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***“Come Down With a Sledgehammer”: FCA  
Enforcement Priorities in the Biden Administration***

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During a question-and-answer session following his opening remarks at the Federal Bar Association Qui Tam Conference earlier this year, Senator Chuck Grassley said that the government needed to “come down with a sledgehammer, not a toothpick” against fraud.<sup>1</sup> Senator Grassley, a co-sponsor of the 1986 Amendments to the federal False Claims Act (FCA or the Act) and a longtime proponent of the Act and its qui tam provision, also weighed in on some timely and controversial aspects of FCA litigation, including the ability of the Department of Justice (DOJ) to dismiss qui tam complaints and how post-*Escobar* courts have construed the Act’s materiality standard.<sup>2</sup> Senator Grassley also observed that times of national crisis are often accompanied by increased fraud, noting that he hoped that a recently announced FCA settlement related to the Paycheck Protection Program (PPP) was “a sign of things to come.”<sup>3</sup>

Senator Grassley’s comments underscore that the Biden DOJ has inherited a wide range of civil anti-fraud enforcement priorities arising from the Coronavirus Aid, Relief, and Economic Security (CARES) Act and the American Rescue Plan Act of 2021, including enforcement under the FCA.

The FCA will no doubt continue to be a powerful tool in the DOJ arsenal, and recent remarks by high-level DOJ officials shed light on where enforcement is headed in 2021. At the same Qui Tam Conference where Senator Grassley made opening remarks, Acting Assistant Attorney General (AAG) Brian Boynton also spoke about the role of the FCA in the new administration.<sup>4</sup> Acting AAG Boynton highlighted the six key FCA enforcement priorities of the Biden DOJ’s Civil Division: (1) pandemic-related fraud, (2) opioids, (3) fraud targeting seniors, (4) electronic health records, (5) telehealth and (6) cybersecurity.

The remarks of Senator Grassley and Acting AAG Boynton strongly indicate that FCA enforcement—especially arising from pandemic-related fraud—will continue to be a DOJ priority and will likely expand during the Biden Administration. Players in the health care industry, who are already familiar with the broad reach of the FCA, are especially likely to come under close scrutiny if they sought or obtained CARES Act relief funds. And companies, both large and small, that sought business-relief funds or loans should also be prepared for review by executive agencies, including the Small Business Administration (SBA) and DOJ, as well as the chance that private qui tam plaintiffs may have filed complaints (still under seal) involving that same conduct.

## *Civil Division FCA Enforcement Priorities*

The following section describes the FCA enforcement priorities of the DOJ’s Civil Division based on Acting AAG Boynton’s recent remarks. These areas are likely to present significant FCA risk in the year ahead and throughout President Biden’s time in office.

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<sup>1</sup> See Q&A at 2021 Federal Bar Association Qui Tam Conference (Feb. 18, 2021), <https://www.youtube.com/watch?v=5sREaKogekI> (last visited March 22, 2021).

<sup>2</sup> *Id.* Senator Grassley has proposed amendments to limit the DOJ’s ability to dismiss qui tam complaints that it has deemed unmeritorious; this would require the DOJ to present evidence to a court stating legitimate reasons why it viewed a case brought by a qui tam relator to be without merit. See Grassley’s Keynote Remarks at 2021 Federal Bar Association Qui Tam Conference (Feb. 18, 2021), <https://www.youtube.com/watch?v=ny0KU2jjEeM&t=10s> (last visited March 17, 2021).

<sup>3</sup> *Id.*

<sup>4</sup> See Department of Justice Press Release, *Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference* (Feb. 17, 2021).

## PANDEMIC-RELATED FRAUD

The Biden Administration is expected to devote significant resources to prosecuting fraud arising from the COVID-19 pandemic (and the government's response to it). Like the housing and financial crisis in 2007–08, which triggered substantial federal government spending and corresponding oversight and enforcement actions for many years, the COVID-19 pandemic has facilitated an injection of trillions of federal dollars into the US economy across multiple sectors. As with any program involving substantial federal monies, concerns of fraud and abuse abound. FCA risks are especially high for businesses and individuals involved in two particular programs established by the CARES Act: the Paycheck Protection Program and the US Department of Health & Human Services (HHS) Provider Relief Fund.

