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NOT QUITE WHAT THE DOCTOR ORDERED: THE THIRD CIRCUIT
PULLS THE PLUG ON OBJECTIVE FALSITY IN *UNITED*
STATES EX REL. DRUDING v. CARE
ALTERNATIVES

JENNA L. SCHAFER*

“[T]here is no kind of dishonesty into which otherwise good people more easily and frequently fall, than that of defrauding [the] government”¹

I. MAKING THE FIRST INCISION: AN INTRODUCTION

The medical profession was once regarded as the embodiment of altruism and incorruptibility—but not anymore.² Rampant health care fraud across the United States has taught federal law enforcement that even otherwise good doctors are capable of defrauding the government.³ Out of necessity, medical providers have become intimately familiar with the government’s primary recovery instrument to combat fraud—the False

* J.D. Candidate, 2022, Villanova University Charles Widger School of Law; B.B.A., *magna cum laude*, 2014, Temple University. I dedicate this Note to three incredible individuals: (1) my mom, Beth Brady, who has *always* believed in me and who taught me that even a seemingly insurmountable task can be accomplished if it is done one step at a time; (2) my fiancé, Matt Guarino, who selflessly supports my professional goals and always finds a way to make me laugh; and lastly, (3) Michel Verleysen, who showers me with optimism and never lets me lose sight of my dreams. Mom, Matt, and Michel—thank you for your endless love and unwavering support. I would also like to thank Charles Widger for his invaluable mentorship and Professor Michael Campbell for his thoughtful critique of this Note. And finally, I would like to recognize my *Villanova Law Review* colleagues for their hard work throughout the editing and publication of this Note.

1. Letter from Benjamin Franklin to the Printer of the London Chronicle (Nov. 24, 1767), in 14 *THE PAPERS OF BENJAMIN FRANKLIN* 315, 315–19 (Leonard W. Labaree & Yale Univ. Press eds., 1970) (describing the negative effect fraud has on the nation’s treasury).

2. See James F. Sweeney, *The Eroding Trust Between Patients and Physicians*, MED. ECON. (Apr. 10, 2018), <https://www.medicaleconomics.com/view/eroding-trust-between-patients-and-physicians> [<https://perma.cc/58JS-GTU2>] (explaining why the doctor-patient relationship has eroded over time and suggesting several methods to get the relationship back on track).

3. Cf. Nick Oberheiden, *I’ve Been Indicted on Healthcare Fraud Charges—Now What?*, NAT’L L. REV. (Oct. 27, 2020), <https://www.natlawreview.com/article/i-ve-been-indicted-healthcare-fraud-charges-now-what> [<https://perma.cc/MY5P-8V6V>] (identifying several examples of health care fraud and noting how the concept of health care fraud is broad and therefore, encompasses a lot of activity).

Claims Act (“FCA”).⁴ Although Congress originally created the FCA to excise wartime profiteering, the FCA’s broad scope has allowed it to endure for more than 150 years and remain applicable across a wide breadth of industries.⁵ Over time, the FCA has developed a reputation for its punitive penalties and qui tam provisions, which enable private whistleblowers to pursue FCA litigation on behalf of the government.⁶

Despite its age, the FCA’s popularity is a more recent phenomenon.⁷ In an effort to encourage qui tam claims, Congress amended the FCA in 1986 by lowering the burden of proof for plaintiffs, raising penalties, increasing maximum awards available to qui tam claimants, and adding anti-retaliation provisions.⁸ In 2009 and 2010, Congress demonstrated its continued commitment to combatting fraud by passing back-to-back FCA amendments that once again expanded the Act’s reach.⁹ As a result of

4. See Press Release, Dep’t of Justice, Justice Department Recovers Over \$2.8 Billion from False Claims Act Cases in Fiscal Year 2018 (Dec. 21, 2018), <https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018> [<https://perma.cc/H3JY-Z8TZ>] [hereinafter Justice Department Recovers Over \$2.8 Billion in 2018] (identifying various industries the FCA polices, including defense, national security, and import tariffs); see also 31 U.S.C. § 3729 (2021) (codifying the FCA).

5. See *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968) (explaining debates surrounding FCA’s enactment indicate it “was intended to reach all types of fraud, without qualification”); see also Melissa E. Najjar, *When Medical Opinions, Judgments, and Conclusions Are “False” Under the False Claims Act: Criminal and Civil Liability of Physicians Who Are Second-Guessed by the Government*, 53 SUFFOLK U. L. REV. 137, 140 (2020) (explaining that Congress’ broad drafting of the FCA enables the law to endure); cf. Press Release, Dep’t of Justice, Justice Department Recovers Over \$3 Billion from False Claims Act Cases in Fiscal Year 2019 (Jan. 9, 2020), <https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019> [<https://perma.cc/KGZ2-VRN6>] [hereinafter Justice Department Recovers Over \$3 Billion in 2019] (“The number and variety of judgments and settlements announced during fiscal year 2019 reflect the diversity of fraud recoveries arising under the [FCA].”).

6. See *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 182 (2016) (“Congress . . . has increased the Act’s civil penalties so that liability is ‘essentially punitive in nature.’” (quoting *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000))); *Winter ex rel. United States v. Gardens Reg’l Hosp. & Med. Ctr.*, 953 F.3d 1108, 1114 (9th Cir. 2020) (commenting that liability imposed by the FCA is “significant”); see Vincent A. Recca, *Healthcare’s Ticking Time Bomb: The 60-Day Rule and Kane*, 44 AM. J. CRIM. L. 239, 243 (2017) (noting that “qui tam” is derived from “the Latin phrase, ‘*qui tam pro domino rege quam pro se ipso in hac parte sequitur*, which translates to who brings the action for the king as well as himself” (quoting ROBIN PAGE WEST, *ADVISING THE QUI TAM WHISTLEBLOWER: FROM IDENTIFYING A CASE TO FILING UNDER THE FALSE CLAIMS ACT* 2 (2nd ed. 2009))).

7. See Justice Department Recovers Over \$3 Billion in 2019, *supra* note 5 (“Recoveries since 1986, when Congress substantially strengthened the civil [FCA], now total more than \$62 billion.”).

8. See *id.* (explaining FCA was strengthened in 1986 when incentives for whistleblowers to bring lawsuits increased).

9. See James J. Belanger & Scott M. Bennett, *The Continued Expansion of the False Claims Act*, 4 J. HEALTH & LIFE SCI. L. 26, 29–35 (2010). Congress passed the Fraud Enforcement and Recovery Act (“FERA”) in 2009 and the Patient Protection

these amendments, the number of FCA claims has been on the rise—with health care fraud being the main target.¹⁰

As health care costs continue to rise at an unprecedented rate, so does the capacity for fraud.¹¹ The federal government is the single largest health care payer in the country, allocating more than a quarter of its annual budget to health care expenditures.¹² In 2019 alone, the federal government spent more than a trillion dollars on health care goods and services.¹³ The Centers for Medicare and Medicaid Services (“CMS”) project that over the next ten years, the annual growth of health care spending will outpace the annual growth of domestic product, with national health care spending reaching \$6.2 trillion by 2028.¹⁴ It is estimated that up to ten percent of federal health care spending is due to fraudulent activity—meaning that health care fraud costs taxpayers billions of dollars each year.¹⁵ With health care costs poised to increase at an unsustainable

and Affordable Care Act (“PPACA” or “ACA”) in 2010, both of which extended the FCA’s reach once again. *See id.* (same); *see also* Kamal Al-Salihi, *Keeping It Simple: Finding Falsity Under the False Claims Act*, 36 WHITTIER L. REV. 431, 443 (2015) (describing 2009 FCA amendments as changes that allowed the FCA to expand its reach to “almost all recipients of federal program funds”).

10. *See* Patricia Meador & Elizabeth S. Warren, *The False Claims Act: A Civil War Relic Evolves into A Modern Weapon*, 65 TENN. L. REV. 455, 456 (1998) (“In recent years, the government has . . . turn[ed] a dated law into a modern nightmare for the health care industry.”); *see also* Najjar, *supra* note 5, at 140 (noting the FCA has increasingly been employed to combat both Medicare and Medicaid fraud).

11. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., FINANCIAL REPORT 24 (2019), <https://www.cms.gov/files/document/cms-financial-report-fiscal-year-2019.pdf> [<https://perma.cc/J2Z3-3UZY>] [hereinafter CMS 2019 FINANCIAL REPORT] (“[T]he American healthcare system is on an unsustainable trajectory, with one in five dollars spent in our economy projected to be spent on healthcare by 2026.”); *see also* Nicole Forbes Stowell, Carl Pacini, Nathan Wadlinger, Jacqueline M. Crain & Martina Schmidt, *Investigating Healthcare Fraud: Its Scope, Applicable Laws, and Regulations*, 11 WM. & MARY BUS. L. REV. 479, 479 (2020) (explaining that “clever fraudsters view the healthcare industry as a lucrative and attractive hotspot for illegal activity”); Recca, *supra* note 6, at 241 (noting that because of Medicare and Medicaid’s combined “cost, dizzying complexity, and national reach, there is tremendous potential for mistakes, fraud, and abuse”).

12. *See Where Do Our Federal Tax Dollars Go?*, CTR. ON BUDGET & POL’Y PRIORITIES (Apr. 9, 2020), <https://www.cbpp.org/sites/default/files/atoms/files/4-14-08tax.pdf> [<https://perma.cc/HW23-ZG97>] (explaining Medicare, Medicaid, the Children’s Health Insurance Program, and the Affordable Care Act marketplace subsidies accounted for twenty-five percent of 2019 budget).

13. *See* CMS 2019 FINANCIAL REPORT, *supra* note 11, at 3 (releasing financial statements that show nearly \$1.1 trillion spent on health care in fiscal year 2019, up nearly eight percent since fiscal year 2018).

14. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., NHE PROJECTIONS 2019–2028—TABLES: TABLE 01 NATIONAL HEALTH EXPENDITURES AND SELECTED ECONOMIC INDICATORS, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected> [<https://perma.cc/FJ9P-SWEY>] (projecting health care spend increases through 2028 based on data through 2018).

15. *See* Lauren E. Davis, *Growing Health Care Fraud Drastically Affects All of Us*, ASS’N CERTIFIED FRAUD EXAM’RS (2012), <https://www.acfe.com/article.aspx?id=>

rate, the government has prioritized health care fraud prevention and recovery in an effort to control rising health care costs.¹⁶

As the COVID-19 pandemic subsides, FCA litigation is anticipated to increase.¹⁷ On March 27, 2020, Congress swiftly passed the Coronavirus Aid, Relief, and Economic Security (“CARES”) Act, which established the Provider Relief Fund, dedicating \$175 billion for health care providers to “prevent, prepare for, and respond” to the COVID-19 pandemic.¹⁸ History has proven that during a national crisis—such as the Civil War or Hurricane Katrina—fraudsters take advantage of relief funding.¹⁹ Understanding this, the government is preparing to “vigorously pursue fraud” resulting from the pandemic.²⁰

The uptick in litigation has and will continue to expose ambiguities in the FCA.²¹ Unlike other elements of the FCA, the falsity element is not statutorily defined and, as a result, considerable judicial ink is spilled over its interpretation.²² A budding circuit split—or rather, what has been *perceived* as a circuit split—exemplifies falsity’s elusiveness by examining whether a physician’s clinical judgment can be considered false under the

4294974475 [https://perma.cc/YMP3-A7N5] (estimating health care fraud accounts for three to ten percent of total health care expenditures).

16. See Meador & Warren, *supra* note 10, at 455 (“The United States Department of Justice has listed health care fraud as a priority, second only to violent crime.”).

17. See Ethan P. Davis, Principal Deputy Assistant Att’y Gen., Remarks on False Claims Act at U.S. Chamber of Com. Inst. for Legal Reform (Jun. 26, 2020) (discussing COVID-19 relief funding and noting the funding is “a lot of money, and it creates a number of opportunities for fraud”); see also Richard Schroeder, Daniel J. Martin & Michael J. O’Brien, *In Coronavirus-Recovery, Haste Makes . . . Fraud, Waste, and Abuse? Managing False Claims Act Compliance Risk in the COVID-19 Crisis*, NAT’L L. REV. (Apr. 9, 2020), <https://www.natlawreview.com/article/coronavirus-recovery-haste-makes-fraud-waste-and-abuse-managing-false-claims-act> [https://perma.cc/P4VB-DSST] (“With great crises comes great compliance risk.”).

18. See Coronavirus Aid, Relief, & Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281 (2020) (outlining the parameters of government relief during the COVID-19 pandemic). To combat the expected fraud, the CARES Act established the Office of the Special Inspector General for Pandemic Recovery to lead the fraud detection efforts. See *id.*

19. See Rebecca M. Ricigliano, David Robbins, Byron R. Brown & Tiffany Wynn, *The CARES Act and Lessons from the Past: What Prior Investigative Responses to Crises Tell Us About the Future*, WESTLAW PRACS. INSIGHTS & COMMENTARIES (Apr. 27, 2020), <https://www.crowell.com/files/20200427-CARES-Act-and-Lessons-From-the-Past-Update.pdf> [https://perma.cc/R55Y-BEMU] (relating relief provided during COVID-19 pandemic to relief provided during hurricanes).

