA, 31 U.S.C. § 3730(c)(5). In *Kurlander*, for instance, the Third Circuit denied the *qui tam* relators' motion to intervene in a criminal case for purposes of sharing in any restitution, opining that "third parties generally have no right to intervene in criminal proceedings," and "no private party has a judicially cognizable interest in a criminal prosecution." 24 F. Supp. 3d at 423–24; *see also United States v. Lustman*, No. 05-40082, 2006 WL 1207145, at *3 (S.D. Ill. May 4, 2006) ("Surely Congress would have explicitly specified criminal prosecutions as an 'alternate remedy' [under the FCA] if it intended" to allow relators to participate in criminal cases.").

Relators often cite two cases—*United States v. Bisig, et al.*, No. 100-cv-335, 2005 WL 3532554 (S.D. Ind. Dec. 21, 2005) and *United States v. Wellcare Health Plans, Inc.*, No. 8:09-cr-203, 2011 WL 4431157 (M.D. Fla. Sept. 21, 2011)—in support of their argument that relators are entitled to share in restitution and forfeiture funds. The issue was not contested in *Wellcare*, however, because the government agreed to escrow a portion of the restitution proceeds to pay to the relator. *See Wellcare*, 2011 WL 4431157, at 2. The *Wellcare* court nevertheless cast doubt on whether the relator could have shared in those criminal proceeds without the government's voluntary escrow of the restitution payments. *See id.* at *1. The court opined that the relator's statutory right to a share was limited to the "proceeds of the action" under the FCA, 31 U.S.C. § 3730(d)(1), which "unambiguous[ly] refer[s] to the intervened qui tam case, not a companion criminal proceeding," *Wellcare*, 2011 WL 4431157, at 1 (emphasis added).

Unlike *Wellcare*, the *Bisig* court squarely considered the issue and said that "whether the United States recovered proceeds of the fraud through the *qui tam* action or through criminal forfeiture, the result should be the same: the relator must be rewarded for its part in uncovering the fraud." *Bisig*, 2005 WL 3532554, at 5. *Bisig* has been roundly criticized in subsequent cases. *See Kurlander*, 24 F. Supp. 3d at 423 ("[Defendants and the Government] assert that *Bisig* was wrongly decided and, as it is not binding on this Court, should be ignored. This Court agrees."); *Lustman*, 2006 WL 1207145, at *3 (finding that *Bisig* "has no precedential value").

As set forth in *Kurlander*, the forfeiture of property—including the seizure and disposition of that property in any related judicial or administrative proceeding—is governed by 21 U.S.C. § 853. *See Kurlander*, 24 F. Supp. 3d at 424 (citing 18 U.S.C. § 982(b)(1)). Under 21 U.S.C. § 853(k):

> [No] party claiming an interest in property subject to forfeiture may—
>
> (1) intervene in a trial or appeal of a criminal case involving the forfeiture of such property under this section; or
>
> (2) commence an action at law or equity against the United States concerning the validity of his alleged interest in the property subsequent to the filing of an indictment or information alleging that the property is subject to forfeiture under this section.

The only exception to this prohibition is set forth in 21 U.S.C. § 853(n)(2), which provides, in relevant part, that only persons with "legal interest in property which has been ordered forfeited to the United States" may petition the court and, even then, the petition is limited to adjudicating "the validity of his alleged interest in the property." The FCA's alternate remedy provision does not create a substantive legal right or give *qui tam* relators a cognizable legal interest in property that has been seized or forfeited in a parallel criminal case. In *United States v. Van Dyck*, the court expressly rejected the relators' argument that they were "partial assignees of [the] [g]overnment's claims pursuant to their qui tam action . . . [which] allege[d] the same fraudulent conduct and [sought] recovery of the same funds as forfeited by Defendant[.]" Order Denying Relators' Motion to Intervene at 10, *United States v. Van Dyck*, No. 2:15-CR-00200 (E.D. Cal. Mar. 30, 2016). Even if the relators could have somehow established the claimed "partial assignment" of forfeiture proceeds, the *Van Dyck* court found that the "Relators ha[d] not shown they ha[d] a recognized interest in the criminal forfeiture proceeding." *Id.*

It is unlikely that relators could establish such priority legal interests in forfeited property, as a legal matter, under 21 U.S.C. § 853(n). To succeed on a third-party claim under 21 U.S.C. § 853(n)(6)(A), a petitioner must establish, in relevant part, that he or she "has a legal right, title, or interest in the property" that "was vested in the petitioner . . . at the time of the commission of the acts which gave rise to the forfeiture of the property[.]" *Id.* (emphasis added). To succeed on a third-party claim under 21 U.S.C. § 853(n)(6)(B), a petitioner must establish that he or she was "a bona fide purchaser for value of the right, title, or interest in the property" and "was at the time of purchase reasonably without cause to believe that the property was subject to forfeiture[.]" *Id.* (emphasis added). Both subsections reference the "relation back" doctrine, which states that "[a]ll right, title, and interest in property [subject to forfeiture] vests in the United States upon the commission of the act giving rise to forfeiture[.]" *Id.* § 853(c).

In the first instance, relators can only succeed on third-party claims in forfeiture under 21 U.S.C. § 853(n)(6)(A) if they can identify a cognizable interest in the forfeited property at the time the fraudulent activities took place. It is unlikely that relators would have such contemporaneous interests, because: (1) relators typically report health care fraud after the illegal conduct has occurred and the fraud proceeds have been generated; and (2) relators' economic interests in the proceeds of an action or settlement of a claim under the FCA only emerge after the fraudulent conduct has occurred. It is also unlikely that relators, by virtue of their statutory interests in a share of civil settlement or judgment proceeds, alternatively qualify as "bona fide purchasers for value" of rights or interests in forfeited property within the meaning of 21 U.S.C. § 853(n)(6)(B). *See, e.g.*, *United States v. Watkins*, 320 F.3d 1279, 1283 (11th Cir. 2003) (noting that a bona fide purchaser is "generally understood to mean one who has purchased for value without notice of any defects in the title of the seller") (quotation omitted). For these reasons, relators may fail to state viable third-party claims to the property or proceeds of criminal forfeiture under 21 U.S.C. § 853(n).

III. Conclusion

To some extent, the challenges involved in resolving parallel health care fraud cases can be summarized by the axiom "more money, more problems." Civil and criminal AUSAs can effectively guide the parties through the financial aspects of these global resolutions, however, by analyzing whether civil settlement payments can be used to offset criminal restitution, directing payments through the civil case

when feasible and appropriate, and anticipating relators' arguments for a share of criminal recoveries.

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Pre-Trial Asset Restraints in the Aftermath of *Luis v. United States*

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I. Introduction

In the aftermath of *Luis v. United States*, 136 S. Ct. 1083, 194 L. Ed. 2d 256 (2016), criminal defendants and legal commentators have raised various arguments that are not supported by the decision itself. Thus, federal prosecutors who seek to freeze a healthcare or bank fraud defendant's substitute assets pretrial need to be aware of—and be ready to dismantle—the many myths that the decision left in its wake.

In *Luis* the United States charged defendant Sila Luis ("Luis") with crimes related to healthcare fraud, including paying kickbacks to run her two home health companies. The government alleged that Medicare had paid Luis' companies approximately $45 million as a result of her fraudulent scheme. The government identified and located approximately $2 million in assets either belonging to Luis or under her control. Because the government had been unable to directly trace most of the $2 million to Luis' health care fraud scheme before her arrest, it filed a separate civil action under 18 U.S.C. § 1345 to freeze her assets up to the amount of the fraud. Section 1345(a)(2) allows for a pretrial restraint of property traceable to a banking law violation or a federal healthcare offense or "property of equivalent value." Thus, the statute allows for a pretrial restraint of substitute assets in these kinds of cases, up to the amount of the fraud loss. With schemes like the one in *Luis*, where the fraud occasioned massive losses to federal healthcare programs, § 1345(a)(2) effectively allows all of a defendant's assets to be frozen before trial.

Luis asked the district court to release frozen funds so that she could pay her counsel of choice in the criminal case, arguing that the Sixth Amendment required it. The district court disagreed, finding that

Luis would be appointed counsel if necessary and that a defendant should not be rewarded for spending the "loot" from her crimes, leaving only untainted assets available for counsel. The Eleventh Circuit affirmed, finding the matter settled by prior Supreme Court precedent in *Kaley v. United States*, 134 S. Ct. 1090, 188 L. Ed. 2d 46 (2014), *Caplin & Drysdale, Chartered v. United States*, 491 U.S. 617, 109 S. Ct. 2646, 105 L. Ed. 2d 528 (1989), and *United States v. Monsanto*, 491 U.S. 600, 109 S. Ct. 2657, 105 L. Ed. 2d 512 (1989).

II. Supreme Court Decision

The Supreme Court in *Luis* vacated the Eleventh Circuit's decision and the district court order and remanded the case. The Court held that the pretrial restraint of untainted substitute assets needed by a criminal defendant to pay defense counsel of choice violated the Sixth Amendment. The plurality opinion was written by Justice Breyer and joined by Chief Justice Roberts and Justices Ginsburg and Sotomayor. Justice Thomas added to the deciding fifth vote but concurred only in the judgment. Justice Kennedy dissented, joined by Justice Alito. Justice Kagan issued a separate dissent.

The plurality opinion was based on a balancing of a defendant's interests, her Sixth Amendment right to counsel of choice, and the government's interest in ensuring that assets are available for forfeiture and restitution to victims. Noting that the right to counsel is "fundamental," Justice Breyer determined that this right trumped the government's interests in assets that were not traceable to the crime, as the government had no interest in those assets prior to conviction. *Luis v. United States*, 136 S. Ct. 1083, 194 L. Ed. 2d 256 (2016). He distinguished the case from *Monsanto*, where the assets were traceable and, under the relation-back doctrine, deemed to be owned by the government as of the commission of the crime. Thus, in cases involving traceable assets, the Court reaffirmed *Monsanto*'s holding that pretrial asset restraints are constitutional. *Id* at 1085. The plurality rejected claims that the constitutional distinction it drew was unworkable. Even though it recognized that money is inherently fungible, it held that district courts would be able to apply tracing principles to distinguish tainted and untainted funds. *Id* at 1087. The plurality also sought to soothe the dissent's concerns by clarifying that the plurality's decision was not a blank check; the requested release of assets must be for a *reasonable* fee. Justice Thomas concurred only in the judgment and rejected the plurality's balancing approach by concluding that the Sixth Amendment requires that a defendant have access to her untainted assets needed to retain counsel of choice. Id at 1097.

In his dissent, Justice Kennedy's argued that the plurality opinion "rewards criminals who hurry to spend, conceal, or launder stolen property by assuring them that they may use their own funds to pay for an attorney after they have dissipated the proceeds of their crime." *Id.* at 1103. He found that Luis' challenge was foreclosed by *Caplin & Drysdale* and *Monsanto*, which did not depend on whether the funds at issue were tainted or untainted, but rather on whether the funds were forfeitable. *Id.* at 1106. Notably, Justice Kennedy explained that the plurality conclusion rested on a faulty premise—that unlike untainted assets, the government had an ownership interest in tainted assets prior to conviction. *Id.* To the contrary, Justice Kennedy argued, the Court's precedents held that the opposite was true. The government does not own property subject to forfeiture until a conviction is obtained. Thus, the dissent saw no constitutional basis to distinguish Luis from the defendant in *Monsanto*. Justice Kennedy concluded that the "true winners today are sophisticated criminals who know how to make criminal proceeds look untainted. They do so every day." Justice Kagan issued a separate dissent, also arguing that the case was controlled by *Caplin & Drysdale* and *Monsanto*, even though she admitted to being troubled by the *Monsanto* decision. *Id.* at 1112.

Because there was no majority opinion in *Luis*, its holding is limited to the conclusion that a criminal defendant has a Sixth Amendment right to use her own untainted property necessary to pay reasonable fees for the assistance of counsel of her choice.

III. Subsequent Cases

The Supreme Court's decision in *Luis* has been raised both in subsequent civil cases under 18 U.S.C. § 1345 and in criminal cases to challenge the government's actions under the forfeiture statutes. It is therefore important to understand the limited scope of the Court's decision:

(1) In *Luis*, the Court ***did not strike down*** *18 U.S.C. § 1345* ***as unconstitutional***. In fact, the Court rejected the petitioner's invitation to read § 1345(a)(2) in a manner that would have effectively invalidated the authority to restrain pretrial substitute assets. By rejecting this reading, the Court was forced to confront the constitutional question, and answered it by holding that such a restraint was invalid only to the extent that it restrained a defendant's untainted assets needed to retain counsel of choice in a criminal case. Beyond that, pretrial restraints of substitute assets under § 1345 remain valid. Thus, if a court releases $100,000 as a reasonable attorney's fee for a criminal defendant's counsel of choice, but the government had restrained $1 million under 18 U.S.C. § 1345, then the remaining $900,000 are still properly frozen under the statute. All other subsections of 18 U.S.C. § 1345, which address other remedies in bank fraud and healthcare fraud cases, similarly survived intact.

(2) Necessarily, then, ***courts may continue to freeze or restrain a defendant's substitute assets before trial***. *Luis* simply placed a limit on such restraint in cases where untainted assets are needed to pay a reasonable fee for retaining criminal defense counsel of choice. This is true both for assets frozen under § 1345 and for assets frozen pursuant to the forfeiture statutes (in jurisdictions that allow pretrial restraints of substitute assets).

(3) ***Luis did not limit pretrial restraints of substitute assets in the Fourth Circuit.*** The Fourth Circuit is the only circuit that permits pretrial restraints of substitute assets under the forfeiture statutes, and *Luis* did not invalidate that body of case law, subject, of course, to a defendant's ability to raise Sixth Amendment challenges.

(4) Although *Luis* certainly held that a defendant is entitled to use her untainted assets needed to pay for her criminal defense, it did not resolve the question of ***what showing a defendant must make to demonstrate a need for those assets***. For example, nothing in any of the opinions in *Luis* calls into question the *Jones-Farmer* line of cases that require a defendant to demonstrate, as a prerequisite to challenging a pretrial restraining order on Sixth Amendment grounds, that she has access to no other assets with which to retain defense counsel of choice. *See United States v. Jones*, 160 F.3d 641, 647 (10th Cir. 1998); *United States v. Farmer*, 274 F.3d 800, 805 (4th Cir. 2001). Prosecutors should reasonably argue that a defendant must first establish such need if she is to raise, and prevail on, a Sixth Amendment challenge. For example, if the defendant placed a $1 million property in the name of a relative or other straw owner in order to conceal it, she should not be able to force the government to release frozen substitute assets to pay for her defense.

(5) Another question that *Luis* left unresolved is the definition of a "***reasonable fee***," which the plurality found had to be released from frozen substitute assets to pay criminal defense counsel. Case law about what constitutes a "reasonable fee" in this context is sparse, especially where defense counsel demands an upfront payment in order to enter a permanent appearance on behalf of a defendant in a criminal case. District courts will have to resolve these issues when the government and defense cannot agree on whether a specific fee is reasonable in a particular case.

(6) *Luis* addressed a criminal defendant's right to seek release of frozen assets only to exercise her Sixth Amendment right to counsel of choice. The Court ***did not address release of funds for any other reason***. Thus, the Court's decision did not address release of funds for living expenses or the defendant's exercise of other constitutional rights, such as those involving speech or religion. The Court focused only on the Sixth Amendment and relied on the unique function of criminal defense counsel and the serious consequences of a criminal conviction. While criminal defendants and civil litigants may argue that *Luis* supports their requests for release of funds for other reasons, the decision simply does not extend so far.

(7) The decision in ***Luis was limited to the pretrial stage*** of a criminal proceeding, and the Court explained the special role played by counsel in assisting a criminal defendant trying to avoid conviction. Criminal defendants have tried to invoke *Luis*, however, in the post-conviction context, where the government is already entitled by law to the defendant's substitute assets to satisfy a forfeiture or restitution order. Courts will need to carefully evaluate arguments that attempt to stretch *Luis* beyond its original context.

(8) ***Luis did not overrule Monsanto***. In fact, the opposite is true. The plurality opinion carefully distinguished its holding from the holding in *Monsanto* by relying on the differences between tainted and untainted assets. In describing this distinction, the Court upheld the validity under the Sixth Amendment of a pretrial restraint of tainted assets, thereby reaffirming the conclusion of *Monsanto*. While Justice Kagan noted that she was troubled by the decision in *Monsanto*, she did not reach the ultimate question of the validity of that holding, and, in any event, no other Justice joined in her dissent. Thus, *Luis* cannot be read to call into question pretrial restraints of tainted assets.

IV. Conclusion

The Supreme Court's decision in *Luis*, while limited to a particular challenge to a pretrial asset restraint under 18 U.S.C. § 1345, will surely be the catalyst for considerable litigation involving asset restraints generally. As the government becomes more aggressive in seeking to forfeit proceeds of fraud and recovering assets to compensate victims of fraudulent schemes, challenges based on *Luis* will surely proliferate. Prosecutors must be ready to clearly explain why *Luis* does not support the weight of the expansive claims being made in its name.

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Fighting Opioid Abuse Under Federal Health Programs With the False Claims Act

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I. Introduction

Prescription opioid pain medications have become a significant drug of abuse in the last several years. While the United States accounts for only 4.6 percent of the world's population, we consume 80 percent of the world's supply of opioids and 99 percent of the world's supply of hydrocodone. L. Manchikanti & A. Singh, *Therapeutic Opioids: A Ten-year Perspective on the Complexities and Complications of the Escalating Use, Abuse, and Nonmedical Use of Opioids*, 11 PAIN PHYSICIANS S63, S63-88 (2008). Nearly 10 million Americans, or 4.1 percent of adults, used opioids in 2013, either without a prescription or in a greater amount, frequency, or duration than prescribed. Tulshi D. Saha, Ph.D., *et al.*, *Nonmedical Prescription Opioid Use and DSM-5 Nonmedical Prescription Opioid Use Disorder in the United States*, 77 J. CLIN. PSYCHIATRY 772, 772-80 (2016).

Some of the doctors who enable opioid-addicted Medicare patients have manipulated Medicare Part D and other federal health care programs so that most of these drugs' cost will be borne by the Federal Government. Their methods include reporting false diagnoses, prescribing for non-covered indications, and prescribing excessive quantities. Since some of these opioid medications have a high cost and, therefore, a high reimbursement rate, these false claims can result in significant losses to the Medicare program. They can also result in patient death. For example, in June 2016, a federal jury found a physician guilty of operating a "pill mill," distributing opioid pain medication for no legitimate medical purpose, leading to the death of a patient. Press Release, U.S. Attorney, E. Dist. of Pa., Jury Finds Philadelphia Doctor Guilty of Running Pill Mill and Causing a Death Through Illegal Distribution (June 29, 2016).

The civil False Claims Act provides a means for combatting opioid abuse by recovering treble damages and civil penalties from the prescribers and those who assist them.

II. Legal Framework

A. Medicare Part D and Medicaid

Medicare coverage for opioid medications is provided in Part D, the prescription drug benefit program available to Medicare recipients who voluntarily enroll. 42 U.S.C. §§ 1395w-102 (2010). Some

non-opioid drugs are separately covered by Medicare Part B, the fee-for-service program, but those drugs are not relevant to this article.

To participate in Part D, a beneficiary must enroll in a Part D Plan of their choice. The beneficiary pays premiums to the Plan's sponsor, which is a private entity approved by the Centers for Medicare and Medicaid Services (CMS). Coverage in the Plan includes deductibles, copayments, and benefit caps. The beneficiary fills the prescription at a pharmacy, which submits a claim to the Plan sponsor, and the sponsor pays the pharmacy directly or through a subcontractor. CMS reimburses the sponsor for varying portions of the prescription costs. *See Omnicare, Inc. v. UnitedHealth Group, Inc.*, 594 F.Supp.2d 945, 948-49 (N.D. Ill. 2009).

To be a "covered Part D drug," a drug must be: (1) dispensable only by prescription; (2) one of the three types of "covered outpatient drug" defined in 42 U.S.C. § 1396r-8(k)(2)(A) (2016); and (3) used for a "medically accepted indication." 42 U.S.C. §§ 1395w-102(e)(1) (2010). Item (2), the "covered outpatient drug" requirement, is met by a drug which is either: (1) approved as safe and effective under 21 U.S.C. § 355 (2015), 21 U.S.C § 357 (1997), or 21 U.S.C. § 355(j) (2015), the Food Drug and Cosmetic Act; (2) commercially used or sold in the United States before October 10, 1962, and has not been determined to be a "new drug"; or (3) approved as a "new drug" under 21 U.S.C. § 355(c) (2015).

Item (3), the "medically accepted indication" requirement, is contained in a clause that is not artfully drafted, but which has been construed by the great majority of courts to be an affirmative requirement applicable to all covered Part D drugs. *See, e.g.*, *Roeder v. Burwell*, No. 1:15-CV-01194, 2016 WL 3461280 at *2-3 (E.D. Va. June 21, 2016) ; *but see Layzer v. Leavitt*, 770 F.Supp.2d 579, 587 (S.D.N.Y. 2011) (holding this language is only illustrative, not definitive). Every subsequent decision has disagreed with *Layzer*. The majority rule can also be arrived at by applying the definition of requirement (2), "covered outpatient drug," which specifically states that it does not include any drug "used for a medical indication which is not a medically accepted indication." 42 U.S.C. §§ 1396r-8(k)(3) (2016).

The most important of these three requirements for present purposes is the third, that the drug be used for a medically accepted indication. The statute and the regulation define this term by incorporating the Medicaid definition in 42 U.S.C. §§ 1396r-8(k)(6) (2016). *See* 42 U.S.C. §§ 1395w-102(e)(4)(A)(ii) (2010); 42 CFR § 423.100 (2016). The discussion in this section therefore applies to both Medicare Part D and Medicaid covered opioid drugs. For ease of reference, this article will refer to both programs as "Part D" coverage. The definition is:

> The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 *et seq*.] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

42 U.S.C. §§ 1396r-8(k)(6) (2016). The compendia referred to are "(I) American Hospital Formulary Service Drug Information; (II) United States Pharmacopeia-Drug Information (or its successor publications); and (III) the DRUGDEX Information System." 42 U.S.C. §§ 1396r-8(g)(1)(B)(i). Access to these compendia is available by contacting the National Security Division of the Justice Management Division, or through a local medical school or pharmacy school library.