### The Paycheck Protection Program (PPP)

Title I of the CARES Act established the PPP, an SBA-administered fund originally in the amount of \$659 billion that was to provide forgivable loans to small businesses struggling because of the pandemic.<sup>5</sup> An additional \$147.45 billion in PPP funds was appropriated as part of the Consolidated Appropriations Act of 2021.<sup>6</sup> To participate in the PPP, borrowers and lenders alike must make multiple certifications to the SBA and thus face potential FCA liability. For instance, a borrower or lender may run afoul of the FCA if it knowingly makes a false certification that it is compliant with the PPP's loan eligibility rules.<sup>7</sup>

Both PPP loan origination and the process for obtaining loan forgiveness present multiple FCA risks. Numerous certifications are required at loan origination—for example, businesses seeking a PPP loan must have certified that the loan was “necessary” to support “ongoing operations” due to then-current economic conditions.<sup>8</sup> The forgiveness process is itself complicated, with three different versions of the forgiveness application, each presenting different certifications and other requirements.<sup>9</sup> Borrower-forgiveness calculations are also complex, which amplifies risks for borrowers and raises questions about the degree of due diligence that a lender must undertake upon receiving those calculations.

Recent changes to the PPP pose additional FCA risks for both borrowers and lenders. Borrowers may now apply for a “second draw” PPP loan—but only if they meet certain, more stringent eligibility requirements (such as the borrower experiencing at least a 25 percent reduction in revenue).<sup>10</sup> Borrowers must expressly certify that they meet these requirements when applying for a second-draw PPP loan.<sup>11</sup> Inconsistencies between first- and second-draw applications

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<sup>5</sup> CARES Act § 1102, Pub. L. No. 116-136, 134 Stat. 281 (2020).

<sup>6</sup> The \$900 billion Consolidated Appropriations Act of 2021, signed into law by then-President Trump on December 27, 2020, increased the allocation of funds to the PPP to over \$800 billion. The PPP alone now rivals the size of the entire stimulus provided in the wake of the 2007–08 financial crisis. See Economic Aid to Hard-Hit Small Businesses, Nonprofits, and Venues Act, § 323(a).

<sup>7</sup> 31 U.S.C. § 3729(a)(1)(B). Under the FCA, “knowingly” is defined as (i) “actual knowledge of the information”; (ii) “deliberate ignorance of the truth or falsity of . . . information”; or (iii) “reckless disregard of the truth or falsity of . . . information.” *Id.* § 3729(b)(1)(A). It requires “no proof of specific intent to defraud.” *Id.* § 3729(b)(1)(B).

<sup>8</sup> See SBA Form 2483 Borrower Application Form (last revised March 18, 2021), <https://www.sba.gov/document/sba-form-2483-ppp-first-draw-borrower-application-form>.

<sup>9</sup> See SBA Loan Forgiveness Application Form 3508 (last revised Jan. 19, 2021), <https://home.treasury.gov/system/files/136/PPP--Loan-Forgiveness-Application-and-Instructions--Form-3508-1192021.pdf>; SBA Loan Forgiveness Application Form 3508EZ (last revised Jan. 19, 2021), <https://home.treasury.gov/system/files/136/PPP--Loan-Forgiveness-Application-Instructions--Form3508EZ-1192021.pdf>; SBA Loan Forgiveness Application Form 3508S (last revised Jan. 19, 2021), <https://home.treasury.gov/system/files/136/PPP--Loan-Forgiveness-Application-Instructions--Form-3508S-1192021.pdf>.

<sup>10</sup> See SBA Form 2483-SD Second Draw Borrower Application Form (last revised March 18, 2021), <https://www.sba.gov/document/sba-form-2483-sd-ppp-second-draw-borrower-application-form>.

<sup>11</sup> *Id.*

may raise eyebrows at the SBA, provoking loan reviews by the agency. These reviews risk uncovering information that suggests requirements were not followed or that certifications were falsely made (on either or both applications) and may even cause the SBA to question whether *the lender* adequately complied with PPP requirements.