20. See Davis, *supra* note 17 (“[W]hile we will vigorously pursue fraud and other illegal activity, we also respect the critical role that the private sector is playing in helping to bring an end to the pandemic and in restarting our economy.”).

21. See Meador & Warren, *supra* note 10, at 456 (“The aggressive use of the [FCA] in the health care industry has highlighted problems in its interpretation.”).

22. See 31 U.S.C. § 3729(b) (2021) (defining other FCA elements—but not falsity).

FCA based on a showing of contradictory expert opinion.²³ In *United States ex rel. Druding v. Care Alternatives*,²⁴ the Third Circuit answered this question with a “straightforward yes.”²⁵

This Note discusses the Third Circuit’s analysis in *Druding* and suggests that the court’s imprecise interpretation and flat rejection of the Eleventh Circuit’s falsity standard created the perception of a circuit split—even though a split may not actually exist.²⁶ Further, this Note argues that the Third Circuit created unnecessary confusion for future cases by failing to (1) replace the falsity standard it rejected and (2) redirect the lower court to the appropriate FCA element—in this case, knowledge, rather than falsity.²⁷ Nonetheless, this Note demonstrates that despite the opinion’s shortcomings, the Third Circuit had substantial reason to reverse.²⁸

To introduce the area of health care fraud that this Note focuses on, Part II discusses hospice fraud and the Medicare Hospice Benefit (“MHB”). After laying the foundation for hospice fraud, Part III examines the government’s main tool in combatting fraud—the FCA. Part IV introduces the so-called circuit split by discussing the Eleventh Circuit’s decision in *United States v. AseraCare, Inc.*²⁹ and the Ninth Circuit’s opinion in *Winter ex rel. United States v. Gardens Regional Hospital and Medical Center*.³⁰ Part V lays out *Druding*’s facts and procedural history. Part VI summarizes the Third Circuit’s holding and reasoning in *Druding*. Part VII critically analyzes the issues in *Druding*. Finally, Part VIII discusses the likely impact of *Druding*.

II. THE MEDICARE HOSPICE BENEFIT: INFECTED WITH FRAUD

Dedicated to palliative care for terminally ill patients, the hospice industry has benefited from increased utilization and heightened societal acceptance of hospice services over the last few decades.³¹ When patients

23. See *United States ex rel. Druding v. Care Alts.*, 952 F.3d 89, 100 (3d Cir. 2020) (rejecting objective falsity standard).

24. *Id.*

25. *Id.* at 95 (recognizing question on appeal as “whether a hospice-care provider’s claim for reimbursement can be considered ‘false’ under the FCA” and explaining “[t]he answer is a straightforward yes”).

26. See Part VII *infra*.

27. For an analysis of *Druding*, see Part VII *infra*.

28. For a more complete critical analysis of *Druding*, see Part VII *infra*.

29. 938 F.3d 1278 (11th Cir. 2019).

30. 953 F.3d 1108 (9th Cir. 2020).

31. See 42 C.F.R. § 418.3 (2019) (defining hospice care); see also *United States ex rel. Druding v. Care Alts.*, 952 F.3d 89, 92 (3d Cir. 2020) (noting the Medical Hospice Benefit was enacted in 1983); see also CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE HOSPICE BENEFITS (2020), <https://www.medicare.gov/Pubs/pdf/02154-Medicare-Hospice-Benefits.pdf> [<https://perma.cc/B6BB-R8NG>] (explaining hospice services may include physical care, counseling, prescription drugs, equipment, and supplies for the terminal illness and related conditions); see also Isaac D. Buck, *A Farewell to Falsity Shifting Standards in Medicare Fraud Enforcement*, 49

elect to enroll in hospice, they agree to receive palliative care—treatment focused on pain relief only—and to forgo curative treatment of their terminal illness.³²

CMS is part of the Department of Health and Human Services (“HHS”) and is the primary payer for hospice services through its hospice benefit, which is referred to as the MHB.³³ The MHB covers services that are (1) offered by Medicare-certified hospice providers and (2) reasonable and necessary for the palliation and management of a Medicare beneficiary’s terminal illness.³⁴ If a service qualifies, Medicare pays the hospice a daily rate for each day the patient is enrolled in hospice—regardless of how much it actually costs to care for the patient.³⁵ This fee-for-service payment model has been criticized for its inadvertent incentive to overbill Medicare by lengthening a patient’s stay—because the longer a patient is on hospice, the more money the provider makes.³⁶

Without a limit on the number of days a patient may be enrolled in hospice benefits, average lengths of stay have been on the rise as more hospice providers enter the market.³⁷ Medicare provides eligible hospice patients with two ninety-day benefit periods, followed by an unlimited number of sixty-day benefit periods.³⁸ Without a cap on the amount of time a patient can be on hospice, some patients are on hospice for years.³⁹

SETON HALL L. REV. 1, 10 (2018) (recognizing hospice care’s soaring popularity has been, in part, due to increasing societal acceptance).

32. See Kathy L. Germinara, *Hospice and Health Care Reform: Improving Care at the End of Life*, 17 WIDENER L. REV. 443, 449 (2011) (noting positive aspects of hospice care not only for terminally ill patients but their families as well).

33. See 42 U.S.C. § 1395c (2021) (noting Medicare provides basic health insurance for individuals who are at least age sixty-five, disabled, or suffering from end-stage renal disease); see also CMS 2019 FINANCIAL REPORT, *supra* note 11, at 2 (describing the history of HHS and CMS).

34. See 42 C.F.R. § 418.1 (2009) (codifying regulation imposed on hospice providers).

35. See 42 C.F.R. § 418.302 (2015) (describing the payment procedures for hospice care).

36. See, e.g., Meador & Warren, *supra* note 10, at 470 (“Overutilization occurs when a provider orders or performs medically unnecessary tests and services. Many parts of the Medicare system restrict the price paid per service, but do not limit the quantity of services provided, producing an incentive for overutilization.”); cf. Stowell et. al., *supra* note 11, at 484 (pointing out that overbilling may be harder to detect than for example, a double-billing error).

37. See Germinara, *supra* note 32, at 462 (“[T]he mere incorporation of a hospice as a for-profit entity . . . tends to raise concerns that the hospice is focused on maximizing profits, perhaps above other goals.”).

38. 42 U.S.C. § 1395f(a)(7)(A) (2021) (discussing conditions of and limitations on payment for services); 42 C.F.R. § 418.21(a) (2006) (describing the duration of hospice care coverage).

39. See Germinara, *supra* note 32, at 448 (acknowledging that some hospice patients are on hospice for years because they are consistently recertified). Compare 42 C.F.R. § 418.309 (2018) (outlining an aggregate cap for Medicare payments to hospice providers), with MEDICARE PAYMENT ADVISORY COMM., REPORT TO CONGRESS: MEDICARE PAYMENT POLICY 325 (2020) https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/

As Medicare's budget for hospice services swells and the number of hospice providers continues to rise, so does the number of qui tam claimants blowing the whistle on hospice fraud.⁴⁰ Between 2000 and 2017, MHB utilization increased 28%, spending increased 400%, and the average length of stay increased 66%.⁴¹ The hospice industry's rapid growth, relatively high provider profit margins, and subjective terminal illness certifications, has raised concerns that claims are being submitted for patients who are not actually near death.⁴²

In an effort to reduce fraudulent activity, Medicare payment is conditioned on a provider's compliance with numerous regulatory requirements.⁴³ Hospice fraud—arguably the latest epicenter of FCA litigation—has brought several regulatory requirements into focus, including that: (1) services rendered must be “reasonable and necessary,” (2) a physician must “certify . . . that a [patient is] terminally ill,” and (3) the physician's certification must be supported with documentation.⁴⁴

mar20_entirereport_sec.pdf [https://perma.cc/B9FY-UXJF] (presenting data gathered by MedPAC to support recommendation to Congress that the hospice aggregate cap should be reduced by twenty percent).

40. NAT'L HOSPICE & PALLIATIVE CARE ORG., NHPCO FACTS & FIGURES 2020 EDITION 18 (2020), <https://www.nhpc.org/wp-content/uploads/NHPCO-Facts-Figures-2020-edition.pdf> [https://perma.cc/7HS8-PZG4] (noting that hospice services account for \$19.2 billion of Medicare's 2018 budget); *see also* Buck, *supra* note 31, at 9–10 (highlighting that the MHB is a quickly growing portion of Medicare's budget and as a result, hospice fraud has become the focus of many FCA cases).

41. *See* MEDICARE PAYMENT ADVISORY COMM., REPORT TO CONGRESS: MEDICARE PAYMENT POLICY 311-13, 316-17, 319 (2019), https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar19_medpac_entirereport_sec_rev.pdf [https://perma.cc/P8A4-TEQX] (indicating that the MHB utilization increased from 22.9% in 2000 to 50.4% in 2017, spending increased from \$2.9 billion in 2000 to \$17.9 billion in 2017, and average length of stay among decedents increased from 53.5 days in 2000 to 88.6 days in 2017).

42. *See id.* (“For hospice providers, Medicare payments exceeded marginal costs by roughly [fourteen] percent in 2016, suggesting that providers have an incentive to treat Medicare patients.”). *See also* Buck, *supra* note 31, at 13 (“The booming business of Medicare's hospice benefit has raised questions about the costly incentives that exist within it.”); Cerminara, *supra* note 32, at 459 (pointing to the tighter controls Congress placed on hospice recertifications in 2011 in support of the argument that Congress “revealed some distrust of hospices” through its legislative activities).

43. *See* Cerminara, *supra* note 32, at 459-60 (explaining that MedPAC—an entity created to advise CMS—expressed concern “regarding the potential for fraud and abuse among for-profit hospices” and as a result, CMS revised some of its regulations); *see generally* SUZANNE MURRIN, HOSPICES SHOULD IMPROVE THEIR ELECTION STATEMENTS AND CERTIFICATIONS OF TERMINAL ILLNESS 1-2 (2016), <https://www.oversight.gov/sites/default/files/oig-reports/oei-02-10-00492.pdf> [https://perma.cc/KDW2-FAPF] (citing several recent cases involving hospice fraud).

44. 42 U.S.C. § 1395y(a)(1)(C) (2021) (noting the medical necessity requirement for hospice services); 42 U.S.C. § 1395f(a)(7)(A)(i) (2021) (requiring a patient to be certified as terminally ill under the MHB); *see* 42 C.F.R. § 418.22(b)(2) (2020) (mandating that a terminally ill certification be supported by documentation).

First, for a claim to be reimbursable under Medicare, the services rendered must be “reasonable and necessary” when benchmarked against acceptable medical standards.⁴⁵ This requirement spans beyond the MHB, to all Medicare-reimbursable claims.⁴⁶ To determine what is reasonable and necessary, CMS suggests considering several factors, including whether the services are (1) “appropriate” in terms of “duration and frequency,” (2) “furnished in accordance with accepted medical standards,” and (3) not excessive in terms of “the patient’s medical need.”⁴⁷

Next, a Medicare beneficiary is eligible for hospice benefits if their attending physician and the hospice medical director certify that they are “terminally ill.”⁴⁸ To be considered terminally ill, a patient must have “a medical prognosis that [their] life expectancy is [six] months or less” if the “illness runs its normal course.”⁴⁹ While physicians have latitude when determining someone’s life expectancy, they do not have “unfettered discretion[.]”⁵⁰ Recognizing the difficulty in estimating life expectancy, CMS admits that “making a prognosis is not an exact science.”⁵¹ Nonetheless, CMS puts boundaries around a physician’s discretion by requiring a clinical basis for certification.⁵²

45. See 42 U.S.C. § 1395y(a)(1)(C) (explaining that for hospice services to be covered under Medicare, they must be “reasonable and necessary for the palliation or management of [the patient’s] terminal illness”).

46. See *id.* § 1395y(a)(1) (identifying the medical necessity requirement as it relates to services reimbursable under Medicare).

47. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PROGRAM INTEGRITY MANUAL § 13.5.4 (2019), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf> [<https://perma.cc/3Q7U-7DJ9>] (summarizing guidance regarding local coverage determinations).

48. 42 U.S.C. § 1395f(a)(7)(A)(i) (describing the terminally ill certification required during the first ninety-day period of a patient’s hospice stay); see *id.* § 1395f(a)(7)(A)(ii) (explaining that after being initially certified as terminally ill, a patient must be re-certified each benefit period).

49. 42 U.S.C. § 1395x(dd)(3)(A) (defining terminally ill); 42 C.F.R. § 418.3 (2019) (defining terminally ill).

