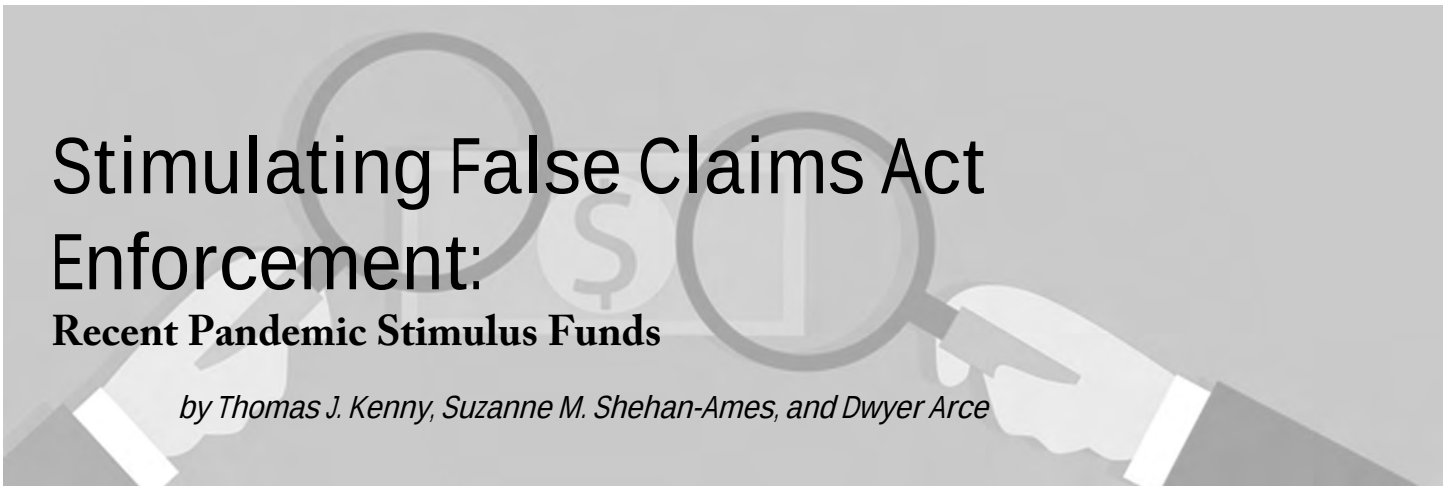

Stimulating False Claims Act Enforcement:

Recent Pandemic Stimulus Funds

by Thomas J. Kenny, Suzanne M. Shehan-Ames, and Dwyer Arce

The COVID-19 pandemic has ushered in massive changes to our society, including an unprecedented $6 trillion in federal stimulus and coronavirus relief funds, consisting of the American Rescue Plan Act of 2021 ($1.9 trillion); the Consolidated Appropriations Act of 2021 ($900 billion); and the Coronavirus Aid, Relief, and Economic Security (CARES) Act ($2.2 trillion). Federal prosecutors and enforcers at all levels predict this tidal wave of new federal funds will lead to unseen levels of federal fraud prosecutions, including in the healthcare arena, which last year accounted for more than 80% of federal fraud recoveries.[1]

With this unprecedented increase in federal spending comes significant opportunities for healthcare and other species of fraud. These extraordinary expenditures will almost certainly be followed by a surge of enforcement activities. Before the CARES Act was even enacted, Deputy Attorney General Jeffrey Rosen commented on the "unfortunate array of criminal activity related to [the] COVID-19 pandemic" and directed all U.S. Attorneys to prioritize the prosecution of COVID-19-related fraud schemes, emphasizing that "[c]apitalizing on th[e] crisis to reap illicit profits or otherwise preying on Americans is reprehensible and will not be tolerated."[2] Indeed, the Department of Justice ("DOJ") has appointed Coronavirus Coordinators in each U.S. Attorney's Office, and the Office of Inspector General for Pandemic Recovery was established, through the Act, to audit and investigate activities and programs funded by the Act.[3] On March 26, 2021, Acting Assistant Attorney General Nicholas McQuaid announced an update on criminal and civil enforcement efforts to combat COVID-19-related fraud, including schemes targeting the Paycheck Protection Program (PPP), Economic Injury Disaster Loan (EIDL) program, and Unemployment Insurance (UI) program.[4] DOJ recently announced it had "charged over a hundred defendants with fraud connected to the Paycheck Protection Program (PPP) and Economic Injury Disaster Loans (EIDL)."[5] More than $36 billion in unemployment benefits have reportedly been paid to improper recipients since the CARES Act was passed in March 2020.[6]

