RESURRECTING THE MONSTER? PROTECTING THE MARKET FROM UNFETTERED COVID-19 FRAUD ENFORCEMENT

Erik Fuqua†

† Major Erik T. Fuqua, USAF, (LL.M. 2021, The George Washington University Law School; J.D. 2011, Baylor Law School; B.A. 2006, The University of Tennessee-Martin) is an acquisition attorney at Robins Air Force Base, Georgia. Major Fuqua previously served as a Medical Law Consultant at Keesler Medical Center, Keesler Air Force Base, Mississippi. He is a member of the Tennessee Bar. The author wishes to thank Professor Christopher Yukins for his helpful insight, encouragement, and practical advice, as well as the late Jack Boese for his guidance and input during the early stages of this project. The author also wishes to thank Andrew Eichner and Patrick Souter for their time and feedback. This article was submitted to partially satisfy the requirements of a Master of Laws degree at The George Washington University Law School. All statements of fact, opinion, or analysis expressed are those of the author and do not reflect the official positions or views of the Department of Defense (DOD), United States Air Force, or any other U.S. Government agency. Nothing in the contents should be construed as asserting or implying U.S. Government authentication of information or DOD or Air Force endorsement of the author's views.

"Money washed through the economy
like water rushing through a broken dam."[1]

INTRODUCTION

The COVID-19 pandemic has produced trillions of dollars in government spending across the globe.[2] In only the first three months of the pandemic, the United States' COVID-19 response contract obligations alone totaled $17.8 billion.[3] Other stimulus programs, such as the Paycheck Protection Program (PPP), accounted for even more spending. For example, under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Congress authorized up to $659 billion for the PPP, which is meant to assist Americans employed by

1. FIN. CRISIS INQUIRY COMM'N, THE FINANCIAL CRISIS INQUIRY REPORT 5 (2011), https://www.govinfo.gov/content/pkg/GPO-FCIC/pdf/GPO-FCIC.pdf [hereinafter THE FINANCIAL CRISIS INQUIRY REPORT].

2. COVID-19 is caused by a novel coronavirus that originated with an outbreak in China in December 2019. Miriam N. Lango, *How Did We Get Here? A Short History of COVID-19 and Other Coronavirus-Related Epidemics*, WILEY (Apr. 30, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7283747/. On January 30, 2020, the World Health Organization (WHO) declared the outbreak a Public Health Emergency of International Concern. *Id.* In mid-February 2020, the first person to person spread of COVID-19 was confirmed in the United States. *Id.* On March 11, 2020, WHO declared COVID-19 a pandemic. *Id.* The United States alone spent over $1.62 trillion out of $1.68 trillion in obligations as of October 1, 2020, with another $801 billion in unobligated funds remaining. *The Federal Response to COVID-19*, DATA LAB (Oct. 2020), https://datalab.usaspending.gov/federal-covid-funding/. As of November 12, 2020, the United States had reported over 10 million cases of COVID-19, and 50.2 million cases had been reported globally. Eileen Sullivan, *Covid-19: U.S. Surpasses 10 Million Coronavirus Cases as Global Cases Top 50 Million*, N.Y. TIMES (Nov. 8, 2020), https://www.nytimes.com/live/2020/11/08/world/covid19-coronavirus-live-updates/10-million-americans-have-tested-positive-for-the-coronavirus.

3. U.S. GOV'T ACCOUNTABILITY OFF., GAO-20-632, COVID-19 CONTRACTING: OBSERVATIONS ON FEDERAL CONTRACTING IN RESPONSE TO THE PANDEMIC 9 (2020) [hereinafter GAO-20-632].

small businesses.[4] This program alone has already produced numerous criminal fraud cases.[5]

In addition to stimulus legislation, President Trump invoked the Defense Production Act (DPA),[6] and President Biden has promised to "fully use" it as well.[7] These factors point to a significant uptick in False Claims Act (FCA) litigation. In fact, a global pandemic, economic downturn, and a new presidential administration may create the perfect storm for FCA enforcement. After the Department of Justice (DOJ) reported decade-low FCA recoveries for fiscal year 2020, practitioners acknowledged the volatile FCA environment and predicted the largest increase in FCA enforcement activity in two decades for fiscal years 2021 and 2022.[8] If this prediction holds true

4. *See Small Business Paycheck Protection Program*, U.S. DEP'T OF THE TREASURY, https://home.treasury.gov/policy-issues/coronavirus/assistance-for-small-businesses/paycheck-protection-program. Through August 8, 2020, lenders approved over 5.2 million loans collectively valued at over $525 billion. U.S. SMALL BUS. ADMIN., PAYCHECK PROTECTION PROGRAM (PPP) REPORT: APPROVALS THROUGH 08/08/2020 2 (Aug. 8, 2020), https://www.sba.gov/sites/default/files/2021-09/PPP_Report%20-%202020-08-10-508.pdf. The most current data available is through August 8, 2020. Congress extended the Program in December 2020 in the Economic Aid to Hard-Hit Small Businesses, Nonprofits, and Venues Act as part of the larger Consolidated Appropriations Act of 2021. *See* Economic Aid to Hard-Hit Small Businesses, Nonprofits, and Venues Act, Pub. L. No. 116-260, §§ 301–348, 134 Stat. 1882, 1993 (2020). For a more detailed discussion of the PPP, its rules, and enforcement-related issues, *see generally* Derek Adams et al., *PPP Enforcement Issues to Watch In 2021*, LAW360 (Jan. 11, 2021, 3:58 PM), https://www.law360.com/governmentcontracts/articles/1343048 (discussing PPP in 2020 as well as anticipated actions in the future).

5. *See Coronavirus Fraud News*, U.S. DEP'T OF JUST., https://www.justice.gov/coronavirus/news. For a regularly updated list of Press Releases announcing charges and dispositions in COVID-related fraud cases. Many of these involve PPP loans. *See also* Roberto J. Gonzalez, et al., PRATT'S GOVERNMENT CONTRACTING LAW REPORT § 66.01 (2021) ("The PPP, in particular, has become a lightning rod of concern . . .").

6. *See* Exec. Order No. 13909, 85 Fed. Reg. 16,227 (Mar. 18, 2020).

7. *See, e.g.*, Garen E. Dodge & Susan Gross Sholinsky, *What's in President-Elect Biden's COVID-19 American Rescue Plan?*, NAT'L L. REV. (Jan. 19, 2021), https://www.natlawreview.com/article/what-s-president-elect-biden-s-covid-19-american-rescue-plan. The DPA likely will increase the number of businesses contracting with the government and comes with its own rules, in addition to those contractors normally work with. *See, e.g.*, Kathryn Jordan Mims et al., *Primer: What Companies in the COVID-19 Vaccine Supply Chain Need to Know About the Defense Production Act*, WHITE & CASE (Jan. 19, 2021), https://www.whitecase.com/publications/alert/primer-what-companies-covid-19-vaccine-supply-chain-need-know-about-defense.

8. Matt Wright & Cara Wulf, *2020 False Claims Act Recoveries Were Down by One-Third in 2020…and That's Bad News for Federal Contractors*, GOVERNMENT CONTRACTS LAW (Jan. 19, 2021), https://www.governmentcontractslaw.com/2021/01/2020-false-

and the DOJ and other enforcement authorities make an aggressive push against COVID-related FCA violations, the impact to the government procurement market could be significant. This potential impact is especially concerning given persistent supply chain issues and the threat shortages in critical health care supplies pose to public health, for both the current pandemic and future crises.

The prospect of overly aggressive enforcement yielding a negative impact on the market is frightening but not unprecedented. The impact of the aggressive enforcement response to the subprime mortgage crisis should serve as a warning to enforcement authorities evaluating COVID-related fraud today and in the years to come, especially fraud related to critical health care supplies. The DOJ aggressively pursued lenders during the subprime mortgage crisis and in the years that followed. From 2009 to 2016, it recovered over $7 billion in FCA settlements and judgments related to housing and financial fraud.[9] Yet these efforts likely exacerbated the effects of the crisis, and not all government agencies appreciated their zealous endeavors. The Department of Housing and Urban Development (HUD) particularly took issue with the DOJ's expansive use of the FCA during this time period. HUD's Secretary described the FCA as "a monster that started chasing everybody around the room, making

claims-act-recoveries-were-down-by-one-third-in-2020-and-thats-bad-news-for-federal-contractors/.

> As the incoming Biden Administration takes office and as the vaccine rollout continues, we are confident that FCA investigations and activity at the federal level will return to (and likely exceed) what we all experienced during the eight years of FCA enforcement under President Obama's Department of Justice. The Civil Division, inspectors general, and would-be relators are all on high alert for FCA enforcement opportunities—and for good reason. From the CARES Act and the Coronavirus Response and Relief Supplemental Appropriations Act of 2021, to all of the other government efforts intended to boost economic activity over the past year (including the President-Elect's new $1.9 trillion stimulus package), at no point in recent memory has the economy been so awash in federal money. Those federal dollars all come with a multitude of strings and accompanying risks. . . . We fully anticipate that FY 2021 and FY 2022 could see the largest increase in FCA enforcement activity in the past two decades.

Id. See also Jeff Overley & Daniel Wilson, *Raucous 2021 Awaits FCA Litigants After Low-Key Year*, LAW360 (Jan. 22, 2021, 11:20 PM), https://www.law360.com/health/articles/1345411/raucous-2021-awaits-fca-litigants-after-low-key-year.

9. Press Release, U.S. Dep't of Just., Fact Sheet: Significant False Claims Act Settlements & Judgments Fiscal Years 2009-2016, 7 https://www.justice.gov/opa/press-release/file/918366/download.

their lives miserable, causing them an inordinate amount of pain."[10] In 2010, depository institutions such as banks and credit unions provided approximately 45 percent of the lender base for Federal Housing Administration (FHA)-insured mortgages.[11] By 2019, that share had dropped to less than 14 percent.[12] Many of these institutions withdrew from FHA lending due to uncertain and unanticipated FCA liability.[13] As a result, HUD and the DOJ signed a Memorandum of Understanding in October 2019 that provides guidance for inter-agency coordination of FCA actions against institutions offering FHA-insured mortgages.[14]

The enforcement response to the current crisis risks resurrecting this FCA monster. Admittedly, both the nature of the crises and the markets at issue are different. However, the enforcement risks associated with the COVID crisis are greater in at least two respects. First, the COVID crisis lacks a large stakeholder to monitor the impact of enforcement and check the DOJ's efforts. The mortgage crisis featured HUD, primarily through the Federal Housing Administration, as a central player and primary government stakeholder.[15] Further, HUD exercised its authority through the lens of regulation and compliance, though failures to adhere to these standards played a significant role in the crisis.[16] While the Department of Health and Human Services (HHS) has a significant public health role, its role in the health care supplies market is much different from HUD's role in the mortgage market, and it lacks a corresponding detailed regulatory

10. Ben Lane, *Exclusive: HUD's Carson on False Claims Act–"The monster has been slayed,"* HOUSING WIRE (Oct. 29, 2019, 7:06 PM), https://www.housingwire.com/articles/exclusive-huds-carson-on-false-claims-act-the-monster-has-been-slayed/ (internal quotation marks omitted) [hereinafter *HUD's Carson on FCA*].

11. Press Release, U.S. Dep't of Just., Departments of Justice and Housing and Urban Development Sign Interagency Memorandum on the Application of the False Claims Act (Oct. 28, 2019), https://www.justice.gov/opa/pr/departments-justice-and-housing-and-urban-development-sign-interagency-memorandum-application [hereinafter Press Release, Interagency Memo on the Application of the FCA].

12. *Id*.

13. *Id*.

14. *See* Memorandum of Understanding Between the Dep't of Hous. and Urb. Dev. and the Dep't of Just., Inter-Agency Coordination of Civil Actions Under the False Claims Act Against Participants in FHA Single Family Mortgage Insurance Programs (Oct. 21, 2019), https://www.hud.gov/sites/dfiles/SFH/documents/sfh_HUD_DOJ_MOU_10_28_19.pdf [hereinafter Memorandum of Understanding].

15. *Role on the Federal Housing Administration (FHA) in Addressing the Housing Crisis*, 111th Cong. 7 (2009) (statement of Hon. Shawn Donovan, Secretary, Dep't of Hous. & Urb. Dev.)

16. *See, e.g.*, THE FINANCIAL CRISIS INQUIRY REPORT, *supra* note 1, at 187.

framework within which it could exercise similar authority in tempering enforcement efforts. Second, the COVID crisis threatens public health and the market at issue must remain stable to continuing protecting public health. While a decrease in bank and credit union participation in the FHA lending market presents legitimate economic and social concerns, it simply does not compare to the threat of death and disease posed by a lack of access to critical medical supplies.

This threat of lack of access to critical medical supplies is especially pertinent given COVID's persistence across the globe. The Delta variant of the COVID-19 virus renewed global concerns, producing sizeable spikes in COVID cases in late July 2021.[17] These spikes led federal and state governments, as well as private companies, to reinstate or expand previously relaxed mask mandates.[18] Further, the long-term impact of the COVID vaccine and its efficacy against variants remain uncertain,[19] and the fragile Personal Protective Equipment (PPE) supply chain environment that produced so many shortages throughout the pandemic appears to be re-establishing itself.[20] In fact, just prior to the Delta variant blossoming in the United

17. *See, e.g.*, Jason Douglas & Gabriele Steinhauser, *The Delta Variant Upends the World's Pandemic Response*, THE WALL STREET JOURNAL (July 25, 2021, 4:47 PM), https://www.wsj.com/articles/thedeltavariant-upends-the-worlds-pandemic-response-11627225200. A variant is a mutated version of a virus, and the Delta variant is one variant of the coronavirus that causes COVID-19 which, as of July 2021, was the most contagious form of the virus. *See* Robert Bollinger & Stuart Ray, *COVID Variants: What You Should Know*, JOHNS HOPKINS MEDICINE (Jan. 14, 2022), https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/a-new-strain-of-coronavirus-what-you-should-know.

18. *See, e.g.*, Meghann Myers, *DoD Mask Mandates are Coming Back for Certain COVID-19 Hotspots*, MILITARY TIMES (July 28, 2021), https://www.militarytimes.com/news/your-military/2021/07/28/dod-mask-mandates-are-coming-back-for-certain-covid-19-hotspots/; Press Release, Office of the Governor, Gov. Edwards Temporarily Reinstates Louisiana's Statewide Mask Mandate as COVID Cases and Hospitalizations Threaten Hospitals' Ability to Serve Communities (Aug. 2, 2021), https://gov.louisiana.gov/index.cfm/newsroom/detail/3301; Michael Wayland, *U.S. Automakers Reinstate Mask Mandates at All Facilities Due to Delta Variant*, CNBC (Aug. 3, 2021, 10:48 AM), https://www.cnbc.com/2021/08/03/us-automakers-reinstate-mask-mandates-due-to-delta-variant.html.

19. *See, e.g.*, Brianna Abbott, *Covid-19 Immune Response Could Be Long Lasting, but Variants Present Risks*, THE WALL STREET JOURNAL (July 16, 2021, 8:42 AM), https://www.wsj.com/articles/covid-19-immune-response-could-be-long-lasting-but-variants-present-risks-11626439371.

20. *See* John Wharton, *America's Broken PPE Supply Chain Must Be Fixed Now*, STAT (June 14, 2021), https://www.statnews.com/2021/06/14/covid-19-proved-america-ppe-supply-chain-must-be-fixed/ ("[D]omestic manufacturers are now facing canceled contracts, as large suppliers, hospital systems, and even state

States, the Government Accountability Office (GAO) observed that "the economic and public health recovery from the pandemic and its effects remain[ed] fragile."[21]

To address these risks, the DOJ needs a transparent evaluation framework for assessing FCA violations and making enforcement decisions to compensate for the lack of a primary stakeholder monitoring market impact. The framework should include factors informed by broader policy concerns. The decision is not as simple as avoiding *de minimis* cases in favor of significant, high-dollar cases, but it instead must consider the broader effect on human health outcomes. These concerns are more subtle, but interested agencies such as HHS, the Defense Health Agency (DHA), and the Veterans Health Administration (VHA), can collaborate with the DOJ to implement an evaluation framework and monitor its usage much like HUD continues to do with the FHA lending market.

Part I of this article will outline the nature of federal spending during COVID-19 and will further discuss the roles of the various players in the enforcement system. Part II will analyze the relationship between regulation and markets generally and the impact enforcement specifically can have on a market, using the impact of enforcement in the wake of the subprime mortgage crisis as an example. Part III will look more closely at the potential impact of aggressive COVID-related FCA enforcement on the market for critical medical supplies and will propose evaluation factors and other tools that the DOJ and other enforcement authorities can use to protect this market.

I. AN OVERVIEW OF COVID SPENDING AND FRAUD ENFORCEMENT

A. Government Procurement and Spending During a Crisis

United States law provides multiple mechanisms to facilitate procurement during a pandemic. The mechanisms are both regulatory and statutory, with the Federal Acquisition Regulation (FAR) providing the most direct guidance subject to certain statutory triggering events.

governments once again turn to overseas manufacturing. China is currently flooding the market, selling some surgical masks for one cent, while American companies are struggling to survive.").

21. U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-551, COVID-19: CONTINUED ATTENTION NEEDED TO ENHANCE FEDERAL PREPAREDNESS, RESPONSE, SERVICE DELIVERY, AND PROGRAM INTEGRITY 6 (2021).

1. The Emergency Procurement Framework

FAR Part 18 governs emergency acquisitions federally. Subpart 18.1 outlines various acquisition flexibilities that are generally available without the requirement of an emergency declaration.[22] These general flexibilities include relaxing the requirement for contractors to be registered in the System for Award Management,[23] relaxing the requirement for contracting officers to submit a synopsis notice,[24] limiting the number of sources and foregoing full and open competition due to an unusual and compelling urgency,[25] choosing not to enforce qualification requirements,[26] and permitting single source solicitations under the simplified acquisition threshold.[27] Subpart 18.2 outlines specific emergency acquisition flexibilities.[28] FAR 18.001 lists the scenarios in which emergency acquisition flexibilities can be used, which includes when the President issues an emergency declaration.[29] The FAR incorporates the Stafford Act's definition of emergency for the purposes of these emergency procurement provisions.[30]

The Defense Production Act (DPA), 50 U.S.C. §§ 4501–4568, also plays a significant role in emergency procurement.[31] The DPA grants the Executive Branch broad authority, to include the authority to require individuals and entities to prioritize existing government contracts as well as to accept and perform new contracts:

> The President is hereby authorized (1) to require that performance under contracts or orders (other than contracts of

22. *See* FAR 18.101.

23. *See* FAR 18.102; FAR 4.1102(a)(3)(iii).

24. *See* FAR 18.103; FAR 5.202(a)(2).

