

PRATT'S GOVERNMENT CONTRACTING LAW REPORT

VOLUME 6

NUMBER 11

November 2020

Editor's Note: False Claims Act and More! Victoria Prussen Spears	369
False Claims Act Enforcement During the COVID-19 Pandemic and Beyond George B. Breen and Alexis Boaz	371
Continued Uncertainty Clouds DOJ's Dismissal Power Under False Claims Act Pablo J. Davis	381
Executive Order Regarding Domestic Production and Purchase of Essential Medicines: A Lot to Unpack and More Than Meets the Eye Merle M. DeLancey Jr. and John M. Clerici	388
Dear Magic 8-Ball—Should I Protest? Critical Protest Implications Following the Federal Circuit's Expansion of <i>Blue & Gold's</i> Waiver Rule in <i>Inverso</i> Ethan M. Brown	393
Government Reliance on Waiver Argument to Keep Price Adjustment Windfall Fails Scott Arnold	398
The Artemis Accords Seek to Propel a New Industry William T. Gordon, Vivasvat Dadwal, and Carson W. Bennett	401

QUESTIONS ABOUT THIS PUBLICATION?

For questions about the **Editorial Content** appearing in these volumes or reprint permission, please call:

Heidi A. Litman at 516-771-2169
Email: heidi.a.litman@lexisnexis.com
Outside the United States and Canada, please call (973) 820-2000

For assistance with replacement pages, shipments, billing or other customer service matters, please call:

Customer Services Department at (800) 833-9844
Outside the United States and Canada, please call (518) 487-3385
Fax Number (800) 828-8341
Customer Service Website <http://www.lexisnexis.com/custserv/>

For information on other Matthew Bender publications, please call

Your account manager or (800) 223-1940
Outside the United States and Canada, please call (937) 247-0293

Library of Congress Card Number:

ISBN: 978-1-6328-2705-0 (print)

ISSN: 2688-7290

Cite this publication as:

[author name], [article title], [vol. no.] PRATT’S GOVERNMENT CONTRACTING LAW REPORT [page number] (LexisNexis A.S. Pratt).

Michelle E. Litteken, GAO Holds NASA Exceeded Its Discretion in Protest of FSS Task Order, 1 PRATT’S GOVERNMENT CONTRACTING LAW REPORT 30 (LexisNexis A.S. Pratt)

Because the section you are citing may be revised in a later release, you may wish to photocopy or print out the section for convenient future reference.

This publication is designed to provide authoritative information in regard to the subject matter covered. It is sold with the understanding that the publisher is not engaged in rendering legal, accounting, or other professional services. If legal advice or other expert assistance is required, the services of a competent professional should be sought.

LexisNexis and the Knowledge Burst logo are registered trademarks of RELX Inc. Matthew Bender, the Matthew Bender Flame Design, and A.S. Pratt are registered trademarks of Matthew Bender Properties Inc.

Copyright © 2020 Matthew Bender & Company, Inc., a member of LexisNexis. All Rights Reserved. Originally published in: 2015

No copyright is claimed by LexisNexis or Matthew Bender & Company, Inc., in the text of statutes, regulations, and excerpts from court opinions quoted within this work. Permission to copy material may be licensed for a fee from the Copyright Clearance Center, 222 Rosewood Drive, Danvers, Mass. 01923, telephone (978) 750-8400.

Editorial Office
230 Park Ave., 7th Floor, New York, NY 10169 (800) 543-6862
www.lexisnexis.com

MATTHEW  BENDER

Editor-in-Chief, Editor & Board of Editors

EDITOR-IN-CHIEF

STEVEN A. MEYEROWITZ

President, Meyerowitz Communications Inc.

EDITOR

VICTORIA PRUSSEN SPEARS

Senior Vice President, Meyerowitz Communications Inc.

BOARD OF EDITORS

MARY BETH BOSCO

Partner, Holland & Knight LLP

MERLE M. DELANCEY JR.