Heightened Scrutiny on Healthcare Providers and Private Equity Owners

Healthcare providers have historically been the focus of federal prosecutors, and in the current environment, providers will be particularly vulnerable given the substantial healthcare funding provided through the relief and stimulus bills. Federal enforcement will continue to focus not only on healthcare providers themselves but also on private equity owners or investors that have come to play a dominant role in healthcare. Indeed, in recent years, DOJ has increasingly focused on private equity owners in False Claims Act enforcement actions and sought to hold them directly responsible for the actions of their portfolio companies.

Just last summer, in addressing DOJ efforts to combat fraud relating to pandemic funding, a senior deputy Attorney General singled out private equity as a particular enforcement target: "Our enforcement efforts may also include, in appropriate cases, private equity funds that sometimes invest in companies receiving CARES Act funds…Where a private equity firm takes an active role in illegal conduct by the acquired company, it can expose itself to False Claims Act liability…Where a private equity firm knowingly engages in fraud related to the CARES Act, we will hold it accountable."[7] For example, on November 19, 2020, DOJ announced that it had entered into a settlement agreement in *United States ex rel. Johnson et*

al. v. Therakos, Inc. et al.[8] with a private equity firm based on conduct of its portfolio company (Therakos) that engaged in improper off-label marketing practices for cancer treatment. Interestingly, the conduct at issue began six years before the private equity firm even acquired the subject company. In 2018, DOJ filed intervened in a False Claims Act action against a compounding pharmacy and its private equity owner in *United States ex rel. Medrano v. Diabetic Care Rx, LLC d/b/a Patient Care America et al.*[9] DOJ focused on factors enabling the private equity owner to exert significant control and oversight over the pharmacy. Both defendants agreed to pay $21 million to settle the claims against them. In an ongoing case, *US ex rel Martino-Fleming v. South Bay Mental Health Center, Inc.*,[10] the District Court denied the private equity firm's motion to dismiss, holding that, "Because it is alleged that [the private equity firm's] members and principals formed a majority on the…Boards and were directly involved in the operations," and noting that "a parent may be liable for the submission of false claims by a subsidiary where the parent had direct involvement in the claims process."[11]

In February 2021, DOJ announced its first indictment related to the CARES Act public health and social services emergency fund (the Provider Relief Fund), which provides funds to support healthcare providers during the COVID-19 pandemic. DOJ alleges a home health agency that had been closed in early 2020 received $37,656.95 from the Provider Relief Fund (likely through the initial automatic distribution paid to all providers participating in Medicare in 2019). Since the home health agency was closed and never operational during the pandemic, it could not use the money on healthcare expenses related to COVID-19, as required by the Provider Relief Fund.[12]

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The False Claims Act

The federal government's most powerful prosecutorial tool for recovering funds lost due to fraudulent activity is the False Claims Act (FCA). The FCA "serves as the government's primary civil tool to address false claims for federal funds or property involving a multitude of other government operations and functions."[13] The FCA prohibits presenting false claims for approval, conspiracy to do the same, failing to return government funds, false receipts, and making a false claim material to an obligation to pay money to the government. Civil penalties for violation of the FCA include up to $22,363 per claim, plus a recovery by the government of three times its damages, plus attorneys' fees.[14]

In 2020, DOJ recovered $2.2 billion in FCA cases.[15] Of that total, "over $1.8 billion relates to matters that involved the health care industry, including drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians."[16] In recent months, DOJ has begun to prioritize FCA actions related to COVID-19 stimulus funding, with "the government open[ing] the most new FCA investigations ever in 2020."[17] In total, "the government and qui tam relators still opened 922 new FCA cases" in 2020—the most ever opened in a single year.[18]

Qui Tam Proceedings

Private whistleblowers, including employees, former employees, competitors, and litigation-funded teams of whistleblower lawyers, will continue to play a dominant role in identifying and exposing federal program fraud. The qui tam, or whistleblower, action is one of the primary enforcement mechanisms under the FCA and allows virtually any person, corporate or individual, who is an original source of facts relating to the fraud to initiate an FCA claim. In recent years, private whistleblowers have initiated the vast majority of all FCA claims filed.[19]