25. *See* FAR 18.104; FAR 6.302-2.

26. *See* FAR 18.108; FAR 9.206-1.

27. *See* FAR 18.110; FAR 13.106-1(b)(1)(i).

28. *See* FAR 18.2.

29. *See* FAR 18.001(d).

30. *See* FAR 2.101 (definitions); Disaster Relief Act Amendments of 1974, 42 U.S.C. § 5122. An emergency "means any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States." *Id*.

31. For a more thorough discussion of the DPA and its use during the early stages of the pandemic in the United States, see generally Lauren R. Greenspoon & Ryan D. Class, *Defending the Producers: Examining Product Liability Protection for Compelled Manufacturing under the Defense Production Act*, 87 DEF. COUNSEL J. 1 (2020); CONG. RSCH. SERV., R43767, THE DEFENSE PRODUCTION ACT OF 1950: HISTORY, AUTHORITIES, AND CONSIDERATIONS FOR CONGRESS (2020).

> employment) which he deems necessary or appropriate to promote the national defense shall take priority over performance under any other contract or order, and, for the purpose of assuring such priority, to require acceptance and performance of such contracts or orders in preference to other contracts or orders by any person he finds to be capable of their performance, and (2) to allocate materials, services, and facilities in such manner, upon such conditions, and to such extent as he shall deem necessary or appropriate to promote the national defense.[32]

Agencies used these emergency mechanisms quickly and frequently from the onset of COVID-19 in the United States.

2. Government Spending During COVID-19

On March 13, 2020, President Trump declared the COVID-19 outbreak in the United States to be a national emergency,[33] triggering procurement flexibilities for United States agencies.[34] On March 18, 2020, President Trump issued an executive order invoking the DPA.[35] Shortly thereafter, President Trump used the DPA to compel General Motors to produce ventilators and General Electric, Medtronic, and 3M to produce supplies such as medical devices and PPE.[36] However, following these early uses, the Trump Administration's later use of the DPA was minimal.[37] After the 2020 Presidential Election, then

32. Defense Production Act of 1950, 50 U.S.C. § 4511(a).

33. *See* Proclamation No. 9994, 85 Fed. Reg. 15,337 (Mar. 18, 2020).

34. This declaration also increased certain thresholds which further facilitated emergency spending. The micro-purchase threshold increased from $10,000 to $20,000 for purchases within the United States and $30,000 for purchases outside the United States. *See* FAR 18.202(a); FAR 2.101 (definitions). The simplified acquisition threshold increased from $250,000 to $750,000 for purchases within the United States and $1.5 million for purchases outside the United States. *See* FAR 18.202(b); FAR 2.101 (definitions). The simplified acquisition threshold for commercial items increased from $7 million to $13 million. *See* FAR 18.202(d); FAR 13.500(a) and (c). Effective October 1, 2020, the emergency threshold for micro-purchases outside the United States increased to $35,000, the emergency simplified acquisition threshold for purchases inside the United States increased to $800,000, and the simplified acquisition thresholds for commercial items increased to $7.5 million for ordinary acquisitions and $15 million for emergency acquisitions. *See* Federal Acquisition Regulation: Inflation Adjustment of Acquisition-Related Thresholds, 85 Fed. Reg. 62,485, 62,487–488 (Oct. 20, 2020).

35. *See* Greenspoon & Class, *supra* note 31, at 2; *see also* Exec. Order No. 13909, 85 Fed. Reg. 16,227 (Mar. 18, 2020).

36. *See* Greenspoon & Class, *supra* note 31, at 2.

37. *See* CONG. RSCH. SERV., IN11470, DEFENSE PRODUCTION ACT (DPA): RECENT DEVELOPMENTS IN RESPONSE TO COVID-19 3 (2020) (noting that the

President-Elect Biden quickly signaled his intent to maximize the use of the DPA.[38] Upon taking office, he issued an executive order concerning the public health supply chain, directing the heads of multiple agencies to "take appropriate action using all available legal authorities, including the Defense Production Act, to fill [pandemic response supply] shortfalls as soon as practicable."[39] He also directed the COVID-19 Response Coordinator to submit recommendations to him that include "whether additional use of the Defense Production Act . . . would be helpful" in addressing public health supply chain issues.[40] On February 5, 2021, the Biden Administration announced plans for its first three DPA actions: issuing priority ratings to orders under contracts with Pfizer to address supply bottlenecks for two COVID-19 vaccine manufacturing components, contracting with six suppliers to build new factories and supply lines in the United States for producing COVID-19 tests, and facilitating the construction of new rubber plants to produce surgical gloves for health care workers.[41]

Agencies used procurement flexibilities heavily from the beginning of the pandemic. Through June 11, 2020, approximately $9.4 billion, or 53 percent, of federal contract obligations were identified by the GAO as noncompetitive obligations.[42] More than two-thirds of these obligations, or $6.9 billion, used the unusual and compelling urgency exception to full and open competition.[43] Approximately 91 percent, or about $5.5 billion, of contract obligations for medical and surgical equipment were not competed.[44]

Legislatively, through September 30, 2020, the United States had dedicated $2.6 trillion to its COVID-19 response.[45] Of that, it had obligated $1.8 trillion and expended $1.6 trillion.[46] Through the CARES Act, Congress initially allocated $349 billion to the PPP and

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Administration's implementation of the DPA appeared "sporadic and relatively narrow" and that "no new DPA Title I prioritization orders for health articles have been observed since April 14").

38. *See* Dodge & Sholinsky, *supra* note 7.

39. *See* Exec. Order No. 14001, 86 Fed. Reg. 7,219 (Jan. 21, 2021).

40. *See id*.

41. Ari Holtzblatt et al., *COVID-19: The Biden Administration's First Deployment of the COVID-19: Defense Production Act*, JD SUPRA (Feb. 17, 2021), https://www.jdsupra.com/legalnews/covid-19-the-biden-administration-s-9963366/.

42. GAO-20-632, *supra* note 3, at 15.

43. *Id.*

44. *Id.*

45. U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-191, COVID-19: URGENT ACTIONS NEEDED TO BETTER ENSURE AN EFFECTIVE FEDERAL RESPONSE 10 (2020) [hereinafter GAO-21-191].

46. *Id.*

$46 billion for Treasury direct lending to the airline industry and national security companies, among other things.[47] Congress added another $284 billion to the PPP as part of a second stimulus package in December 2020.[48]

On the procurement front, the CARES Act expanded government contracting opportunities by "vest[ing] contracting authority in [HHS], the Department of Veterans Affairs, the Department of State, and other government agencies to enter into contracts in support of various public health and safety measures."[49] The new contract opportunities include the authority for the Secretary of Veterans Affairs to contract for telecommunications services to provide "expanded mental health services to isolated veterans through telehealth or VA Video Connect,"[50] the authority for the Department of State and the United States Agency for International Development to enter to contracts "for the provision of personal services . . . to prevent, prepare for, and respond to coronavirus,"[51] and the authority for HHS to contract for blood donor awareness and geriatric health care and to modify existing federal health care contracts under the Public Health and Social Services Emergency Fund."[52] Congress appropriated $231.7 billion to the Public Health and Social Services Emergency Fund for use by HHS.[53] As of October 31, 2020, HHS had obligated $8.9 billion and spent $4.1 billion for the Strategic National Stockpile (SNS) "to purchase PPE and ventilators for immediate use as well as to replenish SNS inventory, among other purposes."[54] For example, in April 2020, HHS entered into contracts with seven

47. *See* Gonzalez et al., *supra* note 5.

48. *See* Consolidated Appropriations Act of 2021, Pub. L. No. 116-260, § 323(d)(1)(A) (2020).

49. *See* Gonzalez et al., *supra* note 5.

50. *Id.* at n.46 (quoting CARES Act, Pub. L. No. 116-136, § 20004, 134 Stat. 281, 585 (2020)).

51. *Id.* at n.46 (quoting CARES Act at § 21010).

52. *Id.* at n.46 (citing CARES Act §§ 3226, 3403, 3610).

53. GAO-21-191, *supra* note 45, at 12; "The Public Health and Social Services Emergency Fund (PHSSEF) is an account through which funding is provided to certain HHS offices, such as the Office of the Assistant Secretary for Preparedness and Response." *Id.* at 137; *see* U.S. DEP'T OF HEALTH & HUM. SERVS., FISCAL YEAR 2019 BUDGET-IN-BRIEF: PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND 129 (2018), https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf. [The Office of the Assistant Secretary for Preparedness and Response] leads the federal public health and medical, preparedness, response and recovery to disasters and public health emergencies, in accordance with the National Response Framework. ASPR coordinates the nation's medical and public health capabilities to help Americans during emergencies and disasters, whatever their cause. *Id.*

54. GAO-21-191, *supra* note 45, at 74.

vendors, including Philips, General Motors, and General Electric, for the purchase of over 187,000 ventilators for the Strategic National Stockpile at a cost of over $2.9 billion.[55] The Department of Defense also spent billions of dollars contracting for COVID-related supplies and services.[56] Agencies have used emergency procurement mechanisms for most of these contracts. A June 2020 National Public Radio (NPR) analysis revealed "more than 250 companies that got contracts worth more than $1 million without going through a fully competitive bidding process."[57] Further, while some of these vendors are established within the industry, many vendors contracting with the government for COVID-related supplies and services are new to the industry and filling gaps created by the continued demand.[58]

This historical spending, relaxed procurement standards, and surge of new vendors into the procurement market will undoubtedly increase fraud investigations and litigation, and it will fall on the fraud

55. *See HHS Announces Ventilator Contract with GM under Defense Production Act*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Apr. 8, 2020), https://www.hhs.gov/about/news/2020/04/08/hhs-announces-ventilator-contract-with-gm-under-defense-production-act.html; *HHS Announces Ventilator Contract with Philips under Defense Production Act*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Apr. 8, 2020), https://www.hhs.gov/about/news/2020/04/08/hhs-announces-ventilator-contract-with-philips-under-defense-production-act.html; *HHS Announces New Ventilator Contracts, Orders Now Totaling Over 130,000 Ventilators*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Apr. 13, 2020), https://www.hhs.gov/about/news/2020/04/13/hhs-announces-new-ventilator-contracts-orders-now-totaling-over-130000-ventilators.html; *HHS Announces Ventilator Contract with GE Under Defense Production Act*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Apr. 16, 2020), https://www.hhs.gov/about/news/2020/04/16/hhs-announces-ventilator-contract-with-ge-under-defense-production-act.html.

56. *See*, *e.g.*, Jane Edwards, *3M, Honeywell, O&M Halyward Awarded $133M in DoD Contracts for N95 Mask Production*, GOVCONWIRE (Apr. 22, 2020), https://www.govconwire.com/2020/04/3m-honeywell-om-halyward-awarded-133m-in-dod-contracts-for-n95-mask-production/; Lt. Col. Mike Andrews, *DOD Contract for 60 N95 Critical Care Decontamination Units: $415M Contract, Each Unit Can Decontaminate 80K N95 Masks Per Day*, U.S. DEP'T OF DEF., (Apr. 13, 2020), https://www.defense.gov/Newsroom/Releases/Release/Article/2148352/dod-contract-for-60-n95-critical-care-decontamination-units-415m-contract-each/; Sec'y of the Air Force Pub. Affs., *DAF ACT Contracting Executes N95 Mask Production for DoD*, U.S. AIR FORCE (May 7, 2020), https://www.af.mil/News/Article-Display/Article/2180225/daf-act-contracting-executes-n95-mask-production-for-dod/.

57. *See* Cheryl W. Thompson et al., *Feds Spend Billions On COVID-19 Contracts, Often Without Fully Competitive Bidding*, NPR (June 9, 2020, 5:01 AM), https://www.npr.org/2020/06/09/869052415/feds-spend-billions-on-covid-19-contracts-often-without-fully-competitive-biddin.

58. *See, e.g.*, *id.* ("For many entrepreneurs, this was a chance to get Americans the protective gear they needed and, while they were at it, make a buck. The government needed masks, face shields and other equipment, and it needed them fast.").

enforcement system to sift through these cases and respond appropriately.

B. The United States Fraud Enforcement System

The False Claims Act (FCA), 31 USC §§ 3729–3733, is the primary civil fraud-fighting tool for the United States government.[59] This section will provide a brief discussion of the various players involved in FCA enforcement, focusing primarily on the DOJ. It will then provide a basic overview of the FCA, describing the context in which COVID-related fraud cases will arise. Finally, it will describe the COVID-related enforcement environment to date, focusing on the DOJ and its response to the pandemic.

1. Enforcement System Players

Multiple players have a role in FCA enforcement. The primary player is the DOJ, though Inspectors General (IGs) and Suspension and Debarment Officials also play important roles.[60] The FCA specifically tasks the DOJ with investigating and litigating FCA violations.[61] Both the Civil Fraud Section at Main Justice and the civil divisions in the individual U.S. Attorneys' Offices litigate these cases.[62] While the DOJ can receive information concerning potential FCA violations from a variety of sources, its primary source for these cases is *qui tam* actions.[63] When *qui tam* cases are filed, the DOJ may intervene and take over the litigation,[64] decline intervention and allow the relator to conduct the case,[65] or seek to dismiss the case.[66] Unlike Offices of Inspector General (OIGs), the DOJ does not have published guidance on which FCA violations to pursue, when to intervene, or

59. For a thorough treatise covering the FCA, *see generally* JOHN T. BOESE & DOUGLAS W. BARUCH, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS (5th ed. 2020). For a more concise overview of the various components of the FCA, see *The False Claims Act: A Primer*, U.S. DEP'T OF JUST., https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf (last visited May 19, 2022).

60. For a thorough discussion of the FCA enforcement players, *see* Lynn Halbrooks & Tim Taylor, *The Enforcement Community*, *in* THE FALSE CLAIMS ACT AND GOVERNMENT CONTRACTS 11 (Brian A. Hill et al. eds., 2017).

61. *Id.* at 23; *see also* 31 U.S.C. § 3730(a).

62. Halbrooks & Taylor, *supra* note 60, at 22.

63. *See id.* at 23; *see also* U.S. DEP'T OF JUST., FRAUD STATISTICS OVERVIEW OCTOBER 1, 1986 – SEPTEMBER 30, 2019 1–3 (2020), https://www.justice.gov/opa/press-release/file/1233201/download.

64. *See* 31 U.S.C. § 3730(b)(4)(A).

65. *See* 31 U.S.C. § 3730(b)(4)(B).

66. 31 U.S.C. § 3730(c)(2)(A).

seek dismissal in a *qui tam* case.[67] The DOJ's Justice Manual merely states, "Civil remedies against fraud should be vigorously enforced."[68] However, as discussed later, recently leaked internal guidance does shed some light on how the DOJ determines which cases warrant dismissal.[69]

OIGs exist within each federal agency and are focused on preventing fraud, waste, and abuse.[70] Some agencies have other offices with jurisdiction to investigate FCA violations, but OIGs primarily handle these investigations in close coordination with the DOJ.[71] OIGs receive fraud allegations from many sources, to include the IG Hotline, the DOJ, and concerned individuals, and they generally receive more referrals than they could ever investigate.[72] OIGs thus tend to develop priorities to sift through these referrals.[73] For *qui tam* cases, the relevant agency's OIG investigates allegations

67. Halbrooks & Taylor, *supra* note 60, at 24.

68. U.S. DEP'T OF JUST., JUSTICE MANUAL-COMMERCIAL LITIGATION § 4-4.110 (2018). The Manual further explains:

> Expeditious enforcement of civil remedies should be undertaken to make the government whole, if possible, and to provide a strong deterrent to fraudulent conduct in similar circumstances. Such enforcement is important to the promotion of the highest ethical standards among those who have dealings with the government or who are employed by it.

Id.; *see also* Halbrooks & Taylor, *supra* note 60, at 24.

69. *See generally* Memorandum from Michael D. Granston, Dir., Commercial Litigation, Fraud Section, to Attorneys of the Commercial Litigation Branch, Fraud Section, U.S. Dep't of Just., 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.

70. Halbrooks & Taylor, *supra* note 60, at 11.

71. *Id*. In fiscal year 2019, investigations across the OIG community produced 1,288 successful civil actions. COUNCIL OF THE INSPECTORS GEN. ON INTEGRITY & EFFICIENCY, ANNUAL REPORT TO THE PRESIDENT AND CONGRESS, FISCAL YEAR 2019, 21 (2019). For comparison, OIG investigations led to an average 1,511 successful civil actions per year since fiscal year 2013, ranging from 1,160 in fiscal year 2018 to 1,861 in fiscal year 2015. *See id.* In 2019, these investigations also produced 4,052 suspensions and debarments. *Id.* at 22. OIG investigations led to an average 5,315 suspension and debarments per year since fiscal year 2013, ranging from 3,785 in fiscal year 2018 to 7,244 in fiscal year 2015. *See id*.

72. *See* Halbrooks & Taylor, *supra* note 60, at 14–16.

73. *Id.* at 16. For example, the Department of Health and Human Services (HHS) OIG outlines its priorities in its strategic plan. *See* U.S. DEP'T OF HEALTH AND HUM. SERVS., HHS-OIG STRATEGIC PLAN 2020-2025, 18–23 https://oig.hhs.gov/media/documents/OIG-Strategic-Plan-2020-2025.pdf. The Department of Defense OIG publishes the Defense Criminal Investigative Service priorities online. *See generally Investigative Priorities*, U.S. DEP'T OF DEFENSE OFF. OF INSPECTOR GEN, https://www.dodig.mil/Components/DCIS/Investigative-Priorities/ (last visited May 19, 2022).

raised in the lawsuits.[74] In potential FCA cases referred from other sources, IG agents coordinate with the DOJ to determine whether it is a case DOJ will pursue.[75]

Suspension and Debarment Officials (SDOs) also play a role in FCA enforcement.[76] Each agency has a designated SDO with authority to make suspension and debarment decisions.[77] The FAR specifically lists fraud as a ground for suspension or debarment.[78] SDO involvement in enforcement is independent of OIG and DOJ involvement, yet they are not entirely cut off. Similar to OIGs and the DOJ, SDOs may obtain evidence of fraud from a variety of sources, to include parallel judicial proceedings, other administrative actions, agency investigations, or non-governmental sources.[79] OIGs will consider referral of fraud findings to the agency's SDO, regardless of whether the DOJ pursues the case.[80] Thus, while an SDO's decision in a fraud case may be based on a criminal conviction or indictment, it may be based on uncharged violations.[81] Further, the SDO's decision in fraud cases is discretionary.[82] FAR 9.402 provides the policy guidance to SDO's for exercising this discretion. Specifically, it explains that suspension and debarment are serious and should "be imposed only in the public interest for the Government's protection" and that "[a]gencies shall impose debarment or suspension to protect the Government's interest and only for the causes and in accordance with the procedures set forth in this subpart."[83]

74. Halbrooks & Taylor, *supra* note 60, at 15.

75. *See id*. at 19.