Partner, Blank Rome LLP

DARWIN A. HINDMAN III

Shareholder, Baker, Donelson, Bearman, Caldwell & Berkowitz, PC

J. ANDREW HOWARD

Partner, Alston & Bird LLP

KYLE R. JEFCOAT

Counsel, Latham & Watkins LLP

JOHN E. JENSEN

Partner, Pillsbury Winthrop Shaw Pittman LLP

DISMAS LOCARIA

Partner, Venable LLP

MARCIA G. MADSEN

Partner, Mayer Brown LLP

KEVIN P. MULLEN

Partner, Morrison & Foerster LLP

VINCENT J. NAPOLEON

Partner, Nixon Peabody LLP

STUART W. TURNER

Counsel, Arnold & Porter

ERIC WHYTSELL

Partner, Stinson Leonard Street LLP

WALTER A.I. WILSON

Partner Of Counsel, Dinsmore & Shohl LLP

Pratt's Government Contracting Law Report is published 12 times a year by Matthew Bender & Company, Inc. Copyright © 2020 Matthew Bender & Company, Inc., a member of LexisNexis. All Rights Reserved. No part of this journal may be reproduced in any form—by microfilm, xerography, or otherwise—or incorporated into any information retrieval system without the written permission of the copyright owner. For customer support, please contact LexisNexis Matthew Bender, 9443 Springboro Pike, Miamisburg, OH 45342 or call Customer Support at 1-800-833-9844. Direct any editorial inquiries and send any material for publication to Steven A. Meyerowitz, Editor-in-Chief, Meyerowitz Communications Inc., 26910 Grand Central Parkway Suite 18R, Floral Park, New York 11005, smeyerowitz@meyerowitzcommunications.com, 646.539.8300. Material for publication is welcomed—articles, decisions, or other items of interest to lawyers and law firms, in-house counsel, government lawyers, senior business executives, and anyone interested in privacy and cybersecurity related issues and legal developments. This publication is designed to be accurate and authoritative, but neither the publisher nor the authors are rendering legal, accounting, or other professional services in this publication. If legal or other expert advice is desired, retain the services of an appropriate professional. The articles and columns reflect only the present considerations and views of the authors and do not necessarily reflect those of the firms or organizations with which they are affiliated, any of the former or present clients of the authors or their firms or organizations, or the editors or publisher.

POSTMASTER: Send address changes to *Pratt's Government Contracting Law Report*, LexisNexis Matthew Bender, 230 Park Ave. 7th Floor, New York NY 10169.

False Claims Act Enforcement During the COVID-19 Pandemic and Beyond

*By George B. Breen and Alexis Boaz**

In remarks addressing the U.S. Department of Justice's top priorities for enforcement actions related to COVID-19, Ethan P. Davis, Principal Deputy Assistant Attorney General for the Civil Division, indicated that the Justice Department plans to "vigorously pursue fraud and other illegal activity." The authors of this article examine the remarks, which provide an indication of how the Department might approach enforcement over the next few years.

Ethan P. Davis, Principal Deputy Assistant Attorney General for the Civil Division of the U.S. Department of Justice ("DOJ") delivered remarks addressing DOJ's top priorities for enforcement actions related to COVID-19 and indicating that DOJ plans to "vigorously pursue fraud and other illegal activity."¹ As discussed below, Davis' remarks not only highlighted principles that will guide enforcement efforts of the Civil Fraud Section under the False Claims Act ("FCA") and of the Consumer Protection Branch ("CPB") under the Food, Drug, and Cosmetic Act ("FDCA") and the Controlled Substances Act ("CSA") in response to the COVID-19 public health emergency ("PHE"), they also provide an indication of how DOJ might approach enforcement over the next few years.