Please note, however, that three district court cases appear to have misread these statutes in a significant way. In both *United States ex rel. Brown v. Pfizer, Inc.*, 2016 WL 807363 *11 (E.D. Pa. Mar. 1, 2016); and *United States ex rel. Cestra v. Cephalon, Inc.*, 2015 WL 3498761 *9 (E.D. Pa. June 3,

2015), the courts looked to the definitions section of Medicare Part D for the definition of "covered Part D drug." They utilized the definition in 42 U.S.C. §§ 1395x(t)(2)(B)(ii)(I), which requires that in order to be covered, the use of certain drugs must not only be supported by one of the approved compendia, but cannot be "identified as not indicated in one or more such compendia." Another district court decision, *United States ex rel. Brown v. Celegne Corp.*, 2014 WL 3605896 *6 (C.D. Cal. 2014), came to the same conclusion based on MEDICARE BENEFIT POLICY MANUAL Ch. 15, § 50.4.5 (Rev. 222, May 13, 2016). Under that reading, in other words, a drug would be covered only if it is supported by at least one compendium and not expressly found *not indicated* by any other compendium.

What these three courts failed to recognize is that the provisions they relied on actually apply only to a small subset of Part D drugs – drugs that are "used in an anticancer chemotherapeutic regimen," *see* 42 U.S.C. §§ 1395x(t)(2)(B)(ii)(I); MEDICARE BENEFIT POLICY MANUAL Ch. 15, § 50.4.5(A) (Rev. 222, May 13, 2016). The more-restrictive definition therefore does not apply to opioids or any of the many other non-cancer drugs covered by Part D. The definition of "medically accepted indication" in 42 U.S.C. § 1395w-102(e)(4)(A) (i) and (ii) and (ii) (2016) confirms this by stating that one set of rules (including those in 42 U.S.C. § 1395x(t)(2)(B)) apply to drugs used "in an anticancer chemotherapeutic regimen," while the Medicaid rules apply to "any other covered Part D drug". MEDICARE BENEFIT POLICY MANUAL Ch. 15, § 50.4.2 (Rev. 222, May 13, 2016).

It is important to recognize that the rule applied by these three decisions' misreading of the law does not impair the Department's enforcement of the False Claims Act. The rule adopted by these three cases would actually broaden the group of claims that would be considered false. Under the correct rule, an off-label use causes a false claim only if the use is not listed as "supported" by at least one compendium. Under the three cases' reading, however, a use would lead to a false claim if either: (1) the use is not listed as "supported" by any compendium; *or* (2) the use is listed as "not indicated" in any compendium. Nonetheless, advocacy in favor of the correct reading of the statutes is the preferred course. Therefore, the error in these decisions should be brought to the court's attention if any of them is cited in a false claim case under Part D.

The Medicare manuals provide additional guidance on Part D drug coverage. The MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL, Ch. 6, § 10.6 (Rev. 18, Jan. 15, 2016), clarifies the statute in some respects. For example, this Manual states that a medically accepted indication "refers to the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication." *Id.* It also states: "Dispensing pharmacists are not required to contact each prescriber to verify a prescription is being used for a medically-accepted indication." *Id.* The Manual encourages Plan D sponsors to use utilization management edits to avoid the use of a drug for non-medically accepted indications. *Id.*

To summarize, Part D and Medicaid cover only prescription drugs used for a "medically accepted indication," which means used either for an indication approved on the Food and Drug Administration (FDA) label, or for an "off-label" indication which is "supported" by one of the approved compendia (except in the two districts noted above). If a drug is prescribed outside of these limitations, it is not a "covered Part D drug," and a claim for payment based on the prescription is a false claim.

B. TRICARE

Drug coverage under the TRICARE program differs from that under Medicare and Medicaid. TRICARE's regulations provide that TRICARE:

> will consider coverage of off-label uses of drugs and devices that meet the definition of Off–Label Use of a Drug or Device in 32 C.F.R. § 199.2(b). Approval for reimbursement of off-label uses requires review for medical necessity and also requires demonstrations from medical literature, national organizations, or technology assessment bodies that the off-label use of the drug or device is safe, effective, and in accordance with nationally accepted standards of practice in the medical community.

32 CFR § 199.4(g)(15)(i)(A), Note 3 (2016). The definition of Off-Label Use in 32 C.F.R. § 199.2(b) (2016), referred to in the quote above, essentially includes any use not approved on a drug's label.

One court considered this TRICARE coverage provision to contain "a much more flexible standard" than that applicable to Medicare and Medicaid. *United States ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F.Supp.3d 504,521 (E.D. Pa. 2015). Another judge in the same district, however, found TRICARE's rule to be an "even stricter regulation[]" than Medicare's and Medicaid's. *United States ex rel. Bergman v. Abbot Laboratories*, 995 F.Supp.2d 357, 370 (E.D. Pa. 2014). As a result, *Gohil* held that the relator's allegations regarding off-label, off-compendium use failed to allege a viable false claim, but *Bergman* held a relator's similar complaint was sufficient. *Id*.

C. FEHB

The drug coverage provided under the Federal Employee Health Benefit Plan (FEHB) is also different from that provided by Medicare and Medicaid. No law or regulation defines when a drug is "medically necessary" for FEHB purposes. Instead, that coverage is spelled out by the plan document applicable to each private plan that administers FEHB coverage for its members. *Gohil*, 96 F.Supp.3d at 521. As a result, the relevant plan document must be consulted to determine whether a given use of a drug has resulted in the submission of a false claim.

III. Establishing Off-Label, Off-Compendium Usage

A. Case-Law Examples

One of the most potent, and therefore most dangerous, synthetic opioids currently available is Fentanyl. The Centers for Disease Control reports that Fentanyl is 50 to 100 times more potent than morphine. CENTERS FOR DISEASE CONTROL, INJURY PREVENTION AND CONTROL, WHAT IS FENTANYL?, (June 3, 2016). Fentanyl is prescribed in the form of transdermal patches or lozenges under the brand names Actiq and Fentora, and as a sublingual spray under the brand name Subsys. The FDA has approved these drugs only for the treatment of breakthrough cancer pain. Physicians are required to enroll in the FDA's Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation Strategy (TIRF-REMS) before they may prescribe, dispense, or distribute a TIRF medication. FOOD & DRUG ADMIN., TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL RISK EVALUATION AND MITIGATION STRATEGY ACCESS, https://www.tirfremsaccess.com/TirfUI/rems/home.action (last visited October 10, 2016).

Several cases have held that Fentanyl, when prescribed and dispensed for an indication that is both off-label and off-compendium (meaning not supported by any of the approved compendia), is not a

covered Part D drug. *Diamond v. Secretary of Health and Human Services*, 2015 WL 367010 *3 (N.D. Ohio Jan. 27, 2015) (Actiq prescribed for muscular dystrophy not a covered Part D drug); *Broome v. Burwell*, 2015 WL 1526532 *1 (D. Ore. Apr. 1, 2015) (Fentanyl lozenges prescribed for chronic back pain not a covered Part D drug); *Rickhoff v. United States Secretary for the Dept. of Health and Human Services*, 2012 WL 6177411 *4 (D. Ariz. Dec. 11, 2012) (Actiq prescribed for failed back syndrome not a covered Part D drug).

The cases cited in the preceding paragraph were actions for review of final administrative decisions by HHS from coverage denials. In order to successfully challenge claims for Fentanyl or other opioids that are prescribed off-label and off-compendium as violations of the False Claims Act, the elements of an FCA violation must be established. The sections below discuss these elements in the context of false prescription and dispensing claims.

B. Basic Elements of the False Claim

The FCA is violated whenever a person "knowingly presents or causes to be presented" a false claim or "knowingly makes, uses, or causes to be made or used, a false record or statement material to" a false claim. 31 U.S.C. §§ 3729(a)(1)(A), (B). (2009). The additional elements implicated by this statutory language are: (1) the identity of the proper defendant(s); (2) falsity; and (3) scienter.

A claim for payment for a drug that has been prescribed off-label and off-compendium is an implied false certification. The claim itself truthfully identifies the drug prescribed and dispensed. However, the claim fails to include the additional information that under the particular circumstances the drug was not prescribed for a medically accepted indication and, therefore, is not a covered drug. This omitted information makes the claim misleading and therefore fraudulent. *Universal Health Services, Inc. v. United States ex rel. Escobar*, 195 L. Ed. 2d 348 (2016). The omitted information is material because it is a statutory requirement of coverage, and the Government routinely denies payment when it is not satisfied. *Id.*

C. Defendant(s)

Three possible types of defendants could be liable for prescription drug fraud: the dispenser, the manufacturer, or the prescriber.

Part D claims are typically presented by the pharmacy that filled the prescription and dispensed the drug. However, the pharmacy or pharmacist is unlikely to submit a false claim "knowingly," because it will not usually know or have reason to know whether the drug was prescribed for an indication that is off-label and off-compendium. As mentioned above, for Part D, the Medicare Prescription Drug Manual specifically states that a dispensing pharmacist is not required to inquire of the prescribing doctor whether the drug is being prescribed for a medically accepted indication. At least one case has held that a dispensing pharmacy was not liable under the FCA for dispensing a drug off-label and off-compendium where it had neither actual knowledge nor reason to know of those facts. *United States ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, 2014 WL 2158412 *5 (N.D. Ga. May 23, 2014). As a result, it will be the rare case where the pharmacist will face potential liability for this kind of fraud.

The drug's manufacturer can face liability if it engages in off-label off-compendium marketing that causes a drug to be prescribed outside the permissible boundaries of Part D. *United States ex rel. Brown v. Pfizer, Inc.*, 2016 WL 807363 *12 (E.D. Pa. Mar. 1, 2016) (denying motion to dismiss complaint alleging off-label and off-compendium marketing of anti-fungal medication, allegedly causing submission of false claims); *United States ex rel. Brown v. Celegne Corp.*, 2014 WL 3605896 *10 (C.D. Cal. July 10, 2014) (denying motion to dismiss complaint alleging off-label and off-compendium marketing of Thalomid and Revlimid, allegedly causing submission of false claims). Suits against the manufacturers, however, will raise issues of causation and First-Amendment defenses that are beyond the scope of this article. *See, e.g.*, *United States ex rel. Cestra v. Cephalon, Inc.*, 2015 WL 3498761 *12 (E.D. Pa. June 3, 2015).

Finally, the doctor who prescribes a drug off-label and off-compendium can be guilty of causing false claims to be submitted. *United States ex rel. Watson v. King-Vassel*, 728 F.3d 707, 712 (7th Cir. 2013) (reversing summary judgment for psychiatrist in FCA case alleging off-label and off-compendium prescribing of psychotropic medications). The doctor obviously will have actual knowledge of whether the drug is being prescribed for a medically accepted indication, or at least will have reason to know, because he will have constructive knowledge of the contents of the publically available compendia. The court in *Watson, supra*, 728 F.3d at 714-15, rejected the doctor's defense that merely writing a prescription does not "cause" a false claim to be submitted under the FCA, using the tort concept of proximate causation to construe that term.

D. Falsity

As mentioned above, a claim for payment will be misleading if it fails to state that the dispensed drug was prescribed off-label and off-compendium. Establishing falsity, therefore, will require establishing that: (1) the indication for which it was prescribed was off-label and off-compendium; and (2) this omitted information was material to the Government.

The Seventh Circuit Court of Appeals has held that in certain circumstances, it is not necessary to present expert testimony to establish that an indication was off-label and off-compendium. *Watson*, 728 F.3d at 715-17. However, it appears from the opinion that this question was easily resolved because the psychotropic medication involved was prescribed for a patient who was too young to satisfy any of the uses approved in the compendia. In the usual case, the best practice will be for the Government's counsel to obtain an expert who can opine that the indication involved was not supported by either the FDA label or by the approved compendia. *See United States ex rel. Brown v. Celegne Corp.*, 2014 WL 3605896 *5 (C.D. Cal. July 10, 2014) ("Whether or not any particular use is 'supported' by the compendia is a complex case-by-case inquiry not susceptible to resolution on a motion to dismiss, and expert testimony is often necessary to discern whether a mention in a compendium in fact constitutes sufficient support.")

What does it mean for an indication to be "supported" by a compendium? Few cases have examined this question. Although the Medicare Prescription Drug Manual, applicable to Part D drugs, does not address this issue, the Medicare Benefit Policy Manual, applicable to Part B drugs, does address it. MEDICARE BENEFIT POLICY MANUAL Ch. 15, § 50.4.5 (Rev. 222, May 13, 2016). At least one case, *Brown v. Celegne, supra*, used the Medicare Benefit Policy Manual rules to interpret the Medicare statute in a Part D case.

According to the Medicare Benefit Policy Manual, an indication is supported, and therefore medically accepted, if it is either: (1) a Category 1 or 2A in the National Comprehensive Cancer Network

Drugs and Biologics Compendium (NCCN); (2) a Class I, IIa, or IIb in the Micromedex DrugDex Compendium; (3) supported by narrative text in the American Hospital Formulary Service-Drug Information (AHFS-DI) compendium; or (4) listed as "Off-Label" and "Evidence Level A" in the Lexi-Drugs compendium. The Medicare Benefit Policy Manual further provides that an indication is *not* supported if it is: (1) a Category 3 in NCCN; (2) a Class III in DrugDex; (3) not supported by narrative text in AHFS-DI; or (4) listed as "Unsupported" in Lexi-Drugs.

The difficulty in applying even the apparently straightforward Medicare Benefit Policy Manual rules, however, is shown by *Tangney v. Burwell*, 2016 WL 2732157 305, 305-321 (D. Mass. May 10, 2016). There, the patient sought Part D coverage for a cannabinoid drug, Dronabinol, prescribed to her for general nausea. DrugDex listed this drug as Category IIb. *Tangney* did not refer to the Medicare Benefit Policy Manual classifications, but it, nonetheless, treated the Category IIb designation as being a medically accepted indication, consistent with the Medicare Benefit Policy Manual. In Tangney's administrative proceedings, a hearing officer held that the drug was covered by Part D, but the Medicare Appeals Council reversed and found it was not covered. The district court reversed the Council, finding that the drug was in fact covered by Part D. The issue was exactly what the Category IIb rating in DrugDex meant in the context of this patient. The listing in DrugDex was based on a single, published study, which had found Dronabinol useful for nausea in a patient who happened to be a cancer patient. The Government argued that this meant that DrugDex "supported" Dronabinol only for cancer patients with nausea. The court disagreed, stating that the study showed that Dronabinol was effective for treating any kind of intractable nausea, regardless of its etiology, because the study's authors did not limit their findings to cancer patients. The court engaged in a thorough analysis of how much deference it should afford to the agency's interpretation of the statute, but it ultimately concluded that *Skidmore* deference rules applied and were not satisfied because the agency's interpretation was not persuasive. *Id.* at 9-11. This discussion further indicates the usefulness of having an expert opine on this subject.

Establishing that the indication was off-label and off-compendium, however, is only the first step in establishing that the claim was fraudulently misleading. *Escobar*, *supra*, replaced the old distinction between conditions of payment and conditions of participation with a requirement that the omitted information be material to the Government's decision to pay, as shown by the evidence. *Escobar*, 136 S.Ct. at 2003-04. *Escobar* defined materiality as being present when either: (1) a reasonable man would attach importance to the matter in determining how to act; or (2) the defendant knew or had reason to know the Government would consider it material, even if a reasonable man would not. *Id.* It will be necessary in a prescription fraud case, therefore, to establish, for example, that it was the Government's routine practice to deny payment when it was made aware that a drug had been prescribed off-label and off-compendia, and that a reasonable man would know, or the defendant knew or had reason to know, this fact. It may be that simply citing to the administrative decisions cited above, denying coverage under those circumstances, will be sufficient to make that showing when the case involves Part D or Medicaid.

E. Scienter

Making a false or fraudulent representation "knowingly" under the FCA requires actual knowledge of falsity or deliberate ignorance of, or reckless disregard of, truth or falsity. 31 U.S.C. § 3729(b)(1)(A) (2009). In this context, actual or constructive knowledge can be easily established for the contents of the Medicare statute and of the label indications and compendia, because they are all

publically available. Actual or constructive knowledge of whether the patient's condition renders the indication for which the drug is prescribed and dispensed not a medically accepted indication, on the other hand, will be provable only if the defendant knew or should have known of that use, or of the likelihood that the drug was being prescribed or dispensed for that use. As mentioned above, this scienter showing may be more difficult for some defendants than for others.

IV. Conclusion

One method for preventing the over-prescribing of potentially harmful opioids is to pursue those who cause the submission of false or fraudulent claims for payment for those drugs under Medicare Part D, Medicaid, and other federal programs. The treble damages and civil penalties awardable under the FCA can provide a powerful incentive for physicians and others to avoid prescribing and dispensing these substances for indications that are not supported by the approved drug compendia.

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The nation is confronted by an enormous public health crisis related to prescription opioid drugs. From 2004 to 2011, emergency room visits in the United States involving the misuse or abuse of prescription opioids—such as oxycodone, hydrocodone, and fentanyl—increased 153 percent. Magdalena Cerdá, Prescription Opioid Abuse: A Profile of Problems and Existing Responses (May 20, 2016) (unpublished presentation at Prescription Drug Awareness Conference, Sacramento State University) (on file with authors). In 2015, 10.3 million people used prescription opioids non-medically. *Id.* Opioid addiction has become a leading cause of death in the United States. Editorial, *Congress Wakes Up to the Opioid Epidemic*, N.Y. TIMES, May 16, 2016, at A22. Seventy-eight Americans now die from opioid overdose every day. President's Statement on the Comprehensive Addiction and Recovery Act of 2016, 2016 WL 3947274 (July 22, 2016).

But the opioid crisis is intertwined with another, more general, law enforcement challenge: the fraudulent billing of prescription drugs. Between 2006 and 2014, spending on drugs by the Medicare Part D program—the optional prescription drug benefit available to Medicare beneficiaries—increased by 136 percent, from $51.3 billion to $121.1 billion. DEP'T OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, QUESTIONABLE BILLING AND GEOGRAPHIC HOTSPOTS POINT TO POTENTIAL FRAUD AND ABUSE IN MEDICARE PART D, HHS OIG Data Brief, No. OEI-02-15-00190, at 2 (June 2015) ("OIG Data Brief"). While the growth of the Part D program includes all manner of prescription drugs, spending for commonly abused Schedule II and III opioids increased by 156 percent, outpacing the growth in spending for all Part D drugs. *Id.* at 3. Fraud schemes involving opioids and other controlled substances reimbursed under the Part D program have increased dramatically. Between May 2010 and 2015, HHS Office of the Inspector General ("OIG") experienced a 134 percent increase in the number of complaints and cases involving the Part D program. DEP'T OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, ENSURING THE INTEGRITY OF MEDICARE PART D, An OIG Portfolio, No. OEI-03-00180, at 13 (June 2015) ("OIG Portfolio"). Both HHS and DOJ consider fraud in the Part D program, particularly with respect to controlled substances, a top priority.

Federal lawyers have at least two civil enforcement mechanisms at their disposal to help address opioid addiction and Part D fraud: the Controlled Substances Act ("CSA") and the False Claims Act ("FCA"). To date, they have been rarely combined. In the past forty-five years, since the passage of the CSA and the amendments to the FCA, there have been only a handful of federal decisions involving the joint use of these two statutes.

The most significant CSA and FCA "dual liability" case was resolved after a key court ruling in 2014. The federal court denied a motion to dismiss the government's complaint in an FCA "whistleblower" or *qui tam* case brought by a former employee against PharMerica, a nationwide, closed door pharmacy (i.e., a pharmacy that serves only institutional customers, like nursing homes), for dispensing opioids without a valid prescription. *United States ex rel. Buth v. PharMerica Corp.*, No. 09-C-0720, 2014 U.S. Dist. LEXIS 122719, at *3 (E.D. Wis. Sept. 3, 2014). After the United States partially intervened and the court's favorable decision, PharMerica agreed to pay $31.5 million to settle both the FCA and CSA allegations and entered into a corporate integrity agreement with the Department of Health and Human Services and a memorandum of understanding with the Drug Enforcement Administration. Under these agreements, PharMerica significantly revised its practices regarding its prescription record-keeping, a positive outcome that reduced the risk that opioids would be improperly dispensed within nursing homes.

In light of the success of the PharMerica settlement, it is worth asking whether a dual liability approach can and should be used by federal civil litigators more frequently, and what the exact criteria for doing so should be. Can the CSA and FCA enforcement schemes be effectively combined, or are they better used separately, on their own, to fight the twin evils of opioid addiction and Part D fraud?

I. The Successful Use of Dual CSA and FCA Liability in *PharMerica*

The potential inter-relationship between the CSA and the FCA was tested recently in *U.S. ex rel. Buth v. PharMerica Corp.*, Case No. 09-CV-720 (Eastern District of Wisconsin). The *PharMerica* matter was initiated by a whistleblower, Jennifer Buth, in 2009. PharMerica is one of the largest long term care pharmacies in the United States. During the time period at issue, PharMerica filled approximately 40 million prescriptions annually, 45 percent of which were paid for by Medicare Part D. Complaint of the United States (Docket No. 44), ¶ 3 (on file with the author). Buth was a licensed pharmacist who worked as an operations manager for a PharMerica pharmacy located in Wisconsin. *Id.* ¶ 11. During the course of her employment, Buth discovered that the PharMerica pharmacy was not complying with the CSA requirements for controlled substance prescriptions, in particular, Schedule II controlled substance prescriptions. Relator's First Amended Complaint (Docket No. 10), ¶ 29 (on file with the author). When her concerns were not addressed by PharMerica management, Buth reported her concerns to DEA. *Id.* at ¶¶ 30-35. Shortly thereafter, Buth filed a *qui tam* complaint under the False Claims Act.

The CSA requires that Schedule II drugs—such as oxycodone and morphine—be dispensed only after a pharmacy receives an original written prescription signed by a practitioner. 21 C.F.R. § 1306.11(a). This requirement has two exceptions: (1) in an emergency situation, the practitioner may call the pharmacy and provide an oral prescription that must be followed-up by the practitioner causing a written prescription to be delivered to the pharmacy within seven days, 21 C.F.R. § 1306.11(d); and (2) prescriptions for nursing home residents may be faxed to the pharmacy by the practitioner. 21 C.F.R. § 1306.11(f). While "refilling" a prescription is a standard practice for many prescription drugs, Schedule II

drugs cannot be "refilled;" that is, the prescriber cannot designate on a prescription that the pharmacist can subsequently dispense another set quantity of the drug without receiving new authorization from the practitioner. 21 C.F.R. § 1306.12(a).