76. *See id*. at 26–27. For a more complete discussion of suspension and debarment, *see generally* THE PRACTITIONER'S GUIDE TO SUSPENSION AND DEBARMENT (Frederic M. Levy & Michael T. Wagner eds., 4th ed. 2018); John Pachter et al., *U.S. Debarment: An Introduction*, *in* THE CAMBRIDGE HANDBOOK OF COMPLIANCE (D. Daniel Sokol & Benjamin van Rooij eds., May 2021); Pascale Hélène Dubois, *Domestic and International Administrative Tools to Combat Fraud & Corruption: A Comparison of US Suspension and Debarment with the World Bank's Sanctions System*, 2012 U. CHI. LEGAL F. 195 (2012); Nathaniel E. Castellano, *Suspensions, Debarments, and Sanctions: A Comparative Guide to United States and World Bank Exclusion Mechanisms*, 45 PUB. CONT. L. J. 403 (2016).

77. Dubois, *supra* note 76, at 199.

78. *See* FAR 9.406-2(a)(1); *see also* FAR 9.407-2(a)(1).

79. *See* Castellano, *supra* note 76, at 413.

80. Halbrooks & Taylor, *supra* note 60, at 19.

81. *See* Castellano, *supra* note 76, at 414.

82. FAR 9.402(a) ("Debarment and suspension are discretionary actions . . .").

83. FAR 9.402(b).

Ultimately, the enforcement systems players are mostly static, and their roles tend to change little over time. Conversely, the scope conduct subject to the FCA varies more and tends to evolve over time. The follow section examines this variety and evolution as they provide the context in which COVID-related FCA cases will arise.

2. The FCA Framework

There is a broad spectrum of fraud under the FCA. One component that contributes to this breadth is the scienter standard. A person satisfies the FCA's scienter standard if that person "has actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information."[84] The FCA does not require proof of a specific intent to defraud,[85] which is unique when compared to fraud standards in other areas of the law.[86] In expressly dropping the specific intent requirement for the FCA, Congress broadened the scope of conduct that the Act might cover.[87] In fact, it is meant to be so broad that it "reach[es] all types of fraud, without qualification, that might result in financial loss to the Government."[88] This more expansive use results in a spectrum of cases ranging from those involving "truly deceitful conduct" to mere inadvertent violations of rules and regulations.[89]

The expansiveness of the FCA fluctuates over time. Materiality and falsity are two FCA components subject to this fluctuation. Materiality essentially looks to the effect of the misrepresentation at issue on the government's decision to pay.[90] A misrepresentation must

84. *See* 31 U.S.C. § 3729(b)(1)(A)(i)–(iii) (2018).

85. *See* 31 U.S.C. § 3729(b)(1)(B) (2018).

86. *See* William E. Kovacic, *The Civil False Claims Act as a Deterrent to Participation in Government Procurement Markets*, 6 SUP. CT. ECON. REV. 201, 217–18 (1998).

87. For a thorough discussion of the term "defraud," its common law usage, the types of fraud, and the interplay between common law fraud and fraud statutes, see Brian Rubens, *Common Law versus Regulatory Fraud: Parsing the Intent Requirement of the Felony Penalty Provision of the Food, Drug, and Cosmetic Act*, 72 U. CHI. L. REV. 1501, 1514–30 (2005).

88. *See* United States v. Neifert-White Co., 390 U.S. 228, 232 (1968).

89. *See* Kovacic, *supra* note 86, at 218.

90. *See* Universal Health Servs. v. United States *ex rel.* Escobar, 579 U.S. 176, 192–93 (2016) (quoting Neder v. United States, 527 U.S. 1, 16 (1999)) (citing Kungys v. United States, 485 U.S. 759, 770 (1988)); *see also* 31 U.S.C. § 3729(b)(4) (2018) (defining "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property").

be material to be actionable.[91] Falsity looks to whether a claim is "false" for purposes of FCA liability. Because the FCA does not define "false" or "fraudulent," the Supreme Court has looked to common law to provide those definitions.[92]

In 2016, the Supreme Court appeared to narrow the materiality standard in *Escobar* and explained that the FCA is not "a vehicle for punishing garden-variety breaches of contract or regulatory violations."[93] More recently, the Supreme Court denied certiorari in a Medicare fraud case where the Third Circuit held that a physician's medical opinion may be "false" under the FCA and that expert testimony challenging that opinion can be appropriate evidence to consider on the question of falsity.[94] Thus, where one case potentially narrowed the scope of materiality for the time being, another has left a broad falsity standard in place in at least some circuits. Administration changes and regulatory changes also contribute to this constant fluctuation, with President Biden's recent Buy American Executive Order serving as one example of the constantly shifting landscape.[95] The heightened scrutiny associated with this order could broaden the scope of claims that courts might consider to be material.[96]

The DOJ's enforcement decisions are driven primarily by *qui tam* cases, where whistleblowers file suit on behalf of the United States. Historically, this was not the case, but Congress significantly bolstered the *qui tam* provisions in 1986.[97] After 1986, the *qui tam* share of the

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91. *See Escobar*, 579 U.S. at 191.

92. United States *ex rel.* Druding v. Druding, 952 F.3d 89, 95 (3d Cir. 2020), *cert. denied sub nom.* Care Alts. v. United States, 141 S. Ct. 1371 (2021) (citing *Escobar*, 579 U.S. at 187).

93. *See Escobar*, 579 U.S. at 194.

94. *See Druding*, 952 F.3d at 98.

95. *See* Exec. Order No. 14005, 86 Fed. Reg. 7475 (Jan. 25, 2021).

96. Sheila A. Armstrong et al., *Biden's Buy American Executive Order May Lead to Increased Fraud Risk and Enforcement*, MORGAN LEWIS (Feb. 1, 2021), https://www.morganlewis.com/pubs/2021/02/bidens-buy-american-executive-order-may-lead-to-increased-fraud-risk-and-enforcement-first100 (describing how "the government's renewed scrutiny of domestic preference laws and increased enforcement of noncompliance" could result in materiality findings for mere technical violations, despite *Escobar's* narrowing of the standard).

97. *See* BOESE & BARUCH, *supra* note 59, at § 1.04. The 1986 amendments to the FCA allowed a qui tam relator to continue as a party even after the government intervenes, increased the relator's percentage of recovery, and guaranteed the relator at least a set fraction of the recovery, absent the existence of disqualifying circumstances. *Id*. The 1986 amendments also introduced protections for relators against retaliation or discrimination. *Id*. More recently, the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010), opened the doors further to *qui*

DOJ's fraud cases began to slowly grow while the number of non-*qui-tam* cases fell.[98] In 1995, *qui tam* cases surpassed non-*qui-tam* cases for the first time and never relinquished the lead.[99] From 2007 to 2019, *qui tam* cases accounted for an average of 82 percent of the DOJ's fraud cases each year.[100] Total recoveries have followed a similar trend, though the year to year fluctuations are greater.[101]

Though the number of *qui tam* cases varies from year to year, historical trends suggest that poor economic conditions create a ripe environment for relators to step forward.[102] The economic conditions created by the pandemic will likely replicate this trend. In the second quarter of 2020, the United States' GDP growth fell by 31.40 percent, the most since the Great Depression.[103] Unemployment reached 14.7 percent, the highest since World War II.[104] Many industries, such as the hospitality and airline industries, have furloughed employees.[105] Even the health care industry has suffered,[106] and health care cases

tam cases. *See* Beverly Cohen, *KABOOM! The Explosion of Qui Tam False Claims Under the Health Reform Law*, 116 PENN ST. L. REV. 77, 96 (2011) ("By both substantially limiting what constitutes public disclosure and substantially expanding the ability of relators to obtain original source protection, the PPACA has tampered with the two predominant limitations to the availability of *qui tam* lawsuits that existed under the 1986 version of the Act. What remains is virtually no protection from otherwise "parasitic" lawsuits that emanate from information disclosed in state and local forums and in private litigation in federal court.").

98. *See* U.S. DEP'T OF JUST., FALSE CLAIMS ACT FISCAL YEAR 2019 STATISTICS 1 (Jan. 9, 2020), https://www.justice.gov/opa/press-release/file/1233201/download.

99. *See id*.

100. *See id*. at 2.

101. *See id*. at 1–2. *Qui tam* recoveries averaged 77 percent of DOJ's total fraud recoveries from 2007 to 2019, ranging from 62 percent in 2016 to 94 percent in 2013. *See id*. at 2.

102. *Cf*. Kovacic, *supra* note 86, at 233 ("Layoffs have created a large pool of potential relators who have less to risk by way of damaging a relationship with an existing employer, and who may have fewer inhibitions with respect to experimenting with new theories of CFCA liability.").

103. Mike Patton, *The Impact of Covid-19 on U.S. Economy and Financial Markets*, FORBES (Oct. 12, 2020, 1:32 PM), https://www.forbes.com/sites/mikepatton/2020/10/12/the-impact-of-covid-19-on-us-economy-and-financial-markets/.

104. *Id*.

105. *Id*.

106. *See, e.g.*, Ani Turner, *Perspective: Health Care Has Recovered Nearly 1 Million Jobs But is Still 590,000 Below February Level*, ALTARUM (Nov. 6, 2020), https://altarum.org/news/health-care-has-recovered-nearly-1-million-jobs-still-590000-below-february-level.

already account for most *qui tam* cases in a normal economy.[107] The ongoing, pandemic-related poor economic conditions will likely only increase the number of relators willing to step forward, both inside and outside the health care industry.[108] A larger pool of willing relators, combined with the increased spending and expanded procurement discussed above, signals an increase in the number of *qui tam* cases in the near future.

3. The FCA Environment During COVID

The DOJ responded quickly to COVID-related concerns. On March 16, 2020, the United States Attorney General released his COVID-19 priorities to all United States Attorneys.[109] His memo was brief and directed offices to "remain vigilant in detecting,

107. For example, 68 percent of all *qui tam* cases in 2020 involved HHS as the primary agency. *See* U.S. DEP'T OF JUST., FALSE CLAIMS ACT FISCAL YEAR 2020 STATISTICS 2 (Jan. 14, 2021), ://www.justice.gov/opa/press-release/file/1354316/download. HHS is an executive department with the mission "to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services." *See About Us*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/about/index.html (last visited May 19, 2022). Importantly, HHS includes the Centers for Medicare & Medicaid Services (CMS), which "provides health coverage to more than 100 million people through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace." *See Centers for Medicare and Medicaid Services*, USA.GOV, https://www.usa.gov/federal-agencies/centers-for-medicare-and-medicaid-services (last visited May 19, 2022). The false claims at issue in most HHS-related FCA cases involve claims submitted to Medicare and Medicaid. *See e.g.*, Letter from Jim Esquea, Assistant Sec'y, U.S. Dep't of Health and Hum. Servs. & Ronald Weich, Assistant Att'y Gen., U.S. Dep't of Just., to the Hon. Charles E. Grassley (Jan. 21, 2011), https://www.healthindustrywashingtonwatch.com/wp-content/uploads/sites/9/2015/06/DOJ-HHS-joint-letter-to-Grassley1.pdf (stating that 98 percent of the health care *qui tam* cases under investigation at that time involved Medicare and Medicaid) [hereinafter Letter from Esquea & Weich].

108. Economists expect the United States economy to add more jobs in 2021 than any year in history, at least based on records going back to 1939. *The Wall Street Journal* reports some forecasts ranging from 5.3 million to 6.7 million jobs added by December 2021. However, even with this record performance, the economy will still be some 4 million jobs short of pre-pandemic levels. Economists expect at least another year of recovery beyond 2021 to make up for pandemic losses. *See* Eric Morath, *This Could Be the Best Year on Record for Job Growth*, THE WALL STREET J. (Jan. 10, 2021, 5:30 AM), https://www.wsj.com/articles/this-could-be-the-best-year-on-record-for-job-growth-11610274600. A recent GAO report similarly noted that "our review of academic studies suggests that the pandemic will likely remain a significant obstacle to more robust economic activity." *See* GAO-21-191, *supra* note 45, at 14.

109. *See generally* Memorandum from the Attorney General to all United States Attorneys (Mar. 16, 2020), https://www.justice.gov/ag/page/file/1258676/download.

investigating, and prosecuting wrongdoing related to the crisis."[110] The Deputy Attorney General issued a similar, follow-up memo just over a week later providing more specifics as to the potential schemes and available legal authorities to use in response.[111] Individual United States Attorney's Offices then began forming COVID-19 fraud task forces with state authorities.[112] Many of these task forces focused on criminal enforcement and protecting individuals,[113] but some highlighted broader areas of concern such as PPE procurement scams and health care and government program fraud.[114]

In early June 2020, DOJ leaders explained to the Senate Judiciary Committee that the Criminal Division was working with other oversight bodies to specifically address concerns related to procurement fraud.[115] In late June, Civil Division leadership outlined its plan for deploying the FCA during COVID-19, noting the expectation that the pandemic environment provides many

110. *Id*. at 2.

111. *See generally* Memorandum from the Deputy Attorney General to all Heads of Law Enf't Components, Heads of Litigating Divs., and United States Attorneys on Dep't of Just. Enf't Actions Related to COVID-19 (Mar. 24, 2020), https://www.justice.gov/file/1262771/download.

112. *See id.*; The United States Attorney's Office Eastern District of Virginia, *EDVA Takes Action Against COVID-19 Fraud in 2021*, U.S. DEP'T OF JUST. (Dec. 20, 2021), https://www.justice.gov/usao-edva/pr/edva-takes-action-against-covid-19-fraud-2021; Karen S. Lovitch & Caitlin A. Hill, *Massachusetts U.S. Attorney's Office Enters into MOU with Office of the Special Inspector General for Pandemic Recovery*, MINTZ (July 30, 2020), https://www.mintz.com/insights-center/viewpoints/2146/2020-07-30-massachusetts-us-attorneys-office-enters-mou-office.

113. *See, e.g., U.S. Attorney Scott Brady and Pennsylvania Attorney General Josh Shapiro Announce Formation of Joint Western Pennsylvania COVID-19 Task Force*, U.S. DEP'T OF JUST. (Mar. 19, 2020), https://www.justice.gov/usao-wdpa/pr/us-attorney-scott-brady-and-pennsylvania-attorney-general-josh-shapiro-announce*; Federal and State Officials Launch Virginia Coronavirus Fraud Task Force*, U.S. DEP'T OF JUST. (Mar. 20, 2020), https://www.justice.gov/usao-edva/pr/federal-and-state-officials-launch-virginia-coronavirus-fraud-task-force.

114. *See, e.g., Connecticut Announces Joint Federal-State COVID-19 Fraud Task Force*, U.S. DEP'T OF JUST. (May 6, 2020), https://www.justice.gov/usao-ct/pr/connecticut-announces-joint-federal-state-covid-19-fraud-task-force.

115. *See COVID-19 Fraud: Law Enforcement's Response to Those Exploiting the Pandemic: Hearing Before the S. Comm. on the Judiciary*, 116th Cong. 1, 7 (2020) (testimony of William Hughes and Craig Carpenito) ("Moreover, the Criminal Division is working closely with General Services Administration OIG, Department of Defense OIG, and Department of Homeland Security OIG, to ensure that taxpayers are not defrauded as the government seeks to procure large quantities of necessary equipment and services on an urgent timeframe."). The joint statement also emphasized that the Department would not tolerate "bad actors who seek to treat the pandemic as an opportunity to defraud their fellow citizens or the government." *See id*. at 1.

unscrupulous actors with the opportunity to profit off fear.[116] The DOJ expanded the Procurement Collusion Strike Force in November 2020 and focused its efforts on COVID-related antitrust issues such as bid rigging, price fixing, and customer or market allocation.[117]

The DOJ brought its first COVID-19 fraud enforcement action on March 22, 2020.[118] It was a criminal fraud case involving a website offering purported World Health Organization vaccine kits and was an early example of bad actors seeking to capitalize on the current crisis.[119] Less than three-weeks later, the DOJ charged an Atlanta man with fraud for attempting to sell millions of nonexistent respirator masks to the Department of Veterans Affairs.[120] However, the primary focus of the DOJ's overall enforcement efforts since these early cases has been on PPP and related COVID-relief fraud.[121]

Even more than a year into the pandemic, it is still too early to know how significant of a surge in FCA litigation COVID-related fraud will produce, both directly and through *qui tam* cases. This uncertainty is largely due to the substantial role *qui tam* cases play in

116. *See 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 JUST. (June 26, 2020), https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims [hereinafter *Deputy Assistant Attorney General Ethan P. Davis Remarks of FCA*].

117. *See Justice Department's Procurement Collusion Strike Force Announces Eleven New National Partners*, U.S. DEP'T OF JUST. (Nov. 12, 2020), https://www.justice.gov/opa/pr/justice-department-s-procurement-collusion-strike-force-announces-eleven-new-national; *Procurement Collusion Task Force*, U.S. DEP'T OF JUST., https://www.justice.gov/coronavirus/DOJresponse#:~:text=The%20Department%20of%20Justice's%20Procurement,as%20bid%20rigging%20and%20collusion (last visited May 19, 2022) ("The [Strike Force] is committed to working with Federal, state, and local government agencies in the wake of the devastation caused by the COVID-19 pandemic to deter, detect, investigate, and prosecute violations of criminal antitrust laws, such as bid rigging and collusion in the competitive bidding process.").

118. *See Justice Department Files its First Enforcement Action against COVID-19 Fraud*, U.S. DEP'T OF JUST. (Mar. 22, 2020), https://www.justice.gov/usao-wdtx/pr/justice-department-files-its-first-enforcement-action-against-covid-19-fraud.

119. *See id*.

120. *See Georgia Man Arrested for Attempting to Defraud the Department of Veterans Affairs in a Multimillion-Dollar COVID-19 Scam*, U.S. DEP'T OF JUST. (Apr. 10, 2020), https://www.justice.gov/opa/pr/georgia-man-arrested-attempting-defraud-department-veterans-affairs-multimillion-dollar-covid. The criminal complaint alleged that the man-made fraudulent misrepresentations in attempt to secure orders 125 million masks and other PPE that would have totaled over $750 million. *Id*.