The SBA Office of the Inspector General (OIG) recently issued two reports concluding that a large number of PPP loans were made in conflict with PPP eligibility rules. On January 11, 2021, the SBA OIG identified approximately \$3.6 billion in PPP loans (57,473 loans) made to potentially ineligible recipients who appeared to be on the Treasury Department's "Do Not Pay" list.<sup>12</sup> On March 15, 2021, the SBA OIG released a second report finding that lenders made more than one PPP loan disbursement to 4,260 borrowers with the same tax identification number or same business name and address (totaling about \$692 million) despite borrowers, at the time, being ineligible to receive more than one PPP loan.<sup>13</sup> The SBA OIG's analysis was initiated in response to a request from the House of Representatives Select Subcommittee on the Coronavirus Crisis to review duplicate loans made through the PPP.<sup>14</sup> Although these SBA OIG reports focus on improving SBA's own internal controls, they make clear that significant oversight of PPP loans will continue and that the scope of potential FCA liability involving the PPP is vast.

These FCA risks are no longer hypothetical. On January 12, 2021, DOJ announced its first settlement with a PPP borrower to resolve allegations that the borrower misrepresented its eligibility for PPP funding and therefore violated the FCA.<sup>15</sup> The Eastern District of California obtained the settlement with SlideBelts Inc., an internet retail company and debtor in bankruptcy, and Brigham Taylor, the company's president and CEO, which agreed to pay \$100,000 in damages and penalties and had already repaid the \$350,000 PPP loan it had fraudulently obtained.<sup>16</sup> As part of the settlement, SlideBelts and Taylor admitted that they made false statements that the company was not in bankruptcy (which under the PPP's implementing regulations made the company ineligible for funds) in order to obtain the PPP loan.<sup>17</sup> Acting AAG Boynton mentioned this settlement in his February remarks, signaling that the PPP is squarely a focus of the Civil Division, especially as more PPP borrowers begin applying for forgiveness.<sup>18</sup>

### **HHS Provider Relief Fund (PRF)**

The CARES Act created the HHS Provider Relief Fund to offer financial assistance to eligible health care providers who were affected by the pandemic.<sup>19</sup> As with the PPP, participation in the fund comes with strings attached that may lead to FCA liability. Health care provider recipients of such payments, including hospitals and doctors, have mandatory

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<sup>12</sup> SBA Inspector General, *Management Alert: Paycheck Protection Program Loan Recipients on the Department of Treasury's Do Not Pay List*, Report No. 21-06 (Jan. 11, 2021), <https://www.sba.gov/sites/default/files/2021-01/SBA%20OIG%20Report%2021-06.pdf>.

<sup>13</sup> SBA Inspector General, *Flash Report: Duplicate Loans Made Under the Paycheck Protection Program*, Report No. 21-09 (March 15, 2021), <https://www.oversight.gov/sites/default/files/oig-reports/SBA/SBA-OIG-Report-21-09.pdf>. Although the Economic Aid Act now allows certain PPP borrowers to receive a second PPP loan, this report analyzed loans during the period predating the start of the "second draw" PPP loan program.

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

<sup>15</sup> Press Release, US Atty's Off., E.D. Cal., *Eastern District of California Obtains Nation's First Civil Settlement for Fraud on Cares Act Paycheck Protection Program* (Jan. 12, 2021).

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> See Department of Justice Press Release, *Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference* (Feb. 17, 2021).

<sup>19</sup> CARES Act, Div. B, Title VIII, Department of Health & Human Services, Office of the Secretary, Public Health and Social Services Emergency Fund. On April 24, 2020, then-President Trump signed a law that provided an additional \$75 billion for this purpose. See Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116-139, 134 Stat. 620, Div. B, Title I (2020).

reporting requirements and must sign an electronic attestation confirming receipt of funds and their agreement to certain terms and conditions.<sup>20</sup> As evidenced by Acting AAG Boynton's remarks, the DOJ will closely monitor the use of these funds for potentially fraudulent activity.

For example, a health care provider must certify that it billed Medicare in 2019; that it provides diagnoses, testing or care for individuals with "possible or actual cases of COVID-19"; and that it is not currently terminated or excluded from participating in Medicare or other federal health care programs.<sup>21</sup> The provider must also certify that the funds "will only be used to prevent, prepare for, and respond to coronavirus," and not to pay for other unrelated expenses.<sup>22</sup> It remains unclear how HHS will determine whether a health care provider has used CARES Act funds "to prevent, prepare for, and respond to coronavirus," though certain fund recipients must comply with reporting requirements to allow HHS "to assess whether recipients properly used PRF payments, consistent with the Terms & Conditions."<sup>23</sup> To avoid FCA liability, fund recipients should ensure that all reports submitted in compliance with these reporting requirements are true and accurate in all material respects.