During her employment, Buth discovered that PharMerica was dispensing scheduled drugs, including Schedule IIs, without a prescription. The primary caregivers in nursing homes are often registered nurses and licensed practical nurses, who typically lack the authority to prescribe medications. However, these nurses are closely involved in distributing and monitoring prescription drugs for the residents. For example, a new resident may come into a nursing facility with discharge orders from the hospital, including recommendations for medications, but without an actual prescription from a physician who is providing ongoing care to the patient, or a resident may have used all the pills in an existing Schedule II prescription and may need additional medication. It is then up to the nursing home staff to contact the prescribers and obtain prescriptions for these medications.

Because the nursing home staff must first contact the treating physician to obtain a prescription, there can be a delay in obtaining the prescription—especially Schedule II prescriptions—as they must wait until the prescriber faxes a prescription to the pharmacy and then the pharmacy dispenses and delivers the drug to the nursing home. Buth discovered that PharMerica circumvented the lawful process of obtaining a prescription from a treating physician by, instead, filling requests for Schedule II drugs that were received from the nursing home staff. United States' Complaint, ¶ 79 (on file with the author). Upon receiving such a request, PharMerica dispensed the drugs to the facility, while simultaneously creating a document that purported to meet the requirements of a prescription (referred to as a "template") and faxed that template to the prescriber for signature. *Id.* Because PharMerica did not receive an actual prescription, the PharMerica pharmacist had to exercise his/her own judgment regarding key elements of the prescription in order to complete the template, including the formulation, dose intervals, and quantity of pills to be dispensed, without having examined the patient or having access to the patient's medical records. *Id.*

Moreover, although there was no indication from the nursing home or the prescriber that there was an "emergency" need for a prescription, many PharMerica pharmacies routinely dispensed a three-day so-called "emergency" supply of the drugs requested by the nursing home staff. United States' Complaint, ¶¶ 81-83 (on file with the author). This purportedly afforded PharMerica seven days to obtain a prescription after dispensing the drug under the CSA rules for an emergency situation. On the third day, PharMerica dispensed additional Schedule II drugs out of the standard 60-day supply, regardless of whether the practitioner had returned the template with a signature. *Id.*

After Buth reported her concerns to the DEA, the DEA served an administrative warrant to obtain prescription records from PharMerica's Wisconsin pharmacy. At the time the DEA executed its administrative warrant, there were multiple boxes of unsigned templates for Schedule II drugs. United States' Complaint, ¶ 81 (on file with the author). In an effort to determine whether these practices were nationwide, diversion investigators executed additional administrative warrants at PharMerica pharmacies in Florida, Colorado, and California. While practices varied somewhat between pharmacies, similar practices involving Schedule II drugs were found in each pharmacy. United States' Complaint, ¶¶ 82 and 83 (on file with the author).

At the time of the conduct at issue, a pharmacy registered with the DEA was liable for a civil penalty of up to $25,000 for each violation if it dispensed a controlled substance without a valid prescription. 21 U.S.C. §§ 842(a)(1) and 842(c)(1). Due to the speed with which the total CSA penalties can accumulate from the large number of Schedule II prescriptions filled by PharMerica, government investigators were selective in the time period audited for determining penalties. However, when evaluating the potential FCA case and the nationwide scope of the conduct, it became necessary to employ a different methodology to determine damages. Therefore, government investigators selected a sample of claims submitted by PharMerica for Schedule II drugs to Medicare Part D for a two-year period. After obtaining the prescription records related to these claims, government investigators evaluated whether there was a valid prescription each time PharMerica dispensed these Schedule II drugs. The results of that review were extrapolated to the universe of Part D claims submitted by PharMerica for purposes of determining the loss to the Medicare program pursuant to the FCA.

After the United States intervened, PharMerica moved to dismiss the United States' FCA claims for failure to state a claim based, in part, on the argument that the claims submitted by PharMerica to the Part D plan were not used to determine payment to the Part D plan by the government. Memorandum of Law in Support of PharMerica's Motion to Dismiss (Dkt. No. 57). PharMerica argued that, because Medicare pays the Part D plans (which are private insurance companies) a fixed monthly payment for each beneficiary enrolled in that Part D plan, there was no claim submitted for the individual prescriptions. PharMerica did not move to dismiss the claims brought pursuant to the CSA.

In response, the United States stated that the "Prescription Drug Event" data (or PDE) that PharMerica caused the plans to submit to CMS was a claim, and that the false representation in the PDE that drugs were dispensed based on a valid prescription was material to the government's decision to pay the Part D plans. United States' Brief in Opposition to PharMerica's Motion to Dismiss (Dkt. No. 61). Specifically, when a claim for payment is submitted to the Part D plan by a pharmacy for filling a prescription, the plan creates an electronic record—the PDE—which includes thirty-seven fields of information about the dispensing event. Among other things, the PDE includes the type of drug that was dispensed, the prescriber, the quantity of the drug, and whether or not the drug is covered under the Medicare Part D benefit. The claim submitted by the pharmacy is then used to generate the PDE, which the plan submits to CMS as a condition of payment. 42 C.F.R. § 423.505(k). CMS then uses the actual costs reported on the PDE to reconcile the advance payments to the Part D plan with the actual costs incurred. CMS, "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)" (April 27, 2006).

Moreover, as to the materiality of PharMerica's CSA violations, the Part D program only pays for drugs that meet the definition of a "covered Part D drug," and drugs are only covered Part D drugs if they are dispensed upon a valid prescription. 42 U.S.C. § 1395w-102(e). *See also*, 76 F.R. 63,018; 63,059 (Oct. 11, 2011). PharMerica billed the plans for Schedule II drugs as if these drugs were legally dispensed by making the representation in the claims data that they were covered Part D drugs when, in fact, PharMerica illegally dispensed drugs without a prescription. Finally, although the PDE is actually submitted to CMS by the Part D plan, the United States alleged that PharMerica caused the submission of the false PDEs to Medicare and, thereby, met the standards of the FCA. 31 U.S.C. § 3729(a)(1)(A).

The district court concluded that the United States adequately pled that PharMerica caused the Part D plans to submit false claims, and rejected the defendant's motion to dismiss the claims brought pursuant to the FCA. Specifically, the court found that the United States had "adequately pled a false or fraudulent claim inasmuch as PharMerica billed plan sponsors for Schedule II drugs knowing that the

drugs were not dispensed upon a valid prescription and caused the plan sponsor, who relied on PharMerica's electronic claim, to inaccurately represent to the United States (CMS) in the PDE record that the drugs were reimbursable Part D drugs." *Buth*, 2014 U.S. Dist. LEXIS 122719, at *15.

Once PharMerica's motion to dismiss was denied, the parties reached an agreement to resolve all claims for $31.5 million, with $8 million attributed to the settlement of the CSA violations and $23.5 million attributed to the FCA violations. The parties entered into separate settlement agreements for the CSA and the FCA violations. Additionally, PharMerica entered into a corporate integrity agreement with HHS and a memorandum of understanding with the DEA that included forward-looking remedial provisions.

II. Other (Less Successful) Dual Liability Cases

In addition to the *PharMerica* matter, federal lawyers and private litigants have pursued dual FCA and CSA liability in several other cases as well, with varying degrees of success. Although the cases discussed below were decided before the Supreme Court's recent endorsement of implied certification in the FCA context, *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), they continue to provide some insight into considerations that should be made when evaluating a dual liability approach.

The decision in *United States v. Paskon*, No. 4:07-CV-1161, 2008 U.S. Dist. LEXIS 91045 (E.D. Mo. Nov. 10, 2008), highlights the challenges with pursuing both FCA and CSA claims against a small provider. In that case, the United States obtained a favorable jury verdict on both FCA and CSA claims that the defendant, a physician, had written medically unnecessary prescriptions for controlled substances in violation of the CSA, and caused false claims for those prescriptions to be submitted to the state Medicaid program. *Id.* at *2. The United States sought damages of $79,113 under the FCA, and civil penalties of $225,000 under the CSA, as well as a permanent injunction barring the defendant from issuing further prescriptions for controlled substances. *Id.* The United States' request was based on FCA provisions that require the trebling of the government's losses, plus a penalty of between $5,500 and $11,000 per false claim (recently increased to between $10,781 to $21,563), and the CSA penalty provision, 21 U.S.C. § 842(c)(1). *Id.* at *3. The court, after carefully parsing the jury's response to certain interrogatories, awarded the United States the minimum FCA penalty of $27,500 for all five false claims, and $1,000 for each CSA violation, for a total of $36,256. *Id.* at *11.

In dramatically reducing the CSA penalties, the court examined four factors: the willfulness of the defendant's conduct; the public harm caused by his violations; the extent to which the defendant profited from the conduct; and his ability to pay. *Id.* at *5-10 (citing *Advance Pharm., Inc. v. United States*, 391 F. 3d 377, 399 (2nd Cir. 2004)). With respect to willfulness, the court acknowledged that the defendant had used "questionable judgment" in prescribing controlled substances, but found that there was insufficient evidence to conclude that he had written the prescriptions "with the intention to do something the law forbids." *Id.* at *7. The court found it "debatable" that defendant's conduct led to patient deaths, since the government had not offered any evidence from the examining pathologists or any statistical evidence for a comparable patient population. *Id.* at *9. And there was no evidence that any portion of the defendant's income was derived from improper payments for prescriptions. *Id.* Perhaps most significantly, however, the court concluded that the defendant was essentially judgment proof, with

a heavily mortgaged home, no savings account or investments, and a tax bill of $823,000. *Id.* at *9-10. Since the defendant had retired and surrendered his DEA registration, the government's request for an injunction was denied as moot. *Id.* at *11. However, *Paskon* was at least a favorable outcome in helping to further establish that a CSA violation for writing invalid prescriptions may support a FCA violation.

The plaintiffs found less successful legal footing in pursuing a dual liability approach in *United States v. Walgreen Co.*, No. CV 13-08473, 2015 U.S. Dist. LEXIS 175359 (C.D. Cal. Jan. 2, 2015), a FCA *qui tam* action in which the United States and State of California declined to intervene and which demonstrates the necessity of establishing that compliance with the subject provisions of the CSA is a prerequisite to payment of a claim by a federal healthcare program. The plaintiff, a former Walgreen's pharmacist, alleged that Walgreen employed three different schemes relating to how it dispensed and billed for prescription drugs in order to defraud the Medicare, Medicaid, and other government programs. *Id.* at *1. Only one of the three schemes involved controlled substances. With respect to this scheme, the relator alleged that Walgreen partially dispensed prescriptions for Schedule II drugs, but then charged for the entire amount of the prescription, even if the patient did not return to pick up the remaining pills when they became available. *Id.* at *8-9. Relator further alleged that Walgreen sometimes dispensed the remaining amount on an incomplete Schedule II prescription more than seventy-two hours after the initial disbursement, in violation of a state pharmacy law and the parallel provisions of the CSA. *Id.*

On Walgreen's motion to dismiss, the court found that relator had adequately alleged falsity as to the first part of the controlled substance scheme. *Id.* at *23. Namely, if Walgreen disbursed less than a full prescription of a Schedule II drug, charged for the full amount, and the patient never received the remainder, then Walgreen effectively overcharged the payer and these claims were factually false. *Id.* But the court went on to conclude that the relator had not adequately alleged that Walgreen had caused these false claims to be submitted knowing that the patient would not return within 72 hours to retrieve the rest of the prescription, and so had not satisfied the FCA's scienter requirement as to this part of the controlled substance scheme. *Id.* at *34.

As to the second part of relator's alleged controlled substance scheme—that Walgreen dispensed incomplete Schedule II prescriptions outside the 72-hour window—the court found that relator had not adequately alleged falsity under the FCA under either an implied or express false certification theory, in that relator did not allege that Walgreen had certified compliance with any federal or California law or regulation governing Schedule II substances. *Id.* at *24-27. Whereas in *PharMerica* the government established that the violations of specific provisions of the CSA were material to Medicare's payment of the claim, that evidence was not presented here. *Id.* at *28, n.4. As a result, the court dismissed all claims relating to controlled substances, noting in passing that "[m]ere regulatory violations do not give rise to a viable FCA action." *Id.* at *15 (quoting *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1170 (9th Cir. 2006)).

Finally, in *United States v. Bedi*, No. 09-CV-616, 2011 U.S. Dist. LEXIS 120193 (S.D. Ill. Oct. 18, 2011), the United States brought claims against a physician and related medical clinics under both the CSA and FCA. The clinics pled guilty to healthcare fraud in a parallel criminal investigation related to claims that were submitted to Medicaid for prescriptions that were issued in violation of the CSA. *Id.* at *1. While the court awarded partial summary judgment for the United States on the FCA claims against the clinics based on their plea to criminal health care fraud, it denied summary judgment on the CSA claims. Moreover, as to the doctor, the court concluded that the plea agreements and stipulations by the clinics in the criminal case, and an open guilty plea by the doctor himself, did not establish that the doctor had been acting as a "pusher." *Id.* at *17. It therefore denied the government's request for summary

judgment on the FCA claims against the doctor, finding that a material dispute existed as to whether the prescriptions were "outside the course of his professional practice or without a legitimate medical purpose." *Id.* This case further demonstrates the distinct nature of the proof necessary to prove claims based on two unique legal theories and the complications inherent in parallel civil and criminal prosecutions.

III. Challenges of Pursuing a Dual Liability Approach

The above cases provide several lessons for federal litigators considering a civil enforcement action under both the CSA and FCA that can be organized around the elements of an FCA claim. In the most basic terms, FCA liability can be imposed on anyone who knowingly presents a false claim to the government, causes another to present a false claim to the government, or knowingly makes or causes to be made a false record (or statement) material to a false claim. 31 U.S.C. §§ 3729(a)(1)(A) and (B). Therefore, establishing FCA liability requires proof of the following elements: (1) a *claim*; (2) *falsity* of the claim (and the record or statement used to get the claim paid); (3) *knowledge* that the claim (and the record or statement made in support of the claim) was false; and (4) *materiality* of the false record or statement to the payment decision. Because FCA claims are fraud-related, the government must plead its claims with plausibility and particularity, as required by the Federal Rules of Civil Procedure 8 and 9(b).

A. Challenges Pertaining to Proof of FCA Elements

Under the FCA, a "claim" is defined broadly to include any request or demand for money that is presented to the United States, or is made to a contractor, grantee, or other recipient, if the money is to be spent or used on the Government's behalf or to advance a Government program or interest. 31 U.S.C. § 3729(b)(2). In the pharmacy context, the claim is the Prescription Drug Event (PDE) that is sent by the dispensing pharmacy to a Part D plan sponsor or Pharmacy Benefit Manager ("PBM"), and then forwarded to CMS as part of the payment process. Courts have rejected defendants' argument that, because the word "claim" does not appear in the PDE record, it should not be considered a claim for purposes of the FCA. *See, e.g., U.S. ex rel. Spay v. CVS Caremark et al.*, 913 F. Supp. 125, 168 (E.D. Pa. 2012). As the district court in *PharMerica* concluded, the PDE can form the basis of FCA liability. *See* 2014 U.S. Dist. LEXIS 122719, at *18-20 (discussing *Spay*).

Federal lawyers face a practical challenge with respect to the FCA claim element in the Part D context: obtaining and analyzing PDE data. This data is voluminous and complex, containing thirty-seven different information fields for each prescription, including the identity of the prescriber, patient, and dispensing pharmacy; the national drug code ("NDC") for the specific medication dispensed; drug coverage status; and the drug dosage, date of dispensing, dispensing status, etc. Some of the PDE data is derived from the underlying prescription. Federal lawyers can obtain the PDE data with the help of an investigator or auditor in their office, an HHS agent, or the CMS Medicare integrity contractor ("MEDIC") in their district charged with helping to provide oversight of the Part D program. Once obtained, PDE data can be sorted and arranged in many different ways to facilitate the detection of prescribing or dispensing patterns that indicate the presence of fraud. In most instances, a dual liability approach will only be worth pursuing if the total amount of paid claims tainted by fraud is significant.

Assuming that a sufficient number of fraudulent PDE claims are at issue, the next challenge that federal lawyers face is establishing that the claims are "false." Pursuant to the FCA, claims are false if they claim reimbursement for services that are either "not reimbursable or were not rendered as claimed." *United States ex rel. Walker v. R&F Props. of Lake Cty., Inc.* 433 F.3d 1349, 1356 (11th Cir. 2005); *see also United States v. Calhoon*, 97 F.3d 518 (11th Cir. 1996). There are several sources that define when a claim is not reimbursable, including agreements between the government and the provider, the statute and regulations that govern the services provided, and common law.

The falsity of a claim can be established by one of two routes. First, services that are not rendered as claimed are facially false. This includes a claim for goods or services that were never provided or that inaccurately describes the goods or services that were provided. In the Part D context, this encompasses situations in which the patient never received any or just a portion of the drugs ("phantom billing"), the drugs dispensed were different than the drugs billed ("up-coding" or "switching"), or the drugs received by the patient were not covered by the government program at issue ("uncovered services"). In the *PharMerica* matter, the government alleged that the PDE claims were false because PharMerica caused the PDEs to reflect that the drugs dispensed were covered by the Part D program when, in fact, they were not covered because the claims lacked valid underlying prescriptions. *Id.* at *10.

Second, falsity can be established by a false certification when a claim "makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). PDE data makes "specific representations" about the drugs provided to patients, and so the first condition is easily met. With respect to the second condition, possible sources of noncompliance with a "statutory, regulatory, or contractual requirement" in the Part D context include: the Part D statute and regulations; the contract between Part D plan sponsors and CMS; the contract entered into by pharmacies with Part D plan sponsors or the pharmacy benefit manager when agreeing to dispense prescription drugs to Medicare beneficiaries; and the agreement health care providers sign when enrolling as a Medicare provider.

Particularly instructive in this context is the court's discussion in *United States et al. v. Walgreen Co.*, No. CV 13-08473 , 2015 U.S. Dist. LEXIS 175359 (C.D. Cal. Jan. 2, 2015), of the relator's attempt to hold Walgreen liable under the FCA for certain dispensing practices. The court held that the relator had adequately alleged facial falsity with respect to the alleged scheme involving controlled substances: disbursing less than a full prescription of a Schedule II drug and charging for the full amount, even when the patient did not pick up the remainder. *Id.* at*23. But it rejected relator's false certification theory for the same conduct, which was premised on patients receiving the remainder of the Schedule II drugs without a new prescription after seventy-two hours from the time the initial disbursement had expired, a time window established by both state and federal regulations. *Id.* The court concluded that an express false certification theory could not be maintained because relator had not alleged that Walgreen's payment claim included an express certification of compliance with the regulation at issue. *Id.* at *24. As for implied false certification, the court concluded that relator had failed "to direct the court to any facts suggesting that Walgreen ever expressly *certified* its general compliance with the law." *Id.* at *26. In a footnote, the court distinguished the successful use of the false certification theory in *PharMerica* on the basis that "the plan sponsor's subcontract with [PharMerica] required [PharMerica] to comply with all applicable federal laws and regulations." *Id.* at *28, n.4. Relator failed to identify a similar contractual provision binding Walgreen.

Even when there is a potential theory based on failure to comply with underlying statutes, regulations, or contracts, the clearer path may be to focus on the facially false elements of the PDE. For example, as presented in the *PharMerica* case, the Part D statute provides that drugs may only be reimbursed under the program if the drug is a "covered outpatient drug." Consequently, one of the elements of the PDE is to designate whether a dispensed drug is a covered outpatient drug. Covered outpatient drugs must be dispensed pursuant to a valid prescription. Under the CSA and many parallel state laws, a prescription must satisfy a number of requirements. For example, the prescriber must be authorized to prescribe controlled substances in the jurisdiction in which he or she is licensed to practice, and must be either registered with DEA or exempt from registration. 21 C.F.R. § 1306.03(a). Perhaps most significantly, in order to be valid, a prescription must be issued "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). This requirement "ensures that patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006). It also "bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Id.* Violation of any one of the above requirements potentially satisfies the FCA falsity requirement.

Assuming that the falsity requirement can be met, federal lawyers seeking to use a dual liability approach must also be able to satisfy the FCA's materiality element. Materiality is defined in the FCA as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). The Supreme Court recently interpreted this definition in the context of the implied false certification theory of FCA liability. Noting that the FCA "is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations," the Court concluded that "[u]nder any understanding of the concept, materiality 'looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Escobar*, 136 S. Ct. at 2002. It further held that "statutory, regulatory, and contractual requirements are not automatically material, even if they are labeled [by CMS] as conditions of payment." *Id.* at 2001. Determining the materiality of a false claim therefore involves a holistic assessment of the tendency or capacity of the undisclosed violation to affect the government decision maker. In the Part D context, it requires examining what importance a "reasonable person" would attach to the alleged misrepresentation in the PDE data (or false certification), or if "the defendant knew or had reason to know" that CMS attached importance to it. *See Id.* at 2002-03 (citations omitted). It is important to work closely with OIG and CMS counsel in order to make this determination.

Although the exact criteria for what constitutes a "material" violation remains undefined, it appears likely that at least some violations of the CSA requirements for a valid prescription for a controlled substance will still pass muster. For example, OIG reports that "CMS now requires plan sponsors to identify invalid prescriber identifiers on Part D drug claims, and submit to CMS only claims with valid prescriber identifiers." OIG Portfolio at 11. CMS also "requires plan sponsors to verify that prescribers have the authority to prescribe," and "has increased monitoring of prescribers through the MEDIC" in order to "identif[y] claims related to providers without prescribing authority." *Id.* This suggests that, in certain contexts, lack of prescriber authority may be a material condition of payment. Again, federal lawyers should work closely with OIG and CMS counsel in order to clarify where this line should be drawn with respect to a particular false claim. This is particularly critical because agency witnesses may have to testify as to the materiality of the violation.