50. *Winter ex rel. United States v. Gardens Reg’l Hosp. & Med. Ctr.*, 953 F.3d 1108, 1114 (9th Cir. 2020) (citing 42 C.F.R. § 412.3(d)(1) (2018)) (“The Medicare program trusts doctors to use their clinical judgment based on ‘complex medical factors,’ but does not give them unfettered discretion to decide whether inpatient admission is medically necessary . . .”).

51. Medicare Program; FY 2015 Hospice Wage Index & Payment Rate Update, 79 Fed. Reg. 50,452, 50,470 (Aug. 22, 2014) (to be codified at 42 C.F.R. pt. 405, 418) (explaining that CMS understands “that the rate of live discharges should not be zero, given the uncertainties of prognostication.”); see *generally* *Brown v. United States*, 737 Fed. Appx. 777, 780-81 (7th Cir. 2018) (reviewing a negligence claim, explaining that “medicine is an inexact science” (internal quotation marks omitted) (quoting *Ross v. Olson*, 825 N.E.2d 890, 893 (Ind. Ct. App. 2005))).

52. See Medicare Program, FY 2015 Hospice Wage Index & Payment Rate Update, 79 Fed. Reg. at 50,470 (“The certification is based on a clinical judgment regarding the usual course of a terminal illness, and recognizes the fact that making medical prognostications regarding life expectancy is not exact. However, . . .

Finally, a terminally ill prognosis must be tethered to a patient's medical records.⁵³ When certifying a patient as terminally ill, a physician must record a "brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less"⁵⁴ Underscoring the importance of the narrative, the regulations stipulate the narrative's substance and location within the certification.⁵⁵ Moreover, the physician's record must contain "clinical information and other documentation" to support the patient's prognosis.⁵⁶ Hospice providers that accept Medicare reimbursements without satisfying these requirements may be subject to FCA liability.⁵⁷

III. ANATOMY OF THE FCA

Congress originally enacted the FCA in 1863 to combat wartime profiteering, but after several amendments, the modern-day FCA is used more extensively now than ever before.⁵⁸ The Civil War era was infested with "crooked" contractors who took advantage of government funding by selling the army sawdust instead of gunpowder, rotting ships, and spoiled food rations.⁵⁹ When confronted with this rampant fraud, Congress passed the FCA to impose civil and criminal liability on those who submit-

[this] does not negate the fact that there must be a clinical basis for a certification.").

53. See *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1295 (11th Cir. 2019) (admitting that "clinical judgments must be tethered to a patient's valid medical records," while also asserting that "the law is designed to give physicians meaningful latitude . . . without fear that [their clinical] judgments will be second-guessed after the fact by laymen in a liability proceeding.").

54. See 42 C.F.R. § 418.22(b)(3) (2020).

55. See *id.* § 418.22(b)(3)(i)–(v) (outlining the acceptable locations for the narrative in relation to the certification).

56. See *id.* § 418.22(b)(2) ("Clinical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record with the written certification"); see also *id.* § 412.46(b) (indicating that an evaluation of a physician's certification necessarily includes a review of the patient's medical records).

57. Cf. *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 192 (2016) (recognizing that "billing parties are often subject to thousands of complex statutory and regulatory provisions[,] the Court found that where a provision is labeled as a condition of payment, the labeling is relevant to a materiality inquiry but not dispositive). For a brief overview of *Escobar* and its impact on the falsity element of the FCA, see *supra* Section II.B.2.

58. See Press Release, Dep't of Justice, Justice Department Recovers Over \$4.7 Billion from False Claims Act Cases in Fiscal Year 2016 (Dec. 14, 2016), <https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016> [<https://perma.cc/45MV-WX37>] (explaining that "Congress amended the [FCA] . . . to give the government a more effective tool against false and fraudulent claims[,] and, as a result, sixty percent of all FCA recoveries in the last thirty years have been obtained since 2009).

59. Justice Department Recovers Over \$2.8 Billion in 2018, *supra* note 4 (noting that during the Civil War, "crooked contractors defrauded the Union Army by selling it sick mules, lame horses, sawdust instead of gunpowder, and rotted ships with fresh paint").

ted false claims to the government.⁶⁰ The FCA has gone through several modifications during its lifespan and is currently in its most robust and powerful form.⁶¹

This Part provides an overview of the modern-day FCA. First, Section III.A discusses the FCA's whistleblower provision which has greatly contributed to the FCA's expansive reach. Next, Section III.B examines the three main elements of a FCA claim, namely (1) knowledge, (2) materiality, and (3) falsity.

A. *Qui Tam Claims: Breathing Life into the FCA*

While authority to enforce the FCA primarily vests with the Attorney General, additional authority vests to whistleblowers.⁶² Under the FCA's whistleblower provision, private individuals, referred to as "relators," may bring a qui tam action on behalf of the government in exchange for a right to retain a portion of the funds recovered.⁶³ After an investigation, the government has the option to either intervene and take over the action, or allow the relator to proceed on their own.⁶⁴ Relators have substantial incentives under the FCA to not only bring a qui tam claim, but to continue its pursuit even when the government does not intervene.⁶⁵ If the government intervenes, relators receive between fifteen and twenty-

60. See *Escobar*, 579 U.S. at 181 (describing the congressional investigations during the Civil War which revealed "a sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed in purchasing the necessities of war." (internal quotation marks omitted) (citing *United States v. McNinch*, 356 U.S. 595, 599 (1958))).

61. See *id.* (explaining that since the FCA's enactment, Congress "has repeatedly amended the Act, but [the Act's] focus remains on those who present or directly induce the submission of false or fraudulent claims"); see also Al-Salihi, *supra* note 9, at 442–43 (summarizing recent FCA modifications, including the added incentives for whistleblowers, expansion of the definition of "claim," as well as the Fraud Enforcement and Recovery Act of 2009 ("FERA") that expanded the scope of liability).

62. See 31 U.S.C. § 3730(a)–(b) (2021) (identifying the parameters of civil actions under the FCA).

63. *Id.* § 3730(b)(1) (recognizing the right of private persons to bring a civil action under the FCA on behalf of the government); see also Al-Salihi, *supra* note 9, at 470 ("The FCA deputizes ordinary citizens to report fraud against the government Inefficiencies arise when qui tam relators fail to comprehend exactly what the FCA is deputizing them to do.").

64. *Id.* § 3730(b)(4) (indicating that the government must decide whether to intervene on the action after the investigatory period ends). Once filed, a qui tam complaint is sealed for at least sixty days while the government investigates the allegations. *Id.* § 3730(b)(2) (imposing that a qui tam 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"); see also Meador & Warren, *supra* note 10, at 467 (recognizing that the amount of time cases remain under seal usually extends "well beyond" sixty days, suggesting that depending on the number of extensions requested by the government, the sealed period could last years).

65. See 31 U.S.C. § 3730(d)(1)–(2) (discussing the awards to qui tam plaintiffs).

five percent of the funds recovered.⁶⁶ Alternatively, if the government decides not to intervene and the relator goes forward on behalf of the government, the relator is entitled to receive between twenty-five and thirty percent of the recoveries.⁶⁷

Prompted in large part by the FCA incentives, whistleblowers are now uncovering fraud at an unprecedented rate.⁶⁸ In fact, \$2.1 billion, or seventy percent, of the \$3 billion recovered in FCA-related recoveries in 2019 stemmed from *qui tam* claims.⁶⁹ *Qui tam* claims are expected to continue to play a critical role in fraud detection, with an average of more than twelve new cases being brought every week.⁷⁰

B. *Triaging the Elements of an FCA Claim*

The FCA permits a cause of action against anyone who defrauds the government.⁷¹ While the FCA has several liability provisions, 31 U.S.C. § 3729(a)(1)(A) (“Subsection (a)(1)(A)”) and § 3729(a)(1)(B) (“Subsection (a)(1)(B)”) are two of the most commonly invoked.⁷² Under Subsection (a)(1)(A), FCA liability is triggered when an individual “knowingly presents, or causes to be presented, a false or fraudulent claim [to the government] for payment or approval[.]”⁷³ Further, under Subsection (a)(1)(B), any person who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]” is liable.⁷⁴

66. *See id.* § 3730(d)(1) (explaining that the amount relators receive depends “upon the extent to which the [relator] substantially contributed to the prosecution of the action”).

67. *See id.* § 3730(d)(2).

68. *See* Justice Department Recovers Over \$3 Billion in 2019, *supra* note 5 (acknowledging “[t]axpayers have benefited greatly” as a result of *qui tam* claimants “who are often required to make substantial sacrifices to bring these schemes to light” (internal quotation marks omitted)).

69. *See id.* (recognizing that as compensation for their effort, *qui tam* claimants took home \$265 million, or roughly nine percent, of the government’s recoveries in fiscal year 2019).

70. *See id.* (“The number of lawsuits filed under the *qui tam* provisions of the [FCA] has grown significantly since 1986, with 633 *qui tam* suits filed this past year—an average of more than 12 new cases every week.”).

71. *See* *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 181 (2016) (clarifying the circumstances when the FCA imposes liability).

72. *See* Christopher L. Martin, Jr., *Reining in Lincoln’s Law: A Call to Limit the Implied Certification Theory of Liability Under the False Claims Act*, 101 CAL. L. REV. 227, 233-34 (2013) (“Sections 3729(a)(1)(A)-(G) establish liability for seven fraudulent acts. Of these seven, the conduct prohibited by subsection (a)(1)(A) has produced the most litigation.”); *see also* Al-Salihi, *supra* note 9, at 445 (explaining that “[o]f the fraudulent acts described in section 3729, subsections (a)(1)(A) and (a)(1)(B) are the subject of the most litigation”).

73. *See* 31 U.S.C. § 3729(a)(1)(A); *see also id.* § 3729(a)(1) (codifying seven areas of FCA liability as well as the corresponding penalties).

74. *Compare id.* § 3729(a)(1)(B) (incorporating the word “material”), *with id.* § 3729(a)(1)(A) (outlining parameters for liability without including the word “material”).

The financial impact of the FCA on health care providers cannot be overstated.⁷⁵ Violators are subject to treble damages, repayment of attorney fees, and civil penalties of up to \$25,076 per false claim in 2022.⁷⁶ Considering that each FCA case often involves tens of thousands of claims, the aggregated penalty amount for each case quickly becomes “astronomical.”⁷⁷ Beyond the financial burden of litigation, health care providers face an additional punishment—exclusion from the government’s health care programs.⁷⁸ When the damages, penalties, fees, and reduction in future earnings are taken together, each cause of action has the potential to cost health care providers millions—or even billions—of dollars.⁷⁹ Despite these high stakes, much ambiguity still remains regarding the FCA’s elements, namely: (1) knowledge, (2) materiality, and (3) falsity.⁸⁰

1. *Knowledge and Materiality*

First, as a testament to its broad scope, the FCA’s knowledge element imposes liability not only on those who intend to defraud it, but also on those who ignore a claim’s obvious defects.⁸¹ As a guide for the legal community, the knowledge element is defined within the FCA.⁸² Under the FCA, a person acts knowingly with respect to the information’s falsity, when that person has: (1) “actual knowledge[.]” (2) “acts in deliberate ignorance[.]” or (3) “acts in reckless disregard[.]”⁸³

75. *Cf. id.* § 3729(a)(1) (identifying the damages and penalties for violating the FCA).

76. *See* 15 C.F.R. § 6.3 (2022) (codifying annual increases to FCA civil penalties, namely, increasing the minimum from \$11,803 in 2021 to \$12,537 in 2022 and increasing the maximum from \$23,607 in 2021 to \$25,076 in 2022).

77. Mark A. Srere, Cliff Stricklin & Laura S. Perlov, *The Changing Landscape of FCA Litigation for Healthcare Providers Due to Increased Civil Penalty Amounts*, BRYAN CAVE LEIGHTON PAISNER LLP (Aug. 17, 2016), <https://www.bclplaw.com/en-US/insights/the-changing-landscape-of-fca-litigation-for-healthcare.html> [https://perma.cc/ZEB5-MQFD] (calling the FCA’s financial burden placed on health care providers “enormous” and “astronomical”).

78. *See* 42 U.S.C. § 1320c-5 (2011) (authorizing the OIG to exclude providers from participation in all federal health care programs).

79. *See generally* Justice Department Recovers Over \$3 Billion in 2019, *supra* note 5 (calling attention to the government’s FCA recoveries during fiscal year 2019, including—but not limited to—recoveries worth \$1.4 billion, \$500 million, and \$624 million from seven drug manufacturers).

80. *See* Al-Salihi, *supra* note 9, at 467 (acknowledging that the “FCA is undoubtedly complex” and to unravel its complexity, providers need a clear understanding of the elements because “a system as complex as private government cannot function efficiently in an environment of acute uncertainty”).