121. *See Coronavirus Fraud News*, U.S. DEP'T OF JUST., https://www.justice.gov/coronavirus/news (last visited May 19, 2022).

federal FCA litigation and the requirement that these cases be filed under seal.[122] While the minimum time a complaint must remain under seal is 60 days, 31 U.S.C. § 3730(b)(3) permits the government to obtain extensions "for good cause shown." Historically, cases remain under seal for an average of 13 months.[123] Yet state FCA cases are beginning to surface. In October 2020, New York City sued a vendor based on a failure to deliver ventilators under a contract with the City.[124] The complaint included claims for over $12 million under the New York False Claims Act.[125] In December, the State of Indiana sued a vender over an attempted sale of more than 100 million N95 masks to the Indiana Economic Development Corporation.[126] The complaint includes a request for unspecified civil penalties under the Indiana False Claims Act.[127] Further, the DOJ's Fiscal Year 2020 Fraud Statistics already indicate an uptick in FCA cases. Although the DOJ reported the lowest amount of FCA recoveries in over a decade, it reported the most new matters since reporting began in 1986.[128] Some practitioners believe that fiscal years 2021 and 2022 could show the largest increase in FCA enforcement in two decades.[129] This likely surge threatens the stability of the markets for critical medical supplies, which are already weakened due to broader COVID-19 impacts.

122. *See* 31 U.S.C.S.§ 3730(b)(2) (LexisNexis 2021). ("The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.").

123. Letter from Esquea & Weich, *supra* note 107, at 14.

124. *See generally* Complaint, City of New York v. Glob. Med. Supply Grp. LLC, No. 9:20-CV-81880 (S.D. Fla. Oct. 8, 2020).

125. *See id*. at 21.

126. *See generally* Complaint for Injunction, Civil Penalties, and Costs, Indiana v. Puznak, No. 49D13-2012-PL-043285 at 1, 4 (Marion Cnty. Sup. Ct. Dec. 9, 2020).

127. *See id*. at 11.

128. *See* FALSE CLAIMS ACT FISCAL YEAR 2020 STATISTICS, *supra* note 107, at 2. Interestingly, the DOJ reported 250 non-qui tam new matters, more than double FY 2018's numbers, and the first time non-qui tam new matters have eclipsed 200 since 1995. *See id*. at 1–2.

129. *See e.g.*, Matt Wright & Cara Wulf, *2020 False Claims Act Recoveries Were Down by One-Third in 2020 . . . and That's Bad News for Federal Contractors*, GOV'T CONTS. L. (Jan. 19, 2021), https://www.governmentcontractslaw.com/2021/01/2020-false-claims-act-recoveries-were-down-by-one-third-in-2020-and-thats-bad-news-for-federal-contractors/.

II. THE IMPACT OF ENFORCEMENT ON THE MARKET

A. The Relationship Between Regulation and the Market

It is axiomatic that regulations and regulatory decisions impact markets, especially for public procurement.[130] Public procurement regulation, and similar economic regulation, have the potential to generate market failures and distort the competition dynamic of their subject markets.[131] Historical analyses indicate that reactionary regulatory intervention can exacerbate the economic and societal effects of a crisis.[132] For example, there was significant public outcry and concerns for price gouging related to the rise in gasoline prices following Hurricanes Katrina and Rita.[133] These disasters caused significant supply disruption and price gouging concerns prompting calls for price control legislation.[134] One analysis estimated "that for a supply interruption on the scale of Katrina and Rita, the total welfare loss from imposing price controls would have totaled $1.9 billion for the September through October 2005 period."[135] Although the impact of enforcement on the market has generated less discussion than the impact of regulation itself, enforcement decisions possess the same potential for negative impact.

The idea that enforcement decisions specifically can impact the broader market is not new. Examples of this effect date as far back as seventeenth century England. Records from the Privy Council of England indicate that in 1620 the threat of *qui tam* lawsuits exacerbated distributional problems in the English grain market.[136] Certain regions had a surplus of grain, depressing market prices and

130. For extensive discussion of the relationship between public procurement, competition, and markets, see generally ALBERT SÁNCHEZ GRAELLS, PUBLIC PROCUREMENT AND THE EU COMPETITION RULES (2d ed. 2015).

131. *Id*. at 38.

132. *Id.*

133. W. David Montgomery et al., *Potential Effects of Proposed Price Gouging Legislation on the Cost and Severity of Gasoline Supply Interruptions*, 3 J. COMPETITION L. & ECON. 357, 358 (2007).

134. *Id*. at 357–58.

135. *Id*. at 387. Early in the current crisis, experts were already comparing the potential economic impact of COVID-19 to the impact of Hurricane Katrina, describing it as a "Katrina-level event-but on a national scale." *See* Jason Bram & Richard Deitz, *The Coronavirus Shock Looks More Like a Natural Disaster Than a Cyclical Downturn*, LIBERTY ST. ECON. (Apr. 10, 2020), https://libertystreeteconomics.newyorkfed.org/2020/04/the-coronavirus-shock-looks-more-like-a-natural-disaster-than-a-cyclical-downturn.html.

136. *See* J. Randy Beck, *The False Claims Act and the English Eradication of Qui Tam Legislation*, 78 N.C. L. REV. 539, 584 (2000).

creating an economic crisis.[137] Though shipments out of these regions could have alleviated these problems, the threat of a *qui tam* lawsuit based on violations of applicable shipping statutes prevented such distribution.[138] Similar concerns arose in the same time period regarding the spice trade and merchant compliance with statutes, but the government intervened to address the concerns.[139] Though these examples involve only *qui tam* cases, the principles apply more broadly to other enforcement actions. Thus, just as reactionary regulatory measures can exacerbate the effects of a crisis, aggressive enforcement of existing measures can have a similar effect. This effect manifested most recently in the wake of the subprime mortgage crisis.

B. The Impact of Mortgage Fraud Enforcement on the FHA Lending Market

The subprime mortgage crisis spanned from 2007 to 2010 and contributed beyond housing to a broader domestic and global financial crisis. Although an in-depth analysis of the various proposed causes of the crisis is beyond the scope of this article, a basic overview provides a helpful context for understanding the DOJ's enforcement response and the effects of that response, specifically on FHA insured mortgage programs.[140] These enforcement efforts continue even today.[141]

1. Overview of the Mortgage Crisis

The Federal Reserve began cutting interest rates in the early 2000s, causing mortgage rates to fall and home financing to rise.[142] Individuals then began withdrawing built-up equity and spending more money while wages remained steady.[143] At the same time, home

137. *Id*.

138. *Id*.

139. *See id*. at 584–585.

140. For a historical overview of the subprime mortgage crisis, *see* Kale Gans, *Anatomy of a Mortgage Meltdown: The Study of the Subprime Crisis, the Role of Fraud, and the Efficacy of the Idaho Safe Act*, 48 IDAHO L. REV. 123, 126–44 (2011). *See also* THE FINANCIAL CRISIS INQUIRY REPORT, *supra* note 1.

141. *See, e.g.*, Press Release, U.S. Dep't of Just., Guild Mortgage Company to Pay Almost $25 Million to Resolve Allegations It Knowingly Caused False Claims to Federal Housing Administration (Oct. 20, 2020) https://www.justice.gov/usao-dc/pr/guild-mortgage-company-pay-almost-25-million-resolve-allegations-it-knowingly-caused.

142. THE FINANCIAL CRISIS INQUIRY REPORT, *supra* note 1, at 5 (stating that refinancing grew "from $460 billion in 2000 to $2.8 trillion in 2003").

143. *Id.*

sales, average home prices, and new home builds began to grow.[144] The Financial Crisis Inquiry Report succinctly captures the real estate environment during these years:

> Encouraged by government policies, homeownership reached a record 69.2% in the spring of 2004, although it wouldn't rise an inch further even as the mortgage machine kept churning for another three years. By refinancing their homes, Americans extracted $2.0 trillion in home equity between 2000 and 2007, including $334 billion in 2006 alone, more than seven times the amount they took out in 1996. Real estate speculators and potential homeowners stood in line outside new subdivisions for a chance to buy houses before the ground had even been broken. By the first half of 2005, more than one out of every ten home sales was to an investor, speculator, or someone buying a second home. Bigger was better, and even the structures themselves ballooned in size; the floor area of an average new home grew by 15%, to 2,277 square feet, in the decade from 1997 to 2007.[145]

Lenders began making unsound loans they had previously avoided.[146] From 2001 to 2007, the overall mortgage indebtedness in the United States climbed from $5.3 trillion to $10.5 trillion, while the average mortgage debt per household rose from $91,500 to $149,500.[147] As one sales and marketing trainer described the lending atmosphere,

> You had no incentive whatsoever to be concerned about the quality of the loan, whether it was suitable for the borrower or whether the loan performed . . . I knew that the risk was being shunted off. I knew that we could be writing crap. But in the end it was like a game of musical chairs.[148]

144. *See id.* (Average home prices rose "67% in eight years by one measure and hitting a national high of $227,100 in early 2006.").

145. *Id.*

146. *See id.* at 7.

147. The FINANCIAL CRISIS INQUIRY REPORT, *supra* note 1, at 7 ("Lenders made loans that they knew borrowers could not afford and that could cause massive losses to investors in mortgage securities. As early as September 2004, Countrywide executives recognized that many of the loans they were originating could result in 'catastrophic consequences.' Less than a year later, they noted that certain high-risk loans they were making could result not only in foreclosures but also in 'financial and reputational catastrophe' for the firm. But they did not stop."). *Id.* at xxii.

148. *Id.* at 8.

The federal government bore much of this "shunted off" risk.[149]

Ultimately, the housing bubble burst. Housing prices peaked nationwide in April 2006.[150] In 2007, home prices dropped 9%, followed by 17% in 2008.[151] By the end of 2009, home prices had dropped 28% from the 2006 peak.[152] Defaults and delinquencies then began rising. In mid-2006, 1.5% of loans less than a year old were in default, and that number peaked at 2.5% by the end of 2007.[153] The default rate on mortgages taken out by borrowers who never made a single payment exceeded 1.5% in early 2007.[154] The rate of serious delinquencies reached 9.7% by the end of 2009, after remaining near 1% for much of the early 2000s after the 2000 recession.[155] For subprime mortgages specifically, the rate of serious delinquencies on adjustable-rate mortgages rose from less than 10% in 2006 to 40% by late 2009.[156] In early 2011, 10.8 million households, or 22.5% of households with mortgages, owed more on their mortgages than their

149. *See id.* at 456. For example, the federal government or entities acting under government control held the credit risk of two-thirds of all the nontraditional mortgages in the financial system. *See id.* For a more detailed discussion of the types of mortgages, their associated risks, and their role in the crisis, see David Schmudde, *Lessons From the Subprime Mortgage Debacle*, 24 PRACTICAL REAL EST. LAW. 9, 11 (2008). Subprime mortgages are especially risky, and the industry largely ignored the risks as the market boomed:

> Subprime mortgages are nonconforming mortgages that do not meet the standard for conforming loans by a substantial amount. Many times these loans were made with no income verification. Many were made for 100 percent of the value of the home. Many more were obtained by borrowers with the worst credit history, a credit score below 580 . . . In 2006, subprime mortgages made up 24 percent of the mortgage market. The default rate on subprime mortgages is 10.5 percent. Subprime borrowers pay significantly higher interest rates, and significantly higher fees. Because many of these borrowers were simply happy to be offered a mortgage, they were willing to accept very onerous terms. It is not unusual to see loans made at a 10–11 annual percentage rate ("APR"). Typical placement fees to mortgage brokers were $10,000 or more. The people who could not qualify for conforming loans were given mortgages when it was unlikely that they could pay. What many people misunderstood was exactly how bad many subprime mortgages actually were. For a large number of these mortgages, any rational person could see that they were very unlikely to be repaid. *Id.*

150. THE FINANCIAL CRISIS INQUIRY REPORT, *supra* note 1, at 214.

151. *Id.* at 215.

152. *Id.*

153. *Id.* For comparison, this number peaked at 1.0% in the 2000 recession. *Id.*

154. THE FINANCIAL CRISIS INQUIRY REPORT, *supra* note 1, at 215.

155. *Id.* A serious delinquency is one that is 90 days or more past due or in foreclosure. *Id.*

156. *Id.* at 216–17.

house was worth.[157] This environment produced a foreclosure crisis that continued for roughly ten years.[158]

As the bubble burst, the effects rippled across the lending industry and global financial market. Many of the big industry players collapsed. Countrywide, which became the largest home-mortgage provider in 2004, was ultimately purchased by Bank of America in January 2008 for four billion dollars in stock, a sixth of Countrywide's market value before the crisis began.[159] Ameriquest closed shop in 2007, and Washington Mutual was purchased by JP Morgan in 2008.[160] The government-created mortgage purchasers Fannie Mae and Freddie Mac likewise collapsed in 2008,[161] and the government had to bail them out at a cost of $191 billion.[162]

157. *See id.* at 403.

158. *See, e.g.*, William R. Emmons, *The End Is in Sight for the U.S. Foreclosure Crisis*, FED. RESERVE BANK OF ST. LOUIS: ON THE ECONOMY BLOG (Dec. 2, 2016), https://www.stlouisfed.org/on-the-economy/2016/december/end-sight-us-foreclosure-crisis; *see also* Les Christie, *Foreclosures Up a Record 81% in 2008*, CNN MONEY (Jan. 15, 2009, 3:48 AM), https://money.cnn.com/2009/01/15/real_estate/millions_in_foreclosure/ ("U.S. foreclosure filings spiked by more than 81% in 2008, a record, according to a report released Thursday, and they're up 225% compared with 2006."). *Id.*

159. Connie Bruck, *Angelo's Ashes: The Man Who Became the Face of the Financial Crisis*, THE NEW YORKER (June 22, 2009), https://www.newyorker.com/magazine/2009/06/29/angelos-ashes.

160. Braden Goyette, *Cheat Sheet: What's Happened to the Big Players in the Financial Crisis*, PROPUBLICA (Oct. 26, 2011, 1:56 PM), https://www.propublica.org/article/cheat-sheet-whats-happened-to-the-big-players-in-the-financial-crisis. Ameriquest was the nation's largest subprime lender in 2005. *Id.* In 2008, Washington Mutual became the largest failure of an insured depositary institution in the history of the FDIC. *Status of Washington Mutual Bank Receivership*, FED. DEPOSIT INS. CORP. (Oct. 23, 2020), https://www.fdic.gov/resources/resolutions /bank-failures/failed-bank-list/ wamu-settlement.html. At the time it failed, it had $307 billion assets, $188 billion deposits, and over 2,300 branches in fifteen states. *Id.*

161. Miranda Marquit & Benjamin Curry, *Fannie Mae and Freddie Mac*, FORBES (Aug. 7, 2020), https://www.forbes.com/advisor/investing/fannie-mae-and-freddie-mac/. The Federal National Mortgage Association (FNMA or "Fannie Mae") and the Federal Home Loan Mortgage Corporation (FMCC or "Freddie Mac") are both Congressionally created, government sponsored enterprises. Both are now publicly-traded companies with the goal of supporting the United States' financial system. They are not lenders but instead purchase mortgages from lenders. They then package the mortgages into securities and sell the securities to investors.

162. Elizabeth Dexheimer, *Fannie Mae and Freddie Mac*, BLOOMBERG (Feb. 28, 2020), https://www.bloomberg.com/quicktake/fannie-mae-and-freddie-mac-irbtxzdk. For a broader discussion on the roles of Fannie Mae and Freddie Mac in the mortgage crisis, *see* Christopher L. Peterson, *Fannie Mae, Freddie Mac, and the Home Mortgage Foreclosure Crisis*, 10 LOY. J. PUB. INT. L. 149 (2009).

The Federal Housing Administration (FHA) was especially susceptible to losses due to the high-risk lending during this time period. In 2012, HUD reported that $70 billion of the FHA Mutual Mortgage Insurance Fund's future claim payments were attributable to its 2007 to 2009 books of business alone.[163] Congress established the FHA in 1934, and it became part of HUD in 1965.[164] FHA insures private mortgage lenders against the possibility of borrowers defaulting on certain mortgage loans and is one of three government agencies that provide such insurance.[165] FHA's purpose today is to provide access to affordable mortgages to households that might not be well-served by the private market and to provide access to mortgages during market downturns by continuing to insure mortgages.[166] In order to make mortgages available to prospective homebuyers who have the income to repay a mortgage but lack the funds to make a down payment, FHA insures lenders who offer these mortgages against the possibility of borrower default.[167] FHA-insured mortgages also tend to have less stringent credit history requirements than conventional loans and thus are particularly attractive to first-time homebuyers, low- and moderate-income households, minorities, and borrowers with lower credit scores.[168] Lenders must determine

163. U.S. DEP'T OF HOUS. & URB. DEV., ANNUAL REPORT TO CONGRESS FISCALYEAR 2012 FINANCIAL STATUS FHA MUTUAL MORTGAGE INSURANCE FUND 2 (Nov. 16, 2012) [hereinafter 2012 FINANCIAL STATUS FHA MUTUAL MORTGAGE INSURANCE FUND].

164. CONG. RSCH. SERV., RS20530 FHA-INSURED HOME LOANS: AN OVERVIEW 1–2 (2019).

165. *Id*. at 1. The other two agencies are the Department of Veterans Affairs and the Department of Agriculture. Because FHA lacks the limiting factors of the other two agencies such as veteran status or rural location, it is the most widely available of the three. *See id*.

166. *Id*. at 2.

167. *See id*.

168. 2012 FINANCIAL STATUS FHA MUTUAL MORTGAGE INSURANCE FUND, *supra* note 163, at 2–3. In fiscal year 2007, the average credit score across all FHA insured single-family loans was 630, with home purchases averaging 635 and refinances averaging 622. More than 40 percent of FHA-insured loans during that period fell in the 500 and 580 credit score categories. *See* U.S. DEP'T OF HOUS. & URB. DEV., FHA SINGLE-FAMILY MUTUAL MORTGAGE INSURANCE FUND PROGRAMS: QUARTERLY REPORT TO CONGRESS FY 2010 Q4 5–6 (2010). For comparison, the average credit score reached 700 in fiscal year 2011 and sat around 670 in fiscal years 2017 and 2018. *See* U.S. DEP'T OF HOUS. & URB. DEV., ANNUAL REPORT TO CONGRESS REGARDING THE FINANCIAL STATUS OF THE FHA MUTUAL MORTGAGE INSURANCE FUND: FISCAL YEAR 2011 7 (2011); U.S. DEP'T OF HOUS. & URB. DEV., ANNUAL REPORT TO CONGRESS REGARDING THE FINANCIAL STATUS OF THE FHA MUTUAL MORTGAGE INSURANCE FUND: FISCAL YEAR 2018 13 (2018). Usually, a credit score lower than 660 is considered subprime. THE FINANCIAL CRISIS

that loan applicants meet FHA requirements by examining such factors as the applicant's credit, financial status, monthly shelter expenses, funds required for closing expenses, effective monthly income, and debts and obligations.[169] They then certify the accuracy of this information to HUD.[170] These certifications, among other things, can subject lenders to FCA liability.