Finally, the FCA's knowledge element requires showing that the defendant knew that the claims at issue (and any statement or record on which the claims are based) were false when submitted. As applied to the Part D context, the prosecutor must obtain evidence that the defendant physician, pharmacy, or other provider knew that the PDE data submitted to a plan sponsor or PBM contained misrepresentations. If the misrepresentations were the result of a false prescription, the prosecutor must obtain evidence that the defendant knew that the prescription was false. Knowledge is defined very broadly in the FCA to mean not only "actual knowledge" but also "deliberate ignorance" of the falsity, or acting in "reckless disregard" of the truth or falsity. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required. *Id.* In the *PharMerica* case, there was evidence that internal PharMerica auditors had previously identified the company's failure to comply with the CSA in regards to prescriptions for scheduled drugs. Complaint, ¶¶ 129-132 (on file with the author). In a PowerPoint presentation that was shared with management, the auditor went so far as to note: "No prescription equals false claim." *Id.* The FCA knowledge or scienter standard can further be met by obtaining internal emails, other documents, or witness testimony that the defendant understood that the PDE data in question, or underlying prescription, was false. Potentially helpful in this regard is that pharmacists have a "corresponding responsibility" to that of physicians under the CSA to ensure that controlled substances are dispensed pursuant to a valid prescription. 21 C.F.R. §§ 1306.04(a) (purpose of issue); 1306.05(f) (manner of issue). This makes it harder for pharmacists to claim ignorance of misrepresentations in prescriptions.

B. Some Additional Practical Considerations

In addition to the above challenges relating to proof of the FCA elements, federal litigators may wish to evaluate certain practical considerations before pursuing a dual liability theory. First, pursuing a nationwide case under two distinct legal theories will likely necessitate a more complex investigation. As stated above, the PharMerica investigation involved both the review of prescription records obtained pursuant to the four DEA administrative inspection warrants, and also the prescription records associated with a nationwide statistically valid random sample of Medicare Part D claims for Schedule II drugs. Similarly, while CSA violations involve strict liability and so do not require evidence of scienter, the registrant's "culpability" may be evaluated during the penalty phase. One element of culpability is the registrant's knowledge of the wrongful conduct. While this element overlaps with the FCA requirement that the provider "knowingly" submitted, or caused to be submitted, false claims, the FCA and CSA utilize different standards that must each be evaluated.

Second, pursuing both penalties under the CSA and damages under the FCA necessitates coordinating with two agencies, HHS and the DEA, rather than one. This can be challenging for agencies who have not frequently worked together in the past and have relatively little experience with the other agency's enforcement authority, priorities, and investigative methods. Compounding the challenge is that HHS and DEA agents have access to different databases pertaining to the prescribing behavior of the same providers, leading to differences in investigative priorities and approaches. This hurdle was overcome in the *PharMerica* matter through many in-person meetings of investigative staff and reviewing officials from both agencies to ensure that everyone understood the contours of both investigations.

Finally, while cases that combine multiple legal theories may increase the potential recovery, the government must also be prepared to address arguments that this involves an inappropriate "double recovery" and results in the provider's inability to pay the full value of the case. As evident from the ruling in *Paskon*, 2008 U.S. Dist. LEXIS 91045, courts may also consider a defendant's ability to pay when awarding CSA penalties that coincide with FCA damages.

IV. Potential Benefits of a Dual Liability Approach

While it is important to keep in mind the challenges presented by a dual liability approach, one should not ignore the potential upside of pursuing both FCA and CSA claims in an appropriate case. In certain circumstances, the benefits may outweigh the risks. First, assuming the subject of a CSA investigation has, in fact, submitted or caused to be submitted false claims to a federal healthcare program, these overpayments can only be recovered by adding a claim under the FCA. While the nature of the violation must and does dictate the remedy sought, the return of money to the Medicare program when CMS inappropriately pays drug claims is an important consideration when determining what approach to pursue.

Second, whereas the CSA, as its name implies, is limited to misconduct relating to controlled substances, the FCA can address misconduct relating to all prescription drugs, both controlled and non-controlled. Adding FCA claims would therefore be the only way to address a provider's misconduct that involved both controlled and non-controlled drugs. Most Part D fraud is not limited to controlled substances. The diversion of controlled substances is sometimes only a tell-tale sign of larger fraudulent activity.

Third, both the DEA diversion investigators and other DOJ and HHS investigators who conduct health care fraud investigations can bring separate but distinct expertise to these cases and should be considered a force-multiplier when combined. While DEA diversion investigators historically have been more focused on individual provider locations due to the nature of obtaining evidence principally through administrative warrants, they are well-versed in both the legal requirements of the CSA and how to investigate potential violations. As a result, diversion investigators are an excellent resource in these cases, enhancing the healthcare fraud knowledge of their colleagues from HHS OIG, the DOJ Civil Frauds Section, and the United States Attorney's Offices, who are more accustomed to pursuing FCA remedies across multiple jurisdictions or nationally.

Fourth, the investigative tools of the DEA and DOJ are mutually supportive. The DEA's primary method of gathering evidence is through administrative inspection warrants that must be obtained for single locations. Executed without notice, DEA agents gain important insights about a provider from these warrants by being physically present at the site where the violations occurred (*e.g.*, that there are boxes of unsigned prescriptions on site). The Civil Frauds Section and the United States Attorney's Offices, although not able to conduct surprise inspections, routinely use subpoenas, including CIDs to gather documents, formal answers to interrogatories, and oral testimony from witnesses. And DOJ investigators have routinely used statistical sampling to extrapolate FCA damages. When properly combined within the legitimate bounds of parallel proceedings, these investigative and analytical tools can help lawyers form a more complete picture of the underlying fraud.

Fifth, determining the fair amount of the CSA penalty can be challenging during the investigative (and potentially settlement discussion) phase as there is no one model for that calculation. Considering the hefty maximum penalty permitted by the statute (recently increased from $25,000 to $62,500 for violations occurring after November 2, 2015), and the potentially large number of violations, significant effort often goes to discussing an appropriate penalty amount in pre-litigation settlement discussions. In the context of litigation, courts have indicated that they will use a variety of factors to determine the

appropriate penalty under the CSA. Some of these factors include: (1) the level of the defendant's culpability; (2) the defendant's profit; (3) the defendant's ability to pay; and (4) harm to the public (including the United States' investigative costs and an estimate of the street value of the controlled substances involved in the conduct). *See, e.g.*, *Advance Pharm. Inc.v. United States*, 391 F.3d 377, 399 (2d Cir. 2004); and *United States v. Salcedo*, 2003 WL 21196843 at *2 (E.D.N.Y. 2003). These factors involve subjective assessments that do not always lead to uniform results. By contrast, the determination of FCA damages using statistical sampling is objective and well-established. This sampling methodology helps to define the settlement value of a case beyond the negotiation of a penalty under the CSA.

Finally, a provider against whom the United States has obtained an FCA judgment is reported to HHS OIG, which can exclude the provider from all federal healthcare programs. This "exclusion authority" is not available under the CSA. The DEA can revoke a registrant's ability to manufacture, distribute, dispense, or prescribe controlled substances, but it does not have the authority to exclude them from healthcare programs. Moreover, while the DEA has recently started using forward-looking remedies similar to HHS's corporate integrity agreements, the practice of entering into a corporate integrity agreement in exchange for a release of the agency's exclusion authority is a common and accepted part of FCA settlements.

V. Extending the Dual Liability Approach

To date, federal lawyers and private relators have pursued a dual liability approach under the FCA and CSA, with varying degrees of success, against at least one closed-door pharmacy (PharMerica), one retail pharmacy (Walgreen), and a physician and several associated medical clinics (*United States v. Bedi*). It appears that, in each instance, the defendant was a DEA registrant. This represents just a small cross-section of the various types of individuals and entities that are subject to the CSA, which imposes both criminal and civil penalties against any person who interferes with the federal government's tightly controlled manufacturing and distribution system for controlled substances.

For example, 21 U.S.C. § 842(a)(1) prohibits "any person . . . who is subject to the requirements of part C [of the CSA] to distribute or dispense a controlled substance in violation of section 829 of this title." Part C sets forth the DEA registration process and applies to "[e]very person who manufactures, distributes, or dispenses any controlled substance or who proposes" to do so. 21 U.S.C. § 822(a). The Supreme Court has interpreted section 842(a)(1) as applying to *all* manufacturers, distributors, and dispensers of controlled substances, both those who registered with the DEA and "those who should have registered but failed to do so." *United States v. Moore*, 423 U.S. 122, 134, n.11 (1975). Therefore, anyone who distributes or dispenses a controlled substance in violation of section 829 of the CSA, which contains the requirements for prescriptions, is subject to CSA penalties. And, by extension, if they either submit or cause a false claim to be submitted to CMS for payment, they are also potentially liable under the FCA.

Physicians who improperly prescribe opioids are appropriate subjects of government investigation in this respect, but the CSA imposes a "corresponding liability" on pharmacists who fill prescriptions "not prepared in the form prescribed by DEA regulations." 21 C.F.R. §§ 1306.04(a) and 1306.05(f). This liability should be kept in mind when scrutinizing the role of physicians and pharmacists in the improper prescribing and billing of controlled substances. Non-registrant business owners have also been held liable for civil penalties under the CSA. *See, e.g.*, *United States v. Clinical Leasing Serv., Inc.*, 759 F. Supp. 310 (E.D. La. 1990), *aff'd*, 925 F.2d 120 (5th Cir. 1991) (non-registrant defendant d/b/a Delta Women's Health Clinic could be liable for civil penalties under § 842(a)(5)); *United States v.*

Poulin, 926 F. Supp. 246, 253 (D. Mass. 1996); *United States v. Stidham*, 938 F. Supp. 808, 814 (S.D. Ala. 1996). Federal lawyers should therefore also evaluate the role of hospitals, drug wholesalers, importers, and manufacturers in causing controlled substances to be dispensed in violation of the requirements of the CSA. All are potentially subject to CSA and FCA dual liability.

VI. Conclusion

Although tested in only a small number of cases, the use of dual liability under the FCA and CSA by federal lawyers and private relators' counsel opens up a potential new front in the federal government's battle against both opioid addiction and Part D fraud. The *PharMerica* decision, in particular, suggests that this approach holds great promise, assuming certain basic conditions are met. First, a dual liability approach is only worth undertaking if the defendant's conduct has resulted in a large number of false claims to the Medicare Part D program. Second, there must be evidence that supports each element of an FCA claim. In particular, there must be evidence of: (1) falsity in the PDE data submitted to PBMs or Part D plan sponsors, or a false certification related in some way to the submission of this data; (2) knowledge by the defendant that the PDE claims, or a record or statement related to the claims, such as the underlying prescription, was false; and (3) materiality. Proof of materiality will require working closely with OIG and CMS counsel to establish what effect defendant's misrepresentation in the PDE data had, or likely would have had, on CMS's payment decision. Third, federal litigators must be willing to take the additional time and expend the resources to build a dual liability case, which is necessarily more complex than a straightforward CSA action. And, finally, federal litigators must be willing to work cooperatively with DEA in this interagency effort. Assuming these conditions are met, then combining the CSA and FCA enforcement schemes can be an effective tool to address violations of the CSA that may lead to diversion of narcotics and Part D fraud.

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Investigating and Prosecuting Opioid Diversion and Tampering Cases Involving Medical Professionals and Institutional Healthcare Providers

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I. Introduction

All too often the news describes accounts of healthcare professionals diverting opioids to feed their own addictions or line their pockets. The District of Colorado has prosecuted a number of diversion cases involving hospital and medical professionals involved in the diversion of powerful, highly addictive opiates, often subjecting patients to blood-borne pathogens and serious bodily injury. Prosecutions involving prescribing professionals like doctors, nurse practitioners, and pharmacists have seen a significant increase. Diverters include every imaginable healthcare professional, including, but not limited to, doctors, pharmacists, nurses, and surgical technicians. This article will probe the considerations common to these types of investigations/prosecutions, including the public health aspects. Specifically, the scope includes diversion and tampering with controlled substances in a hospital setting and the overprescribing of opioids by doctors without a legitimate medical purpose. The article will cover investigation and prosecutorial considerations, including pretrial strategy, trial strategy, and sentencing issues.

II. Opioid Use in the United States

The history of opiate use in the United States dates back almost to the inception of this country. The Controlled Substances Act (CSA) defines "opiate" as "any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability." 21 U.S.C. § 802(18) (2016).

In the strict sense, opiates are drugs derived from opium, and include products like morphine and codeine. In the wider sense, opiates are simply morphine-like drugs. More and more, the term "opiate" is being replaced by the term "opioid," which describes any substance, regardless of its precise properties, which produces morphine-like effects through action on opioid receptors. Heroin, an opiate originally derived from Asian poppy plants, is probably the most readily recognized opiate. Heroin has an extremely high addictive value and has plagued our society for hundreds of years. Even methadone, a common opioid used to treat heroin addiction, has a high addictive value and is prone to be misused. Over the years, a number of opioids have been developed by pharmaceutical companies to treat pain, including, but not limited to, fentanyl, oxycodone, hydrocodone, and hydromorphone. Although they were developed for legitimate purposes of treating pain, these substances are quite often subject to abuse and diversion. "Diversion" is the process of diverting drugs from legitimate channels to illegitimate channels. *United States v. Moore*, 423 U.S. 122, 135 (1975).

III. The Controlled Substances Act and Legitimate Uses for Opioids

Opioids are generally classified as depressants. They can be found in Schedules I through V and are categorized according to their potential for abuse, the existence and nature of any currently accepted medical use in treatment in the United States, and the likelihood of physical or psychological dependence resulting from abuse of the drug. *See* 21 U.S.C. § 812(b), (c) (2012).

Despite these criteria, the scheduling of opioids can be misleading. For example, heroin and fentanyl are Schedule I and II controlled substances, respectively, but that does not necessarily mean that heroin poses a greater risk of harm than fentanyl. Because there are no accepted medical uses for heroin in treatment in the United States, it is a Schedule I controlled substance, and it cannot be prescribed by a physician for medical purposes. Heroin is more often associated with "street use" and addiction. Fentanyl, on the other hand, is a Schedule II controlled substance and is distributed by pharmaceutical companies to pharmacies and hospitals throughout the United States. It is commonly associated with major surgeries involving severe pain such as back surgeries or amputations or with end-of-life palliative care. Fentanyl is often described as being 80 to 100 times more powerful than morphine. It is among the most powerful opioids used in surgeries and has a very high addictive value. Fentanyl is dispensed in numerous vessels, such as vials, ampules, pre-loaded syringes, cassettes, transmucosal tablets, and transdermal patches. Because of its powerful nature, drug seekers and opioid addicts usually start their addiction with milder opioids like oxycodone, hydrocodone, or hydromorphone, and then graduate to using fentanyl. In recent years, the number of deaths associated with fentanyl and opioid abuse has skyrocketed and has drawn attention because of the deaths of a number of celebrities affected by their abuse.

IV. Public Health Agencies

Many states have public health agencies that investigate diversions involving healthcare providers, particularly if there is a risk of transmission of blood-borne pathogens such as HIV or hepatitis. However, many of these agencies are bound by confidentiality restrictions and privileges that impede the use of their information in a criminal investigation. Often, these confidentiality restrictions find their root in the concept of encouraging cooperation from a diverter and minimizing any "chilling effect" on such cooperation if there are administrative or criminal consequences to the cooperation. Close coordination with victims of the diversion, such as hospitals or individuals that were subjected to pain or blood-borne pathogens, is critical to obtaining releases and waivers that may allow the public health agencies an opportunity to provide information that could be subject to the Health Insurance Portability and

Accountability Act of 1996 and implementing regulations at 45 C.F.R. Parts 160 and 164 (collectively, "HIPAA"), the Privacy Act, 5 U.S.C. § 552a (2014), or other state and federal laws and privileges they must observe.

State public health agencies often coordinate with the Centers for Disease Control (CDC) in the investigation of diversion cases involving blood-borne pathogens. The CDC coordinates testing of samples of blood-borne pathogens from patients and compares them with samples obtained from the diverter. For example, hepatitis C can be subdivided into genotype classifications that are probative of whether the virus derived from a patient matched the genotype of the virus in the diverter, increasing the likelihood that the viral infection was transmitted by the diverter. More importantly for criminal prosecutions, because the quantum of proof is "beyond a reasonable doubt," sophisticated testing such as "genetic sequencing," can provide a match to within a degree of certainty of 97 percent and higher that a virus was transmitted by a particular individual.

V. State Regulatory Agencies

In addition to the Public Health Agencies that may be stakeholders in these cases, states may have specific regulatory agencies that regulate the conduct of surgery technicians, nurses, pharmacists, doctors, and other healthcare professionals. They often address regulatory issues associated with professionals, including complaints and disciplinary matters. As such, regulatory agencies are a wealth of information regarding the professional history of medical professionals. The information they possess could well result in evidence admissible in a particular case or "bad acts" evidence admissible under Federal Rule of Evidence 404(b).

Also, most states employ a Prescription Drug Monitoring Program (PDMP) that maintains a record of prescribing by practitioners in that state. The PDMP provides data that demonstrates inordinate prescribing patterns and history according to prescriber, patient, drug, and pharmacy. This information is invaluable in the investigation and prosecution of practitioners who prescribe without a legitimate medical purpose.

VI. Diversion/Theft of Controlled Substances in the Hospital Setting

A. Common Schemes

Like any fraudulent conduct, the range of potential schemes is limited only by the fraudster's imagination. However, some of the most common schemes to divert opioids from hospital healthcare providers include: (1) diversion through the Pyxis machine, (2) forged prescriptions, (3) bedside diversion, and (4) operating room diversion.

The "Pyxis" machine is a device utilized by hospitals to regulate the dispensing of drugs and controlled substances by authorized hospital personnel. It often requires a specific code assigned to each authorized person or is accessed by a biometric means such as fingerprints. In any case, only authorized identified persons can gain access to controlled substances in a Pyxis machine. Additionally, the machine records events of withdrawal according to substances, date, time, and the individual making the withdrawal. The Pyxis machine usually maintains injectable forms of fentanyl in ampules or vials.

Diverters often gain access to vials of fentanyl or other opioids using codes assigned to them and later replace adulterated vials in the machine using the return or cancel function of the machine. A close examination of the Pyxis record will reflect unusual or unauthorized access of the machine and, more importantly, unusual returns of substances to the machine. In a couple of cases, nurse diverters accessed the Pyxis machine, obtained vials of fentanyl with spinning tamper-proof caps, injected the fentanyl, replaced its contents with non-sterile water, used surgical glue to replace the tamper-indicating spinning cap, and returned the adulterated vial to the Pyxis machine. Of course, administration of a non-sterile substance to vulnerable patients carries a high risk of bacterial infection, not to mention the pain inflicted when a patient does not receive the relief the opioid is intended to provide.

This scheme, as well as any other scheme that involves replacement of the contents of fentanyl or any other injectable opioid prior to its use on a patient, presents the real danger that a blood-borne pathogen could be passed from the diverter to a patient if the diverter used a previously-used syringe or needle in administering the fentanyl to himself and then used the same syringe or needle to replace the contents with another substance, such as saline, tap water, or even another drug. Because this is a crime of opportunity where the diverter has only minutes to make a switch and not be detected, addicts are often more concerned with obtaining the effects of the opioid than they are of the safety of patients. It is expedient for them to administer the drug and replace the contents as quickly as possible to avoid detection. Under these circumstances, diverters will dispense with the use of sterile syringes or saline solution in favor of re-using the same syringe and quickly accessing available tap water.

A second common scheme in the hospital setting involves simple fraud; that is, a medical professional forges or fraudulently creates the documentation authorizing the dispensing of a controlled substance, and an order or prescription is then filled because of the fraudulent documentation. Detection of this scheme requires a careful examination of medical records, including medical charts and prescriptions, for patients associated with the false documentation. In addition, prosecution of this type of fraud will require the cooperation of medical professionals like the treating or attending physicians.

Bedside diversion involves the theft of medication as it is delivered to the patient. Often, this type of diversion will involve the theft of pills or capsules immediately prior to administration. Since the patient is in a position of trusting that the necessary medications prescribed by a physician are actually delivered and administered at the time of treatment, this type of diversion is difficult to detect without the help of cooperative medical staff that may have been eye witnesses to the theft and are familiar with the patient and his treatment. A subtype of this type of diversion involving injectable opioids involves drawing opioids directly from containers when it is being administered intravenously. As with the theft and substitution scheme involving the Pyxis machine, this diversion deprives the patient of the pain medication or otherwise dilutes its effects.

As hospitals have become more vigilant at minimizing the window of opportunity for diverters to access opioids in the workplace, diverters avail themselves of any opportunity to steal these substances. In some cases, the diverter will wait until the short period of time between the moment when the anesthesiologist draws injectable opioids from vials immediately prior to surgery and the administration of the purported opioid on the patient. The span of time could be as little as a few minutes if the diverter is prepared with the substitute adulterated substances. These types of diversion are usually detected in the first instance by colleagues that observe suspicious activity by the diverter.

Institutional Controls

Rarely do opioid diverters start with an addiction to injectable, powerful opioids; rather, the diverter gradually increases his dependency on one opioid and then progressively craves and seeks stronger and stronger opioids. Diverters may steal and inject opioids several times a day during the peak of their addiction. Many become functional addicts that are difficult to detect. In spite of the best practices implemented by the healthcare industry to thwart drug diversion, serious addicts will do anything to feed their addiction.

People who divert opioids for their own use within a hospital setting are very similar to common addicts in many regards. They maintain personal and professional relationships in order to conceal their addiction. Most diverters are only detected after several months of diversion because they become experts at concealing their addiction. Quite often, these addicts are personable and affable individuals whom no one suspects of an addiction problem. That is exactly how they are able to succeed in obtaining opioids even in a heavily monitored facility.

At a minimum, healthcare providers committed to preventing diversion and ensuring the health of their patients should conduct comprehensive background investigations of employment candidates, perform drug testing, regularly audit Pyxis machine reports, ensure those machines are placed where other medical professionals can provide formal or informal oversight, and train their employees on how to identify diversion.

Comprehensive Background Investigations. Diverters in the healthcare industry, aided by institutional practices, are able to move from healthcare institution to healthcare institution without detection or law enforcement interdiction in spite of being identified as diverters by prior employers. Healthcare institutions, keenly aware of civil liability, will often use privacy laws like HIPAA and the Privacy Act, as well as common law and state law liability concerns, as reasons not to disclose the misconduct of employees to subsequent employers. Employers will even fail to report obvious criminal conduct to local and state law enforcement, cognizant that such reporting may raise inquiries about the hospital's exposure in relation to its patients, or damage its institutional reputation. In spite of these potential obstacles, healthcare institutions should exercise due diligence in "knowing its employee" and ascertaining the reasons the employee is jumping from institution to institution. Certainly, there are legitimate reasons for job relocation, but those are distinguishable from the suspect circumstances which should accompany termination for opioid theft. Ultimately, without referral to law enforcement by the affected institutions, a diverter will continue to divert until caught.