DOJ'S KEY CONSIDERATIONS & ENFORCEMENT STRATEGY FOR COVID-19

Davis highlighted two key principles that would drive DOJ's COVID-related enforcement efforts: the energetic use of "every enforcement tool available to prevent wrongdoers from exploiting the COVID-19 crisis" and a respect of the private sector's critical role in ending the pandemic and restarting the

* George B. Breen, a member of the firm in the Health Care and Life Sciences and Litigation practices of Epstein Becker & Green, P.C., is chair of its National Health Care & Life Sciences Steering Committee and serves on the firm's Board of Directors. Alexis Boaz is an associate in the firm's Health Care and Life Sciences practice, focusing on fraud and abuse, transactional, regulatory, and compliance matters. The authors may be contacted at ggreen@ebglaw.com and aboaz@ebglaw.com, respectively.

¹ U.S. Dep't of Justice, 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 (June 26, 2020), <https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims> (hereinafter "Remarks from Assistant Att'y Gen. Davis").

economy.² Under that framework, DOJ plans to pursue fraud and other illegal activity under the FCA, which Davis characterizes as “one of the most effective weapons in [DOJ’s] arsenal.”³

However, as DOJ pursues FCA cases, it will also seek to affirmatively dismiss *qui tam* claims that DOJ finds meritless or that interfere with agency policy and programs.⁴ DOJ also plans to collect certain information from *qui tam* relators regarding third-party litigation funders during relator interviews.⁵ DOJ’s emphasis on *qui tam* cases—cases brought under the FCA by relators or whistleblowers—for COVID-related enforcement highlights the impact such matters have on DOJ’s enforcement agenda.⁶

DOJ Will Consider Dismissing Cases that Involve Regulatory Overreach and Are Not Otherwise in the Interest of the United States

Although Davis emphasized that the majority of *qui tam* cases would be allowed to proceed, in order to “weed out” cases that lack merit or that DOJ believes should not proceed, DOJ will consider dismissing cases that “involve regulatory overreach or are otherwise not in the interest of the United States.”⁷ This is consistent with the principles reflected in the 2018 Granston Memo that instructed DOJ attorneys to consider “whether the government’s interests are served” when considering whether cases should proceed and listed considerations for seeking alternative grounds for dismissal of FCA cases.⁸ Davis gave examples throughout his speech of actions DOJ might consider dismissing:

² *Id.*

³ *Id.* In 2019 alone, DOJ obtained over \$3 billion in settlements and judgments from civil fraud and FCA cases, with over \$2.5 billion—or 90 percent—generated from health care-related matters. Press Release, U.S. Dep’t of Justice, 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>; U.S. Dep’t of Justice, Fraud Statistics—Overview (Jan. 9, 2020), <https://www.justice.gov/opa/press-release/file/1233201/download>.

⁴ Remarks from Assistant Att’y Gen. Davis, *supra* note 1.

⁵ *Id.*

⁶ *Qui tam* claims resulted in \$1.9 billion in recoveries, or 73 percent of all healthcare-related FCA recoveries, in 2019. Press Release, U.S. Dep’t of Justice, 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>; U.S. Dep’t of Justice, Fraud Statistics—Overview (Jan. 9, 2020), <https://www.justice.gov/opa/press-release/file/1233201/download>.

⁷ Remarks from Assistant Att’y Gen. Davis, *supra* note 1.

⁸ Memorandum from Michael D. Granston, Director, Commercial Litigation Branch, Fraud Section, U.S. Dep’t of Justice, on Factors for Evaluating Dismissal Pursuant to 31 U.S.C.

- Cases based on immaterial or inadvertent mistakes, such as technical mistakes with paperwork;
- Cases based on honest misunderstandings of rules, terms, and conditions;
- Cases based on alleged deviations from non-binding guidance documents; and
- Cases against entities that reasonably attempted to comply with guidance and “in good faith took advantage of the regulatory flexibilities granted by federal agencies in the time of crisis.”⁹

DOJ litigators have been advised to inform relators of the possibility of dismissal.¹⁰ Additionally, *qui tam* suits based on behaviors temporarily permitted during the COVID-19 pandemic, particularly in circumstances in which agencies exercised discretion to waive or not enforce certain requirements, might “fail as a matter of law for lack of materiality and knowledge.”¹¹