In February 2021, DOJ first charged an individual criminally for misappropriating provider relief funds.<sup>24</sup> The charges allege that the provider received the funds—despite not being operational during the pandemic—and then issued checks to her family members for personal use.<sup>25</sup> While this egregious conduct was charged criminally, it is likely that DOJ will consider using the FCA to police fraudulent conduct involving the PRF that does not rise, in its view, to a criminal violation. Although we may expect that early enforcement actions will focus on individuals and the most egregious cases, enforcement will likely broaden in scope over time.

## OPIOID EPIDEMIC

The FCA will continue to be a potent anti-fraud tool even outside the context of the pandemic. The opioid crisis continues, with the Centers for Disease Control and Prevention (CDC) reporting over 81,000 drug overdose deaths in the United States in a 12-month period ending May 2020—the highest number ever.<sup>26</sup> Enforcement actions against opioid-related fraud and abuse have been a major priority of the federal government in recent years, and two of the largest FCA recoveries ever obtained from the health care industry were obtained from opioid manufacturers.<sup>27</sup> Acting AAG Boynton made clear that FCA enforcement actions against pharmaceutical companies aimed at abating the opioid crisis will

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<sup>20</sup> US Dep't of Health & Human Services, CARES Act Provider Relief Fund: For Providers, <https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/for-providers/index.html> (last accessed March 17, 2021).

<sup>21</sup> US Dep't of Health & Human Services, Acceptance of Terms and Conditions, <https://www.hhs.gov/sites/default/files/terms-and-conditions-provider-relief-20-b.pdf> (last accessed March 17, 2021).

<sup>22</sup> *Id.*

<sup>23</sup> Department of Health & Human Services, General and Targeted Distribution Post-Payment Notice of Reporting Requirements (Nov. 2, 2020), <https://www.hhs.gov/sites/default/files/post-payment-notice-of-reporting-requirements-november-2020.pdf>. The notice requirements were recently updated in accordance with the Coronavirus Response and Relief Supplemental Appropriations Act of 2021. See Department of Health & Human Services, General and Targeted Distribution Post-Payment Notice of Reporting Requirements (Jan. 15, 2021), <https://www.hhs.gov/sites/default/files/provider-post-payment-notice-of-reporting-requirements-january-2021.pdf>.

<sup>24</sup> See Department of Justice Press Release, *Woman First in the Nation Charged with Misappropriating Monies Designed for COVID Medical Provider Relief* (Feb. 11, 2021).

<sup>25</sup> *Id.*

<sup>26</sup> See Department of Justice Press Release, *Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference* (Feb. 17, 2021).

<sup>27</sup> See, e.g., Department of Justice Press Release, *Opioid Manufacturer Insys Therapeutics Agrees to Enter \$225 Million Global Resolution of Criminal and Civil Investigations* (June 5, 2019).

remain a key priority, emphasizing that recent FCA settlements in this space totaled nearly \$2 billion.<sup>28</sup>

## FRAUD TARGETING SENIORS

Another continuing priority of the DOJ is to prevent the abuse of senior citizens, particularly involving concerns about poor or unnecessary health care in skilled nursing facilities. Nursing facilities have come under heavy scrutiny throughout the COVID-19 pandemic, and such scrutiny is likely to continue.<sup>29</sup> Even before the pandemic, skilled nursing facilities faced heightened regulatory scrutiny with the DOJ's launch of its "National Nursing Home Initiative" to "coordinate and enhance civil and criminal efforts to pursue nursing homes that provide grossly substandard care to their residents."<sup>30</sup>

Central to many FCA actions involving skilled nursing facilities are allegations that treatments provided and paid for using government funds were not "medically necessary." For example, in July 2020, DOJ reached a \$16.7 million settlement involving 27 affiliated skilled nursing facilities over allegations that they violated the FCA by submitting false claims to Medicare for rehabilitation therapy services that were not reasonable or necessary.<sup>31</sup> Acting AAG Boynton's remarks demonstrate that similar enforcement actions in this area will continue to be a priority for the Biden DOJ.<sup>32</sup>