Drug Testing. Pre-employment drug testing is important, but it has obvious limitations. Many tests are substance specific, that is, there are very specific tests for specific substances. Therefore, unless a facility is testing for a substance like fentanyl, a test may not detect the presence of a substance of concern. Also, many opioids dissipate in the human body in short periods of time; so, unless the testing occurs within a short period of time after the drug use, it might not be detected by available testing methods.

Similarly, periodic drug testing during employment will tend to deter opioid theft for personal use in the workplace by increasing the risk of detection. However, logistical limitations, such as announcing to the employee that testing will occur too far in advance, might cause a wily diverter to simply abstain

from consuming substances for a short period of time in anticipation of the testing. Unannounced periodic drug testing can have a significant deterrent effect and increase the likelihood of detecting diversion by addicted medical professionals.

Regular Audits of Dispensers/Pyxis Machines. Regular critical examination of Pyxis-generated reports is a proactive measure that hospitals should employ to detect anomalous conduct by its employees. Because the reports are keyed to individuals, a regular examination of these reports will reflect individuals that might be accessing the machine too often or seeking opioids in an inordinate quantity or frequency. Ideally, the review of these reports should be done by an individual familiar with the employees' responsibilities and duties at the hospital.

Placement of Dispensers/Pyxis Machines. The mere placement of the Pyxis machine may serve as an incentive or disincentive to diversion. In many cases, the machines are placed in an isolated room outside the public view or near a bathroom, where the diverter can readily use the opioid without detection. Increasing the exposure or risk of detection by placing the machine near other healthcare professionals will deter illicit access. Some institutions monitor who uses the Pyxis machine with video cameras to provide a deterrent to diversion. Similarly, because opioid theft is a crime of opportunity, having a dispensing system close to a bathroom affords the diverter an opportunity to use the opioids without detection and at minimal risk. For that very reason, it also results in these addicts using unsterile water to conceal their conduct.

Training for Signs of Diversion. Sensitizing all employees about diversion is essential to the detection of diversion activity. Regular training about addiction among medical professionals and the signs of addiction will aid in detecting diversion in a professional setting.

Common Risks to Consider in Hospital Diversion Cases

The CSA defines the term "addict" as "any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction." 21 U.S.C. § 802(1)(2012). Addicts will do virtually anything to access their drugs of choice. As discussed above, they will create documentation to authorize dispensing, access dispensing machines, steal medications as they are delivered to patients, and thereafter hide their tracks to prevent detection. If they do these things while maintaining the appearance of being completely sober—they are functional addicts. While recklessly pursuing drugs to feed their addictions, diverters in the hospital setting often place patients at great risk.

Dilution of Opiates to Avoid Detection. When diverters access injectable forms of opioids, they might not use all the substances in the vials or ampules, thinking they can avoid detection by merely diluting the contents with replacement saline or water. However, a failure to receive the anticipated dosage of an opioid will result in the continuation of pain in the patient, the same as if the patient had not received the pain relief in the first instance. *See United States v. Cunningham*, 103 F.3d 553, 555 (7th Cir. 1996) (removing painkiller from syringes and replacing it with saline solution, among other risks, increased the likelihood the patient would be under-medicated for pain and suffer bodily injury); *United States v. Garnett*, 122 F.3d 1016 (11th Cir. 1997) (risk of bodily injury where defendant removed opioid and replaced it with other tablets, reducing the efficacy of the medications). Additionally, if the dilution occurs using unsterile substances like tap water or is delivered with unsterile syringes or needles, there is an increased risk of bacterial infection or transmission of blood-borne pathogens and viruses.

Investigators and prosecutors must keep in mind that diverters often change tactics because the circumstances surrounding the availability of opioids in a hospital setting are fluid.

"Dirty" Needles and Blood-borne Pathogens. "Dirty" needles are a reference to the re-use of needles or syringes. This term is often associated with patently illicit intravenous drug use of substances like heroin. The dangers associated with the use of dirty needles in a hospital setting are the same as the use of dirty needles on the street; they include the danger of bacterial infection or transmission of blood-borne pathogens like HIV or hepatitis, among others. Because diversion is a crime of opportunity, investigators must be wary of the possibility that dirty needles were used at some time during the course of diversion, possibly exposing patients to life-threatening pathogens and infections.

Sharps Containers and Wasted Opioids. Similarly, hospitals and institutional healthcare providers regularly waste unused opioids administered during surgeries or patient care. Sharps containers are the receptacles placed throughout the facility to safely dispose of needles, syringes and opioids that have been previously used at the facility. Diverters with a severe addiction will throw caution to the wind and retrieve unused opioids from sharps containers for their own use. The obvious danger becomes that they expose themselves to infections, viruses, and blood-borne pathogens of unknown patients from the hospital. This third party contamination could have catastrophic implications if the diverter continues to divert using dirty needles and syringes to tamper with supplies of opiates at the facility.

Tap Water and Toilet Water. As described above, bathrooms at the facility provide an ideal private place where a diverter can inject stolen opioids and cover his or her tracks by replacing the adulterated substances. Because tap water and even toilet water are readily available sources of a substitute substance, diverters often quickly access these in the process of tainting the controlled substances prior to replacing them and concealing their conduct. If the *modus operandi* of the crime include use of facility bathrooms, prosecutors should consider the possibility that the opioids may have been tainted by unsterile water, regardless of whether the diverter has a blood-borne pathogen.

VII. Investigating a Case Involving a Hospital or Healthcare Institution

A. Starting the Investigation

The sources for diversion cases involving healthcare providers, particularly hospital entities, are quite varied and can include whistleblowers, cooperating witnesses, media reports, victims, and the hospitals themselves. As an initial step in investigating any allegation of tampering or diversion, a prosecutor must quickly analyze the necessary investigating agencies in anticipation of setting up a team. From a federal agency perspective, at least five agencies should be considered along with appropriate state and local law enforcement: (1) the Drug Enforcement Administration (DEA), (2) the Food and Drug Administration-Office of Criminal Investigations (FDA-OCI), (3) the Federal Bureau of Investigation (FBI), (4) the Internal Revenue Service-Criminal Investigations Division (IRS-CI), and (5) the Department of Health and Human Services-Office of the Inspector General (HHS-OIG).

The DEA has subject matter expertise because most opioids are addressed by the Controlled Substances Act and the criminal sanctions associated with its enforcement. The DEA also often has both

administrative diversion and tactical diversion groups that regularly deal with the illicit diversion of controlled substances from hospitals.

The FDA-OCI primarily enforces the Food, Drug, and Cosmetic Act, but is also specifically authorized to investigate tampering with consumer products cases. An inordinate number of diversion cases in hospitals involve the diverter covering his or her tracks by replacing controlled substances like opioids with tainted products. This agency has expertise in dealing with these sorts of cases. In addition, the FDA-OCI has access to testing labs that can be instrumental in proving the criminal violation.

The FBI is authorized to investigate all Title 18 and Title 21 violations of law, including those contained in the Controlled Substances Act and the Anti-Tampering Statute. The FBI has access to the manpower and technical resources necessary to quickly and effectively investigate diversion cases.

The IRS-CI, in addition to enforcing the nation's tax laws, is very active in enforcing its money laundering statutes. Typically, this agency provides expertise in investigating financial crimes and tracking the fruits of those crimes.

Finally, if the investigation involves an element of healthcare fraud, particularly in the Medicare or Medicaid healthcare programs, then HHS-OIG has the experience and expertise in navigating the complex intricacies of these programs and can assist in obtaining the necessary evidence to prove that aspect of a case.

B. Cooperation from the Facility

Regardless of whether a case is classified as a controlled substances theft or an anti-tampering case, the hospital facility is likely to be a victim of the crime. In the circumstances where there is a theft or misappropriation, the thefts in the aggregate represent a pecuniary loss to the hospital. In a tampering case or even a potential tampering case, the hospital will suffer losses associated with the diverter's conduct, including testing services provided to potentially affected patients to detect the potential transmission of blood-borne pathogens and viruses like HIV and hepatitis. Additionally, the hospital will suffer a significant reputational harm because of the incendiary publicity surrounding these sorts of cases.

As a result, hospitals often want to be perceived as cooperating with the investigation. As healthcare providers, hospitals are cognizant of their obligations to their patients pursuant to the Privacy Act and HIPAA. Cooperation by hospitals will include access to any internal investigation, access to employee witnesses, coordination of witnesses like anesthesiologists and other healthcare professionals, as well as assisting with obtaining medical records and test results associated with patients pursuant to subpoenas, search warrants, waivers, and releases. It is critical to interface with the hospital counsel or officers as soon as possible in the investigation. Quite often, the hospital will have a substantial desire to bring the diverter to prosecution once the diversion becomes public information.

Hospitals are often reluctant to report diversion because of the potential exposure that such a potentially public disclosure may present. However, subsequent disclosure of diversion which is perceived to have been concealed is often a worse result for the healthcare facility.

C. Cooperation from the Diverter

Interviewing the diverter at the earliest possible instance is critical. The diverter is often the only person who knows the true extent of his criminal conduct. From a public health perspective, it is of paramount importance to establish the *modus operandi* of the diverter and the scope of criminal conduct

in terms of time. Diverters that stop their conduct only because they are caught were likely involved in diversion for a long time, especially if the substance diverted is a strong opioid like fentanyl. Diverters using such powerful opioids have probably been opioid addicts for a substantial period of time. The addiction likely started with less powerful opioids, then gradually increased as the addict's tolerance and dependency increased. Of course, if the diverter is in custody, or even objectively perceives he is in custody, investigators should *Mirandize* the subject prior to the interview and record the interview when practicable.

On the other hand, interviews conducted by the hospital pursuant to an internal investigation can yield powerful admissions against the diverter, and more importantly, allow public health investigators an understanding of the nature and scope of the diverter's conduct. As with any addict, however, statements should be taken with a grain of salt as diverters instinctively tend to minimize conduct. Investigators and prosecutors should endeavor to corroborate any statement from an addict.

D. Grand Jury Subpoenas and Administrative Subpoenas

Most healthcare providers will honor grand jury or administrative subpoenas for personnel and non-medical records associated with a diversion case. However, whether a hospital honors grand jury subpoenas or administrative subpoenas from an investigating agency seems to differ from facility to facility and state to state, depending on the applicable privacy and confidentiality laws. Generally, prosecutors rely on the "law enforcement," "grand jury," and "administrative subpoena" provisions of the HIPAA statute that permit covered entity disclosures of medical records and protected health information of patients and victims. *See* 45 C.F.R. § 164.512(f)(1)(ii)(A)-(C) and 164.512(f)(3) (2016). Hospitals are also permitted to make disclosures to law enforcement of ". . . protected health information that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity." 45 C.F.R. § 164.512(f)(5) (2016).

E. Search Warrants

Search warrants are a traditional law enforcement tool that is helpful in furthering a diversion criminal investigation, particularly when a diverter is uncooperative in the investigation. Search warrants are recognized as a form of process that permits covered entities, like hospitals, to disclose protected health information in a criminal investigation. See 45 C.F.R. § 164.512(f)(1)(ii)(A) (2016). They can also prove invaluable if the investigation determines that the diverter has evidence or instrumentalities of a crime in his or her possession or home. For example, some diverters will remove enough opiates from a hospital to use over a weekend or while they are not at work. If the evidence in a particular case merits, it could support a search warrant for the vehicle or residence of a diverter.

More importantly, if the evidence involves a diverter using "dirty needles," and there is the possibility of the transmission of a blood-borne pathogen, a search warrant executed using accepted medical practices can be sought for blood samples. *See Schmerber v. California*, 384 U.S. 757, 767-68 (1966). Exigent circumstances, such as a reasonable belief that a delay in obtaining the sample would result in the destruction of evidence, might form the basis for a warrantless obtaining of blood samples. Id., at 770-771. Blood samples from the diverter will be necessary to tie the blood-borne pathogen found in a victim back to the diverter through genetic sequencing or other scientific techniques. Likewise,

obtaining urine samples from a putative diverter will require a search warrant. *See Skinner v.Railway* Labor Executive's Ass'n, 489 U.S. 602, 616 (1989). Both urine samples and blood samples can be tested to determine if a diverter has recently ingested opioids; however, the evidence will dissipate over time. Testing for drugs often requires specific testing for specific drugs; therefore, testing without knowledge of the diverted drug will often overlook particular opioids. Hair samples, which can be tested to determine if a person ingested opioids, can be obtained through a grand jury subpoena. *See In re Grand Jury Proceedings Involving Mills*, 686 F.2d 135 (3rd Cir. 1982). However, a safer practice in obtaining hair samples would be to get a search warrant post-indictment, or consider obtaining a search warrant in addition to a grand jury subpoena pre-indictment. Unfortunately, testing hair samples will not yield the precise time of ingestion of opioids.

F. Coordination of Federal and State Law Enforcement

In order to streamline the investigation, all stakeholder law enforcement, both federal and state, should be identified early in the investigation. A coordinated effort will prevent duplication of effort and allow for de-confliction. Coordination of law enforcement will also permit efficient gathering of evidence without wasting valuable resources.

G. Testing and Expert Witnesses

In anticipation of the litigation, prosecutors should, as soon as practicable, identify potential expert witnesses that are likely to be necessary in the litigation. Many of the experts are foreseeable in diversion cases, for example, lab technicians and chemists that test the contents of tampered products, or fingerprint experts to establish that the subject handled a particular vial or syringe. To the extent possible, investigators and prosecutors should take steps to ensure protocols are in place to establish a clean chain of custody for the tested substances. Hospitals and other healthcare institutions conducting internal investigations are not adept at handling or maintaining evidence in a manner that will ensure its admissibility in a criminal prosecution. In a case where blood-borne pathogen transmission is a possibility, the prosecutor should seek expert consulting services, like those of an epidemiologist, in order to understand the science behind the transmission of particular pathogens. This expert may later become a testifying expert or assist the prosecutor in identifying other experts to prove the case.

Other potential expert witnesses may in fact be lay witnesses that serve as percipient witnesses, but may draw conclusions and opinions based on their field of expertise; for example, nurses testifying about the administration of opiates, or anesthesiologists testifying about the use and effects of opiates in surgery. Like any other complex case, the prosecutor should be prepared to timely disclose any potential expert witnesses to ensure their testimony will be available and admissible at trial. *See* Federal Rule of Criminal Procedure 16(a)(1)(G) and (d)(2) (2002). These witnesses will be essential to the successful prosecution of a diversion or tampering case.

VIII. Diversion by Prescribing Professionals ("Pill-Mills")

Doctors, nurse practitioners, and pharmacists involved in prescribing or dispensing controlled substances are subject to the provisions of the Controlled Substances Act, much the same as any other individual. The primary elemental difference, as discussed below, is that the dispensing was "outside the usual course of professional practice" or "not for a legitimate medical purpose."

Often, cases involving these professionals relate to circumstances involving "pill mills." "Pill mills" is a reference to a situation where healthcare professionals fill prescriptions outside the usual course of professional practice or without a legitimate medical purpose, often in large quantities and with a profit motive. As the name implies, it usually involves indiscriminate prescribing to individuals, often "drug seekers" merely seeking opiates to feed a dependency or addiction habit. "Drug seekers" are individuals' dependent or addicted to opiates or other controlled substances that will do almost anything to obtain their drugs of choice. Because of the nature of addiction, they will say or do almost anything to obtain a controlled substance. Pill mills have become commonplace in the United States even though prescribers and pharmacists place their reputations, livelihood, and liberty at risk when they participate in this conduct.

Investigative Techniques. There are certain investigative techniques which are essential to the successful investigation of prescribing professionals, but are different from the techniques discussed above for hospitals and healthcare institutions.

Undercover Agents and Cooperating Witnesses – A thorough investigation should include attempts to introduce undercover agents to the medical practice or to recruit cooperating witnesses who will help investigators get an inside look. By having someone pose as a perspective patient, law enforcement can see and record how the doctor, nurse practitioner, or pharmacist interacted with a patient who received controlled substances outside the usual course of professional practice. Undercover agents and cooperating witnesses should wear or carry equipment which allows them to audio and video record interactions with the subject professionals. However, prosecutors and investigators alike should be mindful of innocent third parties' medical privacy, and incorporate stopgap measures to minimize unnecessary interference with those rights. Audio and video recordings help present a compelling story to a jury and ensure that what happened within the closed exam room is accurately memorialized. Undercover agents are preferable to cooperating witnesses for several reasons. Undercover agents are often trained in how to conduct operations so it is easier to tell whether the prescription was issued outside the usual course of professional practice and so they avoid accusations of entrapment. Additionally, there may be a host of *Brady* and *Giglio* concerns which accompany the use of a cooperating witness since such witness will often have a history with the physician, with other patients, with law enforcement, and with drug abuse. There will be circumstances, however, where a practice may be very guarded, and the only way to get an inside look is to rely upon a cooperating witness who has already been accepted as a patient within the practice. In those instances, using a cooperating witness is likely preferable to having a case which is confined to the cold medical records seized pursuant to a search warrant at the conclusion of the investigation.

Analysis of PDMP, ARCOS, and Pharmacy Dispensing Data – Investigators have access to a great deal of data which can help them understand a medical professional's distribution practices. Prescription Drug Monitoring Programs (PDMPs) exist in nearly every state, and with the use of administrative subpoenas, investigators can access this data to see what prescriptions are being written, who is writing them, who is receiving them, who is filling them, where they are filling them, how often they are filling them, and how the putative patients are paying for them. Diligent physicians and pharmacists should be checking the PDMP during the course of their practice, so obtaining these records for certain patients can also be a helpful way for law enforcement to get a sense of what the medical professional knew at the time of prescribing, or what he should have known. The Automation of Reports

and Consolidated Orders System (ARCOS) is an online reporting system which includes reports from all DEA registrants who manufacture and distribute specific controlled substances pursuant to 21 C.F.R. § 1304.33 (2014) . Like the PDMP, ARCOS can be a great source of data, particularly with regard to the volume of controlled substances being dispensed by certain professionals. Finally, some investigations may afford agents access to pharmacy dispensing records. Pharmacy dispensing records provide one more source of information which can corroborate or clarify the PDMP or ARCOS and aid in analyzing the prescribing practices of a doctor, nurse practitioner, or pharmacy.

Surveillance and Pole Cameras – In a true pill-mill case, surveillance of the medical office or clinic, either by a surveillance team or through the use of pole cameras, will tend to corroborate the patterns and practice common to these sorts of cases; that is, people lining up outside the business and leaving after only a short visit, or unusual hours of operation catering to a suspect clientele. Additionally, surveillance will allow law enforcement to identify people who could prove valuable as witnesses and corroborate evidence at trial.

Search Warrants -- The investigation should strive to be covert until the execution of the search warrant to avoid destruction or manipulation of evidence. Obtaining the source documents is absolutely essential in a case involving physician diversion or overprescribing. At a minimum, the search warrant should yield the baseline documents for the investigation: (1) suspect medical files and charts, (2) log-in records, (3) telephone logs, (4) financial records such as payment records and ledgers, (5) communications between the subject and suppliers like pharmaceutical representatives or potential co-conspirators like pharmacists, (6) communications between the subject and his employees regarding patients, and (7) employee personnel files. Additionally, the investigation should be prepared to seize electronic records in advance of the search. Forensic computer imaging specialists, to the extent available, should be part of the search team. Electronic evidence held by third parties may necessitate a follow-up search warrant. Also, in order to avoid unduly interrupting business operations or depriving true patients of needed care, the team must be prepared to reproduce either copies of medical files or return the original medical files in a short period of time after reproduction. The search team should also be prepared to conduct interviews of office personnel at the time of the execution of the search warrant. The office personnel are invaluable sources of information for the discovery of additional evidence, the operation of the business, the instructions they were given by the medical professionals, and the patterns they saw at the office. This is probably the first and best opportunity investigators will have to interview these sorts of witnesses because the investigation is usually covert until the execution of the search warrant. Contemporaneous interviews are the best approach to get candid interviews of office personnel and even the subject.

Social media – The investigative team should be prepared to view social media sites and applications for potential advertising, promotions, or admissions by the subject. Social media is a potential treasure trove of evidence that can further the investigation or help prove “intent” and “pattern and practice” of dispensing. It can also provide valuable evidence about how the subject markets his or her practice. Investigators must be prepared to preserve the images or information collected from social media to meet discovery obligations and have the material available as evidence in the subsequent prosecution.

IX. Common Criminal Violations and Charging Decisions Involving Healthcare Providers

Although the potential charges associated with a particular case are driven by the facts and evidence, some of the more common diversion-related charges include: (1) tampering with a consumer product, (2) obtaining a controlled substance by deceit or subterfuge, (3) dispensing controlled substances without a legitimate medical purpose, and (4) false statements. The first three offenses obviously involve the diversions themselves, while the false statements charge may develop during the course of the investigation.

A. Tampering with a Consumer Product

This type of offense, in an institutional setting, will by its nature also involve violations of the Controlled Substances Act. That is, the offense conduct will constitute both a violation of Obtaining a Controlled Substance by Deceit or Subterfuge when a substance is acquired, and a Tampering with a Consumer Product offense when the diverter replaces the substance with another substance to conceal the theft.

Statutory Maximums and Pleading the Offense. 18 U.S.C. § 1365(a) (2002) is subdivided into four subsections, each of which may impact the applicable statutory maximum in any particular case:

a) Whoever, with reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk, tampers with any consumer product that affects interstate or foreign commerce, or the labeling of, or container for, any such product, or attempts to do so, shall—

(1) in the case of an attempt, be fined under this title or imprisoned not more than ten years, or both;

(2) if death of an individual results, be fined under this title or imprisoned for any term of years or for life, or both;

(3) if serious bodily injury to any individual results, be fined under this title or imprisoned not more than twenty years, or both; and

(4) in any other case, be fined under this title or imprisoned not more than ten years, or both.

"Bodily injury" means a cut, bruise, burn, disfigurement, physical pain, illness; it also includes impairment of a bodily member, organ, or mental faculty, or any other injury to the body, no matter how temporary. 18 U.S.C. § 1365(h)(3) (2002).

"Serious bodily injury" is bodily injury that involves a substantial risk of death, extreme physical pain, protracted and obvious disfigurement, or protracted loss or impairment of the function of a bodily member, organ, or mental faculty. 18 U.S.C. § 1365(h)(4) (2002).