81. *See generally* Winter *ex rel.* United States v. Gardens Reg’l Hosp. & Med. Ctr., 953 F.3d 1108, 1117 (9th Cir. 2020) (acknowledging Congress’ intent for the knowledge element to be broader than the common law).

82. *See* 31 U.S.C. § 3729(b)(1)(A) (2021) (defining “knowing” and “knowingly” for purposes of the FCA).

83. *See id.* § 3729(b)(1)(B) (clarifying the proof requirement to satisfy the knowledge element of an FCA claim); *see also* Winter, 953 F.3d at 1122 (citing Fed.

Second, the FCA's materiality element—described as “rigorous” and “demanding” by the Supreme Court—acts as a gatekeeper warding off frivolous claims.⁸⁴ The FCA defines “material” as including information that has a “natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”⁸⁵

2. *Falsity*

Finally, falsity is the third element of a FCA claim and unlike the other elements, it is not defined in the FCA.⁸⁶ Rather, the falsity element owes its complexity to the courts that have interpreted it.⁸⁷ Two categories of falsity have developed: factual falsity and legal falsity.⁸⁸ Factual falsity—arguably the more straightforward falsity type—applies when a government contractor misrepresents the goods or services provided to the government.⁸⁹ For example, a claim would be factually false if a physician administered three flu shots but billed Medicare for ten flu shots.⁹⁰ While factual falsity focuses on untrue facts in a claim, legal falsity focuses on the contractor's untrue certification of compliance with statutory or regulatory requirements.⁹¹ For example, a claim would be legally false if an unlicensed therapist billed Medicare for a patient's therapy session even though Medicare only reimburses for sessions conducted by licensed therapists.⁹² In this example, the claim is factually accurate—a therapy

R. Civ. P. 9(b)) (reminding lower courts that the Federal Rules of Civil Procedure stipulate that knowledge may be alleged generally).

84. See *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016) (explaining that an “all-purpose antifraud statute” intended to punish minor noncompliance mistakes (internal quotation marks omitted) (quoting *Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 672 (2008))).

85. See 31 U.S.C. § 3729(b)(4) (defining “material” for purposes of the FCA).

86. See Robert G. Anderson, *Clarification of the Implied False Certification Theory Under the False Claims Act: The Supreme Court's Decision in Universal Health Services, Inc. v. United States ex rel. Escobar*, 29 HEALTH LAW. 33, 33–34 (2016) (describing the basics of the falsity element).

87. See Latoya C. Dawkins, *Not So Fast: Proving Implied False Certification Theory Post-Escobar*, 42 SETON HALL LEGIS. J. 163, 164 (2017) (acknowledging that as the number of FCA cases continues to rise, understanding falsity and materiality has become increasingly more important).

88. See Al-Salihi, *supra* note 9, at 453–59 (explaining difference between legal falsity and factual falsity).

89. See Anderson, *supra* note 86, at 34 (“Factually false claims are easily understood . . .”); Megan E. Italiano, *An Implied Defense: Self-Disclosure Offers A Defense to the Expanded False Claims Liability After Universal Health Services v. Escobar*, 60 WM. & MARY L. REV. 1943, 1951 (2019) (explaining that factually false claims represented the bulk of health care FCA claims historically).

90. See Anderson, *supra* note 86, at 33–34 (illustrating factual falsity).

91. See also *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 741 (10th Cir. 2018) (describing instances of factual falsity, namely, when a claim is submitted with an incorrect description of the goods or services or where the goods or services were never actually provided).

92. See Anderson, *supra* note 86, at 34 (providing example of legal falsity).

session did occur—but the therapist’s noncompliance with the licensing requirement nevertheless renders the claim legally false.⁹³

Legal falsity is further broken down into two categories: (1) express false certification and (2) implied false certification.⁹⁴ Under the express false certification theory of liability, a government contractor expressly represents compliance with a statutory or regulatory requirement, but has not actually complied.⁹⁵ For example, an express false certification claim arises if an unlicensed therapist, when filling out a claim, checks a box certifying compliance with a regulation requiring all therapists to be licensed.⁹⁶ The therapist expressly certified that they satisfied the regulatory requirement even though the therapist is not actually licensed.⁹⁷

In contrast, implied false certification liability may arise when someone simply submits a claim to the government without disclosing their statutory or regulatory violations.⁹⁸ Consider the unlicensed therapist once more: implied false certification liability may apply when the claim is submitted, even if there is nothing on the claim that expressly confirms compliance.⁹⁹ As the most expansive interpretation of falsity, the implied false certification theory was not uniformly applied by the circuit courts until 2016, when the Supreme Court stepped in to resolve the split in *Universal Health Services v. United States ex rel. Escobar*.¹⁰⁰

93. See Jacob J. Stephens, *Dicta Me This: Implied False Certification to Materiality Under the False Claims Act Post-Escobar*, 44 U. DAYTON L. REV. 273, 279–80 (2019) (describing “[f]actually false” statements [as being] routinely associated with incorrect descriptions of goods or services provided, or a request for reimbursement for goods or services that were never provided”); see also *id.* (defining “[l]egally false” statements [as being] false representations or false certifications of compliance with a governing law, statute or regulation, or contractual term.”).

94. See Al-Salihi, *supra* note 9, at 454 (explaining the circuit court split regarding the validity of the implied certification theory of liability as it existed prior to the Supreme Court settling the split in *Escobar*).

95. See *Polukoff*, 895 F.3d at 741 (reasoning that the Supreme Court precedent demonstrates “a more expansive view of ‘false or fraudulent’”).

96. See Italiano, *supra* note 89, at 1949–51 (explaining that “in the health care context, ‘legally false’ claims may arise when an item or service has been provided to patients, but an underlying federal rule was violated, such as nonadherence to a Medicare requirement for participation.”).

97. See Stephens, *supra* note 93 (noting that express false certification claims involve individuals who “‘falsely certif[y] compliance with a particular statute, regulation, or contractual term, where compliance is a prerequisite to payment’ . . . [and it] is irrelevant how the statement is made, as long as [it] relates to a claim for payment from the government.” (quoting *United States ex rel. Conner v. Salina Reg’l Health Ctr.*, 543 F.3d 1211, 1217 (10th Cir. 2008))).

98. See *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 181 (2016) (explaining that it does not matter if the government expressly identifies a condition of payment, rather, what matters is “whether the defendant knowingly violated a requirement that the defendant knows is material to the Government’s payment decision”).

99. See *United States ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1172 (9th Cir. 2006) (discussing the various forms false certification can take including, but not limited to “assertion[s], statement[s], or secret handshake[s]”).

100. 136 S. Ct. 1989 (2016).

In *Escobar*, the Supreme Court unanimously upheld the implied false certification theory of liability, reasoning that false misrepresentations are actionable under the FCA.¹⁰¹ The Court explained that when a statute does not define a term, it is Congress' intent to import the term's well-settled common-law meaning.¹⁰² Without a statutory definition of falsity, the Court relied on common-law fraud principles in defining the FCA's scope.¹⁰³ Given that the common-law meaning of fraud encompasses misleading omissions as a form of false misrepresentation, the Court applied the same reasoning to the FCA.¹⁰⁴

IV. A SUPERFICIAL HAIRLINE FRACTURE: CIRCUIT COURTS RUN INTO COMPLICATIONS WHEN EVALUATING CLINICAL JUDGMENTS AND FCA FALSITY

Recently, and as a matter of first impression, circuit courts have had to determine whether conflicting expert opinions are sufficient to create a triable dispute of fact as to falsity.¹⁰⁵ The so-called circuit split on this matter exists among the Eleventh, Ninth, and Third Circuits.¹⁰⁶

101. *Id.* at 1999, 2002 (reasoning that FCA liability is not constricted to claims containing express falsehoods and stating, “. . . instead of adopting a circumscribed view of what it means for a claim to be false or fraudulent,” concerns about fair notice and open-ended liability “can be effectively addressed through strict enforcement of the Act’s materiality and [knowledge] requirements.” (quoting *United States v. Sci. Applications Int’l Corp.*, 626 F.3d 1257, 1270 (D.C. Cir. 2010))).

102. *Id.* at 1999 (pointing out that when a statutory definition is not provided, Congress’ intends to import the term’s common-law meaning).

103. See RESTATEMENT (SECOND) OF TORTS § 525 (AM. L. INST. 1977) (“One who fraudulently makes a misrepresentation of fact, opinion, intention or law for the purpose of inducing another to act or to refrain from action in reliance upon it, is subject to liability . . .”).

104. See *Escobar*, 579 U.S. at 189 (interpreting the FCA terms, false and fraudulent under common-law fraud in the absence of statutory definitions); RESTATEMENT (SECOND) OF TORTS § 529, cmt. c (AM. L. INST. 1977) (“[A] statement that contains only favorable matters and omits all reference to unfavorable matters is as much a false representation as if all the facts stated were untrue.”); see also *OmniCare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 188–91 (2015) (holding that opinions could be false if not genuinely held or if based on untrue material facts).

105. Compare *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1291 (11th Cir. 2019) (“Neither this Court nor any of our sister circuits has considered the standard for falsity in the context of the Medicare hospice benefit, where the controlling condition of reimbursement is a matter of clinical judgment.”), with *Winter ex rel. United States v. Gardens Reg’l Hosp. & Med. Ctr.*, 953 F.3d 1108, 1114–15 (9th Cir. 2020) (involving a former employee who had the responsibility of reviewing hospital admission criteria).

106. See *Winter*, 953 F.3d at 1114–15; see also *AseraCare*, 938 F.3d at 1284 (reviewing a case involving alleged hospice fraud).

A. *The Eleventh Circuit Transplants Objectivity into the FCA in United States v. AseraCare, Inc.*

In *AseraCare*, the Eleventh Circuit held that reasonable differences in clinical judgment, without more, cannot establish falsity.¹⁰⁷ The Eleventh Circuit reasoned that deference must be given to physicians and explained that a physician's certification cannot trigger FCA liability unless the clinical judgment reflects an "objective falsity."¹⁰⁸ After introducing its new standard, the court clarified what constitutes an objective falsity; namely, situations where (1) the physician fails to assess the patient's condition prior to asserting a clinical judgment; (2) the certifying physician does not believe their clinical judgment is accurate; or (3) the expert testimony demonstrates that no reasonable physician would have reached a similar clinical judgment.¹⁰⁹ Health care providers had reason to celebrate the Eleventh Circuit's ruling, given that *AseraCare* effectively narrowed the FCA's scope—but their celebrations did not last long.

B. *The Ninth Circuit Takes a Noninvasive Approach in Winter ex rel. United States v. Gardens Regional Hospital & Medical Center*

It took less than seven months for the Eleventh Circuit's objective falsity standard to be confronted by another circuit.¹¹⁰ In *Winter*, the Ninth Circuit held that clinical judgments are capable of being false under the FCA.¹¹¹ In contrast to *AseraCare*, in which hospice certifications were the

107. *AseraCare*, 938 F.3d at 1301 (stating that the FCA should not be used as the "[g]overnment's primary line of defense against questionable claims for reimbursement" without a showing that the claim reflected an "objective and knowing falsehood"); see also *id.* at 1297 (holding that "in order to show objective falsity as to a claim . . . the [g]overnment must show something more than mere different of reasonable opinion concerning the prognosis . . .").

108. *Id.* at 1296 ("Nothing in the statutory or regulatory framework suggests that a clinical judgment regarding a patient's prognosis is invalid or illegitimate merely because an unaffiliated physician reviewing the relevant records after the fact disagrees with that clinical judgment."). The court clarified, stating that "a reasonable difference of opinion among physicians reviewing medical documentation . . . is not sufficient on its own to suggest that those judgements—or any claims based on them—are false under the FCA." *Id.* at 1297. Further, the court noted that a "sincerely held clinical judgment" will not be considered false, even if it is later contended to be wrong. *Id.*

109. See *id.* (outlining the scenarios where a claim could reflect an objective falsity).

110. See *Winter*, 953 F.3d at 1108 (issuing its ruling on March 23, 2020); *United States ex rel. Druding v. Care Alts.*, 952 F.3d 89, 89 (3d Cir. 2020) (issuing its ruling on March 4, 2020).