A key legal question raised by two recent "medical necessity" cases is whether the alleged false statement must represent an "objective falsehood." Both the Third Circuit and the Ninth Circuit held last year, in medical necessity cases involving federal health care programs, that proof of an objective falsehood is not required in order to succeed on an FCA claim.<sup>33</sup> In contrast, the Eleventh Circuit has adopted an objective falsity requirement, holding that "a clinical judgment of terminal illness . . . cannot be deemed false, for purposes of the False Claims Act, when there is only a reasonable disagreement between medical experts."<sup>34</sup> In February of this year, the Supreme Court declined an opportunity to resolve this circuit split, denying a petition to review the Third Circuit's decision in *Care Alternatives*.<sup>35</sup> As a result, FCA liability

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<sup>28</sup> See Department of Justice Press Release, *Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference* (Feb. 17, 2021) ("We anticipate continued focus on pharmaceutical companies that marketed opioids with false and misleading statements, paid kickbacks to increase prescriptions, or targeted health care practitioners with a known pattern of problem prescribing.").

<sup>29</sup> See, e.g., Halley Bondy, NBC News, *39% of Covid-19 Deaths Have Occurred in Nursing Homes* (Dec. 8, 2020), <https://www.nbcnews.com/health/39-covid-19-deaths-have-occurred-nursing-homes-many-could-ncna1250374> (last accessed March 17, 2021); US CDC, *Rates of COVID-19 Among Residents and Staff Members in Nursing Homes: United States, May 25–November 22, 2020* (Jan. 15, 2020), [https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e2.htm?s\\_cid=mm7002e2\\_w](https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e2.htm?s_cid=mm7002e2_w) (last accessed March 17, 2021).

<sup>30</sup> See Department of Justice Press Release, *Department of Justice Launches a National Nursing Home Initiative* (March 3, 2020). This initiative is coordinated by DOJ's Elder Justice Initiative, which includes ten regional Elder Justice Task Forces led by representatives from the U.S. Attorneys' Offices, state Medicaid Fraud Control Units, state and local prosecutors' offices, HHS, state Adult Protective Services agencies, Long-Term Care Ombudsman programs and law enforcement.

<sup>31</sup> See Department of Justice Press Release, *Twenty-Seven Skilled Nursing Facilities Controlled By Longwood Management Corporation To Pay \$16.7 Million To Resolve False Claims Act Allegations* (July 13, 2020).

<sup>32</sup> See Department of Justice Press Release, *Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference* (Feb. 17, 2021) ("[T]he Department currently has open investigations across the country focused on nursing homes that are providing deficient care to our nation's seniors. We will continue to pursue these matters actively and aggressively, to protect these vulnerable members of our community.").

<sup>33</sup> In *United States v. Care Alternatives*, 952 F.3d 89, 100–01 (3d Cir. 2020), the Third Circuit "reject[ed] the objective falsehood standard," concluding instead that a "claim may be 'false' under a theory of legal falsity, where it fails to comply with statutory and regulatory requirements." The Ninth Circuit similarly held that the FCA does not include a requirement of proving "objective falsity" in the Medicare reimbursement context. *Winter ex rel. United States v. Gardens Regional Hosp. and Med. Ctr., Inc.*, 953 F.3d 1108, 1113 (9th Cir. 2020).

<sup>34</sup> *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1281 (11th Cir. 2019).

<sup>35</sup> *Care Alternatives v. United States ex rel. Druding*, No. 20-371 (US).

based on medical judgment will continue to present expert battles on summary judgment and may now vary by circuit.

## **ELECTRONIC HEALTH RECORDS (EHR)**

Acting AAG Boynton also highlighted new opportunities for fraud and abuse presented by EHRs. FCA actions in this context are likely to involve alleged misuse of EHR software or misrepresentation of an EHR software's capabilities. Unsurprisingly, CMS previously provided "words of caution" related to EHR, noting concerns such as upcoding and the altering of entry dates from within EHR software.<sup>36</sup>

In January 2020, EHR vendor Practice Fusion agreed to pay \$145 million to resolve criminal and civil investigations, including alleged violations of the FCA,<sup>37</sup> related to misrepresenting the capabilities of its EHR software.<sup>38</sup> DOJ alleged that Practice Fusion falsely obtained a certification from the Office of the National Coordinator for Health Information Technology (ONC) for several versions of its EHR software by concealing that the software did not comply with all the certification requirements.<sup>39</sup> Other recent FCA settlements in this space include a \$63.5 million settlement involving Inform Diagnostics related to subsidies for EHR and free or discounted technology consultation services given in exchange for referrals;<sup>40</sup> a \$57.25 million settlement with Greenway Health related to misrepresenting the capabilities of its EHR product;<sup>41</sup> and an \$18.25 million settlement with an EHR services developer related to allegations it violated the FCA by paying illegal kickbacks to generate sales of its EHR product.<sup>42</sup>