"Consumer product" includes "drugs" as defined in the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 321(g)(1). *See* 18 U.S.C. § 1365(h)(1)(A).

Charging Considerations and the Basic Elements. As with any statute that increases the elements necessary to prove an offense as the statutory maximum increases, great care must be taken to ensure the prosecution does not overextend its theory of prosecution and charge more than it can prove. Pursuant to *Apprendi*, any element that affects the applicable statutory maximum must be pled in the indictment and

proven beyond a reasonable doubt. *Apprendi v. New Jersey*, 530 U.S. 466 (2000). Quite often, it is safer to charge the most basic elements of the offense but include multiple units of prosecution. For example, in a typical tampering case, because of the nature of opioid addiction, the diverter will have accessed the Pyxis machine multiple times over a period of time. Each access will evidence a theft, and each "return" will probably evidence placing a tainted product back in the machine to avoid detection. Under these circumstances, charging multiple events in separate substantive counts will allow the court to consider consecutive sentences to accomplish the *Sentencing Guidelines* sentence without increasing the elemental burden on the government "beyond a reasonable doubt." However, if either "death" or "serious bodily injury" is readily provable at trial, the statutory maximums are raised, and the affirmative findings by the jury will support the sentencing enhancements at sentencing.

Prosecutors must be careful about assessing the quality of their evidence prior to alleging these additional elements. If there is evidence of death or serious bodily injury, the court can consider those circumstances at sentencing by a "preponderance of the evidence" pursuant to the *Sentencing Guidelines* and 18 U.S.C. § 3553(a) (2010) factors, even if they are not alleged in the indictment. *See United States v. Perrien*, 274 F.3d 936 (5th Cir. 2001) (preponderance of the evidence standard continued to apply at sentencing post-*Apprendi*); *see also United States v. Lee*, 625 F.3d 1030 (8th Cir. 2010) (preponderance standard applies for sentencing enhancements after *Booker*).

Also, worthy of note, is that some case law suggests that, although the interstate commerce element is a jury issue, the interstate commerce element must occur at or after the tainting. *United States v. Levine*, 41 F.3d 607, 614 (10th Cir. 1994). Thus, the baseline elements of the offense are as follows:

1. With reckless disregard for and extreme indifference;
2. To the risk that another person would be placed in danger of death or bodily injury;
3. The defendant tampered with a consumer product or the container for such product, or attempted to do so; and
4. Which consumer product affected interstate or foreign commerce.

18 U.S.C. § 1365(a)(4) (2002).

B. Obtaining a Controlled Substance by Deceit or Subterfuge (Controlled Substances Act), 21 U.S.C. § 843(a)(3)

Statutory Maximums and Pleading the Offense. 21 U.S.C. §843(a)(3) (2009) provides, "It shall be unlawful for any person knowingly or intentionally…(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge." A violation of this provision has a four-year statutory maximum, but the statutory maximum may be as high as eight years if the defendant has a prior conviction for certain qualifying offenses. *See* 21 U.S.C. § 843(d) (2009).

Charging Considerations and the Basic Elements. As with the tampering charges, great care should be taken to charge any elements that increase the statutory maximum. Quite often, these charges go hand-in-glove with one another because the person accessing/stealing the controlled substances is driven by an addiction. However, some cases will involve obtaining a controlled substance by deception without evidence of tampering. Those cases will typically involve obtaining the controlled substance for resale; thus, the motive is financially driven and not necessarily driven by addiction. In a pure theft case, not involving the sort of consequences that one might expect in a tampering case, the *Sentencing*

Guidelines will generally be more lenient, as they are driven by a lower base offense level. *See* U.S. SENTENCING GUIDELINES § 2D2.2 (U.S. SENTENCING COMM'N 2015).

Unless there is an enhancement for purposes of raising the statutory maximum, the basic elements of the offense are as follows:

1. The defendant knowingly or intentionally;
2. Obtained a controlled substance;
3. By means of misrepresentation, fraud, forgery, deceit or subterfuge. (Apply only the means applicable to the evidence of a particular case.)

21 U.S.C. § 843(a)(3) (2009).

C. Dispensing a Controlled Substance Without a Legitimate Medical Purpose, 21 U.S.C. § 841 *et seq.*

This type of offense is typically associated with the Controlled Substances Act (CSA) dispensing practices of doctors, nurse practitioners, and pharmacists, but it could also form criminal liability for pharmacies and other organizational entities involved in the distribution of controlled substances. As described below, the key additional element that applies to healthcare professionals who are permitted to dispense or distribute controlled substances in some circumstances, that is not required for non-healthcare professionals, is that the dispensing was "not for a legitimate medical purpose or was outside the usual course of professional practice." This additional element finds its source in the Code of Federal Regulations:

> A prescription for a controlled substance to be effective must be issued **for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice**. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the ordinary course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of this Act, 21 U.S.C. § 829 (2016) and the person knowingly filling such purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04 (2005) (emphasis added); United States v. Moore, 423 U.S. 122 (1975); *United States v. Schneider*, 704 F.3d 1287 (10th Cir. 2013).

Statutory Maximums, Statutory Minimums, and Pleading the Offense. The Controlled Substances Act, particularly the provisions associated with the distribution or dispensing of controlled substances, involves different statutory maximums driven by the respective schedules of the controlled substances involved in the offense. *See, e.g.*, 21 U.S.C. § 841(b)(1)(C), (b)(1)(E)(i), (b)(2), and (b)(3) (2010). Additionally, the Controlled Substances Act provides increased statutory maximums or statutory minimums when certain aggravating factors are proven. For example, a statutory maximum might be increased if "death resulted" or there was "serious bodily injury" in a particular case. If the government

alleges and proves death resulted from the distribution of a Schedule II controlled substance, the statutory penalty becomes no less than 20 years, and up to life imprisonment. When death results from a Schedule III controlled substance, the maximum imprisonment increases from 10 years to 15 years. There is no difference in the maximum punishment if death results from a Schedule IV or V controlled substance.

If an aggravating fact increases the statutory maximum or imposes a mandatory minimum, that aggravating fact should be considered elemental and must be pled in the indictment. *See Apprendi v. New Jersey*, 530 U.S. 466 (2000). Although, in *United States v. Cotton*, the Supreme Court opined that failure to plead the element that increases the statutory maximum was subject to a plain error analysis. *United States v. Cotton, 535 U.S. 625 (2002)*. Further, a failure to properly plead an offense might result in a directed verdict or judgment of acquittal because of claims of substantive or constructive amendment to the indictment or that there was a fatal variance in the Indictment. *See Stirone v. United States*, 361 U.S. 212 (1960); *United States v. McKinney*, 53 F.3d 664 (5th Cir. 1995).

In order to avoid a dismissal of the offense for failing to plead the elements of the offense, or a potential directed verdict on the counts at trial, the prosecutor should allege the additional element that applies, even if it is not a "statutory element": that the conduct was "not for a legitimate medical purpose or outside the usual course of professional practice." *See United States v. Outler*, 659 F.2d 1306 (5th Cir. 1981). It is also better practice to cite 21 C.F.R. § 1306.04 (2005), which forms the basis of the offense in the Indictment, in order to assure the defendant was on notice of the offense charged by the grand jury, assure that the defendant can prepare a defense to the charge alleged, and assure that the defendant can address a potential claim of double jeopardy. *See* Bartell v. United States, 227 U.S. 427 (1913); *See also United States v. Haas*, 583 F.2d 216 (5th Cir. 1978). In *Haas*, the Fifth Circuit recognized that the court had "the sound discretion" to grant a bill of particulars where the averments of the indictment are inadequate, and reversed the dismissal. *See Haas*, 583 F.2d at 221.

Elements. The critical elements associated with this offense found its origin in the above-cited regulation but were more specifically honed by common law, as follows:

1. The defendant knowingly or intentionally dispensed or distributed, or caused to be dispensed or distributed, [one or more controlled substance(s)] as charged in the Indictment;
2. The substance was in fact [name controlled substance]; and
3. At the time of the distribution or dispensing, the defendant's actions were not for a legitimate medical purpose or were outside the usual course of professional medical practice.

21 U.S.C. § 841(a)(1) (2010); *see*, *United States v. Moore*, 423 U.S. 122 (1975); *United States v. Schneider*, 704 F.3d 1287 (10th Cir. 2013); *United States v. Nelson*, 383 F.3d 1227, 1233 (10th Cir. 2004).

In *Burrage v. United States*, the United States Supreme Court clarified that the "death resulted" language of the Controlled Substances Act requires proof of "but for" causation. *Burrage v. United States*, 134 S. Ct. 881, 187 L. Ed. 2d 715 (2014). Thus, the government must establish that there is a causal link between the controlled substance and the death, presumably through expert witnesses. In a recent trial in the District of Colorado, the court instructed the jury that the following additional elements must be proven beyond a reasonable doubt for the defendant to be found guilty of distributing a Schedule II controlled substance from which death resulted:

1. That the alleged decedent used the fentanyl which the defendant dispensed, distributed, or caused to be dispensed or distributed to the alleged decedent;
2. That this use of the fentanyl by the alleged decedent caused her death; and
3. That this use of the fentanyl by the alleged decedent was a cause without which her death on the alleged date would not have occurred.

While district courts may articulate the requirements of *Burrage* differently, the takeaway is that "but for" causation is a high burden which requires precision in charging and very specific proof at trial. Great attention should be given to the strength of the evidence before a decision is made to charge distribution of a controlled substance—particularly a Schedule II controlled substance—from which death resulted.

Charging Considerations. As with any criminal case, the evidence will drive the appropriate charges. In a pill mill case involving a single individual, the potential charges might include: (1) Controlled Substances Act violations, 21 U.S.C. § 841 (2010) *et seq.*; (2) Healthcare Fraud, 18 U.S.C. § 1347 (2010); (3) Money Laundering, 18 U.S.C. §§ 1956 (2016) and 1957 (2012); and (4) Aiding and Abetting, 18 U.S.C. § 2 (1951). The money laundering charges, which can be predicated on qualified "specified unlawful activity" including Controlled Substances Act violations and Healthcare fraud, are an important aspect of the indictment because it facilitates the admissibility of motive evidence like "promotion," "concealment," and how monies derived from the unlawful activities were spent.

If the case involves multiple individuals and organizations, the potential offenses may also include: (1) Conspiracy to Violate the Laws of the United States, 18 U.S.C. § 371 (1994); (2) Conspiracy to Dispense or Distribute a Controlled Substance without a Legitimate Medical Purpose, 21 U.S.C. § 846 (1988); and Conspiracy to Commit Money Laundering, 18 U.S.C. § 1956(h) (2016). The advantage of charging conspiracy counts—where they are supported by the evidence—is that, because they are "ongoing crimes," all the illicit distribution conduct during the course of the conspiracy is relevant, admissible conduct intrinsic to the offense, and relevant conduct at sentencing if the conduct of the co-conspirators is "reasonably foreseeable" and within the scope of the defendant's agreement, rather than discrete events associated with substantive counts which may or may not be admissible at trial or relevant conduct in an aggregate at sentencing. *See United States v. Miranda-Santiago*, 96 F.3d 517 (1st Cir. 1996); *United States v. Johnson*, 445 F.3d 339 (4th Cir. 2006) (aggregation of drug quantities involved in separate charges); *compare United States v. Dugger*, 485 F.3d 236 (4th Cir. 2007) (although similar offenses involved the sale of drugs, none of the other factors supported relevant conduct finding). In *United States v. Hayes*, the court opined that non-doctor professionals, like pharmacists, are subject to the Controlled Substances Act if they conspire with a physician: ". . . Nor do we think that Congress intended to allow pharmacists to aid doctors in becoming pushers. When a pharmacist fills a prescription that he knows is not a prescription within the meaning of the regulations, he is subject to the penalties of § 841." *United States v. Hayes*, 595 F.2d 258 at *261 (5th Cir. 1979). A deliberate ignorance instruction may be appropriate to prove the knowledge element of an offense. *See United States v. Neville*, 82 F.3d 750 (7th Cir. 1996).

Units of prosecution should be consistent throughout the indictment. A count may properly charge the offense occurred on or about either the prescribing date or the dispensing date, but it is best

practice to keep the theory of prosecution consistent throughout the indictment. Similarly, ranges of "on or about" dates which are inclusive of several prescribing occasions should be avoided to prevent confusion, especially if there are multiple substances alleged in the count. While the law may technically permit grouping several wrongful distributions together in the interest of lenity, there are several practical reasons why that may not be the best practice. Alleging ranges of "on or about" dates which include several separate prescribing occasions, arguably, will: invite a bill of particulars; make the government's proof less manageable at trial; confuse the jury as to which conduct is alleged to be wrongful; complicate the *Guideline* calculations; or lead to a motion to dismiss for vagueness of the allegations.

Expert Witnesses. Before any charging decision is made in regards to a medical professional's professional conduct, it is vitally important to make certain a duly qualified medical expert is available to examine the medical records and review reports associated with the investigation. That expert should be prepared to testify and offer opinions at trial. Undoubtedly, these sorts of cases will ultimately be determined after a "battle of the experts," with each opining as to whether the dispensing conduct was for a "legitimate medical purpose" or "outside the usual course of professional practice." Rarely will the other elements of the offenses be contested because they will be supported by medical records, copies of the prescriptions, PDMPs, and pharmacy dispensing records. The retained government medical expert should, at a minimum, be able to credibly address the specific area of practice in which the defendant was involved. For example, a physician specializing in pain management should receive serious consideration as the expert if the defendant purportedly prescribed for "chronic pain management."

Also worthy of consideration is whether multiple experts are necessary to either prove the case or rebut anticipated factual and legal defenses. For example, a pharmacologist or retail pharmacy expert may be necessary to address appropriate prescribing quantities and patterns in a case involving pharmacy misconduct or witnesses, or to opine as to why a particular prescribing pattern is an anomaly based on his experience or the literature.

Multiple Drugs Issue, Statutory Maximums, and Verdict Forms. As discussed briefly above, the Controlled Substances Act provides different applicable statutory maximums and minimums for different controlled substances depending on the substance or its schedule. This might present an *Apprendi* issue to the unwary prosecutor at the charging stage, or an unanimity issue at trial. Great care should be taken to ascertain the bases of the offenses charged in the indictment. Although the Controlled Substances Act and pertinent case law pertaining to duplicity do not prohibit charging multiple controlled substances in a single count, the defendant should be advised of the highest statutory maximum applicable under the Controlled Substances Act. Further, if a factor like "death resulted" is part of the government's case, and it increases the applicable statutory maximum, then it must be pled in the indictment. *See Apprendi v. New Jersey*, 530 U.S. 466 (2000). If the statutory maximum is different for different substances alleged in the same count, or the quantities trigger different statutory maximums, because these factors affect the applicable statutory maximum, a special verdict regarding the jury's findings of guilt should be submitted as to each substance. *See United States v. Wettstain*, 619 F.3d 577, 592-93 (6th Cir. 2010) (sentence vacated where jury did not determine specific drug quantity beyond a reasonable doubt and sentence exceeded statutory maximum).

As discussed above, in *Burrage v. United States*, 134 S. Ct. 881, 187 L. Ed. 2d 715 (2014), the Supreme Court clarified that the "death resulted" language of the Controlled Substances Act requires proof of "but for" causation. This task may be considerably more difficult in poly-drug cases. It is important to consider that there may be synergistic effects of the use of multiple controlled substances that could complicate the analysis. Failure to properly charge or prove aggravating factors that raise the

statutory maximum may result in the application of a lower ceiling at sentencing. *See United States v. Angle*, 254 F.3d 514 (4th Cir. 2001). The prosecutor may decide to seek charges without the additional elemental burden, like "death resulted," in favor of making that a sentencing issue with the lower burden of preponderance of the evidence.

Should the evidence at trial involve multiple drugs or whether the particular controlled substances, either individually or in combination with another controlled substance, were prescribed without a legitimate medical purpose, the prosecutor should consider either a unanimity instruction or a special verdict in relation to each controlled substance.

Civil Versus Criminal Remedies. Prosecution of healthcare professionals for the dispensing of controlled substances "without a legitimate medical purpose" or "outside the usual course of professional practice" is a criminal enforcement action that should be distinguishable from civil negligence conduct or even gross negligence in the prosecutor's mind. *See United States v. McIver*, 470 F.3d 550 (2006) (the district court distinguishes civil liability from criminal liability). One court, citing Supreme Court *dicta* in *United States v. Moore*, observed "physicians who depart from the usual course of medical practice were subject to the same penalties as street pushers." Such conduct depicts the practitioner as abandoning his role as a professional and acting like a common drug dealer. *See United States v. Nelson*, 383 F.3d 1227, 1233 (10th Cir. 2004) *citing United States v. Moore*, 423 U.S. 122, 138, 143 (1975); *see also United States v. Feingold*, 454 F.3d 1001 (9th Cir. 2006). The prosecutor should consider the gravity and impact of a criminal prosecution and determine, based upon the evidence, whether a criminal prosecution is warranted. The United States Attorney's Manual (USAM) addresses the consideration of alternative remedies in determining whether a prosecution is appropriate as to individuals. *See Principles of Federal Prosecution*, U.S. Attorneys' Manual § 9-27.220 (2009). Additionally, the USAM provides the factors that should be considered if a corporate or business entity should be prosecuted. Corporate criminal exposure is subject to the *Principles of Federal Prosecution of Business Organizations* that was incorporated into the USAM in August 2008. Section 9-28.300 of the USAM enumerates a non-exhaustive list of considerations for prosecutions of business entities. U.S. Attorneys' Manual § 9-28.300 (2008).

Pitfalls and Special Issues. The potential issues and pitfalls involved in complex cases targeting medical professionals are too numerous to address effectively in an article of this length and scope. However, there are a number of issues that seem to be consistent in almost every case. This article will only address the most common issues: (1) medical records; (2) scope of practice; (3) drug-seekers; (4) treating addiction and prescribing patterns; (5) good faith; (6) opposing experts; and (7) the testifying defendant.

Medical Records – Prosecutors and investigators handling cases involving medical professionals must ensure all the relevant medical records are seized during the execution of search warrants in the investigative phase of the case. The medical records are the foundation of the case because they form the basis of the expert's opinion on the critical element of criminal liability. They also provide a window into the medical professional defendant's rationale and likely defenses at trial. The warrant should be narrowly tailored to obtain the necessary evidence of crime and avoid a "general warrant" or overbroad warrant argument.

Scope of Practice – The "scope of practice" for various professionals is often governed by state laws or regulations. It is critically important that the prosecutor and testifying medical expert understand the acceptable scope of practice for particular medical professionals prior to determining whether dispensing conduct was "for a legitimate medical purpose." For example, a nurse practitioner in a particular state might not be authorized to prescribe or dispense controlled substances.

Drug-Seekers - Particularly in "pill mill" cases, drug-seeker witnesses/victims present unique problems. Although the concepts of comparative or contributory negligence are civil in nature, the realities of jury trial work necessitate that prosecutors realistically assess these individuals in the context of their case. The jury may inadvertently consider relative responsibility in its deliberations. Jury instructions regarding the credibility of witnesses generally and the credibility of drug users specifically will alert the jury about how to weigh their testimony. Additionally, defendant healthcare providers will use these types of witnesses to create the impression they acted based on fraudulent or false representations by this dubious group; thus, setting themselves up as victims of key government witnesses. Prosecutors should be prepared, if they are relying heavily on drug-seeker witnesses, to address the medical histories documented in the available medical files or address medical histories through the medical expert witness.

Treating Addiction and Prescribing Patterns – The prosecution should be prepared to address the treatment of addiction, in addition to the treatment of pain, as a potential legitimate purpose for prescribing. Implicit within the practice of medicine is the notion that doctors exercise prudent medical judgment constrained by applicable standards of care, their ethical and professional responsibilities, and the law. The prescriber's pattern of prescribing may have been influenced by not only the pain reported by the patient, but also by whether the patient has a tolerance or addiction to a particular substance. Although 21 C.F.R. §§ 1306.04 and 1301.28 explicitly prohibit most providers from issuing prescriptions for "detoxification treatment" or "maintenance treatment," there are still some creative ways for the defense to rebrand these as legitimate medical purposes within the circumstances of a particular case. The pain management expert should be able to assist the prosecutor in identifying patterns of prescribing that are consistent with the appropriate treatment of a medical condition and the pain associated with it, as well as patterns of prescribing addressing those circumstances along with the applicable addictions in a particular case. Also, the prosecution should be prepared to address the propriety of addiction treatments. For example, the DEA requires specific registration/licensure for a practitioner to prescribe suboxone for addiction treatment.

Good Faith – Always keep in mind that "Good Faith" may be raised by the evidence of a particular case, even if the indictment only alleges CSA violations, particularly in cases where the evidence suggests a defendant may have acted with good intentions and the honest exercise of best professional judgment. *See United States v. Moore*, 423 U.S. 122, 129 (1975); *United States v. Hurwitz*, 459 F.3d 463 (4th Cir. 2006); *see also United States v. Voorhies*, 663 F.2d 30, 34 (6th Cir. 1981) (affirming instruction that "Good faith . . . means good intentions and honest exercise of best professional judgment as to a patient's medical needs. It connotes an observance of conduct in accordance with what a physician should reasonably believe to be proper medical practice."). Good faith is an objective standard, not a subjective standard. *United States v. Hurwitz*, 459 F.3d 463 (4th Cir. 2006). The burden to disprove good faith is on the government beyond a reasonable doubt if the evidence raises the defense. *See United States v. Merrill*, 513 F.3d 1293, 1305-06 (11th Cir. 2008) (government has burden of proving no legitimate medical purpose for drug use and instruction on 'good faith' did not relieve the prosecution of proving all the elements beyond a reasonable doubt); *see also United States v. Hopkins*, 744 F.2d 716,

718 (10th Cir. 1984) (good faith instruction in mail fraud case involving willful state of mind required if properly requested and supported by the evidence). In preparation for trial, prosecutors should be ready for this issue and should be prepared to address why the conduct was not done in good faith.

Off-label prescribing rules that may be applicable to physicians pose potential problems in confronting a good faith defense. That is, normally the FDA does not regulate the practice of medicine, and therefore, unlike other individuals or entities, does not prohibit the prescribing of approved drugs for unapproved purposes by physicians. This potential excuse for prescribing whatever the physician believes is appropriate is a red herring that is inapposite to whether the prescribing or dispensing was for a "legitimate medical purpose" or "outside the course of professional practice." Still, the concepts could confuse a jury in considering whether a defendant acted in good faith or because of accident or mistake. The prosecutor should be prepared to argue against the position that the doctor thought he could prescribe for "any reason" in support of a "good faith" defense.