111. See *Winter*, 953 F.3d at 1117 ("[O]pinions are not, and have never been, completely insulated from scrutiny." (internal quotation marks omitted) (quoting *United States v. Paulus*, 894 F.3d 267, 275–76 (6th Cir. 2018))). The court noted that the Tenth Circuit previously recognized medical judgements can be false under the FCA if the judgement is not considered "reasonable . . . under the government's definition of the phrase." *Id.* at 1118 (internal quotation marks omitted) (quoting *United States ex rel. Polukoff v. St. Mark's Hospital*, 895 F.3d 730, 742 (10th Cir. 2018)).

focus, the *Winter* court faced questions relating to Medicare's medical necessity requirement for inpatient admissions.¹¹² Nonetheless, these cases are comparable because they both focus on a physician's clinical judgment in relation to one of Medicare's regulatory requirements.¹¹³

In the Ninth Circuit's carefully constructed *Winter* opinion, the court suggested that its analytical approach did not conflict with the Eleventh Circuit's approach in *AseraCare* for three reasons.¹¹⁴ First, in the Ninth Circuit's view, the Eleventh Circuit ruled on whether a reasonable disagreement between physicians, without more, is sufficient to establish falsity—not whether a medical opinion could ever be false.¹¹⁵ Second, relying on an *AseraCare* footnote, the Ninth Circuit asserted that the Eleventh Circuit did not intend for its objective falsity standard to apply beyond hospice certifications.¹¹⁶ Finally, as a back-up, the Ninth Circuit included a one sentence disclaimer indicating that, “to the extent that *AseraCare* can be read to graft any type of ‘objective falsity’ requirement onto the FCA, we reject that proposition.”¹¹⁷

V. STITCHING TOGETHER A QUI TAM CLAIM: THE FACTS AND PROCEDURE OF *DRUDING*

The same month that the Ninth Circuit issued its ruling in *Winter*, the Third Circuit also weighed in on the matter.¹¹⁸ In *Druding*, four former employees filed a qui tam complaint in the United States District Court for the District of New Jersey against their former employer and hospice pro-

112. See *Winter*, 953 F.3d at 1112–13 (involving a qui tam claimant alleging that a hospital falsely submitted claims to Medicare for inpatient admissions that were not medically necessary).

113. See Najjar, *supra* note 5, at 149–52 (finding similarities between *AseraCare*, a case involving medical necessity, and *United States v. Paulus*, 894 F.3d 267 (6th Cir. 2018), a case involving criminal FCA liability).

114. See *Winter*, 953 F.3d at 1118–19 (reasoning that its ruling is not contradicted by the Eleventh Circuit's findings in *AseraCare*). But see *id.* at 1120 (admitting that the evidence presented goes beyond a mere difference in expert testimony).

115. *Id.* at 1118–19 (emphasis added) (looking past the Eleventh's circuit's language regarding objectivity, the Ninth Circuit asserts that the *AseraCare* holding should not be interpreted to apply to all subjective statements).

116. *Id.* at 1119 (explaining that the *AseraCare* court specifically noted that the objective falsehood standard does not “necessarily apply to a physician's certification of medical necessity”); see also *AseraCare*, 938 F.3d at 1300 n.15 (distinguishing *United States ex rel. Polukoff v. St. Mark's Hospital*, 895 F.3d 730 (10th Cir. 2018), by noting the factual differences between medical necessity claims, such as the one in *Polukoff*, and hospice claims).

117. *Winter*, 953 F.3d at 1119 (citing *United States ex rel. Druding v. Care Alts.*, 952 F.3d 89,94 (3d Cir. 2020)) (holding the FCA does not require a plaintiff to plead objective falsehood because any opinion, even that of a physician, can be false or fraudulent).

118. See *Druding*, 952 F.3d at 91 (“This case requires us to consider whether and when clinical judgements can be considered ‘false’ in the context of the [FCA].”).

vider, Care Alternatives, Inc.¹¹⁹ The relators alleged the hospice provider knowingly submitted false claims to Medicare.¹²⁰ More specifically, the relators argued the hospice provider admitted patients who were not actually terminally ill and pressured employees to alter medical records to make patients appear eligible for the MHB.¹²¹ After an investigation spanning more than seven years, the government decided not to intervene and the relators proceeded with the suit on their own.¹²²

Medical records from a sampling of forty-seven patients were produced during discovery and both sides presented expert testimony regarding the accuracy of the patients' prognoses.¹²³ Specifically, the relators' medical expert opined that of the forty-seven patients whose records were reviewed, twenty-one—or roughly forty-five percent—were either (1) ineligible for hospice for all or part of the time they were enrolled in hospice, or (2) had incomplete records.¹²⁴ Moreover, the relator's expert found that of the 603 hospice certification periods for those forty-seven patients, 214—or approximately thirty-five percent—were improperly certified for hospice eligibility.¹²⁵ In contrast, the hospice provider's medical expert testified that each patient prognosis was reasonable.¹²⁶

Following discovery, the hospice provider filed a motion for summary judgment.¹²⁷ Focusing solely on the falsity element, the district court granted the hospice provider's motion.¹²⁸ The court identified the con-

119. *Druding v. Care Alts.*, (District Ct. *Druding I*), 164 F. Supp. 3d 621, 625 (D.N.J. 2016) (ruling on the first summary judgment motion).

120. *Druding v. Care Alts., Inc.* (District Ct. *Druding II*), 346 F. Supp. 3d 669, 672 (D.N.J. 2018), *rev'd & remanded sub nom.*, United States ex rel. *Druding v. Care Alts.*, 952 F.3d 89 (3d Cir. 2020) (providing the factual background for the plaintiff-relators claim).

121. *Id.* at 677–81 (exploring the limited evidence that the relators provided).

122. *Id.* at 671 (explaining that the government, despite declining to intervene, would nevertheless remain an interested party in the matter); see also 31 U.S.C. § 3730(b)(2) (2021) (indicating that after investigating the claims raised, the government has the option to intervene and proceed with an action brought by a qui tam claimant).

123. *District Ct. Druding II*, 346 F. Supp. 3d at 681 (providing the conflicting expert findings of two physicians).

124. *Id.* (explaining the relator's expert testimony).

125. *Id.*

126. See *District Ct. Druding II*, 346 F. Supp. 3d at 681; see also Appellant's Reply Brief at 15, United States ex rel. *Druding v. Care Alts.*, 2019 WL 1894640 (3d Cir. 2019) (C.A.3) (asserting that the district court overlooked the relator's expert's opinion that even if confined to the fifteen patients identified in the complaint, twelve of the fifteen—or eight percent—were inappropriate for hospice care for at least part of their stays).

127. See *District Ct. Druding II*, 346 F. Supp. 3d at 684 (denying Care Alternative's second motion to dismiss for a supposedly deficient Written Disclosure Statement but granting Care Alternative's motion for summary judgment).

128. *Id.* at 687 (identifying similarities between two other district court cases, namely, that every patient was physician-certified for the hospice benefit, that there was no evidence that any physician received a kickback to certify a patient, and that no particular physician was accused of certifying ineligible patients); see

flicting expert testimony as the only viable evidence of falsity and held that without more, the relators had presented insufficient evidence of “objective falsity.”¹²⁹ Echoing the points made in *AseraCare*, the district court explained that a reasonable difference in medical opinion is insufficient to create a triable dispute of fact for falsity.¹³⁰ On appeal, the Third Circuit reversed the district court’s grant of summary judgment, reasoning that a physician’s expert opinion is not immune from scrutiny.¹³¹ On February 22, 2021, the Supreme Court declined to review the Third Circuit’s decision in *Druding*, leaving the so-called circuit split to linger.¹³²

VI. THE THIRD CIRCUIT OPTS FOR AN INVASIVE APPROACH IN *DRUDING*

Unlike the Ninth Circuit, which took a more nuanced approach in *Winter*, the Third Circuit opted for a bolder tactic in *Druding*.¹³³ The

also *United States v. AseraCare, Inc.*, 176 F. Supp. 3d 1282, 1283 (N.D. Ala. 2016), *vacated & remanded sub nom. United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019) (“When hospice certifying physicians and medical experts look at the very same medical records and disagree about whether the medical records support hospice eligibility, the opinion of one medical expert alone cannot prove falsity without further evidence of an objective falsehood.”); *see also United States ex rel. Wall v. Vista Hospice Care*, No. 3:07-CV-00604-M, 2016 WL 3449833, at *17 (N.D. Tex. June 20, 2016), *appeal dismissed*, *United States ex rel. Wall v. Vista Hospice Care*, No. 17-11478, 2018 WL 3054767, at *1 (5th Cir. Jan. 11, 2018) (“[A]n FCA claim about the exercise of [a physician’s clinical] judgment must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment, not a matter of questioning subjective clinical analysis.”).

129. *Compare District Ct. Druding II*, 346 F. Supp. 3d at 688 (granting the summary judgment motion), *with United States v. Paulus*, 894 F.3d 267, 275 (6th Cir. 2018) (“[O]pinions are not, and have never been, completely insulated from scrutiny. At the very least, opinions may trigger liability for fraud when they are not honestly held by their maker, or when the speaker knows of facts that are fundamentally incompatible with his opinion.”).

130. *See District Ct. Druding II*, 346 F. Supp. 3d at 688 (explaining that the “ultimate issue is not whether the certification of hospice eligibility was correct or incorrect, but rather whether it was knowingly false.”); *see also id.* at 687 (emphasizing that there is no binding authority that directly contradicts applying an objective falsehood standard).

131. *See United States ex rel. Druding v. Care Alts.*, 952 F.3d 89, 91 (3d Cir. 2020) (rejecting the objective falsehood requirement for FCA falsity). In reaching this conclusion, the Third Circuit relied in part on the common-law definition of fraud. *See id.* at 95.

132. *See Petition for Writ of Certiorari at 2, Care Alts. v. United States* (U.S. 2020) (No. 20-371), 2020 WL 5657690 (asking “[w]hether a physician’s honestly held clinical judgment regarding hospice certification can be ‘false’ under the False Claims Act based solely on a reasonable difference of opinion among physicians.”); *see also Care Alts. v. United States*, No. 20-371, 2021 WL 666386 (U.S. 2021) (denying certiorari on February 22, 2021).

133. *See Stephen A. Wood, Falsity Under the False Claims Act—The Need for An Objective Standard of Proof*, WASH. LEGAL FOUND. (June 2, 2020), <https://www.wlf.org/2020/06/02/wlf-legal-pulse/falsity-under-the-false-claims-act-the-need-for-an-objective-standard-of-proof/> [https://perma.cc/JWQ3-WL6B] (describing *Winter* as “less troubling” than *Druding* due to the procedural timing and nuanced facts of the case).

Third Circuit's opinion began with a statutory analysis, moved on to discuss two types of falsity, considered conflicting expert opinion as proof of falsity, and finally, flatly rejected the objective falsity standard—thereby creating the perception of a circuit split.¹³⁴

Focusing on the FCA's plain language at the outset of its analysis, the Third Circuit identified two flaws in the district court's reasoning.¹³⁵ First, the Third Circuit reasoned that opinions are capable of being false under the FCA.¹³⁶ Because the FCA does not statutorily define "false" and "fraudulent," the court looked to the common-law to fill the definitional gap.¹³⁷ Relying on Supreme Court precedent, Third Circuit jurisprudence, as well as the Restatement (Second) of Torts, the court concluded that under common-law, an opinion—expert or not—can be false.¹³⁸

Second, the court held that the objective falsity standard improperly conflates knowledge and falsity.¹³⁹ In the Third Circuit's view, the district court's description of objective falsity included reference to a physician's state of mind by using the words, "knowingly" and "believed," thereby merging knowledge and falsity.¹⁴⁰ The Third Circuit reasoned that by

134. See Debra A. Weinrich & Dana Petrillo, *Mere Disagreement or Knowing Falsehood: The Circuit Split on False Claims Act "Falsity"*, WHITE & WILLIAMS LLP (Mar. 11, 2020), <https://www.whiteandwilliams.com/resources-alerts-Mere-Disagreement-or-Knowing-Falsehood-The-Circuit-Split-on-False-Claims-Act-Falsity.html> [https://perma.cc/SP5X-YZEV] (explaining the perceived circuit split).

135. See *Druding*, 952 F.3d at 95 ("As with any statutory interpretation question, our analysis begins with the text." (citing *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 187 (2016))).

136. See *id.* (reasoning that a difference of opinion can show falsity under the FCA). But see *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 189 (2015) (reviewing a securities law case, the court reasoned that an opinion "is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way").

137. *Druding*, 952 F.3d at 95 (stating that under the common law, opinions can be false for purposes of liability). But see *Anderson*, *supra* note 86, at 33 (referring to the lack of a definition for "false" and "fraudulent" as "one of the most glaring anomalies or oversights in the FCA").

138. See generally *Omnicare*, 575 U.S. at 190 (discussing securities law, explaining that "[a] reasonable investor does not expect that every fact known to an issuer supports its opinion statement"); see *Druding*, 952 F.3d at 95; see also RESTATEMENT (SECOND) OF TORTS § 525 cmt. c (AM. L. INST. 1977) ("[A] statement that a particular person . . . is of a particular opinion or has a particular intention is a misrepresentation if the person in question does not hold the opinion or have the intention asserted."); see also *id.* § 539 cmt. a ("Frequently a statement which, though in form an opinion upon facts not disclosed or otherwise known to their recipient, is reasonably understood as implying that there are facts that justify the opinion or at least that there are no facts that are incompatible with it.").

139. *Druding*, 952 F.3d at 96 (explaining that the "plain language of the FCA denotes [knowledge] as an element independent of falsity" (first citing 31 U.S.C. § 3729(a)(1)(A) (2021); then citing *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017))).