## **TELEHEALTH**

The Biden DOJ is also likely to be keenly focused on telehealth-related fraud, especially given the increased usage of telehealth during the pandemic.<sup>43</sup> By 2025, the global telehealth market is expected to reach \$191.7 billion—nearly five times the estimated size of the market in 2020.<sup>44</sup> Much of this increased usage relates to relaxed telehealth regulations—for example, the CARES Act created a temporary waiver of the face-to-face requirement for visits between home dialysis patients and their physicians, hospice-care eligibility, and certain home health services.<sup>45</sup>

As Acting AAG Boynton noted, the DOJ has recently brought actions where medical providers asserted that claims arose from telehealth visits, when in fact doctors were simply paid kickbacks to approve them and no telehealth interaction

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<sup>36</sup> CMS, *Electronic Health Records Provider* (Dec. 2015), <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/docmatters-ehr-providerfactsheet.pdf> (last accessed March 17, 2021).

<sup>37</sup> Settlement Agreement between the United States and Practice Fusion, Inc., <https://www.justice.gov/usao-vt/press-release/file/1239631/download> (last accessed March 17, 2021).

<sup>38</sup> See Department of Justice Press Release, *Electronic Health Records Vendor to Pay \$145 Million to Resolve Criminal and Civil Investigations* (Jan. 27, 2020).

<sup>39</sup> *Id.*

<sup>40</sup> See Department of Justice Press Release, *Pathology Laboratory Agrees to Pay \$63.5 Million for Providing Illegal Inducements to Referring Physicians* (Jan. 30, 2019).

<sup>41</sup> See Department of Justice Press Release, *Electronic Health Records Vendor to Pay \$57.25 Million to Settle False Claims Act Allegations* (Feb. 6, 2019).

<sup>42</sup> Press Release, US Atty's Off., D. Mass., *Athenahealth Agrees to Pay \$18.25 Million to Resolve Allegations that It Paid Illegal Kickbacks* (Jan. 28, 2021).

<sup>43</sup> As noted by Acting AAG Boynton, "I also expect a continued focus on telehealth schemes, particularly given the expansion of telehealth during the pandemic." Department of Justice Press Release, *Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference* (Feb. 17, 2021).

<sup>44</sup> PR Newswire, *The Worldwide Telehealth/Telemedicine Industry is Estimated to Reach \$191.7 Billion by 2025* (Dec. 8, 2020), <https://www.prnewswire.com/news-releases/the-worldwide-telehealthtelemedicine-industry-is-estimated-to-reach-191-7-billion-by-2025--301188307.html> (last accessed March 17, 2021).

<sup>45</sup> See CARES Act §§ 3705, 3706 & 3707.

occurred. Additionally, relaxed telehealth provisions are set to expire at the end of the COVID-19 public health emergency, and enforcement of prior, more stringent telehealth requirements is expected to resume. Providers therefore need to be mindful of these changing regulations over the next year.

## CYBERSECURITY

FCA risks associated with cybersecurity-related fraud are also likely to remain a focus during the Biden Administration. With the growing and serious threat of cyberattacks, federal agencies now rely heavily on robust cybersecurity protections to safeguard vital governmental data and information. As Acting AAG Boynton noted, if the federal government pays for systems or services that purport to comply with required cybersecurity standards but fail to do so, “it is not difficult to imagine a situation where False Claims Act liability may arise.”<sup>46</sup>

For example, in *United States ex rel. Markus v. Aerojet Rocketdyne Holdings, Inc., et al.*, the US District Court for the Eastern District of California held that a contractor’s failure to disclose noncompliance with federal cybersecurity requirements could constitute an FCA violation, even where the contractor had disclosed *some* of its noncompliance.<sup>47</sup> This case, coupled with Acting AAG Boynton’s remarks, makes clear that failure to comply with federal cybersecurity requirements will continue to form the basis of FCA actions.