Opposing Experts – Be prepared to cross-examine opposing experts as well as the defendant in these cases. If the government has complied with its disclosure obligations pursuant to Federal Rule of Criminal Procedure 16, the prosecutor should persist in the request for reciprocal discovery which, in the case of an expert, should disclose the basis of the opinion, the qualifications of the expert, a description of the opinion itself, and might also include the disclosure of expert reports. *See* Fed. R. Crim. P. 16(b)(1)(C)(2002). All of this information is fodder for effective cross examination. Particularly helpful are articles or publications attributable to the expert because such literature will almost necessarily address concerns and limitations regarding prescribing practices. However, at trial, be careful not to "take on" the expert in his field of expertise; rarely does this work out for the attorney. Control the cross-examination with leading questions and focus on eliciting strategic concession points.

The Testifying Defendant. In preparing for trial, assume that the defendant will testify. If the defendant chooses to take the stand, the prosecutor must be prepared to effectively cross-examine the defendant with the facts of the case, other bad acts (subject to limitations set by the court), evidence of bias, and credibility evidence, like any other witness. Because this type of witness is a percipient lay witness as well as an expert witness, caution should be exercised to not get into a contest regarding matters outside the prosecutor's expertise. Ideally, matters involving medical decisions were addressed by the government's expert in its case-in-chief, or might be addressed by a rebuttal witness.

D. False Statements

The credibility of diverters is often reflected of the nature of their offenses. Diversion by its very nature impugns the defendant's honesty. If investigators are able to conduct an interview of the defendant early in the investigation, there is a significant likelihood the defendant will minimize or lie about involvement in the diversion of opiates. Because false statements are consistent with the underlying offenses involving diversion, these additional charges will enhance the prosecution and allow admissible evidence of dishonesty to be considered by the trier of fact.

Elements. The elements of making False Statements in violation of 18 U.S.C. § 1001(a)(2) (2006) are as follows:

1. The defendant made a false statement or representation to the government; specifically, [as described in the Indictment];
2. The defendant made the statement knowing it was false;
3. The defendant made the statement willfully, that is deliberately, voluntarily and intentionally;
4. The statement was made in a matter within the jurisdiction of the executive branch of the United States Government; and
5. The statement was material to the government agency.

   A fact is "material" if it has a natural tendency to influence or is capable of influencing a decision of the government agency. It is not necessary that the agency was in fact influenced in any way.

Tenth Circuit Pattern Jury Instructions – Criminal, No. 2.46.6 (2011); *United States v. Harrod*, 981 F. 2d 1171, 1175 (10th Cir. 1992); *United States v. Schulte*, 741 F.3d 1141, 1148 (10th Cir. 2014).

Charging Considerations. There is no downside in attempting to obtain a proper interview of the defendant. If the defendant tells the truth, it will go a long way to understanding the extent of the damage caused and provide powerful evidence in the prosecution of substantive offenses. If the defendant makes false statements, those statements are admitted at trial in a different light when they are presented as the basis of a false statements charge rather than exculpatory statements. Caution must be exercised to ensure the defendant is not a represented party; and that, if there is an issue regarding custodial detention, that the defendant is *Mirandized* and that the interview is recorded, if practicable. *See Attorney General Holder Announces Significant Policy Shift Concerning Electronic Recording of Statements: New Guidelines Create Presumption That Interviews of Federally Detained Persons Will Be Electronically Recorded* (May 22, 2014).

Consistent with the positions the Solicitor General has taken, the Department argues that the term "willfully," as used in 18 U.S.C. § 1001 (2006) prosecutions, "requires proof that the defendant knew his conduct was unlawful" rather than that the defendant acted "deliberately and with knowledge" that his statements were false. This concern can be addressed by formal advisement in a written declaration advising the interviewer of criminal liability for making false statements, or an oral advisement prior to the interview. Addressing this issue prior to the interview will be powerful evidence that the defendant's statement was indeed "willful."

As with any false statement prosecution, it is important to clearly define the question and response that form the basis of the false statement. Short of a formal deposition or court reporter transcribing the testimony, the best way to establish the false statement is by recording the interview. Again, if the interview is pursuant to custodial detention, it should be recorded when practicable pursuant to Department policy. Even if the interview is not pursuant to custodial arrest, overt or covert recording will provide the best evidence of chargeable false statements. It is far easier to prove statements attributable to a defendant if it is a recorded statement. However, the lack of a recording is not a bar to the prosecution for false statements. *See United States v. Schulte*, 741 F.3d 1141, 1151-52 (10th Cir. 2014) (testimony, memorandums, and contemporaneous notes all established the context of the interview).

X. The Prosecution

A. Motion to Sever Defendants or Counts

If the indictment includes various theories of criminal liability, for example, Healthcare Fraud counts and CSA counts, a prosecutor should be prepared to address a severance of counts motion based on prejudicial joinder of counts pursuant to Rules 8(a) and 14(a) of the Federal Rules of Criminal Procedure. *See Zafiro v. United States*, 506 U.S. 534 (1993). Further, an indictment that includes multiple defendants that does not include conspiracy allegations may invite a motion to sever defendants, particularly if there is disproportionate criminal activity constituting prejudicial spillover by one defendant on another defendant. *See United States v. DeLeon*, 641 F.2d 330 (5th Cir. 1981) (defendants charged in same conspiracy properly joined in the same indictment); *see also*, *United States v. Phibbs*, 999 F.2d 1053, 1067 (6th Cir. 1993) (severance not warranted unless defendant can demonstrate substantial prejudice from evidentiary spillover from one defendant to another).

B. Motions *in Limine*

Whenever professionals are implicated in a diversion case, it is important to inquire into the professional history of the diverter. Often, regulatory agencies have dealt with the diverter in similar instances to that being prosecuted. An investigation into prior conduct by the diverter may well result in the discovery of "other bad acts" evidence governed by Federal Rule of Evidence 404(b). If such is the case, a motion *in limine* may be the best way for the defense or even the prosecution to get a pretrial ruling as to the admissibility, or limited admissibility, of the evidence pursuant to Federal Rules of Evidence 104, 401, and 403 (1974).

C. Business Records

As discussed above, a great deal of the evidence in these types of case will likely involve business records held by numerous entities, including pharmacies, hospitals, labs, doctor offices, and others. In order to determine the admissibility of those records in advance of trial, the prosecution should provide notice of its intent to use those business records at trial pursuant to Federal Rules of Evidence 902(11) and 803(6). This will provide the court an opportunity to consider their admissibility pretrial, subject to establishing relevance or other limitations, and alleviate the necessity to call unnecessary witnesses in a complex trial. *See* Federal Rules of Evidence 104, 401, and 403 (1974).

D. Protective Orders

Because of the inherent nature of the discovery in diversion cases, it is likely to involve protected health information. The prosecutor should be sensitive to the disclosure of protected health information in the process and should consider obtaining a protective order from the court as soon as practicable pursuant to Federal Rule of Criminal Procedure 16(d)(1) (2002). This issue can be addressed with defense counsel as early as the Initial Appearance phase of the proceedings, and the motion for such a protective order will likely be without objection.

E. Voir Dire/Jury Selection

To the extent the court permits jury *voir dire* by the parties, it is important that a prosecutor ask questions regarding the jury panel's experience with the medical profession. A more-sophisticated juror having experience as a medical professional is desired in diversion cases. Even potential jurors who have

somehow dealt extensively with the medical profession, either because they or a loved one has received treatment for pain, will be a desired juror because of their understanding of the legitimate uses for opioids. Likewise, a potential juror that has witnessed the ravages of addiction is a favorable juror for the prosecution.

It is also important that questions posed to the panel include inquiries into the bias or prejudice any prospective juror might have regarding the appropriate use of opioids for "pain management." Some jurors could be sympathetic to the addiction to opiates, or may have liberal feelings about the use of opioids in general. Those attitudes should be the subject of inquiry during *voir dire*.

F. Opening Statement

Establish the theme of your case as soon as possible. For example, in a hospital diversion case, the theme might include that the diverter was more concerned about feeding an addiction than the safety or health of the patients. In an over-prescribing case, the theme might include the concept that a doctor abandoned his role as a healer in favor of becoming a common drug dealer. If the evidence will ultimately support a motive, such as addiction or profit, opening statement provides the opportunity to alert the jury to that evidence.

As with all prosecutions, the opening statement is a roadmap of the case. However, in diversion cases, in addition to addressing the anticipated facts, the prosecution has the opportunity to preview anticipated expert testimony and explain the jargon the jury is likely to hear in the case. Because of the technical nature of medical testimony and medical records, this is the best opportunity to acclimate the jury to the technical details in a case.

In a pill-mill case, the prosecution may involve a series of narratives regarding various patients over a period of time. The prosecutor must be prepared to address, in summary form, the facts supporting the lack of a legitimate medical purpose for the prescribing as to each patient. These cases are complex and involve lengthy testimony; a failure to prepare the jury for the evidence will risk the details being lost in the testimony of a long trial.

G. Handling the Witnesses at Trial

"Drug Seeker" Witnesses. Drug-seeking witnesses are problematic for a number of reasons, including perception problems and continuing drug-seeking issues. Whenever dealing with drug-seeker witnesses, it is important to remember a prosecutor's discovery obligations pursuant to *Brady* and *Giglio.* These types of witnesses will often continue seeking controlled substances during the pendency of the litigation. Not only should the prosecution inquire of any bad acts from the witness, the prosecution should also obtain a recent criminal history from law enforcement.

Witness Coordinators are instrumental in maintaining a good relationship with these difficult witnesses. Their interpersonal skills will be instrumental in handling these witnesses at trial. To the extent a Witness Coordinator is available, the prosecution must work closely with that person to ensure the appearance of the witness and that discovery obligations are met.

Preparing drug seekers to testify is important for both the prosecutor and the witness. The prosecution should have a law enforcement agent available to memorialize any difference in the stories these witnesses tell during this process to ensure the government's *Brady* and *Giglio* obligations are met. An additional benefit to a pretrial interview is that rapport is built with the witness and the witness will

understand the scope and direction of direct examination. Many of these witnesses have been on the other side of prosecutions and might be intimidated by testifying for the prosecution. Also, these types of witnesses may change their testimony on the stand. A prudent prosecutor should be prepared to handle these witnesses as hostile witnesses, if necessary. *See* Federal Rules of Evidence 607 (2011) and 611(c)(2) (2011).

Expert Witnesses. Expect *Daubert* challenges to your experts. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1983) (Federal Rule of Evidence Rule 702 provides the standards for the admission of expert testimony); *Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137 (1999) (the gatekeeper function of trial courts is applicable to expert testimony of all types, not merely scientific knowledge testimony). Diversion cases are going to involve medical and technical experts. In addition to the Rule 16(g) disclosures, the prosecutor must be certain the expert passes muster under Federal Rule of Evidence 702. It is not unusual for the defense to contest the government's expert in order to gain insight into the extent of their testimony or otherwise test the quality of the expert's testimony. It might also afford the defense the opportunity to discover avenues for cross-examination at trial.

Like most professionals, expert witnesses are most cooperative when they are able to coordinate their schedule with advance notice. Again, a Witness Coordinator in regular contact with these witnesses can address scheduling concerns and allow the prosecution team flexibility in preparing for trial and ultimately calling the witness at a time when their testimony makes the most sense in a trial. It is also important to remember to update disclosures regarding these witnesses, including any contracts or remuneration to be provided to these witnesses for their testimony.

Diversion cases, particularly prescription pill-mill cases, could rise or fall on the expert's testimony. A prosecutor must spend time with the witness in preparation for trial. Experts need direction as to the scope of direct examination and might be interested in the likely scope of cross-examination in preparation for their testimony.

H. Effective Closing Arguments

Opening Closing Argument. Generally, the opening argument should mirror the opening statement, but should include the evidence most favorable to the government's theory of the case. This is the government's opportunity to summarize the evidence that supports the government's theories, especially in a long trial or where the evidence was muddled by the defense. Great care must be taken not to not lose the jury with references to unnecessary or boring testimony. The focus should be on the most memorable testimony that will resonate with the jury. If the charges are particularly complicated, a review of the elements in the jury instructions, with a reference to the evidence supporting each element, will help the jury focus on the important evidence.

If the defense referenced evidence in their opening statement that was an inaccurate representation of the evidence, this is the time for the prosecution to address it with the jury. The defense will be in the unenviable position of either dismissing the argument or addressing it in their closing argument.

Rebuttal Closing. At a minimum, the rebuttal closing should accomplish two things: (1) restate the theory of the case for the government, and (2) address the defense argument with references to the evidence or reasonable inferences that can be drawn from the evidence.

XI. Sentencing

A. The Crime Victims' Rights Act (CVRA), 18 U.S.C. § 3771

It is imperative that prosecutors keep the CVRA in mind as they prosecute diversion cases involving victims. Diversion cases are important primarily because of the specific and general deterrence to those that threaten the public health by their diversion activities. As discussed above, diversion cases will involve both individual and institutional victims. Prosecutors are mandated by the CVRA to consider the victim rights as they prosecute Federal crimes. 18 U.S.C. § 3771(f) (2015). The CVRA defines a "crime victim" as ". . . a person directly and proximately harmed as a result of the commission of a Federal offense or an offense in the District of Columbia." 18 U.S.C. § 3771(e)(2)(A) (2015) .

The CVRA provides the following rights to crime victims:

1. The right to be reasonably protected from the accused;
2. The right to reasonable, accurate, and timely notice of any public court proceeding, or any parole proceeding, involving the crime or of any release or escape of the accused;
3. The right not to be excluded from any such public court proceeding, unless the court, after receiving clear and convincing evidence, determines that testimony by the victim would be materially altered if the victim heard other testimony at that proceeding;
4. The right to be reasonably heard at any public proceeding in the district court involving release, plea, sentencing, or any parole proceeding;
5. The reasonable right to confer with the attorney for the Government in the case;
6. The right to full and timely restitution as provided in law;
7. The right to proceedings free from unreasonable delay;
8. The right to be treated with fairness and with respect for the victim's dignity and privacy;
9. The right to be informed in a timely manner of any plea bargain or deferred prosecution agreement;
10. The right to be informed of the rights under this section and the services described in section 503(c) of the Victim's Rights and Restitution Act of 1990 (42 U.S.C. § 10607(c) (1994)) and provided contact information for the Office of the Victims' Rights Ombudsman of the Department of Justice.

18 U.S.C. § 3771(a) (2015).

B. The *Sentencing Guidelines:* Drug Counts and Tampering Counts

The Controlled Substances Act applies to virtually all diversion activity, both by professionals and non-professionals. Conviction under the Controlled Substances Act may result in a wide range of *Sentencing Guidelines* calculations before application of the 18 U.S.C. § 3553(a) (2010) factors. *See Gall*

v. United States, 552 U.S. 38 (2007) (the guidelines remain the "initial benchmark" for sentencing); *see also Kimbrough v. United States*, 552 U.S. 85 (2007). Also, the Anti-Tampering Statute provides stiff penalty ranges for violations. Consistent with the intent of Congress in the underlying statute, the advisory *Sentencing Guidelines* reflect the sentiment that this type of conduct deserves consideration of a serious sentence. *See United States v. Booker*, 543 U.S. 220 (2005) (making the guidelines advisory). Application of the *Sentencing Guidelines* begins with a consideration as to what constitutes "relevant conduct." U.S. SENTENCING GUIDELINES §1B1.3 (U.S. SENTENCING COMM'N 2015). Substantive drug offenses under the Controlled Substance Act fall under U.S. SENTENCING GUIDELINES § 3D1.2; (U.S. SENTENCING COMM'N 2015) and, U.S. SENTENCING GUIDELINES § 3B1.3(a)(2) (U.S. SENTENCING COMM'N 2015) which that the relevant conduct includes conduct which is ". . . the same course of conduct or common scheme or plan" even if it is outside the offenses of conviction. On the other hand, the tampering counts, to the extent they involve separate harm, are not grouped and are addressed by an adjustment to the base offense level applicable to the case. Because a typical diversion case might involve both groupable distribution allegations and non-groupable tampering allegations, it is appropriate to calculate the applicable *Guidelines* under both theories and apply the greater applicable Guidelines calculation. *See* U.S. SENTENCING GUIDELINES § 5G1.2 (U.S. SENTENCING COMM'N 2015).

In a typical Controlled Substances Act case, the court determines the relevant conduct and applies the Drug Quantity tables associated with the aggregate quantities of controlled substances pursuant to U.S. SENTENCING GUIDELINES § 2D1.1 (U.S. SENTENCING COMM'N 2015), with enhanced base offense levels if certain conditions are met. For example, U.S. SENTENCING GUIDELINES § 2D1.1(a)(2) (U.S. SENTENCING COMM'N 2015) provides that in circumstances where the defendant is convicted of an offense under 21 U.S.C. § 841(b)(1)(A)-(C) (2010), and "the offense of conviction establishes that death or serious bodily injury resulted from the use of the substance," the base offense level is 38. However, in a case involving the obtaining of a controlled substance by forgery, fraud, deceit, or subterfuge, the base offense level is set at level 8. U.S. SENTENCING GUIDELINES § 2D1.1(U.S. SENTENCING COMM'N 2015). If there are no special circumstances like "death resulted" or "serious bodily injury," the calculation that drives the base offense level in the *Sentencing Guidelines* may involve painstaking calculations of "actual" active controlled substances converted to a "marijuana equivalent." Some drugs have favorable conversion rates while others do not. For instance, one gram of oxycodone is equal to 6,700 grams of marijuana. Thus, one distribution involving 90 pills, each containing 30mg of oxycodone, would start at a base offense level of 14. On the other hand, every unit (tablet) of a Schedule IV controlled substance only accounts for .0625 grams of marijuana. Thus, a distribution involving even 10,000 tablets of Xanax is a base offense level 6. A prosecutor should calculate the *Sentencing Guidelines* early in the case in order to have the proper perspective when charging and negotiating pleas.

In addition, the court can consider a role adjustment which could result in a reduction of up to four levels for a mitigating role, or an increase of up to four levels for an aggravating role. U.S. SENTENCING GUIDELINES § 3B1.1(U.S. SENTENCING COMM'N 2015) AND U.S. SENTENCING GUIDELINES § 3B1.2 (U.S. SENTENCING COMM'N 2015). Pursuant to U.S. SENTENCING GUIDELINES § 3B1.3 (U.S. SENTENCING COMM'N 2015), the court can consider an additional two-level adjustment for the use of a "Special Skill" if the defendant used a special skill or professional ability. A medical license and a DEA registration are required to write prescriptions and will often be considered as the use of a special skill or professional ability to commit the criminal activity. Further, as a healthcare professional, the defendant

may have been in a position of private trust when he diverted controlled substances or prescribed controlled substances without a legitimate medical purpose or outside the usual course of professional practice. Pursuant to U.S. SENTENCING GUIDELINES § 3A1.1(b)(1) (U.S. SENTENCING COMM'N 2015), the court may consider an additional two-level adjustment because the defendant knew or should have known that the victims of the offense were "vulnerable victims" because of their physical and/or mental condition when he diverted or over-prescribed controlled substances without a legitimate medical purpose or outside the usual course of professional practice. Additionally, if there were "a large number of vulnerable victims," the court may consider another two-point adjustment to the base offense level. U.S. SENTENCING GUIDELINES § 3A1.1(b)(2) (U.S. SENTENCING COMM'N 2015). Of course, the *Guidelines* calculations are driven by the facts of a particular case, and it is difficult to anticipate categorically whether the Controlled Substances Act counts or the Anti-Tampering counts will result in a higher base offense level without comparing and contrasting both calculations.

A typical Tampering counts analysis begins with the base offense level of 25. U.S. SENTENCING GUIDELINES § 2N1.1 (U.S. SENTENCING COMM'N 2015). If there are Specific Offense Characteristics indicating the offense of conviction involved victims that sustained permanent or life-threatening bodily injury, the base offense level is increased by 4 levels. *See* U.S. SENTENCING GUIDELINES § 2N1.1(b)(1) (U.S. SENTENCING COMM'N 2015). Aggravating or mitigating role adjustments will not likely exist in a typical case, but this adjustment will turn on the number of participants; thus, there could be an increase in base offense levels as high as four levels, or a decrease of as much as four levels. *See* U.S. SENTENCING GUIDELINES § 3B1.1 (U.S. SENTENCING COMM'N 2015) and U.S. SENTENCING GUIDELINES § 3B1.2(U.S. SENTENCING COMM'N 2015) . The court can also consider a two-level adjustment because of the use of a "special skill" or "abuse of a position of public or private trust" pursuant to U.S. SENTENCING GUIDELINES § 3B1.3 (U.S. SENTENCING COMM'N 2015). Also, the court may apply a two-level adjustment if the defendant knew or should have known that the victims of the offense were "vulnerable victims" because of their physical or mental condition when the tampered products were administered. U.S. SENTENCING GUIDELINES §3A1.1(b)(1) (U.S. SENTENCING COMM'N 2015). If there were a large number of vulnerable victims pursuant to U.S. SENTENCING GUIDELINES §3A1.1(b)(2) (U.S. SENTENCING COMM'N 2015), the court may increase the base offense level by an additional 2 levels. Because these counts do not group if there is a separate harm to separate victims and the offenses of conviction involve the ". . . permanent, life-threatening, or serious bodily injury of more than one victim," Chapter Three, Part D, relating to multiple counts is applicable. Pursuant to Chapter 3, §3D1.3, up to an additional 5-level increase may be applicable.

Once the proper calculation of the *Sentencing Guidelines* produces a sentencing range, the court must apply the factors designated in 18 U.S.C. § 3553(a) (2010). In *Gall*, cited *supra*, the Supreme Court determined sentences are reviewed for reasonableness under an abuse of discretion standard. *See also United States v, Reinhart*, 442 F.3d 857, 862 (5th Cir. 2006) (the abuse of discretion standard applies to both guideline and non-guideline sentences). The court may impose concurrent or consecutive sentences after considering the factors in 18 U.S.C. § 3553(a) (2010). *See* 18 U.S.C. § 3584 (a) and (b) (1984).