140. See *id.* (reasoning that requiring evidence that a physician lied establishes a knowledge element that is inconsistent with the FCA); see also *Druding v. Care Alts., Inc. (District Ct. Druding II)*, 346 F. Supp. 3d 669, 676 (D.N.J. 2018), *rev'd & remanded sub nom.*, *United States ex rel. Druding v. Care Alts.*, 952 F.3d 89 (3d Cir.

combining two elements into a single standard, the objective falsity standard was inconsistent with the plain language and established application of the FCA.¹⁴¹

Next, the Third Circuit faulted the objective falsity standard for circumscribing falsity to be factual falsity.¹⁴² Relying on Supreme Court precedent, Third Circuit case law, and persuasive authority from the Tenth Circuit, the court underscored the validity of a FCA claim based on a theory of legal falsity.¹⁴³ The court asserted that under a theory of legal falsity, FCA liability is triggered by showing a provider's noncompliance.¹⁴⁴ Accordingly, the court explained that a hospice provider's noncompliance with either the MHB's terminal illness requirement or the documentation requirement presents a basis for a viable legal falsity claim.¹⁴⁵

Following its discussion on factual and legal falsity, the Third Circuit rejected the district court's "bright-line" rule that a physician's opinion cannot be false.¹⁴⁶ Emphasizing that doctors are capable of lying—just like any other person—the court held that conflicting medical expert opinion can be sufficient to support a legal falsity claim.¹⁴⁷ The Third Circuit pointed out that the practice of medicine often includes compli-

2020) (reasoning that the falsity element of the relators claim is lacking because they were unable to single out a particular doctor who certified a patient whom that physician "believed was not hospice eligible" (emphasis added)).

141. *Druding*, 952 F.3d at 96 (addressing provider's concerns regarding excessive FCA liability and emphasizing the rigorous requirements for knowledge and materiality—but not falsity).

142. *Id.* at 96–97 (noting that "legal falsity necessarily encompasses situations of factual falsity").

143. *Id.* at 97 (finding support in a Tenth Circuit opinion, where an allegation of legal falsity was upheld); *see also* *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 741 (10th Cir. 2018), *cert. dismissed sub nom. Intermountain Health v. United States ex rel. Polukoff*, 139 S. Ct. 2690 (2019) (distinguishing between factual falsity and legal falsity).

144. *Druding*, 952 F.3d at 96 (3d Cir. 2020) (elaborating that falsity encompasses "liability based on non-compliance with regulatory instructions and not just objectively verifiable facts"). The court explained that the relators must show the hospice provider failed to meet at least one of the MHB's conditions of payment and determined that "disagreement between experts as to a patient's prognosis" is evidence of non-compliance. *Id.* at 97.

145. For an overview of legal falsity, *see supra* Section III.B.2.

146. *Druding*, 952 F.3d at 98 ("[R]eliability and believability of expert testimony . . . is exclusively for the jury to decide." (internal quotation marks omitted) (quoting *United States v. Paulus*, 894 F.3d 267, 277 (6th Cir. 2018))); *see also Paulus*, 894 F.3d at 270–71 (involving a lawsuit against a cardiologist where expert testimony was used to demonstrate that the cardiologist overstated angiogram blockages to increase number of procedures performed).

147. *Druding*, 952 F.3d at 98 (explaining that testimony challenging a medical opinion is appropriate evidence for a jury to consider when determining falsity). *But see Paulus*, 894 F.3d at 276 (finding that a cardiologist was convicted under the criminal FCA statute "for misrepresenting facts, not giving opinions[,] explaining that "it would be an insult to common sense and the practice of medicine to say that [the cardiologist] was not measuring facts (or attempting to do so) when [the cardiologist] conducted the angiograms at issue here").

cated scientific theories and reasoned that expert testimony is an appropriate means to explain the depth of an alleged lie to a jury.¹⁴⁸

Finally, the Third Circuit concluded its opinion by bluntly rejecting the Eleventh Circuit's rationale in *AseraCare*.¹⁴⁹ In support of its decision, the court reiterated that subjective opinions are capable of being false and repeated that falsity and knowledge must be considered independently in its jurisdiction.¹⁵⁰ Moreover, the Third Circuit explained that the Eleventh Circuit focused too heavily on the MHB's terminal illness certification requirement and undervalued the documentation requirement.¹⁵¹

VII. GETTING A SECOND OPINION: A CRITICAL ANALYSIS OF *DRUDING*

Although the Third Circuit had substantial reason to reverse, its analysis in *Druding* is difficult to defend for three reasons.¹⁵² First, the court's interpretation of the objective falsity standard is inconsistent with the Eleventh Circuit's opinion in *AseraCare*.¹⁵³ Second, the Third Circuit missed an opportunity to distinguish the facts of *AseraCare*.¹⁵⁴ Third, the court asserted that the objective falsity standard conflates knowledge and falsity, but failed to meaningfully strengthen that assertion.¹⁵⁵

A. *Stabilizing Druding: Prescribing a More Consistent Interpretation of AseraCare*

In response to the Third Circuit's flat rejection of the objective falsity standard, commentators were quick to announce yet another circuit split

148. *Druding*, 952 F.3d at 98 (“[M]edical opinions may be ‘false’ and an expert’s testimony challenging a physician’s medical opinion can be appropriate evidence for the jury to consider on the question of falsity.”).

149. *Id.* at 99 (departing from the Eleventh Circuit’s objective falsehood framework to FCA falsity); see also Patrick M. Hagan, *Two Circuits Hold the FCA Does Not Require “Objective Falsity,” Creating Confusion on the Appropriate Standard*, DINSMORE & SHOHL LLP (Mar. 31, 2020), <https://www.dinsmore.com/publications/two-circuits-hold-the-fca-does-not-require-objective-falsity-creating-confusion-on-the-appropriate-standard/> [https://perma.cc/T6C9-Q3V7] (discussing the perceived circuit split).

150. See *Druding*, 952 F.3d at 99 (reiterating reasons for rejecting the objective falsity standard).

151. See *id.* (acknowledging that the district court issued its opinion prior to the Eleventh Circuit’s affirmance of *AseraCare*).

152. See Wood, *supra* note 133 (identifying inconsistencies in the *Druding* opinion).

153. See *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1291 (11th Cir. 2019) (agreeing with the *general sense* of the district court’s ruling it was reviewing); see also *id.* at 1297 (adopting a standard that “in order to properly state a claim under the FCA . . . [a plaintiff] must identify facts and circumstances surrounding a patient’s certification that are inconsistent with the proper exercise of a physician’s clinical judgement”).

154. For a discussion on how the Third Circuit could have distinguished *AseraCare*, see *infra* Section VII.B.

155. For consideration of how the Eleventh Circuit’s objective falsity standard may be a knowledge analysis disguised as falsity, see *infra* Section VII.C.

in FCA litigation—but that classification is overstated.¹⁵⁶ The Third Circuit seemed to focus on the word “objective,” instead of attempting to understand the Eleventh Circuit’s intended meaning of “objective” and “falsity” when brought together.¹⁵⁷ In other words, the Third Circuit’s primary contention with the Eleventh Circuit’s objective falsity standard may boil down to the naming convention used.¹⁵⁸

The circuits involved in the so-called circuit split all agree that expert testimony may be used to establish a triable dispute of fact for FCA falsity.¹⁵⁹ Contrary to the holding in *Druding*, the objective falsity standard is not limited to factual falsity.¹⁶⁰ The Third Circuit argued that the Eleventh Circuit’s objective falsity standard only embraces factual inaccuracies, and therefore, excludes conflicting expert opinion because opinions are subjective.¹⁶¹ However, objective falsity, as described in *AseraCare*, includes situations where expert testimony is employed to establish that *no reasonable* physician would have certified the patient’s terminally ill prognosis.¹⁶² Accordingly, the objective falsity standard does not exclude ex-

156. Compare Jessica E. Joseph, Lawrence M. Kraus, Christopher J. Donovan, Lori A. Rubin, Judith A. Waltz, et al., *Third Circuit Creates Budding Circuit Split in United States v. Care Alternatives, Ruling That “Objective Falsity” Is Not Required Under FCA*, FOLEY & LARDNER LLP (Mar. 10, 2020), <https://www.foley.com/en/insights/publications/2020/03/third-rules-objective-falsity-not-required-fca> [https://perma.cc/HC9X-5RSE] (naming it a “budding circuit split”), with Lori A. Rubin, Jessica E. Joseph, Lisa M. Noller, Pamela Johnston, Thomas F. Carlucci & Michael J. Tuteur, *Ninth Circuit Holds an “Objective Falsehood” Is Not Required for Violation of False Claims Act*, 10 NAT’L L. REV. 278 (Apr. 20, 2020) (suggesting it may be too early to call it a circuit split), and Samantha P. Kingsbury, *Ninth Circuit Joins Several Others in Finding that Lack of Medical Necessity Claims Can Proceed Under the False Claims Act*, MINTZ (Apr. 2, 2020) (“[I]t may be premature to describe the views of the various federal circuits to have considered this issue as a true ‘split’ requiring resolution by the highest court.”).

157. See *United States ex rel. Druding v. Care Alts.*, 952 F.3d 89, 96–97 (3d Cir. 2020) (focusing on the subjective nature of opinions).

158. See Rubin, *supra* note 156 (explaining difference between courts in so-called split may be just “semantics”).

159. See *Druding*, 952 F.3d at 97 (holding a “disagreement between experts as to a patient’s prognosis may be evidence of [falsity]”); see also *Winter ex rel. United States v. Gardens Reg’l Hosp. & Med. Ctr.*, 953 F.3d 1108, 1120 (9th Cir. 2020) (pointing out that the plaintiff “allege[d] more than just a reasonable difference of opinion”); see also *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1297 (11th Cir. 2019) (“[A] reasonable difference of opinion among physicians reviewing medical documentation ex post is not sufficient on its own [to establish falsity].” (emphasis added)).

160. See *AseraCare*, 938 F.3d at 1297 (holding that objective falsity is shown when the plaintiff provides something more than a mere difference of reasonable opinion).

161. *Druding*, 952 F.3d at 97 (“According to the District Court, a medical expert’s opinion is false for purposes of FCA liability only when there is evidence of factual inaccuracy. In other words, opinions being subjective, a differing medical conclusion regarding a patient’s prognosis alone is not enough to show the certifying physician’s determination of terminal illness was factually incorrect.”).

162. See *AseraCare*, 938 F.3d at 1297 (describing scenarios when an objective falsity could be found).

pert testimony altogether; rather, expert opinion is permitted when it demonstrates that the certifying physician got the prognosis so wrong that no reasonable physician would have come to the same conclusion.¹⁶³

Moreover, the Third, Ninth, and Eleventh Circuits agree that clinical judgments *can* be false.¹⁶⁴ While the Eleventh Circuit called for deference to be given to a medical expert's good-faith opinion, it did not seek to completely immunize physician's from FCA liability.¹⁶⁵ The Eleventh Circuit established an evidentiary threshold based on the reasonability of a clinical judgment to avoid frivolous claims aimed at second guessing reasonable medical opinion.¹⁶⁶ In fact, the Eleventh Circuit noted that it was "[l]eaving aside the question [of] whether the substance of an opinion, by itself, c[ould] ever be deemed to constitute an objective falsity[.]"¹⁶⁷ In other words, expert testimony may be used to show falsity, but to be effective, the testimony needs to demonstrate that no reasonable physician would have reached the same conclusion.¹⁶⁸

By rejecting the objective falsity standard outright without replacing it, the Third Circuit has provided little guidance to the legal community on how to approach falsity in future cases.¹⁶⁹ Beyond the Third Circuit's lack of direction, the Supreme Court has declined to step in to provide clarification.¹⁷⁰ Without proper guidance, lower courts will continue to

163. See *id.* (noting that "expert evidence" can be used to reveal flaws in clinical judgment); see also Murad Hussain, Manvin S. Mayell & Emily Reeder-Ricchetti, *Is This Any Message to Send Our Medical Heroes? Second-Guessing the Clinical Judgments of Doctors on the Front Line*, ARNOLD & PORTER (Mar. 27, 2020), <https://www.arnoldporter.com/en/perspectives/blogs/fca-qui-notes/posts/2020/03/is-this-any-message-to-send-our-medical-heroes> [<https://perma.cc/RNC8-MADE>] ("Both savvy patients and doctors know that a contrary second opinion or clinical judgment does not necessarily mean that the first opinion was wrong, let alone false or fraudulent.").

164. See *Druding*, 952 F.3d at 98 (asserting "medical opinions may be 'false'"); see also *Winter*, 953 F.3d at 1119 (reasoning that opinions regarding medical necessity can be false or fraudulent); *AseraCare*, 938 F.3d at 1297 (providing clear examples of ways in which clinical judgements would be false).