2. FCA Enforcement of Mortgage Fraud

United States ex rel. Dougherty v. Guild Mortgage Company illustrates the sort of FHA-related FCA claims that arose out of the mortgage crisis.[171] The *Dougherty* complaint alleges that from 2006 to 2012 Guild certified to HUD that over 40,000 mortgages met HUD's requirements and were eligible for FHA insurance.[172] However, Guild allegedly knew that many of the loans were not in fact eligible for FHA insurance, and as a result FHA paid over $100 million in insurance claims on defaulted Guild loans.[173] Guild's issues were related to inexperienced staff, failure to provide proper training, and pressure and incentives placed on loan officers and underwriters to originate and approve more FHA loans.[174] Guild's alleged practices are consistent with the overall lending environment during the boom years.[175] Guild conducted internal reviews of its FHA loans every month as required by HUD, and those reviews identified over 1,400 materially deficient loans from June 2006 to September 2012.[176]

INQUIRY REPORT, *supra* note 1, at 451. Credit scores below 660 also indicate a relatively high default probability. Memorandum from Office of the Comptroller of the Currency Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, Office of Thrift Supervision on Expanded Guidance for Subprime Lending Programs 3 (Jan. 31, 2001), https://www.occ.gov/news-issuances/bulletins/2001/bulletin-2001-6a.pdf.

169. 2012 FINANCIAL STATUS FHA MUTUAL MORTGAGE INSURANCE FUND, *supra* note 163, at 4.

170. One mechanism of certifying this information in the years leading up to the mortgage crisis was with Form HUD-92900-A. *See* U.S. DEP'T OF HOUS. & URB. DEV., FORM HUD-92900-A (2005) (on file with author).

171. *See* Jury Trial Demanded, United States *ex rel.* Dougherty v. Guild Mortg. Co., No. 3:16-CV-02909, at 1 (S.D. Cal. filed Dec. 13, 2013).

172. *Id.*

173. *Id.*

174. *Id.*

175. *Cf.* THE FINANCIAL CRISIS INQUIRY REPORT, *supra* note 1, at xxii ("[M]ajor financial institutions ineffectively sampled loans they were purchasing to package and sell to investors. They knew a significant percentage of the sampled loans did not meet their own underwriting standards or those of the originators.").

176. Jury Trial Demanded, United States *ex rel.* Dougherty v. Guild Mortg. Co., No. 3:16-CV-02909, at 2 (S.D. Cal. filed Dec. 13, 2013).

However, Guild did not report a bad loan to HUD before June 2013.[177] Guild was required to certify the accuracy of the eligibility information on a Form HUD-92900-A for each loan, which HUD and FHA then relied upon to determine whether to provide FHA insurance.[178] The complaint alleges Guild submitted false Forms HUD-92900-A for several loans,[179] specifically by entering data that "overstated the borrower's income and lacked integrity."[180] The DOJ ultimately intervened in the case, and Guild settled the claims in October 2020 for $24.9 million.[181]

It is difficult to clearly describe the DOJ's overall enforcement strategy during the mortgage crisis. The agency received significant criticism for its response efforts, both internally and externally. In March 2014, the DOJ Office of Inspector General reported on its audit of the agency's efforts to address mortgage fraud between fiscal years 2009 and 2011.[182] On the criminal side, the report explained:

> DOJ and its components have repeatedly stated publicly that mortgage fraud is a high priority and during this audit we found some examples of DOJ-led efforts that supported those

177. *Id*.

178. *Id.* at 11. *See also* FORM HUD-92900-A, *supra* note 170. ("The undersigned lender makes the following certifications . . . to induce the Department of Housing and Urban Development - Federal Housing Commissioner to issue a firm commitment for mortgage insurance or a Mortgage Insurance Certificate under the National Housing Act.").

179. Jury Trial Demanded, United States *ex rel.* Dougherty v. Guild Mortg. Co., No. 3:16-CV-02909, at 11 (S.D. Cal. filed Dec. 13, 2013).

180. *See id*. at 18–28.

181. Press Release, U.S. Dep't of Just., Guild Mortgage Company to Pay Almost $25 Million To Resolve Allegations It Knowingly Caused False Claims To Federal Housing Administration (Oct. 20, 2020) https://www.justice.gov/usao-dc/pr/guild-mortgage-company-pay-almost-25-million-resolve-allegations-it-knowingly-caused ("The settlement announced today resolves allegations that Guild Mortgage Company knowingly approved materially ineligible loans that later defaulted and resulted in claims to FHA for mortgage insurance, failed to comply with material program rules that require lenders to maintain quality control programs to prevent and correct underwriting deficiencies, and failed to self-report materially deficient loans that it identified."). For an example with a different type of alleged bad behavior, see Complaint for Violations of False Claim Act, United States *ex rel.* Lagow v. Countrywide Fin. Corp., No. 09-CV-02040, at 9 (E.D.N.Y. May 13, 2009) (alleging that Countrywide inflated appraisals to ensure loans qualified for FHA insurance.). The case ultimately resulted in a $1 billion settlement. Susanna Kim, *Bank of America, Countrywide Whistleblower Kept 3-Year Secret*, ABC NEWS (July 14, 2012), https://abcnews.go.com/Business/millionaire-bank-america-countrywide-whistleblower-search-job/story?id=16772967.

182. OFF. OF THE INSPECTOR GEN., U.S. DEP'T OF JUST., AUDIT OF THE DEPARTMENT OF JUSTICE'S EFFORTS TO ADDRESS MORTGAGE FRAUD i (Mar. 13, 2014), https://oig.justice.gov/reports/2014/a1412.pdf.

> claims . . . However, we also determined during this audit that DOJ did not uniformly ensure that mortgage fraud was prioritized at a level commensurate with its public statements.[183]

The report also noted some examples of civil enforcement initiatives but explained that the DOJ's case management system did not adequately track cases in a way to accurately reflect its mortgage fraud efforts.[184] External criticism focused more on criminal prosecution. *Frontline* heavily criticized the criminal response after the March 2014 audit report release.[185] However, it spoke more favorably of the agency's civil response, noting billions recovered in penalties and borrower relief.[186] For FCA cases specifically, the DOJ had a record year in fiscal year 2014, recovering nearly $6 billion.[187] That total was driven by $3.1 billion recovered due to housing and mortgage fraud, primarily involving FHA lending.[188] Bank of America's $1.85 billion settlement covered FHA-related false claims

183. *Id*.

184. *Id*. at i–ii.

185. Jason M. Breslow, *Watchdog Calls Out DOJ for Mortgage Fraud Response*, FRONTLINE (Mar. 13, 2014), https://www.pbs.org/wgbh/frontline/article/watchdog-calls-out-doj-for-mortgage-fraud-response/.

> In 2012, Attorney General Eric Holder announced that the initiative had resulted in charges against 530 criminal defendants for schemes that cost homeowners more than $1 billion in estimated losses. It turns out, according to the report, that only 107 defendants were charged. Estimated losses, meanwhile, were revised to $95 million–91 percent less than the department's original tally. . . . To date, no single Wall Street executive has faced criminal prosecution for fraud related to the sale of bad mortgages.

Id. For similar criticisms, see Gretchen Morgenson & Louise Story, *In Financial Crisis, No Prosecutions of Top Figures*, N.Y. TIMES (Apr. 14, 2011), https://www.nytimes.com/2011/04/14/business/14prosecute.html ("[T]he Justice Department also rejected calls to create a task force devoted to mortgage-related investigations, leaving these complex cases understaffed and poorly funded, and only much later established a more general financial crimes task force."); *see also* Peter J. Henning, *Prosecution of Financial Crisis Fraud Ends With a Whimper*, N.Y. TIMES (Aug. 30, 2016), https://www.nytimes.com/2016/08/30/business/dealbook/prosecution-of-financial-crisis-fraud-ends-with-a-whimper.html ("The lack of cases identifying individuals for any misconduct related to the financial crisis has become an all-too common complaint. What will be additionally disheartening to many is that even those few cases that were brought have now ended up largely as defeats for the government.").

186. Breslow, *supra* note 185.

187. *Justice Department Recovers Nearly $6 Billion from False Claims Act Cases in Fiscal Year 2014*, U.S. DEP'T OF JUST. (Nov. 20, 2014), https://www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014.

188. *Id*.

allegations, and it acknowledged that it "misrepresented the quality of loans to Fannie Mae, Freddie Mac and the FHA."[189] SunTrust's $418 million settlement was based on similar FHA-related allegations.[190] Ultimately, although the DOJ recovered billions through FCA enforcement, its efforts produced unintended consequences on the lending market.

3. The Impact of FCA Enforcement on the Lending Market

In July 2014, a Federal Housing Finance Agency Office of Inspector General report triggered concerns when it highlighted the growth of nonbank mortgage companies in the government mortgage loan market.[191] The shift also triggered speculation as to the role of enforcement settlements in banks' decisions to leave the market.[192] In 2015, the concerns began to coalesce and the Mortgage Bankers Association specifically began complaining of the mechanism and effect of FCA enforcement.[193] David Stevens, then CEO of the Mortgage Bankers Association, described the FCA enforcement as "using a bazooka on what might be even minor defects in loan files."[194] The concerns also prompted Quicken Loans to sue HUD and

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189. *Id.*

190. *Id.*

> SunTrust admitted that from 2006 to 2012, it originated and underwrote FHA-insured mortgages that did not qualify for federal insurance under the FHA program, failed to institute an effective quality control program to identify noncompliant loans and failed to report the noncompliant loans it did identify to the FHA as required.

Id.

191. FED. HOUS. FIN. AGENCY, OFF. OF INSPECTOR GEN., RECENT TRENDS IN THE ENTERPRISES' PURCHASES OF MORTGAGES FROM SMALLER LENDERS AND NONBANK MORTGAGE COMPANIES 20–21 (2014) (noting an increase in Fannie Mae mortgage purchases from nonbank mortgage companies from 33.2 percent in 2011 to 46.6 percent in the first three quarters of 2013. Freddie Mac showed an increase of 8.4 percent to 20.5 percent over the same time period.) *Id.*; *see also* Brena Swanson, *Nonbanks Pounce on Mortgage Market*, HOUSING WIRE (July 18, 2014), https://www.housingwire.com/articles/30703-nonbanks-pounce-on-mortgage-market/.

192. *E.g.*, Ben Lane, *FHFA Watchdog Raises Concerns About Nonbanks*, HOUSING WIRE (July 17, 2014), https://www.housingwire.com/articles/30681-fhfa-watchdog-raises-concerns-about-nonbanks/ ("Whether it's due to massive settlements stemming from fraudulent pre-crisis lending practices, like the one that Bank of America announced on Tuesday, or due to shrinking mortgage originations, like JPMorgan Chase announced on Wednesday, the big banks are hurting in the mortgage business.").

193. *Mortgage Bankers Association on the Attack Against False Claims Act*, CORP. CRIME REP. (Oct. 23, 2015), https://www.corporatecrimereporter.com/news/200/mortgage-bankers-association-on-the-attack-against-false-claims-act/.

194. *Id.*

DOJ over their FCA investigation and enforcement approach.[195] In July 2017, David Stevens again raised concerns related to FCA enforcement and called for the end of the use of the FCA in the mortgage lending industry.[196] He acknowledged the need for a well-regulated industry but explained that using the FCA to this end was "an inappropriate and harmful response that only reduces access to credit for qualified borrowers, harming the entry level buyer and those on the lower end of home price ranges in America."[197] He raised the concern that simple clerical errors in loans that end up in default can expose lenders to billions of dollars in risk.[198] He then recommended that HUD and DOJ consider Fannie Mae and Freddie Mac's administrative remedial procedures and explained the current market impact of FCA enforcement.

> The unfortunate outcome is hurting homeownership and housing for potential FHA borrowers who are often first time buyers and minorities. Many large lenders have either exited the FHA program entirely or significantly scaled back the business with overlays to credit standards in an effort to make sure that they never get exposed to FCA risk.[199]

In September 2017, the Board of Governors of the Federal Reserve System described the reduction of the largest banks' mortgage lending to low- and moderate-income households in recent years and offered FCA enforcement as one possible reason for the decline.[200] HUD Secretary Ben Carson voiced these concerns in his

195. Complaint, Quicken Loans Inc. v. United States, No. 15-CV-11408, at 1 (E.D. Mich. Apr. 17, 2015).

196. *See* David Stevens, *The False Claims Act Has No Place in Housing*, HOUSING WIRE (July 17, 2017), https://www.housingwire.com/articles/40701-the-false-claims-act-has-no-place-in-housing/.

197. *Id*.

198. *See id*.

> This is important because HUD has been using the FCA to review loans that go into default over a number of years from a lender. They do this usually by sampling a percentage of defaults and then taking the percentage of errors and applying that to the entire portfolio of loans originated. This can result in literally billions of dollars of risk to lenders who participate in the program. Why? Because the FCA comes with penalties that are treble the actual damages. For example, a $200,000 loan with an immaterial clerical error that goes into default and generates a loss for FHA of $50,000 can cost the lender 3 times the actual damages, or $150,000 in the above case. This is for one loan. *Id.*

199. *Id*.

200. *See* Neil Bhutta et al., *The Decline in Lending to Lower-Income Borrowers by the Biggest Banks*, BD. OF GOVERNORS OF THE FED. RSRV. SYS. (Sept. 28, 2017),

October 2017 testimony before the House of Representatives Financial Services Committee.[201] In July 2018, the Department of the Treasury released its fourth report in response to Executive Order 13,772, which called for the Treasury to identify laws and regulations that are inconsistent with the Order's Core Principles.[202] The report acknowledged the residential mortgage market's "fundamental shift in composition since the financial crisis" and attributed some of the shift to "post-crisis regulatory environment, including enforcement actions brought under the False Claims Act for violations related to government loan insurance programs."[203] It specifically found that "[t]he use of the FCA to impose civil liability for violations of mortgage origination and servicing requirements has likely contributed to the exit of traditional commercial lenders from federal mortgage programs, raising the cost and limiting borrower access to

https://www.federalreserve.gov/econres/notes/feds-notes/the-decline-in-lending-to-lower-income-borrowers-by-the-biggest-banks-20170928.htm.

201. *See The Future of Housing in America: Oversight of the Department of Housing and Urban Development: Hearing Before the H. Comm. on Fin. Sers.*, 115th Cong. 54–55 (2017) (statement of Ben Carson, Secretary, U.S. Dep't of Hous. and Urb. Dev.). The following exchange between Sen. David Trott of Michigan and Secretary Carson demonstrates these concerns:

> Mr. Trott: So let's talk about the FHA program. There is a great article from the HousingWire from July of this year, written by David Stevens from the MBA. And it talks about the unprecedented use of the False Claims Act by HUD and the Department of Justice, starting around 2011, under President Obama. And the False Claims Act is a very important Federal statute…And so I am all for the False Claims Act being used. But are you familiar at all with how it has been used in the context of FHA lending–
> Secretary Carson: Yes
>
> Mr. Trott: And some of the ramifications of that?
> Secretary Carson: Very much so.
> Mr. Trott: . . . So do you have any plan . . . to quickly address that problem?
> Secretary Carson: Yes. We are already addressing that problem, our staff along with the DOJ staff, and we are committed to getting that resolved, because it is ridiculous, quite frankly. And I am not exactly sure why there had been such an escalation previously, but the long-term effects of that escalation is obviously providing fewer appropriate choices for consumers, and that is exactly the opposite of what we should be doing.

202. *See* Press Release, U.S. Dep't of the Treasury, Treasury Releases Report on Nonbank Financials, Fintech, and Innovation (July 31, 2018), https://home.treasury.gov/news/press-releases/sm447. *See also* U.S. DEP'T OF THE TREASURY, A FINANCIAL SYSTEM THAT CREATES ECONOMIC OPPORTUNITIES: NONBANK FINANCIALS, FINTECH, AND INNOVATION: REPORT TO PRESIDENT DONALD J. TRUMP 3 (2018) [hereinafter FINANCIAL SYSTEM REPORT]; *see also* Exec. Order No. 13772, 82 Fed. Reg. 9,965 (Feb. 3, 2017).

203. FINANCIAL SYSTEM REPORT, *supra* note 202, at 11.

mortgage credit for federally insured or guaranteed loans."[204] Regarding the broader market impact of the FCA enforcement efforts, the report explained "[t]he departure of depositories from federally insured mortgages has likely had negative impacts on borrower access to credit by reducing the available lending universe and encouraging remaining lenders to add credit and risk overlays to their underwriting to mitigate lower credit quality, but nonetheless creditworthy, borrowers."[205]

4. The HUD-DOJ Memorandum of Understanding

In October 2019, the DOJ entered into a Memorandum of Understanding (MOU) with HUD to address FCA enforcement efforts directed at participants in FHA insurance programs.[206] Per HUD, the MOU "is intended to address concerns that uncertain and unanticipated FCA liability for regulatory defects led to many well-capitalized lenders, including many banks and credit unions . . . to largely withdraw from FHA lending."[207] HUD's press release further explains that this withdrawal by banks and credit unions has shifted the origination share of depository institutions to 14 percent of FHA-insured mortgages compared to 45 percent in 2010.[208] Thus, while neither the MOU nor HUD's press release specifically mention the DOJ's aggressive enforcement efforts, the language of both, and the fact that the MOU was even necessary, tie the DOJ's enforcement efforts to the withdrawal of these institutions from the FHA lending market. Secretary Carson's separate statements clarified the connection:

> [Banks] were in before and obviously they were in because it was beneficial to them. And then the housing crisis occurred and all of the sudden, the False Claims Act became a monster that started chasing everybody around the room, making their lives miserable, causing them an inordinate amount of pain. So they got out. But now, the monster has been slayed.[209]

The MOU outlines the coordination expectations and respective responsibilities of HUD and DOJ for FHA-related FCA claims.[210] It

204. *Id*. at 97. For a more thorough discussion of how DOJ and HUD used the FCA in the mortgage context, *see id*. at 110–13.

205. *Id*. at 110.

206. *See generally* Memorandum of Understanding, *supra* note 14.

207. Interagency Memo on the Application of the FCA, *supra* note 11.

208. *Id*.

209. *HUD's Carson on FCA*, *supra* note 10.