DOJ Will Now Include a Series of Questions During Relator Interviews to Identify Third-Party Litigation Funders

During each relator interview, DOJ has instructed line attorneys to ask a series of questions to identify whether the relator or their counsel has a third-party litigation funding agreement,¹² which is an agreement in which a third party—such as a commercial lender or a hedge fund—finances the cost of litigation in return for a portion of recoveries.¹³ Under the new policy detailed in Davis’ speech, if a third-party funder is disclosed, DOJ will ask for the following:

- The identity of the third-party litigation funder;
- Information regarding whether information of the allegations has been

3730(c)(2)(A) (Jan. 10, 2018), <https://www.insidethefca.com/wp-content/uploads/sites/300/2018/12/Granston-Memo.pdf>.

⁹ Memorandum from Michael D. Granston, Director, Commercial Litigation Branch, Fraud Section, U.S. Dep’t of Justice, on Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A) (Jan. 10, 2018), <https://www.insidethefca.com/wp-content/uploads/sites/300/2018/12/Granston-Memo.pdf>.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ Litigation Funding Transparency Act of 2019, S. 471 (2019); Press Release, Grassley Leads Lawmakers in Introducing Bill to Improve Transparency of Third Party Financing in Civil Litigation, Off. of Sen. Grassley (Feb. 13, 2019), <https://www.grassley.senate.gov/news-releases/grassley-leads-lawmakers-introducing-bill-improve-transparency-third-party>.

shared with the third party;

- Whether the relator or their counsel has a written agreement with the third party; and
- Whether the agreement between the relator or their counsel and the third party includes terms that entitles the third-party funder to exercise direct or indirect control over the relator's litigation or settlement decisions.

Relators must inform DOJ of changes as the case proceeds through the course of litigation.¹⁴ While Davis characterizes these changes as a “purely information-gathering exercise for the purpose of studying the issues,” the questions are in furtherance of DOJ's ongoing efforts to uncover the potential negative impacts third-party litigation financing may have in *qui tam* actions.¹⁵ The questions Davis referenced in his remarks reflect DOJ's concerns with third-party litigation funding as expressed by Deputy Associate Attorney General Stephen Cox in a January 2020 speech.¹⁶ Davis emphasized that DOJ particularly sought to evaluate the extent to which third-party litigation funders were behind *qui tam* cases DOJ investigates, litigates, and monitors; the extent of information sharing with third-party funders; and the amount of control third-party funders exercised over the litigation and settlement decisions.¹⁷ While the Litigation Funding Transparency Act of 2019 has remained inactive since its introduction in February 2019 by Senator Grassley¹⁸ and the 2018 proposal by the U.S. Court's Advisory Committee on Civil Rights' Multidistrict Litigation Subcommittee to require disclosure of third-party litigation funding remains under consideration,¹⁹ DOJ's plans to include this line of questioning potentially signals DOJ's intention to take more concrete and significant steps to address third-party litigation funding in the future.

¹⁴ Remarks from Assistant Att'y Gen. Davis, *supra* note 1.

¹⁵ *Id.*

¹⁶ U.S. Dep't of Justice, Deputy Associate Attorney General Stephen Cox Provides Keynote Remarks at the 2020 Advanced Forum on False Claims and Qui Tam Enforcement (Jan. 27, 2020), <https://www.justice.gov/opa/speech/deputy-associate-attorney-general-stephen-cox-provides-keynote-remarks-2020-advanced>.

¹⁷ Remarks from Assistant Att'y Gen. Davis, *supra* note 1.

¹⁸ Litigation Funding Transparency Act of 2019, S. 471 (2019); Press Release, Grassley Leads Lawmakers in Introducing Bill to Improve Transparency of Third Party Financing in Civil Litigation, Off. of Sen. Grassley (Feb. 13, 2019), <https://www.grassley.senate.gov/news/news-releases/grassley-leads-lawmakers-introducing-bill-improve-transparency-third-party>.