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Qui tam proceedings are filed under seal by private parties and served on DOJ, prompting a federal investigation of the claims. The government then has the option of either proceeding with the action in place of the private party or declining to take action. "If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim."[20] "If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds."[21]

Whistleblower claims present particularly difficult problems for healthcare providers. Specifically, the confidential nature of the initial filing (under seal) and the length of time cases remain under seal mean the risks posed by such claims may be unknown to the healthcare provider defendant. Indeed, whistleblower claims remain hidden from the provider for months, and often years, before the cases are either disclosed to the defendant by DOJ through a partial lifting of the seal (and settlement dialogue between DOJ and the defendant) or when DOJ makes an intervention decision and unseals the complaint and portions of the court docket. What this long period of secrecy may mean for providers is that they often do not know a whistleblower case has been filed for months if not years, nor that they are under investigation, that the whistleblowing employee or competitor is still on the scene, that their damages may be increasing daily, and that they may be creating new and damning facts. In effect, a sealed whistleblower action may place a provider under intense DOJ and agency scrutiny, but the provider may be going about its potentially wrongful activities without knowing it.

Be Prepared

Providers may first become aware of a whistleblower suit in different ways: through their receipt of a Civil Investigative Demand, or CID, from DOJ; through a "contact letter" from DOJ seeking to explore the facts alleged in the whistleblower complaint; sometimes through an inadvertent disclosure or suggestion by the whistleblower that a complaint has been filed; sometimes through suspicious agency activity, including heightened audits, regulatory inquiries, and/or investigative contacts with provider employees or contractors. When providers learn of the likely or certain filing of a qui tam suit (or related investigations), the question becomes: what should that provider do?

While each situation is unique and should be considered individually,[22] healthcare providers and other recipients of COVID-19 funds should proactively develop a plan for how to address wrongdoing reported by a state or federal regulator investigating the use of such funds or if they receive information from an employee, a compliance hotline call, or a com-

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petitor suggesting that improper conduct has occurred. When made aware of such allegations, an internal investigation will often be warranted, after which the need for further action may be considered. Such actions could include preemptive disclosure to regulatory authorities, repayment of suspect reimbursement, preparation of a defense posture in advance of litigation, and/or negotiation of settlement. In some cases, FCA claims may be covered by private insurance and thus the provider's policies should be reviewed and appropriate notices considered. Because FCA investigations may be conducted in parallel with simultaneous regulatory and criminal investigations, it is important to consider all potential sources of exposure emanating from the allegations.

Outside counsel may also be retained to assist and/or to advise regarding the risks posed under the FCA or other potential federal criminal and civil statutes.[23] Given the uncertainties attendant to FCA investigations, and the significant risks involved, particularly in the healthcare arena, a proactive approach is essential to avoid the most significant penalties. Even with counsel, however, significant recoveries still regularly occur. Some examples of these recoveries include a pharmaceutical company that "paid over $591 million to resolve claims that it paid kickbacks to doctors to induce them to prescribe its drugs."[24] Other examples involve the attestation requirements for compliance with the terms and conditions of receipt of stimulus funds.[25]

Impact of Recent Court Decisions

Several recent cases have broadened the reach of the FCA in regard to compliance with terms and conditions of payment. Under the FCA, the "implied false certification theory" can, at least in some circumstances, provide a basis for liability if a provider submits a claim for payment but fails to disclose a violation of a contractual, statutory, or regulatory provision. In *Universal Health Servs., Inc. v. United States*,[26] the United States Supreme Court rejected an argument the implied certification theory is "limited to express conditions of payment." Instead, "whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry."[27]

In *United States v. Care Alternatives*,[28] the United States Court of Appeals for the Third Circuit took the implied certification theory one step further. In *Care Alternatives*, the Third Circuit rejected an argument that clinical judgments of physicians or other health care providers cannot be "untrue" under the FCA, holding FCA falsity "encompass[es] circumstances where a claim for reimbursement is non-compliant with requirements under the statute and regulations."[29] In doing so, the Third Circuit rejected the United States Court of Appeals for the Eleventh Circuit's holding in *United States v. AseraCare, Inc.*,[30] which found "a reasonable difference of opinion among physicians reviewing medical documentation ex post is not sufficient on its own to suggest that those judgments . . . are false under the FCA." This circuit split could have significant implications for a provider who certifies, for example, that a patient's treatment or death was related to COVID-19.[31]