## *The Role of Data*

Acting AAG Boynton concluded his remarks by discussing the role of data in determining not only the types of FCA cases that may be brought, but also *how* those cases will be identified. Especially in the Medicare and Medicaid space, DOJ has developed sophisticated data analytics that allow it to identify suspicious billing patterns across different types of health care providers—a way to identify billing or prescribing trends and extreme outliers. For instance, DOJ has indicated that its data allows it to demonstrate and quantify suspicious relationships, such as a physician offering controlled-substance prescriptions to patients who are likely to divert those prescriptions elsewhere. As Acting AAG Boynton noted, the Civil Division is actively using data analytics to identify these very situations.

Other DOJ officials have made similar remarks. For example, in December 2020, Deputy AAG Michael Granston commented that “you can expect the Civil Division to expand its reliance on data analysis,” particularly in the Medicare context, to uncover fraud schemes not identified by whistleblowers.<sup>48</sup> Although there seems to be a focus on the health care industry, Deputy AAG Granston also made clear that the “benefits of data analysis extend beyond just the health care arena,” emphasizing that the Civil Division is using data analytics to “combat other types of frauds, including COVID-19 related misconduct that may give rise to False Claims Act liability.”<sup>49</sup>

Qui tam relators also utilize data analytics, and have been for some time, including to plead both falsity and scienter in the absence of traditional “inside” information about a company’s practices, thus expanding the scope of cases that may

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<sup>46</sup> See Department of Justice Press Release, *Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference* (Feb. 17, 2021).

<sup>47</sup> *United States v. Aerojet Rocketdyne Holdings, Inc.*, 381 F. Supp. 3d 1240, 1249 (E.D. Cal. 2019) (denying defendant’s motion to dismiss, holding that the qui tam plaintiff plausibly pled that defendant’s failure to disclose its noncompliance was material). This case is currently in discovery.

<sup>48</sup> See Department of Justice Press Release, *Remarks of Deputy Assistant Attorney General Michael D. Granston at the ABA Civil False Claims Act and Qui Tam Enforcement Institute* (Dec. 2, 2020).

<sup>49</sup> *Id.*

be brought by a qui tam plaintiff.<sup>50</sup> As “big data” continues to be the new normal, both DOJ and private plaintiffs will certainly be looking to harness its power to identify, bring and prove FCA cases.

## *Conclusion*

All signs point to increased FCA enforcement in the years ahead by the Biden DOJ. Companies that have availed themselves of CARES Act or other pandemic-related funds should be prepared for heightened scrutiny from regulators, which includes not only the DOJ but also Congress and the oversight bodies created by the CARES Act, such as the Office of the Special Inspector General for Pandemic Recovery (SIGPR),<sup>51</sup> the Pandemic Response Accountability Committee (PRAC)<sup>52</sup> and a five-member congressional oversight commission.<sup>53</sup> But that’s not all: the Act’s qui tam provision remains as popular and potent as ever, and recipients of pandemic-related funds must be prepared for their conduct to be a prime target of private lawsuits as well.

With a team of veteran litigators, prosecutors and former DOJ lawyers, WilmerHale brings significant knowledge and experience to defending against FCA litigation brought by relators, the DOJ and state attorneys general. Please reach out to the authors of this alert or your WilmerHale contacts should you have any questions.

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<sup>50</sup> For example, Integra Med Analytics, LLC, has brought multiple FCA actions as a qui tam plaintiff using a statistical analysis of hospital data to plead falsity. The Fifth Circuit recently upheld the dismissal of one such case, where Integra Med Analytics used statistical analysis of inpatient claims data in an attempt (rejected by the trial and appellate courts) to show that the defendant health care provider’s higher rates of coding could not be explained by patient characteristics. See *United States ex rel. Integra Med Analytics, L.L.C. v. Baylor Scott & White Health*, 816 F. App’x 892, 895 (5th Cir.), cert. denied, 141 S. Ct. 905 (2020).

<sup>51</sup> The SIGPR is charged with auditing and investigating loans, loan guarantees and other investments made by the Secretary of the Treasury under Title IV of the CARES Act.

<sup>52</sup> PRAC is a new committee of inspectors general from various federal departments and agencies created to promote transparency and support oversight of CARES Act funds.

<sup>53</sup> The commission will conduct oversight of the Treasury Department and the Board of Governors of the Federal Reserve as they implement the CARES Act’s economic stabilization provisions. CARES Act § 4020(a)–(b).