¹⁹ Advisory Committee on Civil Rules, Civil Rules Agenda Book (Nov. 1, 2018), https://www.uscourts.gov/sites/default/files/2018-11_civil_rules_agenda_book_0.pdf.

DOJ'S ENFORCEMENT PRIORITY AREAS

COVID-Related Enforcement

DOJ plans to “deploy the [FCA] against those who commit fraud related to the various COVID-19 stimulus programs,” particularly focusing on the Provider Relief Fund (“PRF”) and the Paycheck Protection Program (“PPP”), stimulus programs put into place by the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) that impose numerous enforceable requirements on recipients.²⁰ Davis stressed that the significant sums of money made available by these and other similar COVID-related stimulus programs presented significant opportunity for fraudulent activity.

DOJ Will Take Enforcement Action Under the FCA for Knowing Violations of the Terms and Conditions of the PRF

DOJ plans to target PRF recipients that knowingly violate the program's Terms and Conditions.²¹ The CARES Act appropriated \$100 billion to the PRF to reimburse qualifying hospitals and providers for health care-related expenses or lost revenues attributable to COVID-19.²² The Paycheck Protection Program and Health Care Enhancement Act appropriated an additional \$75 billion to the PRF.²³ Recipients were required to attest to the Terms and Conditions of the PRF or were deemed to have accepted the Terms and Conditions if the recipient did not remit funds within 90 days of receipt.²⁴ The Terms and Conditions enumerate certain permitted uses of the grants, including to prevent, prepare for, and respond to COVID-19 and to reimburse health-care related expenses or revenues attributable to COVID-19.²⁵ The Terms and Conditions also prohibit certain uses of the funds, such as using the funds to reimburse expenses or losses that another source had the obligation to reimburse or that had already been reimbursed.²⁶ The PRF requires recipients to meet certain eligibility criteria, including having provided diagnoses, testing,

²⁰ Remarks from Assistant Att’y Gen. Davis, *supra* note 1.

²¹ *Id.*

²² The CARES Act, Pub. L. No. 116–136 (2020).

²³ Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116–139 (2020).

²⁴ U.S. Dep’t of Health & Human Servs., CARES Act Provider Relief Fund Frequently Asked Questions (June 19, 2020), <https://www.hhs.gov/sites/default/files/provider-relief-fund-general-distribution-faqs.pdf> (hereinafter “PRF FAQs”).

²⁵ *Id.*

²⁶ Dep’t of Health & Human Servs., Acceptance of Terms and Conditions (2020), <https://www.hhs.gov/sites/default/files/terms-and-conditions-provider-relief-30-b.pdf>.

or care for individuals with possible or actual cases of COVID-19.²⁷ While the Terms and Conditions specify noncompliance would be “grounds for the Secretary to recoup some or all of the payment made from the Relief Fund,”²⁸ Davis’ speech highlights that knowing violations may also subject entities to enforcement under the FCA.²⁹

DOJ Will Continue Its Enforcement Initiatives to Identify and Prosecute Fraud Related to the PPP Under the FCA, Particularly Focusing on Borrowers that Falsely Certify Compliance

The Civil Division has implemented initiatives to combat fraud in the PPP and will prioritize using the FCA to target PPP borrowers that falsely certify compliance with requirements of PPP loans.³⁰ The CARES Act created the PPP loan program to incentivize small businesses to keep employees on their payroll for eight weeks by making loans forgivable if used for certain expenses, such as “payroll, rent, mortgage interest, or utilities.”³¹ For eligibility, the Small Business Administration (“SBA”) requires PPP borrowers to certify that the “economic uncertainty makes [the] loan request necessary to support the ongoing operations”³² and to agree to certain program criteria.³³ The borrower must confirm compliance with these requirements when applying for loan forgiveness.³⁴ The amount of the loan forgiveness may be reduced if the number of full-time employees declines or if salaries and wages decrease.³⁵ While Davis emphasized that “if a company is eligible for a loan and submits certifications in good faith, that company will have nothing to fear from the

²⁷ PRF FAQs, *supra* note 24.