210. *See generally* Memorandum of Understanding, *supra* note 14.

describes five aspects of HUD and DOJ's decision-making process for potential FCA enforcement:

- First, it acknowledges HUD's expectation that violations will be primarily enforced through HUD's administrative proceedings.[211]
- Second, when HUD identifies violations that may merit FCA enforcement, it will refer those to the Mortgagee Review Board (MRB) for evaluation.[212] The MRB will apply HUD's two-fold "FCA Evaluation Standards" in conducting its evaluation.[213] The first of these standards imposes a quantity or monetary threshold on the violations.[214] The second of these standards requires "aggravating factors warranting pursuit of FCA litigation such as evidence that the violations are systemic or widespread."[215] As an overarching principle for evaluating violations, the MOU explains that "HUD recommends that FCA matters be pursued only where such action is the most appropriate method to protect the interests of FHA's mortgage insurance programs, would deter fraud against the United States, and would generally serve the best interests of the United States."[216]
- Third, in both cases referred to DOJ by a party other than HUD and those DOJ initiates directly, DOJ will confer with HUD during all phases of the case.[217] In conferring, HUD will provide its views on the case, to include its support or opposition to pursing FCA enforcement and whether the case would meet HUD's FCA Evaluation Standards.[218]
- Fourth, in *qui tam* cases specifically, HUD may recommend DOJ seek dismissal if HUD does not support the case.[219] HUD will apply its FCA Evaluation Standards here as well, but this provision

211. *Id*. at 2–3.
212. *Id*. at 3.
213. *Id*.
214. *See id*. ("Tier 1 or equivalent violations exist in at least 15 loans, or Tier 1 or equivalent violations exist in loans with unpaid principal balance (UPB) or claims of at least $2.0 million.").
215. *See* Memorandum of Understanding, *supra* note 14, at 3.
216. *See id*.
217. *Id*.
218. *Id*.
219. *Id*.

includes as a justification for opposition a situation where "the litigation threatens to interfere with HUD's policies or the administration of its FHA lending program and dismissal would avoid these effects."[220]

- Fifth, HUD may pursue other remedial actions as necessary even if the MRB declines referral or recommends against FCA litigation.[221]

Whether the MOU achieves its objective of encouraging banks to return to the FHA and broader government loan market remains to be seen. Some industry insiders are skeptical.[222] These loans offer minimal returns in exchange for their higher risk, and most banks are unable to take the risk.[223] Further, with the FCA hanging over their heads, "[i]n order for a bank or nonbank to service loans in the government market, the operations must be essentially error free."[224] The mortgage origination landscape has shifted significantly in the years since the mortgage crisis and the subsequent enforcement efforts. The Financial Stability Oversight Council outlined these changes in its 2019 annual report:

> Nonbank mortgage companies have assumed a larger role in the origination and servicing of residential mortgages over the past decade . . . Among the 25 largest originators and servicers, nonbanks currently originate approximately 51 percent of mortgages and service approximately 47 percent, up from just 10 percent and 6 percent in 2009, respectively. Nonbanks are particularly heavily involved in the origination of mortgages that are securitized by Ginnie Mae and the Enterprises, accounting for 85 percent of Ginnie Mae MBS, 60 percent of Fannie Mae MBS, and 53 percent of Freddie Mac MBS in 2019.[225]

220. *See* Memorandum of Understanding, *supra* note 14, at 3–4.

221. *Id*. at 4.

222. *See* Christopher Whalen, *Return of Banks to Government Loan Market Still Doubtful*, NAT'L MORTG. NEWS (Jan. 13, 2020, 4:02 PM), https://www.nationalmortgagenews.com/opinion/return-of-banks-to-government-loan-market-still-doubtful.

223. *See id*.

224. *Id*.

225. FIN. STABILITY OVERSIGHT COUNCIL, 2019 ANNUAL REPORT 42 (2019), https://home.treasury.gov/system/files/261/FSOC2019AnnualReport.pdf. The report uses the term "Enterprises" to refer to Fannie Mae and Freddie Mac. *See id*. at 7.

The report speculated as to the various factors that may have contributed to this shift, though risk was a common theme.[226] It specifically noted a possible “aversion to potentially significant legal and reputational risks that may arise from delinquencies and foreclosures.”[227] Whether for good or ill, it may be too little too late for the MOU to have any measurable impact on the mortgage market today. Nevertheless, the MOU and the circumstances that produced it can help the DOJ and other enforcement authorities shape their COVID-related enforcement approach to avoid similar significant impacts on the health care market.[228]

III. COVID-RELATED ENFORCEMENT AND THE MARKET

There is minimal guidance currently for assessing market impact of COVID-related enforcement decisions, or even market impact of enforcement decisions generally. Some regulations, executive orders, and legislation touch on it and at the very least support the notion that it is a valid enforcement consideration. The DOJ also has some limited, existing guidance to support this idea. However, despite supporting the idea that market impact is a valid consideration, this DOJ guidance does not specifically address how to assess market impact and what role that assessment plays in enforcement decisions, specifically in the context of enforcement decisions with public health consequences such as with COVID-19. To address those gaps, this section proposes evaluation factors and implementation mechanisms that the DOJ and other enforcement authorities can use to account for market impact.

A. Existing Authorities Addressing Market Consideration

The Federal Acquisition System depends on a stable marketplace. Though it does not explicitly reference market impact, the FAR outlines broader considerations that depend on a stable market. FAR 15.404-4(a)(2) acknowledges the importance that contractors make a reasonable profit to “stimulate efficient contract performance, attract the best capabilities of qualified large and small business concerns to Government contracts, and maintain a viable industrial base.”[229]

226. *Id.* at 42.
227. *Id.*
228. This shaping is especially important since “. . . if the 2008 financial crisis is any guide, the distribution of COVID-19 relief funds can be expected to spur investigative activity for years to come.” *See* Gonzalez, *supra* note 5.
229. FAR 15.404-4(a)(2).

Further, competition is one of the pillars of the United States procurement system.[230] Thus, while other factors play a role in fostering competition, a robust competitive regime requires commitment to the marketplace.[231]

These market themes surface periodically in both executive orders and legislation. Most recently, executive orders responding to COVID-19 and the 2021 National Defense Authorization Act (NDAA) have voiced concerns related to regulatory and enforcement impact on markets for health care supplies. For example, Section 849 of the 2021 NDAA directs the Secretary of Defense to analyze the sourcing and industrial capacity of certain critical supplies and consider various procurement actions to protect the associated supply chains.[232] In doing so, the Secretary should consider economic implications, as well as the impact of those actions on the market for those goods and services.[233] President Trump's May 19, 2020 Executive Order outlining efforts to promote economic recovery in the wake of COVID-19 similarly acknowledged these concerns.[234] The order directed federal agencies to remove barriers to "the innovation, initiative, and drive of the American people."[235] It then specifically outlined the President's policy expectations for federal agencies:

> Agencies should address this economic emergency by rescinding, modifying, waiving, or providing exemptions from regulations and other requirements that may inhibit economic recovery, consistent with applicable law and with protection of the public health and safety, with national and homeland security, and with budgetary priorities and operational feasibility. *They should also give businesses, especially small*

230. Steven L. Schooner, *Desiderata: Objectives for a System of Government Contract Law*, PUB. PROCUREMENT L. REV. 2002, 103, 104. *See also* FAR 1.102-2(a)(5) ("It is the policy of the [Federal Acquisition System] to promote competition in the acquisition process.").

231. *Id.*; GRAELLS, *supra* note 130, at 63 ("From an economic point of view, public procurement regulations should be seen as regulatory mechanisms that try to foster competition among potential sellers in order to extract the best possible economic conditions in all transactions conducted by the public buyer.").

232. William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Pub. L. No. 116-283, 134 Stat. 3388 (codified as 10 U.S.C. 10713(b)(1)(B)).

233. *Id.* at § 849(a)(2) ("The analyses conducted pursuant to paragraph (1) shall consider national security, economic, and treaty implications, as well as impacts on current and potential suppliers of goods and services.").

234. Exec. Order No. 13924, 85 Fed. Reg. 31,353 (May 22, 2020); *see Deputy Assistant Attorney General Ethan P. Davis Remarks of FCA*, *supra* note 116.

235. Exec. Order No. 13924, 85 Fed. Reg. 31,353 (May 22, 2020).

> *businesses, the confidence they need to reopen by providing guidance on what the law requires; by recognizing the efforts of businesses to comply with often-complex regulations in complicated and swiftly changing circumstances; and by committing to fairness in administrative enforcement and adjudication.*[236]

It also directed agency heads to consider whether to formulate enforcement discretion priorities that "decline enforcement against persons and entities that have attempted in reasonable good faith to comply with applicable statutory and regulatory standards."[237]

Some courts have also recognized the validity of these market impact concerns. For example, in *United States ex rel. Sequoia v. Sunland Packing House Co.*, the United States District Court for the Eastern District of California acknowledged that broader economic impact is a legitimate ground for the government to seek dismissal of a *qui tam* case.[238] *Sequoia* is a unique and complex FCA case involving the California citrus market. It involved 27 partially consolidated FCA cases with claims based on alleged violations of certain citrus regulations.[239] The United States Department of Agriculture presented multiple government interests in support of the

236. *Id*. at 31,353–54 (emphasis added).

237. *Id*. at 31,354–55.

238. 912 F. Supp. 1325, 1345–46 (E.D. Cal. 1995).

239. *Id*. at 1328. The court also established what subsequently became known as the *Sequoia* test for determining whether the government's decision to dismiss a *qui tam* case is justified: "A two step analysis applies here to test the justification for dismissal: (1) identification of a valid government purpose; and (2) a rational relation between dismissal and accomplishment of the purpose." *Id*. at 1341. The Ninth Circuit affirmed the district court's adoption of this standard on appeal. *See* United States *ex rel.* Sequoia Orange Co. v. Baird-Neece Packing Corp., 151 F.3d 1139, 1145 (9th Cir. 1998). The Tenth Circuit has also adopted this standard. *See* Ridenour v. Kaiser-Hill Co., 397 F.3d 925, 936 (10th Cir. 2005). The D.C. Circuit rejected the *Sequoia* test, holding instead that the government possesses an unfettered right to dismiss a *qui tam* case. *See, e.g.*, Swift v. United States, 318 F.3d 250, 252 (D.C. Cir. 2003). The Fifth Circuit recently refused to adopt either test, holding that the government met the *Seqouia* standard to the extent it applied. *See* United States *ex rel.* Health Choice All. v. Eli Lilly & Co., 4 F.4th 255, 268 (5th Cir. 2021). District courts in circuits without an established precedent fall into both camps. *See* United States *ex rel.* Sibley v. Delta Reg'l Med. Ctr., 2019 U.S. Dist. LEXIS 48150, *2 (N.D. Miss. 2019) (holding that the government possesses the unfettered discretion to dismiss a *qui tam* case); *see* United States v. EMD Serono, Inc., 370 F. Supp. 3d 483, 487–89 (E.D. Pa. 2019) (adopting the *Sequoia* test). The appropriateness of either of these tests is beyond the scope of this article. However, the test applicable to a given case will determine whether and to what extent the DOJ must articulate a justification for dismissal. This variance makes it difficult to ascertain through court dockets DOJ trends for dismissal justifications.

DOJ's motion to dismiss the case, including the desire "to curtail the drain on private resources resulting from the litigation."[240] The government sought "to protect economic viability of the citrus industry" and was concerned that the litigation would bankrupt the defendants.[241] The court's analysis centered around the Agricultural Marketing Agreement Act of 1937 (AMAA).[242] The AMAA's aims included protecting the financial health and ensuring the economic vitality of the agricultural industry.[243] As such, the court concluded that dismissing the claims was a rational means of advancing the government's interests under the AMAA.[244]

The *Sequoia* court's analysis demonstrates the legitimacy of accounting for the potential market impact of aggressive COVID-related fraud enforcement today. The fact that *Sequoia* involved a statute with explicit goals of fostering market health does not detract from this point. The AMAA merely provided the context for the analysis. There is no requirement that the government interest at issue have some statutory or other explicit policy basis. Even if such a requirement exists, the market concerns voiced in executive orders and the 2021 NDAA provide ample justification for the government to assert such an interest in COVID-related cases.[245] Similarly, if the DOJ and other enforcement authorities developed their own policies related to market impact, those policies should provide similar foundation for a motion to dismiss in *qui tam* cases in jurisdictions following the *Sequoia* test.

B. The DOJ's Limited Existing Guidance

The DOJ does not ignore market impact completely. During the late-1990s, following a failed push by the American Hospital Association to amend the FCA, then-Deputy Attorney General Eric

240. *Sequoia*, 912 F. Supp. at 1341–42.
241. *Id*. at 1344.
242. *See id*. at 1345–47.
243. *Id.* at 1345–46.
244. *Id*. at 1346.
245. For example, Executive Order 14,001 "directs immediate actions to secure supplies necessary for responding to the pandemic, so that those supplies are available, and remain available, to the Federal Government and State, local, Tribal, and territorial authorities, as well as to America's health care workers, health systems, and patients." Exec. Order No. 14001, 86 Fed. Reg. 7,219, (Jan. 26, 2021). It then directs various agency heads to assess "the extent to which liability risk, regulatory requirements, or other factors impede the development, production, and procurement of pandemic response supplies, and any actions that can be taken, consistent with law, to remove those impediments." *See id.*

Holder issued a memo addressing the use of the FCA in health care cases.[246] The memo recognized the market impact of enforcement at least in the context of rural and community health care providers. It directed attorneys working on cases involving these providers to "consider the impact an action may have on the community being served" and acknowledged that "care must be taken to consider the community's interest in access to adequate health care" when making enforcement decisions.[247] This consideration appears to have been workable. At the six-month review of the memo Deputy Attorney General Holder concluded that "the Guidance Memorandum - and the policies and procedures contained therein - has been extremely effective and that major revisions are not necessary at this time."[248]

Additionally, the Criminal Division instructs its attorneys to consider market impact when evaluating a business's inability to pay a criminal fine or penalty.[249] Specifically, in considering collateral consequences, attorneys are permitted to "consider whether the proposed monetary penalty is likely to cause layoffs, product shortages, or significantly disrupt competition in a market."[250] Interestingly, although the Civil Division's version of this memo contains a similar paragraph on collateral consequences, it lacks any mention of market impact.[251]

The DOJ also considers market impact to a degree when evaluating *qui tam* cases for dismissal. The FCA gives the government the authority to dismiss these cases brought by whistleblowers.[252] The leaked "Granston Memo" from 2018 outlined the factors Fraud

246. Memorandum from Eric H. Holder, Jr., Deputy Attorney General to All United States Attorneys (June 3, 1998), https://www.justice.gov/archives/dag/memo-guidance-use-false-claims-act-civil-health-care-matters-june-3-1998. *See also* BOESE & BARUCH, *supra* note 59, at § 1.04.

247. Memorandum from Eric H. Holder, Jr., *supra* note 246.

248. Memorandum from Eric H. Holder, Jr., Deputy Attorney General, U.S. Dep't of Just. on Guidance on the Use of the False Claims Act in Civil Health Care Matters to All United States Attorneys (Feb. 3, 1999), https://www.justice.gov/sites/default/files/dag/legacy/2008/06/27/holder-02031999.pdf. *See also* BOESE & BARUCH, *supra* note 59, at § 1.04.

249. Memorandum from Brian A. Benczkowski, Assistant Attorney General, U.S. Dep't of Just. on Evaluating a Business Organization's Inability to Pay a Criminal Fine or Criminal Monetary Penalty to All Criminal Division Personnel (Oct. 8, 2019), https://www.justice.gov/opa/speech/file/1207576/download.

250. *Id*.

251. *See* Memorandum from Ethan P. Davis, Acting Assistant Attorney General, U.S. Dep't of Just. on Assessing an Entity's Assertion of an Inability to Pay to All Civil Division Employees (Sept. 4, 2020), https://www.justice.gov/civil/page/file/1313361/download.

252. *See* 31 U.S.C. § 3730(c)(2)(A).

Section attorneys should consider when conducting these evaluations.[253] The memo notes the fact that the FCA does not provide specific grounds for dismissal and that the government expends significant resources monitoring and evaluating these cases.[254] It then provides a non-exhaustive list of seven factors the Department can use to evaluate cases for dismissal.[255] At least one of these factors touches on market impact: the third factor labeled "Preventing Interference with Agency Policies and Programs."[256] Most of the discussion of this factor focuses on interference with particular agency efforts.[257] However, the discussion concludes by noting that "there may be instances where an action is both lacking in merit and raises the risk of significant economic harm that could cause a critical supplier to exit the government program or industry."[258]

More recently, Civil Division leadership included broader economic and innovation impact when addressing the use of the FCA during COVID-19. On June 26, 2020, Ethan Davis, Principal Deputy Assistant Attorney General for the Civil Division, outlined some principles to guide the Civil Division's enforcement efforts.[259] Mr. Davis acknowledged the "critical role" the private sector plays in ending the pandemic and restarting the economy.[260] He further explained how agency partners, such as the FDA and HHS, have exercised enforcement discretion in areas where regulations might

253. *See generally* Memorandum from Michael D. Granston, Dir. Com. Lit. Brach, Fraud Section on Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A) to Commercial Litigation Branch, Fraud Section Attorneys (Jan. 10, 2018), https://www.insidethefca.com/wp-content/uploads/sites/300/2018/12/Granston-Memo.pdf.

254. *Id*.

255. *Id*. The seven factors are (1) curbing meritless *qui tams*, (2) preventing parasitic or opportunistic *qui tam* actions, (3) preventing interference with agency policies and programs, (4) controlling litigation brought on behalf of the United States, (5) safeguarding classified information and national security interests, (6) preserving government resources, and (7) addressing egregious procedural errors. *Id*. at 3–7.

256. *Id*. at 4–5.

257. One example is the intent of the Department of Agriculture to replace the regulations upon which a relator based its claims. Memorandum from Michael D. Granston, Dir. Com. Lit. Brach, Fraud Section on Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A) to Commercial Litigation Branch, Fraud Section Attorneys 5 (Jan. 10, 2018), https://www.insidethefca.com/wp-content/uploads/sites/300/2018/12/Granston-Memo.pdf.

258. *Id*. at 5.

259. *Deputy Assistant Attorney General Ethan P. Davis Remarks of FCA*, *supra* note 116.