Focus on Stimulus Funds

The current regulatory environment is particularly volatile for the pharmaceutical and medical device sectors. Since March of last year, the FDA has issued 77 new guidance documents outlining new or modified guidelines for key risk areas such as diagnostic testing, patient monitoring and adverse event reporting, conduct of clinical trials, and supply chain integrity.[32] Although these guidance documents do not in and of themselves have the force of law, the CARES Act does create significant new statutory obligations around supply chain integrity for both pharmaceutical and device manufacturers. These manufacturers must now report to the FDA any anticipated disruptions to the supply of drugs and devices that are "critical to the public health during a public health emergency." In addition, covered manufacturers must now create and maintain redundancy risk management plans to identify and evaluate risks to the supply chain of the drug or device.[33]

Outside the FCA, healthcare enforcers have many other tools, including criminal penalties and disqualification from participation in government healthcare programs. Other civil remedies are available to states, many of which have enacted some version of the FCA as a state statute. For example, in Nebraska, health care-related false Medicaid claims are specifically targeted by the False Medicaid Claims Act.[34] This statute creates civil liability under Nebraska law when a false Medicaid claim is presented and satisfies statutory criteria very similar to its FCA counterpart. In Nebraska, false and fraudulent conduct will be examined by a multi-agency "Health Care Fraud Task Force" and Medicaid fraud comes within the ambit of the Medicaid Fraud and Patient Abuse Unit of the Attorney General's office.[35]

In light of this heightened scrutiny of the recipients of COVID-19-related stimulus funds, it will be essential for businesses to update and carefully manage their regulatory compliance programs in order to avoid liability.[36] Such programs, voluntary reporting of issues identified through these programs, and corrective action can help mitigate any liability.[37] To date, very few FCA cases relating to pandemic funding have been publicly reported. Unfortunately, given the long time periods in which whistleblower actions remain under seal and unreported, little comfort can be taken from the absence of public cases: predictions of a flood of new FCA cases may yet come to pass and providers should prepare for the deluge.

Endnotes

[1] Dept. of Justice Press Release, Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020 (Jan. 14, 2021), https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020.

[2] Memoranda from the Deputy Attorney General to all heads of law enforcement components, heads of litigating divisions, and United States Attorneys (March 24, 2020), https://www.justice.gov/file/1262771/download.

[3] Special Inspector General for Pandemic Recovery, https://www.sigpr.gov/ (last viewed April 20, 2021).

[4] Dept. of Justice Office of Public Affairs, *Statement of Acting Assistant Attorney General Nicholas McQuaid on DOG Enforcement Efforts to Combat COVID Fraud* (March 26, 2021), https://www.justice.gov/opa/video/statement-acting-assistant-attorney-general-nicholas-mcquaid-doj-enforcement-efforts.

[5] Dept. of Justice Criminal Division, *Fraud Section Enforcement Related to the CARES Act*, U.S. Dep't of Justice, https://www.justice.gov/criminal-fraud/cares-act-fraud (last viewed April 20, 2021).

[6] Greg Iacurci, *Scammers have taken $36 billion in fraudulent unemployment payments from American workers*, CNBC (Jan. 5, 2021), https://www.cnbc.com/2021/01/05/scammers-have-taken-36-billion-in-fraudulent-unemployment-payments-.html.

[7] Dept. of Justice Civil Division, *Principal Deputy Assistant Attorney General Ethan P. Davis delivers remarks on the False Claims Act at the U.S. Chamber of Commerce's Institute for Legal Reform*, U.S. Dep't of Justice (June 26, 2020), https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims.

[8] No. 12-cv-1454 (E.D. Pa.); *See* Dept. of Justice Press Release, Former Owners of Therakos, Inc. Pay $11.5 Million to Resolve False Claims Act Allegations of Promotion of Drug-Device System for Unapproved Uses to Pediatric Patients (November 19, 2020), https://www.justice.gov/usao-edpa/pr/former-owners-therakos-inc-pay-115-million-resolve-false-claims-act-allegations.