²⁸ Dep’t of Health & Human Servs., Acceptance of Terms and Conditions (2020), <https://www.hhs.gov/sites/default/files/terms-and-conditions-provider-relief-30-b.pdf>.

²⁹ Remarks from Assistant Att’y Gen. Davis, *supra* note 1.

³⁰ *Id.*

³¹ U.S. Dep’t of Treasury, Small Business Paycheck Protection Program (n.d.), <https://home.treasury.gov/system/files/136/PPP%20--%20Overview.pdf>.

³² U.S. Small Business Admin., Paycheck Protection Program Borrower Application Form (Apr. 2020), <https://www.sba.gov/sites/default/files/2020-04/PPP-Borrower-Application-Form-Fillable.pdf>.

³³ U.S. Small Business Admin., Paycheck Protection Program (n.d.), <https://www.sba.gov/funding-programs/loans/coronavirus-relief-options/paycheck-protection-program>.

³⁴ U.S. Small Business Admin., Paycheck Protection Program Loan Forgiveness Application (June 16, 2020), <https://www.sba.gov/sites/default/files/2020-06/PPP%20Loan%20Forgiveness%20Application%20Instructions%20%28Revised%206.16.2020%29-508.pdf>.

³⁵ U.S. Dep’t of Treasury, Small Business Paycheck Protection Program (n.d.), <https://home.treasury.gov/system/files/136/PPP%20--%20Overview.pdf>.

Civil Division,” he also mentioned that DOJ would coordinate efforts with the Office of the Inspector General at the SBA to identify “potential wrongdoing that warrants investigation.”³⁶

DOJ Will Also Focus Enforcement Efforts on Other Stimulus and Assistance Programs

DOJ will pursue FCA actions for fraud in other COVID-19 assistance programs when participants attempt to “skirt” requirements, similarly to DOJ’s efforts with the PPP.³⁷ For example, Davis specifically mentioned that DOJ would bring FCA actions against the borrowers and lenders violating eligibility and other covenants of the Federal Reserve’s Main Street New Loan Facility,³⁸ a loan program appropriated by the CARES Act for “small and medium-sized businesses that were in sound financial condition before the onset of the COVID-19 pandemic.”³⁹

DOJ Will Target Private Equity Investors that Knowingly Engaged in Fraudulent Activity Related to the CARES Act

DOJ’s enforcement actions would not be limited to entities themselves, but, as Davis emphasized, DOJ plans to take action against private equity firms that have taken “an active role in illegal conduct” of acquired companies that are recipients of CARES Act funds.⁴⁰ Similar to how acquisitions of companies within the health care industry generally open up private equity firms’ exposure to liability under the FCA, Davis stated, “Where a private equity firm knowingly engages in fraud related to the CARES Act, we will hold it accountable.”⁴¹

COVID-19 Enforcement from the CPB

In addition to detailing FCA enforcement of COVID-related actions, Davis highlighted that the CPB of the Civil Division—which has “tripled in size since 2017”—will work with the U.S. Food and Drug Administration (“FDA”) and the U.S. Drug Enforcement Administration to enforce the FDCA and the CSA

³⁶ Remarks from Assistant Att’y Gen. Davis, *supra* note 1.

³⁷ *Id.*

³⁸ *Id.*

³⁹ Fed. Reserve, Main Street New Loan Facility (June 8, 2020) <https://www.federalreserve.gov/newsevents/pressreleases/files/monetary20200608a1.pdf>; Bd. of Governors of the Fed. Reserve, Main Street Lending Program (July 8, 2020), <https://www.federalreserve.gov/monetarypolicy/mainstreetlending.htm>.

⁴⁰ Remarks from Assistant Att’y Gen. Davis, *supra* note 1.