165. See *Druding*, 952 F.3d at 100 ("The Eleventh Circuit also determined that clinical judgments cannot be untrue." (citing *AseraCare*, 938 F.3d at 1297)).

166. See *Winter*, 953 F.3d at 1119–20 (concluding that its opinion did not conflict with the Eleventh Circuit's rationale).

167. *AseraCare*, 938 F.3d at 1302; see *Winter*, 953 F.3d at 1119 (explaining that the Eleventh Circuit "clearly did not consider all subjective statements—including medical opinions—to be capable of falsity").

168. For further discussion on the Eleventh Circuit's holding in *AseraCare*, see *supra* Section IV.A and accompanying notes.

169. See Rubin, *supra* note 156 (acknowledging that the somewhat "incongruous standards will no doubt be the subject of FCA cases moving forward"); see generally Hussain, *supra* note 163 (providing an overview of the court's analysis in *Druding*).

170. See Brian F. McEvoy, Asher D. Funk & Dayna C. LaPlante, *SCOTUS Declines to Review False Claims Act Cases on Falsity and Medical Judgment*, POLSINELLI PC (Feb. 24, 2021), <https://www.polsinelli.com/intelligence/scotus-declines-to-review-false-claims-act> [<https://perma.cc/SVU6-FPHF>] (noting Supreme Court de-

struggle to determine when, if ever, a medical expert's opinion can create a triable dispute of fact as to falsity.¹⁷¹

B. *Different Underlying Conditions: A Comparison of the Facts and Procedure of Druding and AseraCare*

As a way to soften the blow of its flat rejection of the objective falsity standard, the Third Circuit could have distinguished *AseraCare* in three ways.¹⁷² First, *Druding* involves an appeal of an order granting summary judgment while *AseraCare* involves a case that had already gone to trial.¹⁷³ Second, unlike *AseraCare* where the conflicting expert testimony merely created a reasonable difference in opinion, the expert in *Druding* testified that no reasonable physician would have concluded that the patients at issue were terminally ill.¹⁷⁴ The expert testimony in *Druding* provided the very thing that the Eleventh Circuit said was missing in *AseraCare*—an *unreasonable* difference in expert opinion.¹⁷⁵ Third, while the plaintiffs in *Druding* alleged that the required documentation for several patients was either missing or incomplete, the plaintiffs in *AseraCare* made no such argument.¹⁷⁶ In fact, the Eleventh Circuit even pointed out that the parties were in agreement that “each patient certification was supported by a meaningful set of medical records”¹⁷⁷ Consequently, the Third Circuit's assertion that the Eleventh Circuit undervalued the documentation requirement is without merit because there was no documentation complaint in *AseraCare*.¹⁷⁸

clined to review Third Circuit's decision in *Druding*, as well as Ninth Circuit's ruling in *Winter*).

171. See *id.* (encouraging health care providers to be prepared to demonstrate the reasonability of their medical opinion).

172. For further discussion on *AseraCare*, see *supra* Section IV.A. For further discussion on the facts of *Druding*, see *supra* Section V.A.

173. See *United States v. AseraCare, Inc.* 938 F.3d 1278, 1290 (11th Cir. 2019) (providing the procedural posture of the case); *United States ex rel. Druding v. Care Alts.*, 952 F.3d 89, 91 (3d Cir. 2020).

174. See *AseraCare*, 938 F.3d at 1287 (noting that the government's expert testified by giving an “expert opinion” as to what constitutes “terminally ill”); see also *Druding*, 952 F.3d 89, 94 (3d Cir. 2020) (noting that the plaintiff's physician testified that “any reasonable physician would have reached the conclusion he reached”).

175. See *Druding*, 952 F.3d at 100 (acknowledging the Eleventh Circuit's reasonability threshold for the objective falsity standard yet asserting that the Eleventh Circuit held that “clinical judgments cannot be untrue”).

176. Compare *Druding*, 952 F.3d at 94 (noting that the plaintiff's physician found that the medical records regarding the status of several patients were incomplete), with *AseraCare*, 938 F.3d at 1289 (highlighting that the sole question posed to the jury was which medical opinion “sounded more correct”).

177. *AseraCare*, 938 F.3d at 1288. The court further explained that a “physician's clinical judgment dictates eligibility as long as it represents a reasonable interpretation of the relevant medical records.” *Id.* at 1294.

178. Compare *id.* at 1288 (noting that each patient's medical records were supported by “meaningful” documentation), with *Druding*, 952 F.3d at 94 (describing the medical records as “incomplete” for some of the patients).

C. *Objective Falsity: Showing Symptoms of Knowledge*

The objective falsity standard may simply be a knowledge analysis disguised as falsity.¹⁷⁹ While the Third Circuit acknowledged that the objective falsity standard conflates falsity and knowledge, the Third Circuit failed to fully examine the extent to which the objective falsity standard is influenced by knowledge.¹⁸⁰ More specifically, the Third Circuit failed to discern that the three objective falsity scenarios that the Eleventh Circuit discussed, align with the three types of knowledge statutorily defined in the FCA.¹⁸¹

The Eleventh Circuit's first example of objective falsity involved a physician certifying that a patient was terminally ill for Medicare, when in reality, the doctor did not actually believe that the patient had less than six months to live.¹⁸² While the Eleventh Circuit discussed this example in the context of falsity, it is more relatable to the FCA's knowledge element, which requires that a defendant have "actual knowledge" of the false information.¹⁸³ That is, the doctor in this scenario had actual knowledge that the patient was not terminally ill despite completing a Medicare certification that indicated otherwise.¹⁸⁴

The next objective falsity scenario involved a certifying physician failing to examine a patient's medical records prior to making a clinical judgment.¹⁸⁵ Once again, despite the Eleventh Circuit's attempt to describe this example in the context of falsity, it is better aligned with knowledge.¹⁸⁶ More specifically, this example is a good representation of the second type of knowledge which prohibits government agents from acting

179. *But see* Wood, *supra* note 133 (explaining how the Third Circuit's argument that the district court conflated falsity and knowledge is indefensible).

180. *See Druding*, 952 F.3d at 96 (asserting that the objective falsity standard conflates knowledge and falsity and supporting that assertion in three small paragraphs).

181. *See id.* (missing an opportunity to discuss the three examples of objective falsity presented by the Eleventh Circuit in *AseraCare*); 31 U.S.C. § 3729(b)(1)(A) (defining knowledge requirement as actual knowledge, deliberate ignorance, or reckless disregard).

182. *AseraCare*, 938 F.3d at 1297 (spending a small portion of its opinion exemplifying the standard it had just created).

183. *See* 31 U.S.C. § 3729(b)(1)(A) (presenting the knowledge element of the FCA).

184. *But see* Richard Doan, *The False Claims Act and the Eroding Scierter in Healthcare Fraud Litigation*, 20 ANNALS HEALTH L. 49, 66 (2011) ("Innocent mistakes, negligent actions, and flawed reasoning are purportedly not actionable under the FCA.").

185. *AseraCare*, 938 F.3d at 1297 (describing examples of objective falsity).

186. *See United States v. Hercules, Inc.*, 929 F. Supp. 1418, 1422–23 (D. Utah 1996) (discussing the House Judiciary Subcommittee's commentary surrounding the 1986 FCA amendments that broadened the knowledge element to encompass not only actual knowledge, but reckless disregard, and deliberate ignorance in an effort to avoid the "ostrich-with-[their]-head-in-the-sand" problem (internal quotation marks omitted)).

in “deliberate ignorance of the truth or falsity of the information[.]”¹⁸⁷ By not reviewing a patient’s medical records prior to determining that the patient is terminally ill, there is a good argument to be made that the physician acted with deliberate ignorance of the information contained in that patient’s medical records.¹⁸⁸

Finally, in its third example, the Eleventh Circuit explained that an objective falsity may exist when expert evidence shows that no reasonable physician could have agreed with the certifying physician.¹⁸⁹ Once again, this scenario is more appropriately aligned with the third knowledge category—“reckless disregard.”¹⁹⁰ When a physician makes a determination that no other reasonable physician would have come to, there is a strong argument to be made that that physician acted with reckless disregard of the truth.¹⁹¹ While the Eleventh Circuit attempted to fit these examples in the context of falsity, they neatly fall into the three categories of knowledge.¹⁹²

This overlap demonstrates that objective falsity may be less of a falsity standard and more of a knowledge standard.¹⁹³ Thus, *Druding* and other

187. 31 U.S.C. § 3729(b)(1)(A). For a more detailed description of the knowledge element, see *supra* Section III.B.1.

188. See generally Doan, *supra* note 184 (“Proving deliberate ignorance requires evidence that the provider purposely avoided learning of, or blinded itself to, the falsity of the submitted claims.”).

189. *AseraCare*, 938 F.3d at 1297 (highlighting three examples of objective falsity and leaving open the possibility that other scenarios could invoke the objective falsity standard).

190. See 31 U.S.C. § 3729(b)(1)(A); see also MICHAEL P. MATTHEWS & A. JOEL RICHLIN, WHAT CONSTITUTES “RECKLESS DISREGARD” UNDER THE FCA?, COMPLIANCE TODAY 22 (2013), <https://www.foley.com/-/media/files/insights/publications/no-date/what-constitutes-reckless-disregard-under-fca/files/what-constitutes-reckless-disregard-under-fca/fileattachment/32013compliancetoday.pdf> [<https://perma.cc/LGF3-C7R2>] (“Courts have interpreted the reckless disregard standard as requiring various iterations of ‘extreme’ or ‘aggravated’ gross negligence or somewhere ‘on a continuum between gross negligence and intentional harm.’”); see generally *United States ex rel. K & R Ltd. v. Mass. Hous. Fin. Agency*, 530 F.3d 980, 983 (D.C. Cir. 2008) (noting that under the FCA, reckless disregard is an “extreme version of ordinary negligence” (internal quotation marks omitted) (quoting *United States v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997))).

191. See MATTHEWS & RICHLIN, *supra* note 190, at 25 (identifying the types of evidence that support a finding of no reckless disregard, one of which is adhering to industry practice which is an especially strong argument when documented, for example, in an industry publication); see also *United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 531 (6th Cir. 2012) (holding that the defendants did not recklessly disregard the truth or falsity of the information for several reasons, one of which is that the defendant followed industry practices).

192. See generally Doan, *supra* note 184 (discussing the three categories of FCA knowledge).

193. See *United States ex rel. Trim v. McKean*, 31 F. Supp. 2d 1308, 1315 (W.D. Okla. 1998) (“The gravamen of a false claim focuses on the conduct of the defendant, and inquiries into the defendant’s purpose and intention in filing the requests for payment or reimbursement.” (citing *United States v. Krizek*, 111 F.3d 934, 939 (D.C. Cir. 1997))).

cases that examine truthfulness of a clinical judgment appear to focus on the wrong element.¹⁹⁴ That is, *Druding* should be reviewed in the context of knowledge, not falsity.¹⁹⁵ Centering the analysis on falsity, rather than knowledge, has resulted in unnecessary confusion and has thwarted the efforts to adopt a uniform approach to FCA liability.¹⁹⁶ Although the Third Circuit missed an opportunity to explicitly direct the district court to the knowledge element, the Third Circuit had substantial reason to reverse given that its review was limited to the falsity element.¹⁹⁷

VIII. THE SIDE EFFECTS OF *DRUDING*: TREATING THE FCA LIABILITY IMBALANCE

Although the circuit split may be artificial, the resulting confusion is real and will likely have far-reaching implications.¹⁹⁸ As a result of this uncertainty, health care providers face substantial risk.¹⁹⁹ In an attempt to test the limits of the FCA, opportunistic relators may take advantage of the lack of clarity in the law by bringing FCA claims against providers for actions that look less like fraud and more like innocent mistakes.²⁰⁰ Forced to defend themselves in near-frivolous lawsuits, health care providers could face mounting FCA liability.²⁰¹

194. Compare *United States ex rel. Druding v. Care Alts.*, 952 F.3d 89, 100 (3d Cir. 2020) (“[W]e find that objectivity speaks to the element of [knowledge], not falsity.”), with Gregory R. Merz, *Supreme Court Declines to Clarify the Standard for Proof of Falsity Under the False Claims Act*, LATHROP GPM (Feb. 25, 2021) <https://www.lathropgpm.com/newsroom-alerts-72627.html> [<https://perma.cc/2DPT-6NLN>] (explaining the issue as one of falsity, not one of knowledge).

195. Cf. *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr.*, 953 F.3d 1108, 1117 (9th Cir. 2020) (relying on the Supreme Court's ruling in *Escobar*, to explain that the FCA's rigorous materiality and knowledge elements are sufficient to address concerns of fair notice and open-ended liability).

196. See *Druding*, 952 F.3d at 100 (acknowledging that when knowledge is folded into a falsity test, issues arise—namely, the court fails to fully consider evidence of knowledge).