260. *See id*.

hamper innovation and stated that the Civil Division was similarly "committed to ensuring that American businesses have the certainty and level playing field needed to respond to the pandemic and to make the economy roar back to life."[261] In addressing the CARES Act specifically, Mr. Davis provided some insight into the proper use of the False Claims Act during a public health crisis:

> At the same time, however, we will be careful not to discourage businesses, health care providers, and other companies from accessing in good faith the important resources that Congress made available in the CARES Act. While companies have an obligation to comply with federal law in submitting claims for payment, the Supreme Court has held that the "False Claims Act is not 'an all-purpose antifraud statute,'" nor is it "a vehicle for punishing garden-variety breaches of contract or regulatory violations." Rather, the Act applies only to *knowing* violations of federal law that are *material* to the government's payment decisions. Complying with thousands of rules, terms and conditions, and complicated guidance can be a dizzying task under normal circumstances; it is significantly more difficult in times like today.[262]

Mr. Davis also pointed to regulatory measures HHS has taken to encourage entities and individuals to produce countermeasures to fight COVID-19 and explained, "We likewise want to make sure that the risk of unwarranted False Claims Act liability does not discourage companies from helping to address the current health threat."[263]

C. Risks Associated with Aggressive COVID-Related Enforcement

Aggressive enforcement poses increased risk to the government procurement market for critical health care supplies. While the broader health care market has weathered aggressive enforcement for decades now,[264] the FCA nevertheless presents a higher degree of fraud liability risk to participants in the government procurement market

261. *Id.*
262. *Id.*
263. *Id.*
264. *See generally* U.S. DEP'T OF JUST., FRAUD STATISTICS OVERVIEW OCTOBER 1, 1986 – SEPTEMBER 30, 2020, https://www.justice.gov/opa/press-release/file/1354316/download (identifying fraud statistics from October 1, 1986 - September 30, 2020). Cases in which the Department of Health and Human Services is the primary client agency have made up on average 62 percent of all FCA new matters and provided for 83 percent of all FCA dollars recovered since 2000, with the percentage of new matters dropping below 50 percent only one year during that time frame. *See id.*

than do fraud statutes governing the commercial market. For example, unlike most other civil fraud laws which require specific intent to deceive, the FCA has a lower "deliberate ignorance" or "reckless disregard" mens rea standard.[265] This lower standard risks deterring participation in the government procurement market,[266] and it does not align with the standards that apply in the commercial sector.[267] Specifically, it "weakens the traditional requirement that misleading conduct be intentional" and "requires the plaintiff to bear a notably lighter burden of proof in establishing the fact of fraud."[268] An unfettered, aggressive enforcement push in the wake of COVID-19 would most likely magnify these differences, further discourage participation in the government procurement marketplace, and even disrupt the broader market for critical supplies.[269]

The 2021 NDAA recognized the vulnerability of the United States' supply chain for critical health care items.[270] Section 713 took two significant steps to address these concerns for the Armed Forces. First, it amended 10 U.S.C. § 2501(a) and added "the provision of drugs, biological products, vaccines, and critical medical supplies required to enable combat readiness and protect the health of the armed forces" to the objectives of the national security strategy for national technology and industrial base.[271] Second, it directed the Secretary of Defense to assess "gaps or vulnerabilities in the national technology and industrial base . . . with respect to drugs, biological products, vaccines, and critical medical supplies," through

265. Castellano, *supra* note 76, at 439.

266. *See id.* at n.264.

> While this lowered mens rea requirement may better enable the government to deter and punish fraudulent behavior and more easily recoup any losses, it may also deter participation, and thus lower competition, in public procurement markets, potentially resulting in the inflated prices, reduced quality, and stifled innovation typical of markets with insufficient competition. *Id.*

267. *See* Kovacic, *supra* note 86, at 217–18.

268. *Id.*

269. *Cf.* GRAELLS, *supra* note 130, at 62–63 ("[I]nasmuch as public procurement rules impose (or allow for) a certain market behavior that differs from that of a private buyer . . . they constitute a potential source of market imperfection or market failure . . .").

270. *See generally* William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Pub. L. No. 116-283, 134 Stat. 3388 (codified as 10 U.S.C. 10713(b)(1)(B)) (stating the authorization for appropriations for the 2021 fiscal year 2021 for certain activities of the Department of Defense and Department of Energy).

271. § 713(a). "'[C]ritical medical supplies' includes personal protective equipment, diagnostic tests, testing supplies . . ." *Id.* at § 713(b)(5)(B).

consultation with HHS, the FDA, and any other federal agencies as appropriate.[272] The assessment should identify shortages of these supplies and "defense and geopolitical contingencies" that could disrupt the supply chain.[273] The assessment should identify barriers to the production of these items in the United States, "including with respect to regulatory barriers by the Federal Government,"[274] and it should assess "economic factors . . . that threaten the viability of domestic manufacturers."[275] Section 849 acknowledges concerns related to sourcing and industrial capacity of certain "High Priority Goods and Services," including pharmaceuticals, medical devices, therapeutics, vaccines, diagnostic medical equipment and consumables, and personal protective equipment.[276] It includes corrective options such as restricting procurement to suppliers in the United States, suppliers in the national technology and industrial bases, or suppliers in other allied nations, as well as prohibiting procurement from selected sources or nations.[277] Finally, it acknowledges the potential economic implications of agency responses, as well as the impact of those responses on the market for relevant goods and services.[278] Section 861(a) further directs the Secretary of Defense to leverage small businesses "to eliminate gaps and vulnerabilities in the national technology and industrial base" and to "expand the number of small businesses in the national technology and industrial base."[279]

These provisions reflect Congress's ongoing concern with the DOD's supply chain that is at least consistent with, if not a result of, broader national supply chain problems that arose at the beginning of the pandemic and continue through today. One of the most significant supply chain concerns has been the shortage of PPE, which developed almost immediately as countries rushed to stockpile items such as masks and face shields.[280] In March 2020, HHS estimated that ninety

272. § 713(b)(1).

273. § 713(b)(2).

274. § 713(b)(2)(D).

275. § 713(b)(2)(F)(iv).

276. § 849(c).

277. § 849(a)(1).

278. *See* § 849(a)(2) ("The analyses conducted pursuant to paragraph (1) shall consider national security, economic, and treaty implications, as well as impacts on current and potential suppliers of goods and services."). § 849(a)(2).

279. § 861(a).

280. *See* Tom Simonite, *How Decades of Offshoring Led to a Mask Shortage in a Pandemic*, WIRED (Mar. 29, 2020, 7:00 AM), https://www.wired.com/story/decades-offshoring-led-mask-shortage-pandemic/.

percent of surgical masks and seventy percent of respirators such as N95 masks were made overseas.[281] Prior to the pandemic, China made half of the world's masks.[282] While it increased production after the pandemic hit, it supplemented its stockpile through donations and purchases of much of the rest of world's supply.[283] Domestic companies began shifting their production to compensate for the skyrocketing demand, but as *Wired* noted in March, "[b]uilding out new production capacity in a country that spent decades economizing through offshoring is not easy."[284] Thus, within a month of the Office of the Assistant Secretary for Preparedness and Response opening the Strategic National Stockpile (SNS) to distribute PPE and related supplies, the SNS's inventory was nearly depleted.[285]

During this time, the Federal Emergency Management Agency (FEMA) formed the Supply Chain Stabilization Task Force with HHS, DOD, and other agencies "to address widespread shortfalls amidst the global competition for life-saving equipment," and the Task Force quickly began significant efforts to stabilize the supply chain for these critical medical supplies, most notably through Project Airbridge.[286]

281. *Id.*

282. Keith Bradsher & Liz Alderman, *The World Needs Masks. China Makes Them, but Has Been Hoarding Them*, N.Y. TIMES (Apr. 2, 2020, 10:25 PM), https://www.nytimes.com/2020/03/13/business/masks-china-coronavirus.html.

283. *Id.* For a more specific summary of China's impact on the domestic PPE supply chain, see CONG. RSCH. SERV., COVID-19 AND DOMESTIC PPE PRODUCTION AND DISTRIBUTION: ISSUES AND POLICY OPTIONS, R46628, 3 (2020) [hereinafter COVID-19, DOMESTIC PPE PRODUCTION, AND DISTRIBUTION].

284. Simonite, *supra* note 280.

285. U.S. GOV'T ACCOUNTABILITY OFF., GAO-20-625, COVID-19: OPPORTUNITIES TO IMPROVE FEDERAL RESPONSE AND RECOVERY EFFORTS 108, 24 tbl.1 (2020).

286. *See Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic: Hearing Before the S. Comm. on Homeland Sec. and Gov't Affs.*, 116th Cong. 5–6 (2020) (testimony of Peter Gaynor and RADM John Polowcayk). U.S. GOV'T ACCOUNTABILITY OFF., GAO-20-625, COVID-19: OPPORTUNITIES TO IMPROVE FEDERAL RESPONSE AND RECOVERY EFFORTS 110–111 (2020):

> [Project Airbridge] was created to reduce the time it takes for six large U.S. medical supply distributors to bring PPE and other critical supplies from overseas manufacturers into the country for their respective customers. According to FEMA, the agency pays for the air transportation of the supplies from overseas into the United States. Once the supplies are in the country, the medical suppliers distribute 50 percent to areas of need, as indicated by Centers for Disease Control and Prevention data. They then distribute the remaining 50 percent through their normal commercial networks, although the federal government has purchased some of these supplies to provide to states, according to FEMA officials. According to FEMA's website, this effort reduces shipment time from weeks to days. *Id.* at 111.

Yet the supply chain issues persist. In December 2020, the Congressional Research Service noted that "[PPE] shortages continue to be a factor in the ongoing federal, and nationwide, response to the COVID-19 pandemic."[287] On January 21, 2021, immediately upon taking office, President Biden issued an executive order directing multiple executive agency leaders to identify ongoing shortfalls, recommend solutions, and develop a long-term supply chain resilience strategy.[288] While leaders and experts continue to identify and respond to these issues, the supply chain for critical medical supplies remains vulnerable and appears likely to remain that way for the foreseeable future.[289] As COVID-related FCA investigations develop, agencies must consider these ongoing supply chain vulnerabilities as they make enforcement decisions.

Reflexive government responses have already produced examples internationally of the negative consequences of unfocused intervention. Similar to gas prices following Hurricanes Katrina and Rita, early price spikes in items such as face masks and hand sanitizers prompted concerns across the globe.[290] Italy tried to control the price of face masks and produced a shortage in return.[291] In April 2020, Italy's government imposed a cap of fifty European cents (approximately $0.54) plus tax on face masks and also discouraged domestic companies from importing masks.[292] A mask shortage ensued: domestic companies who had refocused their production towards masks halted their efforts, and pharmacists were unable to

287. COVID-19, DOMESTIC PPE PRODUCTION, AND DISTRIBUTION, *supra* note 283. The Report succinctly summarized the ongoing issues and concerns:

> According to a September 2020 Government Accountability Office (GAO) report, PPE shortages "remain due to a limited supply chain with limited domestic production and high global demand." The Food and Drug Administration (FDA) has listed multiple categories of PPE on its medical device shortage list. In addition, recent independent surveys show that acute PPE shortages continue to be an issue in nursing home environments, as well as generally among the domestic nurse population. In response, Congress has issued letters, introduced legislation, and opened investigations as a means of studying and potentially addressing the extended PPE shortage issue. *Id.* (internal citations omitted).

288. *See* Exec. Order No. 14001, 86 Fed. Reg. 7,219 (Jan. 21, 2021).

289. *See, e.g.*, *Healthcare Supply Chain Disruptions in 2022*, CONCORDANCE HEALTHCARE SOLUTIONS (Jan. 12, 2022), https://www.concordancehealthcare.com/blog/healthcare-supply-chain-disruptions-in-2022.

290. *Cf.* Montgomery, *supra* note 133, at 357–58.

291. *See, e.g.*, Alberto Mingardi, *Italy's Covid Price-Control Fiasco*, WALL ST. J. (May 18, 2020, 7:00 PM), https://www.wsj.com/articles/italys-covid-price-control-fiasco-11589842827.

292. *Id.*

obtain masks at low enough prices to sell at the cap.[293] Conversely, Italy's hand sanitizer market illustrates the market's ability to compensate when left mostly alone. When hand sanitizer prices soared in February 2020, more companies entered the market to make it and compensate for the skyrocketing demand.[294] As a result, bottles began reappearing on the shelves and by May had nearly returned to pre-COVID prices.[295]

The United States nearly saw similar innovation quashed through government intervention. Many American distilleries responded to hand sanitizer scarcity by shifting their production. The FDA complicated these efforts early on by requiring that the distilleries use denatured alcohol.[296] Denaturing involves "adding unpleasant substances to deter consumption" by children or confused individuals, but the World Health Organization does not recommend using it.[297] The two permitted denaturants faced their own shortages or were not readily available in the United States.[298] The requirement also meant the distilleries spent additional time and effort cleaning their lines later, since they ordinarily want their products to taste good.[299] Then, at the end of 2020, the FDA rewarded the distilleries' efforts with over $23,000 in fees, though HHS voided the fees in short order.[300] Yet even with HHS's intervention, this series of events has likely discouraged similar efforts now and in the future.

The government should hope for and encourage the innovation of distilleries that shifted their efforts to produce hand sanitizer to compensate for skyrocketing demand. Whether these companies act altruistically, opportunistically, or through some combination of the two is immaterial. The key consideration is market participation to meet critical needs, both in the procurement market and in the broader commercial market.

293. *Id.*

294. *See id.*

295. *See id.*

296. *See* Richard Williams, *FDA is Slowing Down Production of Hand Sanitizers*, THE HILL (Mar. 28, 2020, 9:00 AM), https://thehill.com/opinion/healthcare/489839-fda-is-slowing-down-production-of-hand-sanitizers.

297. *Id*.

298. *Id*.

299. *Id*.

300. *See* Emily Price, *HHS Voids Hefty FDA Fees Targeting Craft Distillers That Produced Hand Sanitizer*, FORBES (Jan. 1, 2021, 5:55 PM), https://www.forbes.com/sites/emilyprice/2021/01/01/hhs-has-voided-hefty-fda-fees-on-craft-distillers-that-produced-hand-sanitizer/.

D. Proposals for Better Consideration of Market Impact

Principles drawn from critiques of anti-price gouging regulation and legislation can help shape the DOJ's COVID-related evaluation framework, as well as those of other enforcement authorities. As noted earlier, Italy's efforts to control mask prices backfired while the market for hand sanitizers compensated appropriately.[301] That result was no surprise since economists generally agree that price controls can often ensure sustained shortages of the products at issue.[302] Rising prices in the face of increased demand carry many beneficial side effects, to include encouraging existing and new suppliers to bring more supply to the market and encouraging those with excess supplies to sell them to others.[303] Left alone, this phenomenon further spurs innovation and builds the capacity to similarly adjust in the face of future crises.[304] Conversely, government intervention can exacerbate shortages by discouraging increased production, reduce the incentive for vendors to bring more supplies to market, encourage vendors to redirect supplies to different markets, including foreign markets, and create uncertainty in the face of subjective regulatory criteria.[305] Removing these sorts of barriers to entry typically produces increased competition, lower costs, and a more stable market.[306] Thus, World Bank economists have cautioned governments to exercise the "utmost care" in pursuing legal actions against price gouging so as to avoid curbing supply or discouraging innovation and quality, noting specifically that limiting firms' freedom to set prices can reduce

301. *See* Mingardi, *supra* note 291.

302. *See* Ryan Bourne, *Abolish Price and Wage Controls*, CATO INSTITUTE (Sep. 15, 2020), https://www.cato.org/publications/pandemics-policy/abolish-price-wage-controls. For a broader, international analysis of price controls reaching similar conclusions, see Justin-Damien Guénette, *Price Controls: Good Intentions, Bad Outcomes* (World Bank Grp., Pol'y Rsch. Working Paper No. 9212, 2020).

> While they may be introduced with the best intentions to improve social outcomes, available evidence suggests that price controls often undermine growth and development, impose fiscal burdens and can weaken the effectiveness of monetary policy. . . . Important social, fiscal and environmental costs are likely to follow, as well as adverse consequences for investment and employment, and productivity growth. *Id.* at 3.

303. *See* Bourne, *supra* note 302 at 4–5.

304. *See id.* at 5.

305. *See id.* at 6.

306. *See* Guénette, *supra* note 302, at 12.

incentives to compete.[307] These principles translate well to an analysis of enforcement.

Unfettered COVID-related FCA enforcement similarly risks discouraging increased production, reducing the incentive for market entry, encouraging existing vendors to refocus their efforts away from critical areas, and creating uncertainty regarding the risk of FCA liability. The response of banks and credit unions to the DOJ's post-mortgage crisis enforcement efforts demonstrates the similarity of these risks. Again, as mortgage fraud enforcement efforts progressed, banks and credit unions left the FHA lending market.[308] They stopped offering FHA-related products or at least minimized those offerings, and instead refocused their efforts on different, less risky markets.[309] During this exodus, the common concern was uncertainty regarding risk of FCA liability.[310] Similar enforcement efforts in the wake of COVID-19 could produce similar results, especially with vendors of critical medical supplies such as PPE. "The availability of effective PPE is critical to the ongoing pandemic response, but also has broader public health, emergency preparedness, and national security implications."[311] COVID-19 demonstrated the vulnerabilities of the global supply chains for goods and materials related to PPE and the difficulties of maintaining production during a public health crisis.[312] Government agencies, as well as the broader health care community, relied on existing vendors to expand their efforts in the PPE market and new vendors to enter the market to compensate for the demand.[313]

307. TANJA GOODWIN & RODRIGO BARAJAS, THE WORLD BANK, SAFEGUARDING HEALTHY COMPETITION DURING COVID-19 5 (2020), https://thedocs.worldbank.org/en/doc/497031588957886202-0130022020/original/SafeguardingHealthyCompetitionDuringCOVID19.pdf.

308. *See* Interagency Memo on the Application of the FCA, *supra* note 11.

309. *Id.*

310. *Id.*

311. COVID-19, DOMESTIC PPE PRODUCTION, AND DISTRIBUTION, *supra* note 283, at ii.

312. *Id*. at 2.

313. *See* Shefali Kapadia, *3M Increases N95 Production Rate to 2.5B Annually*, SUPPLY CHAIN DRIVE (Jan. 28, 2021), https://www.supplychaindive.com/news/3m-n95-mask-respirator-production-ppe-supply-chain/594073/. 3M is one example of a vendor increasing production. It produced over 2 billion N95 respirators globally in 2020, four times its 2019 production rate. *Id.* To assist with this increase, it added over 120,000 square feet to its largest United States respirator plant in South Dakota. *Id.* As part of these efforts, 3M received multiple contract awards, especially from the Department of Defense. Press Release, U.S. Dep't of Def., DOD Awards $126 Million Contracts to 3M, Increasing Production of N95 Masks, (May 6, 2020), https://www.defense.gov/Newsroom/Contracts/Contract/Article/2411921/. *See also*

Unfettered enforcement risks spotlighting the risk of FCA liability that often accompanies such efforts. As the need for these supplies continues, and as the United States seeks to strengthen the relevant supply chains to be better prepared for future efforts, unfettered enforcement will likely discourage the new industrial base from increasing its liability risk through increased production and can likewise scare away potential new vendors who are unwilling to shoulder the risk associated with entering the government procurement market. These effects are especially likely in a global market where high demand persists and vendors can simply redirect their efforts to markets with lower risk, which effectively means the rest of the world given the uniqueness of the FCA.