⁴¹ *Id.*

against pharmaceutical companies, medical device companies, and others in the life sciences space using civil and criminal enforcement “to safeguard consumers from COVID-related scams and unsafe products.”⁴² CPB initiated action early in the PHE, targeting entities that offered fraudulent or unapproved products to consumers.⁴³ In furtherance of these efforts, Davis highlighted three areas that CPB plans to include in its scope of focus for COVID-related actions:

- CPB will increase oversight over scammers and their facilitators within the “telecommunications, financial, and marketing industries,” as CPB anticipates scammers will attempt to shift their existing fraudulent schemes from targeting the Social Security Administration and Internal Revenue Service to COVID-related programs, such as the CARES Act stimulus programs.⁴⁴
- CPB will take action domestically and abroad to ensure that products comply with safety regulations, particularly focusing on drugs and active pharmaceutical ingredients.
- CPB will also prioritize making sure that companies “ensure the integrity and accuracy of their clinical trials,” particularly as companies expedite developing drugs and medical devices in response to COVID-19.⁴⁵

Davis stated that DOJ would work with FDA to ensure that enforcement efforts were consistent with regulatory flexibilities and emphasized “when a company seeks in good faith to operate within this regulatory framework, it should not have to fear first learning of government disapproval through a civil or criminal action.”⁴⁶

Beyond COVID-19: Other Priorities of the Civil Division

Despite the focus on COVID-related actions, Davis provided a reminder that DOJ will continue its broader enforcement activities, specifically targeting the six high-priority areas summarized below:

1. *Enforcement in the Opioid Industry.* The opioid crisis remains a key priority for enforcement actions. DOJ will continue using all civil and criminal tools available under the FCA, the FDCA, and the CSA—such as civil injunctive, forfeiture, and penalty provisions—to target

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.*

the entire opioid drug distribution chain, including pharmaceutical companies, drug wholesalers, pharmacies, and physicians in enforcement actions responsive to the opioid crisis.⁴⁷

2. *Electronic Health Records.* DOJ will pursue electronic health record companies under the FCA for activities that involve corruption and fraudulent activity related to the information provided to physicians, such as in a recent case in which Davis noted an electronic health record company accepted kickbacks for “using its software to promote opioid prescriptions to doctors.”⁴⁸
3. *Medicare Part C.* DOJ expects to continue its FCA enforcement activities in the Medicare Advantage sphere, as Davis noted Medicare Advantage Organization plans currently cover an estimated one-third of Medicare beneficiaries.
4. *Nursing Home and Fraud on the Elderly.* DOJ’s National Nursing Home Initiative—launched in March—will continue coordinating investigations of nursing homes and will bring civil and criminal enforcement actions against nursing homes that “provide grossly substandard care to their residents.”⁴⁹
5. *Dietary Supplements.* The CPB plans to increase resources dedicated to fraud enforcement in the dietary supplement industry, particularly due to the market’s comparatively low regulatory oversight and concern over imported dietary supplement ingredients.
6. *Data Privacy.* To address the growing threat of data misuse, the CPB will use the civil penalty provisions of the Federal Trade Commission Act to take enforcement action in the data privacy and security field and will further work in coordination with DOJ’s Antitrust Division and the Federal Trade Commission to hold companies and individuals accountable for breaking “the law in acquiring, storing, or using consumer data.”⁵⁰

LOOKING FORWARD

Throughout his speech, Davis stressed that the Trump administration would focus efforts on “knowing violations of federal law that are material to the government’s payment decisions” and on cases “where the borrower knowingly

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

failed to comply with material legal obligations and certifications.”⁵¹ Further, Davis acknowledged compliance with the “thousands of rules, terms and conditions, and complicated guidance” would be a dizzying task under normal circumstances.”⁵² Indeed, the complex and uncertain regulatory framework created by the PHE and the relief programs highlight the potential vulnerabilities well-intentioned entities may face as DOJ tries to identify and prosecute actual unscrupulous actors attempting to commit fraud during the COVID-19 pandemic. Businesses and individuals across the health care system—particularly recipients of stimulus funds—must diligently ensure compliance with regulatory flexibilities and requirements and should document such efforts, particularly since, as Davis noted, “these are still early days.”⁵³

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*