C. Variances and the Ultimate Sentence Based on the 18 U.S.C. § 3553(a) Factors

Pursuant to *Gall, Kimbrough*, and their progeny, the sentencing judge may ultimately consider the 18 U.S.C. § 3553(a) (2010) factors in fashioning a reasonable sentence. Our analysis will focus on those factors most germane to diversion cases:

(2) the need for the sentence imposed—

(A) to reflect the seriousness of the offense, to promote respect for the law and provide a just punishment for the offense;

(B) to afford adequate deterrence to criminal conduct;

(C) to protect the public from further crimes of the defendant; and

(D) to provide the defendant with the needed educational or vocational training, medical care, or other correctional treatment in the most effective manner;

. . .

(7) the need to provide restitution to victims.

18 U.S.C. 3553(a) (2010).

The facts of each case are unique and will result in varying sentences based on the applicable factors. However, the above factors may, in an appropriate case, provide a reasonable basis for a variant sentence. In *United States v. Parker*, a case prosecuted in the District of Colorado, the sentencing judge painstakingly analyzed the application of the sentencing factors in applying an upward variance to a sentence of 360 months' imprisonment for a surgery tech who infected over a dozen patients with Hepatitis C as a result of her diversion of fentanyl. In an unpublished opinion, the Tenth Circuit stated, "There is nothing whimsical about the facts of Parker's case, nor the sentence imposed by the district court." *See United States v. Parker*, 413 Fed.Appx. 90, 95, 2011 WL 573448, **5 (10th Cir. 2011). The sentence was affirmed.

XII. Conclusion

Although the frequency of offenses involving healthcare professionals seems to be on the rise, the likely truth is that these offenses have always existed but were concealed by the diverters or not brought to light by the institutions. Regardless, it is of paramount importance that prosecutors protect the public health and safety by deterring diversion conduct and avail themselves of whatever legal theories are available to stop this dangerous conduct rooted in addiction or greed.

ABOUT THE AUTHORS

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Protection of Addiction Treatment Records While Investigating Health Care Fraud Crimes

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I. Introduction

In 1970 and 1974, Congress enacted legislation meant to protect the privacy of persons seeking substance abuse (alcohol and drug) treatment. Congress feared that local and federal agents would use addiction treatment records to punish treatment patients—for example, by charging them with drug possession—and that the records could harm recovering substance abusers in connection with housing and employment. The statute and regulations "are intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment." 42 C.F.R. § 2.3(b)(2). The stated purpose contained in the legislative history is similar:

> Every patient and former patient must be assured that his right to privacy will be protected. Without that assurance, fear of public disclosure of any drug abuse or of records that will attach for life will discourage thousands from seeking the treatment they must have if this tragic national problem is to be overcome.

H. Conf. Rep. No. 92-920, 92nd Cong., 2d Session (1972), *reprinted in* (1972) U.S.C.C.A.N. 2072.

With these concerns in mind, Congress enacted one of the most stringent privacy laws in the United States Code and directed the Secretary of Health and Human Services ("HHS") to develop regulations to support the statutory scheme. HHS, in turn, implemented regulations that restrict *all* access to these records—including law enforcement access—in a way that can make the investigation of health care fraud difficult.

Two distinct issues brought this obscure piece of legislation to the fore. First, the heroin and opioid epidemic greatly increased the number of people seeking addiction treatment. Second, the Affordable Care Act ("ACA") both allowed individuals in a key age group (18- to 26-year-olds) to remain insured through their parents' insurance and required insurance companies to reimburse for substance abuse treatment in the same way that they reimburse for other types of treatment. These factors combined to make substance abuse treatment potentially hugely profitable. When the potential for large profits

combines with a vulnerable population (drug abusers, especially young drug abusers), a perfect recipe exists for fraud and abuse.

II. The Statute and Corresponding Regulations

Section 290dd-2 of Title 42, "Confidentiality of Records," states that the records of the "identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall . . . be confidential and disclosed only for the purposes and under the circumstances expressly authorized" by the statute. 42 U.S.C. § 290dd-2(a). *Disclosure* is prohibited for "any information which would identify a patient as an alcohol or drug abuser;" and is prohibited for "any information obtained by the program for the purpose of diagnosis, treatment, or referral for" substance abuse treatment. 42 C.F.R. § 2.12(c)(3).

The Secretary of HHS, acting through the Administrator of the Substance Abuse and Mental Health Services Administration ("SAMHSA") is tasked with monitoring whether hospitals and other facilities comply with § 290dd-2. 42 U.S.C. §§ 290aa(d)(12); 290dd-2(g). Regulations to facilitate compliance are promulgated at 42 C.F.R. §§ 2.1, *et seq*.

A. What Records Are Covered?

This broad statute covers virtually any record that contains a patient's name, date of birth, or other identifier (e.g., Social Security number, photograph, insurance identification number). *See* 42 C.F.R. § 2.11. The statute also covers individual patient records where those identifiers have been removed, if the records still contain notes of diagnosis, prognosis, or treatment (e.g., doctor's notes regarding treatment, insurance claims documents containing diagnosis codes).

In order for this disclosure bar to apply, the "substance abuse education, prevention, training, treatment, rehabilitation, or research" program or activity must be "directly or indirectly assisted" by a federal department or agency. 42 U.S.C. § 290dd-2(a). Regulations define "federally assisted" to include "being carried out under a license, certification, registration, or other authorization granted by" any federal agency, including being a certified Medicare provider, being authorized to conduct methadone maintenance or dispense controlled substances used in the treatment of alcohol or drug abuse, and being granted tax-exempt status. *See* 42 C.F.R. § 2.12(b).

Many suspect private substance abuse treatment facilities actively avoid accepting Medicare in an attempt to avoid federal prosecution, and an investigation may initially appear to involve only private insurance. Nevertheless, upon closer review, "indirect" federal assistance may be found because: (1) the target entities sometimes use the HHS website to enroll patients in Affordable Care Act plans; (2) many target entities and/or their medical directors are licensed, certified, registered or otherwise regulated by a federal agency; (3) some Medicare Part C plans bear the names of the private insurance companies that manage the plans, so the treatment facilities accept them unwittingly; and (4) a number of Federal Employee Health Benefits ("FEHB") plans and other federal agency health plans (e.g., U.S. Postal Service, Amtrak) likewise bear the names of the private insurance companies rather than their federal sponsors. The substance abuse treatment program is considered "federally assisted," even if the federal agency does not directly reimburse the program, so long as the program receives "financial assistance in

any form, including financial assistance which does not directly pay for the alcohol or drug abuse diagnosis, treatment, or referral activities." 42 C.F.R. § 2.12(b)(3)(i).

The Drug Enforcement Administration, in conjunction with HHS/SAMHSA, registers doctors to provide office-based opioid treatment ("OBOT"). *See* 21 U.S.C. § 823(d); 42 U.S.C. § 290bb-2a. SAMHSA also certifies some treatment providers, 42 C.F.R. §§ 8.1, *et seq.*, and laboratories performing urine and blood testing are certified by the Centers for Medicare & Medicaid Services ("CMS") through the Clinical Laboratory Improvement Amendments ("CLIA"). *See* 42 C.F.R. §§ 491.1, *et seq.*

Although there is a dearth of case law on which entities and providers are directly or indirectly assisted by the federal government, caution dictates that public and private substance abuse treatment providers, "sober homes," and similar entities should be treated as though covered by the privacy mandate.

B. What Records Are Exempt?

Only records that are "maintained in connection with the performance of" a federally assisted substance abuse prevention/treatment/rehabilitation program are given this privacy protection. 42 U.S.C. § 290dd-2(a). Thus, the mere fact that a record mentions substance abuse does not make the record confidential. For example, if a patient is brought to a hospital's emergency room due to a drug overdose, the E/R records are not covered by § 290dd-2. However, if the patient is later transferred to the hospital's in-house detox facility for substance abuse treatment, then the records maintained by the detox facility *are* covered. *See* 42 C.F.R. §§ 2.11 (defining "program"); 2.12(e)(1).

The statute allows disclosures to medical personnel for medical emergencies, for conducting scientific research, management audits, financial audits, and program evaluation, as well as within the Uniformed Services and the Department of Veterans Affairs. 42 U.S.C. § 290dd-2(b)(2)(A), (b)(2)(B), and (e). Treatment program personnel also are permitted to disclose to law enforcement the circumstances of a patient's commission of a crime or a threat to commit a crime on the premises or against program personnel, but that disclosure is strictly limited. *See* 42 C.F.R. § 2.12(c)(5).

Civil Assistant U.S. Attorneys and HHS agents involved in civil investigations of Medicare fraud may fall within the audit and evaluation exception for documents related to Medicare claims, *see also* 42 C.F.R. § 2.53, but that is beyond the scope of this article which focuses on criminal investigations. However, be advised that if a civil investigator or civil AUSA obtains the records for purposes of a Medicare audit and evaluation, including for purposes of a civil or administrative investigation of the program, the civil investigator or AUSA cannot disclose patient identifying information to anyone or use that information for any other purpose. 42 C.F.R. § 2.53(c). The information cannot be used for a criminal investigation without a court order. 42 C.F.R. § 2.53(d). Agents and AUSAs who conduct both civil and criminal investigations should familiarize themselves with United States v. Shinderman, 2006 WL 522105 (D. Me. Mar. 2, 2006) ("*Shinderman I*"), and United States v. Shinderman, 432 F. Supp. 2d 149 (D. Me. 2006) ("*Shinderman II*"), which contain an extensive discussion of whether the case agent was keeping the "civil hat" on to avoid the court order requirement. Also note that records obtained via the audit and evaluation exception can never be used to prosecute a patient; even with a court order, the records can be used only to prosecute program employees. 42 C.F.R. § 2.62.

C. Is There a Law Enforcement Exception?

Unlike the Health Insurance Portability & Accountability Act ("HIPAA"), there is no exception that allows disclosure of the confidential substance abuse records to law enforcement and use of the records in criminal prosecutions. In fact, the statute and regulations explicitly provide otherwise:

> (a) General. The patient records to which these regulations apply may be disclosed or used only as permitted by these regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conduct by any Federal, State, or local authority. . . .
>
> (b) Unconditional compliance required. The restrictions on disclosure and use in these regulations apply whether the holder of the information believes that the person seeking the information already has it, has other means of obtaining it, *is a law enforcement or other official*, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by these regulations.

42 C.F.R. § 2.13.

Issuing a subpoena or obtaining a search warrant does not obviate the confidentiality provision. In fact, the regulations make clear that someone covered by the confidentiality rule cannot comply with a search warrant or subpoena unless a court order obtained pursuant to 42 U.S.C. § 290dd-2 is obtained contemporaneously with the search warrant. *See* 42 C.F.R. § 2.61. Nor is a § 290dd-2 order sufficient to obtain the records. *See Id* Instead, one must obtain a § 290dd-2 order to authorize the collection of confidential information, and then issue a subpoena or obtain a search warrant to compel the production of the information. *See Id*

These restrictions apply not only to collection of information from the treatment providers themselves, but also to third party payers, including public and private insurance. *See* 42 C.F.R. §§ 2.11 (defining third party payer); 2.12(d)(2)(i) (restricting third party payers from disclosing information).

Disclosing or using this confidential patient information without a prior court order is a criminal offense punishable by a maximum $500 fine for the first violation and by a maximum $5,000 fine for each subsequent offense. 42 U.S.C. § 290dd-2(f); 42 C.F.R. §§ 2.3(b)(3); 2.4. Violations are reportable to the U.S. Attorney where the violation occurs. 42 C.F.R. § 2.5. However, suppression is *not* the remedy for gathering the evidence without a proper order in place, except in the Ninth Circuit. *See, e.g.*, Rogers v. England, 246 F.R.D. 1 (D.D.C. 2007); United States v. Corona, 849 F.2d 562 (11th Cir. 1988); People v. Barrett, 135 Cal. Rptr. 2d 103 (3d DCA 2003) (noting that the regulations do not specify suppression as a remedy for violation); *but see* United States v. Eide, 875 F.2d 1429 (9th Cir. 1989); Shinderman II, 432 F. Supp. 2d at 151 (declining to decide whether suppression is a potential remedy for violation). Violation of the confidentiality provisions also cannot form the basis of a § 1983 action. *See* Doe v. Broderick, 225 F.3d 440 (4th Cir. 2000). Nonetheless, proceeding without an order could expose the investigative team to misconduct allegations.

III. How to Properly Obtain Confidential Patient Records

Although it appears that getting the records is impossible, the statutory and regulatory scheme does provide for two means of obtaining them—consent or court order. Both the statute and the regulations provide detailed information about what must be included in the consent and the application and order.

A. Consent

Any confidential patient record can be disclosed with prior written consent of the patient, but only in accordance with the consent and the regulations. 42 U.S.C. § 290dd-2(b)(1); 42 C.F.R. § 2.33. The consent must describe the purpose of the disclosure and a description of the type of records to be disclosed. 42 C.F.R. § 2.31(a). The consent also must provide the patient with notice regarding the right to revoke the consent and the date, event, or condition that will terminate the consent. *Id* The regulations even provide a sample consent form, but the form does not cover all of the items that might be useful in an investigation. Two sample forms are available to AUSAs on the EOUSA Health Care Fraud intranet site.

B. Court Order

In most cases, records of a single patient or even a handful of patients will not be sufficient, and the investigative team will need to gather all of the entity's records from the entity itself and/or the third party payers. Doing so will require a court order:

> Whether or not the patient . . . gives written consent, the content of such [confidential patient] record may be disclosed . . . (C) [i]f authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor, including the need to avert a substantial risk of death or serious bodily harm. In assessing good cause, the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

42 U.S.C. § 290dd-2(b)(2). The statute specifically prohibits the use of patient records "to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient" in the absence of a court order. 42 U.S.C. § 290dd-2(c). Obtaining permission to use patient records to prosecute patients requires more proof of harm than obtaining permission for prosecution of the treatment facility. *See* 42 C.F.R. § 2.65(d) (requiring, in addition, that the court find that the crime involved is "extremely serious" and that the person or entity holding the records has been represented by independent counsel).

Pursuant to § 290dd-2(b)(2), the elements of an application and order are: (1) an application to a court of competent jurisdiction, which could be the federal or state court where potential charges would be filed; (2) a showing of good cause; and (3) the inclusion of appropriate safeguards against unauthorized disclosure.

1. Who may seek an order and what procedures are followed?

Any law enforcement or prosecutorial agency having jurisdiction over the program's activities may file an application. 42 C.F.R. § 2.66(a)(1). The application may be filed as a separate miscellaneous proceeding, in connection with a grand jury proceeding, or as part of a pending civil or criminal action against the program or person holding the records. 42 C.F.R. § 2.66(a)(2). The application and order cannot contain any patients' names, unless the patient gave consent or the application and order have been sealed. *Id*

The application can include a request to proceed without giving notice to the patients, program, or person holding the records, and that decision is left to the court's discretion. 42 C.F.R. § 2.66(b). However, at a later date, the patients, program, or person holding the records must be provided notice and the opportunity to seek revocation or amendment of the order. *Id* Any challenge by those persons is limited to addressing the statutory and regulatory criteria for the issuance of the court's order. *Id*

2. How is good cause shown?

Good cause includes, but is not limited to, a substantial risk of death or serious bodily harm to anyone. 42 U.S.C. § 290dd-2(b)(2). To find good cause, "the court *must* find that: (1) [o]ther ways of obtaining the information are not available or would not be effective; and (2) [t]he public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services." 42 C.F.R. § 2.64(d).

In most instances the investigative team will need to collect "confidential communications," e.g., physician notes of the patient's statements. To obtain "confidential communications," the application must further show that disclosure is necessary: (1) "to protect against an existing threat to life or of serious bodily injury;" or (2)" in connection with investigation or prosecution of an extremely serious crime, such as one which directly threatens loss of life or serious bodily injury." 42 C.F.R. § 2.63(a). Some courts have held that billing fraud is sufficient to show the general "good cause" requirement but not sufficient to show the heightened requirement for "confidential communications." *See, e.g.*, *In re August, 1993 Regular Grand Jury*, 854 F. Supp. 1380 (S.D. Ind. 1994). The privilege of confidentiality afforded to the patient's communication is a strong one and should not be lightly abrogated. *Mosier v. American Home Patient, Inc.*, 170 F. Supp. 2d 1211 (N.D. Fla. 2001). The decision whether to grant an order authorizing such disclosure is within a court's "broad discretion." *Fannon v. Johnston, 88 F. Supp. 2d 753 (E.D. Mich. 2000)*.

3. What protections must be included in the court's order?

A proposed order should include a number of mandatory protections, including:

- All patient identifying information must be deleted from any document made available to the public. 42 C.F.R. § 2.66(d)(1).
- No information obtained through the order will be used to conduct any investigation or prosecution of a patient. 42 C.F.R. § 2.66(d)(2).
- Disclosure must be limited to those parts of the patients' records that are essential to the investigation. 42 C.F.R. § 2.64(e)(1).
- Disclosure must be limited to the investigative team. 42 C.F.R. § 2.64(e)(2).
- The records must be protected from inadvertent or purposeful disclosure that could harm the patient, the physician-patient relationship, or the treatment services. 42 C.F.R. § 2.64(e)(3).
- The records must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use. 42 C.F.R. § 2.16(a).

Finally, as noted above, a court order authorizes obtaining and using the confidential information, but that order must be accompanied by a subpoena, search warrant, or other compulsory process describing the items to be collected. The same applies for written consent.

IV. Roadmap to a Successful Prosecution

Although these investigations are fraught with difficulties, there are ways to successfully maneuver through the landmines. Patience and mapping out a strategy at the beginning are necessary. Rather than starting with the treatment and insurance records, you need to look to other sources of information to make a showing of "good cause" sufficient to authorize disclosure.

A. Witness Interviews and Consent

An investigation never begins with a subpoena. It starts with a tip or intelligence that a particular provider may be violating the law. Start with those tips, and conduct interviews that, hopefully, lead to one or more patients or parents. Approach those interviews with consent forms in hand and liberally ask for consent to obtain records. Ask patients whether the physician-patient relationship was legitimate at the target organization. Determine whether patients are suffering harm while purportedly receiving treatment at the target organization.

B. Information That Is Not Covered by the Confidentiality Rules

Seek out information that is not covered by Title 42. For example, confer with the local Fire Rescue unit and local law enforcement to determine how often they are responding to the target treatment center or sober home. Subpoena, in accordance with HIPAA, nearby emergency rooms for records of overdoses. Document the overdose problem in the area. Consider interviewing parents of overdose victims to determine where their children were allegedly receiving treatment.

C. Obtain and Analyze Financial Records

Bank records are not covered by Title 42 because the records are not "maintained in connection with the performance of any program . . . relating to substance abuse . . . treatment." 42 U.S.C. § 290dd-2(a). Bank statements, deposits, and cancelled checks may show unlawful kickback payments, the failure to collect co-insurance, and other evidence of health care fraud.

D. Draft an Application for a Disclosure Order and, Perhaps, an Undercover Order

Once you have gathered sufficient evidence to show "good cause," apply for and obtain an order authorizing disclosure of the confidential patient records. Regulations also cover the use of undercover agents and informants to investigate the program, 42 C.F.R. § 2.67, so consider filing a separate application for permission to use undercover agents. Samples of these applications and orders are available to AUSAs on the EOUSA Health Care Fraud intranet site.

Once you have the order, conduct a meeting with the entire investigative team and orally instruct them on the confidentiality rules. This meeting is similar to a "minimization meeting" when a wiretap order is obtained. Provide a copy of the instructions to each member of the team and have each member sign a form certifying that they understand their obligations. Maintain control of the confidential documents that are obtained in accordance with the court order, and use labels and confidentiality protocols in place for electronic records.

E. Issue Subpoenas and/or Search Warrants

Once you have the order in hand, subpoena the insurance companies and treatment providers, or obtain search warrants for the treatment providers and any electronic medical record systems. Remember that if you are seeking records covered by Title 42 you must serve a copy of the disclosure order along with the subpoena or search warrant. Advise the subpoenaed party that they should encrypt and/or password protect patient identifying information to protect its confidentiality.

While collecting records, consider whether you need patient identifying information from all of the subpoenaed parties or if you can tailor your request to avoid collecting information that you will need to redact later. Start thinking about how to catalog and redact the collected records for purposes of discovery.

F. Prepare for Discovery

Prior to issuing discovery, obtain a court order authorizing disclosure to opposing counsel and putting a protective order in place. The order should limit opposing counsel from making any further disclosures and requiring the return or destruction of the information upon completion of the case.

V. Conclusion

Cases involving the exploitation of substance abusers in treatment present many challenges. They require careful research and planning and close coordination with the investigative team. While many of these regulations appear anachronistic, keep in mind that they were put in place to protect the victims of the crimes you are investigating. Your attention to these rules will build trust between you and the victims you are trying to protect.

ABOUT THE AUTHOR

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Marie has received the Attorney General's Award for Fraud Prevention, the Director's Award for Superior Performance as a Criminal Assistant U.S. Attorney, the National Crime Victims' Rights Service Award, the Florida Insurance Fraud Education Committee's Prosecutor of the Year Award, the Coalition against Insurance Fraud's Prosecutor of the Year Award, and has twice received the Southern District of Florida's Timothy Evans Award for Excellence. AUSA Villafaña received her undergraduate degree from Cornell University and her J.D. from the University of California at Berkeley and is a Certified Fraud Examiner. She has lectured on formulating large-scale insurance fraud investigations and prosecutions and money laundering.

Note from the Editor . . .

First, we want to thank Denise Simpson, Healthcare Fraud and Affirmative Civil Enforcement Coordinator, Office of Legal and Victim Programs at the Executive Office for United States Attorneys, for her leadership in finding authors, working with them to complete their articles and working with us to publish this important issue on health care fraud. Any value this issue has to you, the reader, in the field or at headquarters is a direct result of her outstanding effort. Second, I want to encourage you, the reader, to continue to send us your suggestions for issue topics and ways to improve the Bulletin. Since our last request, we have received several suggestions, and we appreciate them all. Our goal here at the Bulletin is to make this journal valuable to the work you do. Your input is vital in helping us reach that goal.

I hope you enjoy this issue and find it helpful in your work. We are very excited about our next topic Forensic Science. Assistant Director Gretchen Shappert of the Office of Legal and Victim Programs at the Executive Office for United States Attorneys is spearheading that issue. Forensic Science is a current and important topic. Please look for the issue at the end of January.

Thank you,

Tate Chambers