1. Proposed Evaluation Factors

The solution, especially for COVID-related fraud, is not to simply allow fraud to run rampant out of fear of disrupting the market. Instead, it is a thoughtful and intentional framework, with specific evaluation factors to account for market impact, to analyze COVID-related fraud and determine the most appropriate cases to pursue. The DOJ and other enforcement authorities should use the following factors in evaluating and prioritizing COVID-related FCA cases:

- Will an enforcement action cause, exacerbate, or otherwise contribute to shortages?
- What are the potential indirect impacts of enforcement on similarly situated vendors and potential new vendors?
- What is the likelihood the action will significantly disrupt competition in the relevant procurement market?
- Has the vendor attempted in reasonable good faith to comply with applicable regulatory and statutory standards?
- Did the conduct at issue threaten public health?; and

Josh Salman et al., *Rookie Middlemen Muddle the Government's Effort to Buy Coronavirus Supplies*, USA TODAY (Updated Jan. 26, 2021), https://www.usatoday.com/in-depth/news/investigations/2020/07/23/covid-ppe-face-mask-shortage-draws-new-companies-us-contracts/5459884002/ (summarizes of the role of new vendors in the PPE market). Though the article is presented as a cautionary tale, it nevertheless demonstrates the significant role played by new PPE vendors in the government procurement market. *Id.* Opportunistic motivations notwithstanding, these new vendors filled a $2.7 billion need. *Id.*

- Is FCA litigation the most appropriate mechanism for addressing the conduct at issue?

These factors are derived from principles found in the HUD-DOJ MOU and the various executive orders, legislation, press releases, and analyses of related issues such as price gouging laws and mortgage fraud enforcement that have been previously highlighted in this article. For example, executive orders and legislation during the first year of the pandemic voiced concerns related to shortages and the fragile supply chain.[314] Press releases and the HUD-DOJ MOU indicate the ability of enforcement to negatively reshape markets.[315] These items have also acknowledged the utility of taking a closer look at a vendor's scienter and considering alternatives to FCA litigation.[316] Collectively, the factors also recognize the unique risks associated with FCA liability that generally apply to vendors doing business with the government.[317]

First, enforcement authorities should consider whether an action will cause, exacerbate, or otherwise contribute to shortages. Practically, this factor should be easy to apply, as it is already a factor the Criminal Division considers in evaluating a business organization's claimed inability to pay a fine or monetary penalty.[318] This consideration should also include the potential public health consequences of a shortage, as well as the consequences of prolonging or exacerbating that shortage. It must also avoid narrowly focusing only on the parties to the case under review and must instead include a broader consideration of the implications and likelihood of more widespread enforcement against similarly situated vendors in the market at issue and how that enforcement might affect other, non-public participants in the market.[319]

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314. *See, e.g.*, Exec. Order No. 14001, 86 Fed. Reg. 7,219 (Jan. 21, 2021); William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Pub. L. No. 116-283, 134 Stat. 3388 (codified as 10 U.S.C. 10713(b)(1)(B)).

315. *See, e.g.*, Interagency Memo on the Application of the FCA, *supra* note 11; *see* Memorandum of Understanding, *supra* note 14 at 1. While the MOU does not explicitly mention the enforcement impact on markets, its mere existence is a testament to the connection. *Id.*

316. *See, e.g.*, Exec. Order No. 13924, 85 Fed. Reg. 31,353 (May 22, 2020); *see* Memorandum of Understanding, *supra* note 14, at 2–3.

317. *See, e.g.*, Castellano, *supra* note 76, at 438–39; Kovacic, *supra* note 86, at 217–18.

318. *Cf.* Memorandum from Brian A. Benczkowski, *supra* note 249, at 3.

319. GRAELLS, *supra* note 130, at 71 ("[I]t is particularly important to stress the existing buying competition between the public and other buyers . . . and to analyse the possible existence of *waterbed effects* that result from competition-distorting

Second, enforcement authorities should consider the potential indirect influence of the action on similarly situated vendors and potential new vendors. The Civil Division acknowledged the potential for enforcement to "discourage companies from helping to address the current health threat."[320] This analysis should include the existing and projected global demand for the supplies at issue, the status and stability of the supply chain, and the existing regulatory and related hurdles facing new entrants to the market. Effectively, this analysis requires the enforcement authority to switch sides, consider market conditions and the risk associated with potential *perceived* FCA liability in the market, then ask questions such as "would I enter this market as a new vendor," "would I increase my production in this market as an existing vendor," and "would I be tempted to divert my supplies to another market with less liability risk, such as the commercial market or a foreign market."

Third, enforcement authorities should consider whether the action will significantly disrupt competition in the procurement market for the supplies at issue. This factor is also already used by the Criminal Division to a limited extent in assessing inability to pay.[321] Applying it more broadly to COVID-related fraud will further assist government efforts in maximizing competition. Similar to the first two evaluation factors, this factor will be somewhat fluid. For example, in some portions of the COVID-related procurement market new vendors were coming out of the woodwork to compete for contracts.[322] However, this occurrence will not be uniform across all markets and will fluctuate with global demand and supply. Also, it is important that enforcement authorities appreciate the broader market for these supplies as they consider the likelihood of disruption and not focus solely on the procurement market itself.[323] Although the procurement market is the focus of this discussion, the procurement market for these supplies functions within a broader, global market.[324] Thus,

public procurement rules and that have a negative impact on the commercial conditions applicable to non-public buyers.") (emphasis in original).

320. *Deputy Assistant Attorney General Ethan P. Davis Remarks of FCA*, *supra* note 116.

321. *Cf. id.*

322. *See* Salman, *supra* note 313.

323. *See* GRAELLS, *supra* note 130, at 63 (". . . [B]y losing perspective and isolating the analysis of public procurement mechanisms from the market with which they interact, their effects on competition dynamics are generally not taken into consideration and, consequently, most conclusions and normative recommendations remain partial and, sometimes, flawed.")

324. *See id.*

enforcement-related disruption may more directly impact the broader market, with a ripple-effect on the procurement market, or vice versa.

Fourth, enforcement authorities should consider whether the vendor at issue attempted in reasonable good faith to comply with applicable regulatory and statutory standards. Although since revoked by President Biden,[325] President Trump's Executive Order 13,924 demonstrates that this consideration is practical and workable.[326] In the present context, implementation of this factor might include only pursuing cases where the vendor possesses a higher level of knowledge than the statutory minimum of "reckless disregard,"[327] or even focusing on cases with an indication of a specific intent to defraud. This adjustment would be similar to HUD's second FCA Evaluation Standard which considers the existence of "aggravating factors warranting pursuit of FCA litigation such as evidence that the violations are systemic or widespread."[328]

Fifth, enforcement authorities should consider whether the conduct itself posed a public health risk. The markets at issue in the present context involve critical medical supplies, so procurement fraud in these markets has public health implications. For example, in the early days of COVID-19 in the United States, FEMA purchased $10.2 million in testing supplies that ultimately were contaminated and unusable.[329] The public health threats posed by contaminated and unusable testing kits are obvious: infected patients could receive false negative results and spread the virus further. However, not every case will involve such obvious threats. Enforcement authorities should work to quantify the threat posed by the conduct in each case and weigh that against any market threat posed by the enforcement action itself.

Sixth, enforcement authorities should consider whether FCA litigation is the most appropriate mechanism for addressing the conduct. This factor echoes HUD's overarching recommendation in

325. *See* Exec. Order No. 14018, 86 Fed. Reg. 11,855 (Feb. 24, 2021).

326. *See* Exec. Order No. 13924, 85 Fed. Reg. 31,353–55 (May 22, 2020) ("The heads of all agencies shall consider whether to formulate, and make public, policies of enforcement discretion that . . . decline enforcement against persons and entities that have attempted in reasonable good faith to comply with applicable statutory and regulatory standards. . .") *See id*.

327. *Cf*. 31 U.S.C. § 3729(b)(1)(A)(iii) (2021).

328. *See* Memorandum of Understanding, *supra* note 14, at 3.

329. *See* Ryan Gabrielson & J. David McSwane, *FEMA Ordered $10.2 Million in COVID-19 Testing Kits It's Now Warning States Not to Use*, PROPUBLICA (June 26, 2020, 5:29 PM), https://www.propublica.org/article/fema-ordered-10-2-million-in-covid-19-testing-kits-its-now-warning-states-not-to-use.

the HUD-DOJ MOU.[330] In many cases, administrative measures may more appropriately address the conduct at issue, while at the same time posing less threat to the markets. This determination will depend on the analysis of the previous factors. For example, if the risk of impact on the supply chain, other vendors, and the broader market is low, and the conduct is egregious, then this factor will likely point towards FCA litigation. That said, there may be situations where market impact risk is high, but FCA litigation is nonetheless the most appropriate mechanism for addressing the conduct.

2. Implementation Mechanisms

The DOJ can incorporate these evaluation factors into some of the existing tools already at its disposal to ensure that it accounts for market impact in its COVID-related enforcement decisions. The first of these tools is the use of memoranda of understanding with collaborating agencies. The HUD-DOJ MOU provides an excellent template for developing additional MOUs to address similar concerns in other markets. The second tool is the use of working groups. The DOJ has a long history of using working groups to assist with identifying fraud and making enforcement decisions.[331] The recently formed HHS False Claims Act Working Group is one such group that is already primed for addressing COVID-related fraud issues.[332]

The DOJ and agencies impacted by COVID-related fraud can use the HUD-DOJ MOU as a starting point for maximizing the collaborative enforcement effort. HHS, DHA, and the VHA are just three agencies that should develop MOUs of this style to ensure that enforcement decisions do not harm the markets that support their programs. These agencies could develop their own FCA evaluation framework using the factors proposed above for referring cases to the DOJ. The MOUs should also outline a similar process for conferring on and evaluating *qui tam* cases.

The DOJ has a long history of using interagency working groups to assist with fraud enforcement on both the criminal and civil

330. *See* Memorandum of Understanding, *supra* note 14, at 3 ("HUD recommends that FCA matters be pursued only where such action is the most appropriate method to protect the interests of FHA's mortgage insurance programs, would deter fraud against the United States, and would generally serve the best interests of the United States.").

331. *See* Press Release, Dep't of Health and Hum. Servs., HHS Announces False Claims Act Working Group to Enhance Efforts to Combat Fraud and Focus Resources on Bad Actors (Dec. 4, 2020) [hereinafter HHS Announces FCA Working Group].

332. *See id.*

divisions.[333] In more recent history, the Enforcement Committee of the Financial Fraud Enforcement Task Force (FFETF) created eight working groups to focus on certain enforcement priority areas.[334] The DOJ used one of these, the Mortgage Fraud Working Group, along with the Criminal Division's separate mortgage fraud working group, to assist with fighting mortgage fraud during the mortgage crisis era.[335]

The HHS False Claims Act Working Group is a valuable tool that can be adjusted to ensure enforcement authorities account for market impact.[336] HHS formed this working group in partnership with the DOJ and the HHS Office of Inspector General on December 4, 2020, "to combat fraud and abuse by identifying and focusing resources on those who seek to defraud the American taxpayers."[337] "The group is comprised of former DOJ False Claims Act and health care fraud prosecutors, former private counsel for health care and life sciences companies, and HHS attorneys with extensive experience with HHS' most vulnerable payment programs."[338] The group's goal is to "protect government funds by identifying potential False Claims Act violations and referring them to DOJ and OIG," as well as to "aid DOJ and OIG in False Claims Act actions by providing HHS' views on the intricate legal frameworks of the agency's numerous funding programs."[339] The group is also intended to "provide a focal point within the agency for consultation about legal requirements and recommendations about alleged violations."[340]

HHS and DOJ can easily adjust this working group to incorporate the proposed factors and assess market impact in FCA cases. That task aligns well with the goals mentioned in the press release. One of the group's current roles is to provide targeted training to the HHS

333. *See id.*

334. U.S. DEP'T OF JUST. OFF. OF THE INSPECTOR GEN., AUDIT OF THE DEPARTMENT OF JUSTICE'S EFFORTS TO ADDRESS MORTGAGE FRAUD 4 (Mar. 2014). The FFETF was created by Executive Order on November 17, 2009, with the mission of advising the Attorney General on the investigation and prosecution of financial crimes related to the financial crisis and economic recovery efforts at the time. *See id.*; Exec. Order No. 13519, 74 Fed. Reg. 60,123 (Nov. 19, 2009).

335. *See* U.S. DEP'T OF JUST. OFF. OF THE INSPECTOR GEN., *supra* note 334, at 4–6. The audit indicates that these groups were not used to their full potential. Specifically, the audit found that despite the existence of these working groups, the DOJ do not ensure that mortgage fraud was prioritized appropriately. *See id*. at i.

336. *See* HHS Announces FCA Working Group, *supra* note 331.

337. *Id*.

338. *Id*.

339. *Id*.

340. HHS Announces FCA Working Group, *supra* note 331.

programs that are most vulnerable to fraud and abuse to enable HHS personnel to "better detect and refer potential false claims to DOJ and OIG."[341] To be effective, this training requires a broader understanding of the programs themselves and the market for those programs since vulnerabilities may be tied to unique aspects of the programs as well as to the market that supports those programs. The working group can integrate the proposed factors into this training. As HHS refers cases to DOJ and OIG, those referrals should include an analysis using the proposed factors as well as discussion of the nature and stability of the market in which the contractor participates, the contractor's role and share of that market, the potential economic impact of an enforcement action on the contractor and its personnel, and the potential economic impact of enforcement actions against additional market participants. The referral should include a generalized summary with some type of scoring (e.g., minimal, moderate, significant), combined with a recommendation or some degree of advisory or cautionary statement, sufficient to inform DOJ's and OIG's enforcement decisions. This process would also achieve the collaborative goals of Department of Justice Manual § 4-4.110.[342]

341. *See id.*

342. *See Justice Manual*, THE UNITED STATES DEP'T OF JUST., https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.110 (last updated Dec. 2019). This section of the Manual discusses civil fraud litigation generally. On collaboration, it states:

> In any False Claims Act matter, the USAO or Fraud Section attorneys will confer with the relevant agency during the investigative, litigation, and settlement phases of the matter. The Department's attorneys will solicit the agency's views on the False Claims Act matter, including, for example, on the falsity and materiality aspects of any alleged violations of the relevant agency requirements, in order to assist the Department in determining whether the elements of the False Claims Act can be established. In a qui tam action, if the agency does not support the whistleblower's pursuit of the matter, the agency may recommend that the Department seek dismissal of the case . . . While the decision whether to seek dismissal remains the exclusive authority of the Department, the Department will consult with the agency in making such a decision. These principles apply to all False Claims Act matters.

Id. Though this language focuses more on the legal aspects of a case, an agency's views on a matter certainly can include, and should include the agency's assessment of market impact. After all, this paragraph references the HUD-DOJ MOU, explaining that the MOU "reflects the coordination principles above." *Id.* In outlining its FCA Evaluation standards, the MOU states, "HUD recommends that FCA matters be pursued only where such action is the most appropriate method to protect the interests of FHA's mortgage insurance programs." Memorandum of Understanding, *supra* note 14, at 3. Given HUD's overarching concern of protect the market that supports its FHA mortgage insurance programs, this appropriateness recommendation certainly will consider market impact.

HHS and DOJ can also augment the working group by bringing more agencies and individual perspectives to the table. As it currently stands, only attorneys sit on the working group.[343] Economists, health care professionals and administrators, and others with a broader understanding of the market would enhance the working group's effectiveness, both in assessing market impact as well as in performing the currently planned functions. Broader agency representation should provide a similar enhancement. Agencies such as DHA and the VHA have similar concerns and work with the same markets as HHS, despite having slightly different missions.[344] As a result, they also generate the same sorts of FCA cases. Interagency participation on assessing market impact of enforcement decisions will bring diverse perspectives that ensure meaningful assessments while ensuring that no one agency shoulders this collaborative load on health care related cases with the DOJ. Interagency participation also compensates for the lack of a dominant, central stakeholder such as HUD provides with mortgage fraud.

OIGs and SDOs can use these evaluation factors at the agency level for their respective functions. For OIGs, the factors can assist in developing priorities for sifting through referrals. They will also assist OIGs in their coordination efforts with the DOJ and will be especially useful in determining whether to pursue administrative remedies in cases the DOJ declines.[345] Lastly, the factors will assist OIGs in deciding which cases to refer to the agency's SDO.[346] Likewise, SDOs can use these factors in making debarment decisions. Certainly protecting the market falls within the broader "public interest" policy considerations of FAR 9.402(b). SDOs could use these factors similarly to how they might use the U.S. Sentencing Guidelines and

343. *See* Thomas Sullivan, *HHS Announces Creation of False Claims Act Working Group*, POLICY & MEDICINE, (Dec. 10, 2020), https://www.policymed.com/2020/12/hhs-announces-creation-of-false-claims-act-working-group.html.

344. DHA's mission is focused on delivery of health services to Military Health System beneficiaries. *Defense Health Agency*, MILITARY HEALTH SERVICES, https://www.health.mil/About-MHS/OASDHA/Defense-Health-Agency (last visited Feb. 19, 2021). The VHA's mission is focused on delivery of health services to eligible veterans enrolled in the VA health care program. *About VHA*, U.S. DEP'T OF VETERANS AFFAIRS, https://www.va.gov/health/aboutvha.asp (last visited May 19, 2022).

345. *Cf*. Halbrooks & Taylor, supra note 60, at 19.

346. *Cf. id*. ("Many OIGs have written policies requiring agents to consider a suspension-and-debarment referral in each investigation.").

DOJ's *Evaluation of Corporate Compliance Programs* in evaluating compliance programs.[347]

CONCLUSION

Government spending in response to COVID-19 has already produced numerous fraud cases, and it will continue to do so in the coming years. In the procurement community, the environment is ripe for an explosion in FCA cases over at least the next two fiscal years. The DOJ brought aggressive FCA enforcement into a similar environment in the wake of the subprime mortgage crisis, birthing a monster in the process that scared away established participants in the FHA lending market. HUD eventually coordinated with the DOJ to slay that monster but not before the monster had reshaped the FHA lending market for the foreseeable future. The DOJ and other enforcement authorities must be careful to avoid resurrecting this monster in the wake of COVID-19. Bad conduct should definitely be addressed to some degree, but unfettered, aggressive FCA enforcement with repeated news releases touting the millions or billions recovered is not the best method in this environment of continued high demand and vulnerable supply chains. The markets for the critical medical supplies at issue are more diverse and lack the compliance backbone and central stakeholder such as HUD to protect them as fraud enforcement ramps up. As such, the DOJ must develop and implement an evaluation framework specific to these COVID-related fraud cases to avoid further market disruption and to maintain a stable, competitive industrial base for the procurement system to obtain these items. By adopting the factors proposed above and implementing them through tools such as memoranda of understanding with relevant agencies and existing working groups, the DOJ and the broader enforcement community can ensure that fraud is appropriately addressed while ensuring the stability of these markets now and for the next crisis.

347. *See* AM. BAR ASS'N, THE PRACTITIONER'S GUIDE TO SUSPENSION AND DISBARMENT 164–65 (Frederic M. Levy & Michael T. Wagner eds. 4th ed. 2018).