[9] No. 15-cv-62617 (S.D. Fla.).

[10] No. 15-cv-13065 (D. Mass).

[11] Order, dated September 21, 2018.

[12] McGuireWoods LLP, *First Provider Relief Fund Indictment*, JDSupra (February 26, 2021), https://www.jdsupra.com/legalnews/first-provider-relief-fund-indictment-8791397.

[13] Dept. of Justice Press Release, Justice Department Recovers over $3 Billion from False Claims Act Cases in Fiscal Year 2019 (Jan. 9, 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019.

[14] Dept. of Justice Civil Division, *The False Claims Act*, U.S. Dep't of Justice (last updated: Jan. 14, 2021) https://www.justice.gov/civil/false-claims-act.

[15] Dept. of Justice Press Release, Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020 (Jan. 14, 2021), https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020.

[16] *Id*.

[17] *2020 Year-End False Claims Act Update*, Gibson, Dunn & Crutcher LLP (Jan. 27, 2021), https://www.gibsondunn.com/wp-content/uploads/2021/01/2020-year-end-false-claims-act-update.pdf.

[18] *Id*.

[19] *Kutak Rock Healthcare Attorneys Discuss Fraud at 2020 NSBA Virtual Annual Meeting*, Kutak Rock LLP (Oct. 16, 2020), https://www.kutakrock.com/newspublications/news/2020/10/healthcare-attorneys-discuss-fraud.

[20] 31 U.S.C. § 3730(d)(1).

[21] 31 U.S.C. § 3730(d)(2).

[22] The information provided in this article does not, and is not intended to, constitute legal advice. Interested readers should contact their attorney to obtain advice with respect to any particular legal matter.

[23] The federal False Claims Act provides for both civil and criminal penalties. A party convicted of submitting false claims to a federal health care program can be subject to up to five years in prison plus a fine of $25,000. *See* 42 U.S.C. § 1320a-7b. As such, entities known to be under investigation should be aware of the possibility of parallel civil and criminal investigations and should plan accordingly, including by consultation with counsel.

[24] Dept. of Justice Press Release, Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020 (Jan. 14, 2021), https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020.

[25] William B. Eck, *COVID-19: Provider Relief Funds, Attestation, And The False Claims Act*, MONDAQ (Nov. 4, 2020). https://www.mondaq.com/unitedstates/financing/1001722/covid19-provider-relief-funds-attestation-and-the-false- claims-act.

[26] 136 S. Ct. 1989, 1999, 195 L. Ed. 2d 348 (2016).

[27] *Id*.

[28] 952 F.3d 89 (3d Cir. 2020).

[29] *Id*.

[30] 938 F.3d 1278, 1297 (11th Cir. 2019).

[31] The Ninth Circuit joined the Third Circuit, reaching a similar holding in *Winter ex rel. United States v. Gardens Regional Hospital and Medical Center, Inc.*, 953 F.3d 1108 (9th Cir. 2020) ("[W]e hold that the FCA does not require a plaintiff to plead an 'objective falsehood.'" A physician's certification that inpatient hospitalization was "medically necessary" can be false or fraudulent for the same reasons any opinion can be false or fraudulent. These reasons include if the opinion is not honestly held, or if it implies the existence of facts—namely, that inpatient hospitalization is needed to diagnose or treat a medical condition, in accordance with accepted standards of medical practice—that do not exist[.]").

[32] *COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders*, U.S. Food & Drug Admin. (current through Apr. 23, 2021), https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders.

[33] CARES Act, Pub. L. No. 116-136, § 3112, 134 Stat. 281 (2020).

[34] Neb. Rev. Stat. §§ 68-934 to 68-947.

[35] Kutak Rock Healthcare Attorneys Discuss Fraud at 2020 NSBA Virtual Annual Meeting, Kutak Rock LLP (Oct. 16, 2020), https://www.kutakrock.com/newspublications/news/2020/10/healthcare-attorneys-discuss-fraud.

[36] *Id*.

[37] Dept. of Justice Office of Public Affairs, *Department of Justice Issues Guidance on False Claims Act Matters and Updates Justice Manual*, U.S. Dep't of Justice (May 7, 2019), https://www.justice.gov/opa/pr/department-justice-issues-guidance-false-claims-act-matters-and-updates-justice-manual.