197. See *id.* at 100–01 (noting that the district court prematurely granted summary judgment and therefore, missed the opportunity to evaluate knowledge).

198. See Matthew Curley & Jeff Gibson, *Supreme Court Declines to Weigh in on Key Falsity Question*, JD SUPRA (Feb. 24, 2021), <https://www.jdsupra.com/legalnews/supreme-court-declines-to-weigh-in-on-9450768/> [<https://perma.cc/3LQU-3J7A>] (observing the ongoing issues regarding subjective clinical decisions and describing the Supreme Court's decline to review the Third Circuit's opinion as a “missed opportunity”).

199. See *id.* (noting that allowing hindsight review of a physician's clinical opinion poses significant issues for providers).

200. See Drew Newman & Pamela Amaechi, *A River Too Far: Extending the False Claims Act to Subjective Medical Opinions*, 26 WESTLAW J. HEALTH CARE FRAUD 01 (July 7, 2020) (examining implications of *Druding* and observing that “relators may try to exploit the reasonable differences of physician's judgement”).

201. See *id.* (acknowledging “inherit unfairness” of *Druding* and predicting that the broad standard adopted by Third Circuit will lead to an increase in FCA allegations).

As lower courts attempt to interpret the circuit court's rulings, health care providers should anticipate varying applications of the FCA across jurisdictions.²⁰² Providers practicing in multiple states should strive to stay up-to-date on whether courts in their jurisdictions require proof of objective falsity in FCA cases.²⁰³ While health care providers should be ready to defend the reasonableness of their clinical judgments, they should not expect to be insulated from FCA liability merely by demonstrating that a reasonable difference in opinion exists.²⁰⁴

While recent analyses have focused on the falsity element, knowledge is likely to play a more prominent role in future court opinions.²⁰⁵ As a result of the Supreme Court declining to review the Third Circuit's opinion in *Druding*, health care providers seeking dismissal of a FCA claim may be compelled to reframe their arguments by focusing less on falsity and more on knowledge.²⁰⁶ However, this shift could be costly for health care providers because unlike falsity, knowledge only needs to be alleged generally at the pleading stage.²⁰⁷ Moreover, knowledge can be difficult for defendants to disprove at the summary judgment phase given that the

202. Cf. Jonathan M. Cohen & Daniel S. Cohen, *Iron-ing Out Circuit Splits: A Proposal for the Use of the Irons Procedure to Prevent and Resolve Circuit Splits Among United States Courts of Appeals*, 103 CALI. L. REV. 989, 996 (June 2020) (examining the problems that circuit splits yield, one of which is "uncertain and disparate" applications of the law).

203. See McEvoy, *supra* note 170 (discussing the options for national employers, one of which is to aggressively file motions in limine aimed at eliminating conflicting expert opinion).

204. See Lawrence Vernaglia, Alexis Bortniker, Rachel Goodman & Jessa Boubker, *HHS Provider Relief Funds and the Strings and Risks Attached: What Compliance Officers Need to Be Thinking About Now*, 22 J. HEALTH CARE COMPLIANCE 5, 5 (2020) (emphasizing the compliance efforts providers must undertake in light of the "[b]illions of dollars in new revenue streams [that] came into hospitals, health systems, physician organizations, long-term care facilities, and other players" as a result of COVID-19).

205. See generally Julia McLetchie, David Bastian & Katie Wellington, *Deepening Circuit Split About Falsity of Medical Opinions Invites a U.S. Supreme Court Decision*, HOGAN LOVELLS (Feb. 9, 2020), <https://www.lexology.com/library/detail.aspx?g=11ef6e6d-48ea-40dc-9edf-13f63c6c8574> [<https://perma.cc/36KZ-Q7DJ>] (explaining that knowledge may be the next frontier for FCA cases when it comes to evaluating subjective opinion).

206. See *id.* (noting that the Third Circuit's decision "may lead defendants to focus or reframe arguments on the [knowledge] element of the FCA").

207. See *id.* (explaining the procedural timing of allegations pertaining to the knowledge element); cf. Stuart Delery et al., *2020 Mid-Year False Claims Act Update*, GIBSON DUNN (July 17, 2020), <https://www.gibsondunn.com/2020-mid-year-false-claims-act-update/> [<https://perma.cc/FZ3P-UZU4>] (acknowledging that at pleading stage, knowledge may be alleged generally pursuant to Rule 9(b) of the Federal Rules of Civil Procedure and that there is no requirement for a specific intent to defraud under the FCA); see also *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr.*, 953 F.3d 1108, 1122 (discussing knowledge in relation to Rule 9(b) of the Federal Rules of Civil Procedure).

FCA does not require a specific intent to defraud.²⁰⁸ Health care providers involved in a FCA suit may be forced to choose between litigating through the discovery process, taking their chances at trial, or settling—all of which result in significant costs.²⁰⁹

In addition, the lack of clarity in the law may stifle innovation and job opportunities in the medical field.²¹⁰ Hospitals and provider practices may be less inclined to put money toward research and development when faced with a sharp increase in FCA liability, mounting litigation expenses, and a heightened need to allocate more of their budget toward compliance initiatives.²¹¹ Further, health care providers are not only caregivers in the community, they are also employers.²¹² As providers search for ways to cover the increasing costs associated with FCA compliance and litigation, they may be forced to reduce their payroll expense by laying off employees.²¹³ In more extreme cases where hospitals or provider practices are already operating on razor-thin margins, higher litigation expenses could mean the difference between serving the public and going out of business.²¹⁴

In the wake of *Druding*, quality and access to health care may decline as well.²¹⁵ Out of fear of costly litigation, hospice providers may be overly

208. See McLetchie, *supra* note 205 (noting that the difficulties of disproving the knowledge element on summary judgment will “limit FCA defendants’ chances of obtaining dismissal”).

209. See *id.* (highlighting the expenses health care providers must consider even if they are defending themselves against meritless claims).

210. Cf. Regina E. Herzlinger, *Why Innovation in Health Care Is So Hard*, HARV. BUS. REV. (May 2006), <https://hbr.org/2006/05/why-innovation-in-health-care-is-so-hard> [<https://perma.cc/C3JU-7PDD>] (identifying several obstacles to innovation in the industry—most of which relate back to finances).

211. See *id.* (emphasizing that innovation requires the appropriate funding).

212. See Earlene K.P. Dowell, *Health Care Still Largest U.S. Employer: Census Bureau’s 2018 County Business Patterns Provides Data on Over 1,200 Industries*, U.S. CENSUS BUREAU (Oct. 14, 2020), <https://www.census.gov/library/stories/2020/10/health-care-still-largest-united-states-employer.html> [<https://perma.cc/R6G3-ZSRZ>] (identifying that in 2018, the health care sector—the largest employer in the country—employed more than 20.5 million people).

213. Cf. Ben Teasdale & Kevin A. Shulman, *Are U.S. Hospitals Still “Recession Proof”?*, NEW ENG. J. MED. (Sept. 24, 2020), <https://www.nejm.org/doi/full/10.1056/NEJMp2018846> [<https://perma.cc/E2QQ-FB2P>] (explaining how hospitals are no longer recession proof and estimating that “hospitals will lose \$95 billion in annual revenue because of the shift from private to public insurance . . .”). Hospitals responded to this impact with layoffs, furloughs, and pay cuts. See *id.*

214. Cf. *id.* (examining how the COVID-19 pandemic could exaggerate a hospital’s financial struggles); see also Adrian Diaz, Karan R. Chhabra & John W. Scott, *The COVID-19 Pandemic And Rural Hospitals—Adding Insult To Injury*, HEALTHAFFAIRS (May 2, 2020), <https://www.healthaffairs.org/doi/10.1377/forefront.20200429.583513/> [<https://perma.cc/XB7S-JRJQ>].

215. See Najjar, *supra* note 5, at 155 (“The Sixth and Tenth Circuits’ broad readings of the FCA have the potential to chill physicians’ decisions to provide care to Medicare and Medicaid patients, which in turn, may cause a decline in the quality and access to healthcare.”).

conservative when certifying a patient's terminal illness.²¹⁶ That conservatism could lead to patients not being able to access palliative care until it is too late.²¹⁷ Further, considering that government-sponsored health programs already pay less than private health insurers, providers may refuse to treat Medicare and Medicaid patients if the FCA liability risk is excessive.²¹⁸ Given that Medicare and Medicaid primarily cover the elderly, disabled, and poor, an increase in FCA liability could leave the country's most vulnerable populations with limited or no access to quality medical care.²¹⁹

Due to the high levels of uncertainty in this area of FCA law, now, perhaps more than at any other time in the FCA's 150-year history, health care providers need to prioritize compliance.²²⁰ Given the punitive nature of the FCA's penalties, the multitude of complex statutory and regulatory requirements, as well as the "significant compliance risks and challenges" associated with COVID-19 relief funds, providers should implement or strengthen their existing compliance programs.²²¹ When developing a robust compliance program, providers should reference the compliance guidelines created by the Office of the Inspector General ("OIG").²²² As an example, the OIG recommends that hospices, at a minimum, implement a compliance program with seven features: (1) develop

216. See Cerminara, *supra* note 32, at 469 (warning that broadening the FCA could lead to a chilling effect where patients will not have the appropriate access to hospice services).

217. *Cf. id.* (explaining how physicians historically approached pain-management conservatively out of fear of prosecutorial and regulatory government efforts).

218. Compare Eric Lopez, Tricia Neuman, Gretchen Jacobson & Larry Levitt, *How Much More Than Medicare Do Private Insurers Pay? A Review of the Literature*, KASER FAM. FOUND. (Apr. 15, 2020), <https://www.kff.org/medicare/issue-brief/how-much-more-than-medicare-do-private-insurers-pay-a-review-of-the-literature/> [<https://perma.cc/R4WS-TSSM>] (observing that private insurers pay nearly double what Medicare pays), with Belanger, *supra* note 9, at 38 ("It is the rare provider that can choose to eschew federal dollars and, therefore, the specter of a FCA case looms large.").

219. See Najjar, *supra* note 5, at 157 (noting that the risk of liability may disincentivize physicians from treating Medicaid patients and asserting that this is "too significant of a risk to place on the nation's most vulnerable populations"); see also Vernaglia, *supra* note 204, at 11 (explaining that HHS has made it clear that it will be taking efforts to prevent and uncover fraud).

220. See generally Dawkins, *supra* note 87, at 168 ("[T]he FCA is one of the strongest antifraud statutes.").

221. See Vernaglia, *supra* note 204, at 5 (describing the immense compliance risks associated with the COVID-19 provider relief funds noting that many "are still playing catch-up with the documents, commitments, certifications, and other conditions that flew around like snowflakes in a blizzard from March [2020] to July [2020]."); see generally Cynthia A. Howell, *Rough Road Ahead for Businesses?—The Impact of the Supreme Court's Ruling in Universal Health Services, v. United States ex rel. Escobar*, 19 DUQ. BUS. L.J. 97, 112–13 (2017) (describing effective internal compliance programs).

222. See Off. of Inspector Gen., *Compliance Guidance*, U.S. DEP'T OF HEALTH & HUM. SERVS., <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>

and distribute written standards of conduct, (2) designate a compliance officer, (3) develop and implement ongoing training, (4) create and maintain a system so employees may report compliance issues, (5) audit internally, (6) establish disciplinary mechanisms, and (7) respond promptly to any detected offenses.²²³

Druding's impact is not isolated to the health care sector.²²⁴ Any entity receiving government funding is subject to FCA liability.²²⁵ Notably, as the pandemic begins to subside, the 5.2 million businesses that received COVID-19 relief funding could be subject to FCA liability.²²⁶ Unlike health care providers, many of these businesses do not regularly do business with the government and therefore, are unaware of the FCA's complexities and significant punitive penalties.²²⁷ A business that is unfamiliar with the FCA may underestimate the need to mitigate FCA exposure at the outset by making compliance a priority, documenting any mitigation efforts taken, and quickly addressing any mistakes that happen.²²⁸ As the novelty of the pandemic wears, the FCA and the legal uncertainty perpetuated by *Druding* will likely become an area of focus for courts as those businesses struggle to defend themselves in FCA proceedings.²²⁹

[<https://perma.cc/WNP9-NLZU>] (last visited Feb. 22, 2022) (providing compliance guidance to various sectors of the health care industry).

223. See OIG Compliance Program, Guidance for Hospices, 64 Fed. Reg. 54,031, 54,034 (Oct. 5, 1999) (recommending seven elements for a hospice's compliance program).

224. Cf. John Partridge, James Zelenay, Jonathan Phillips, Ryan Bergsieker, Sean Twomey, Reid Rector, Allison Chapin, Michael Dziuban, Jasper Hicks, Julie Hamilton & Eva Michaels, 2020 Year-End False Claims Act Update, GIBSON DUNN (January 27, 2021), <https://www.gibsondunn.com/wp-content/uploads/2021/01/2020-year-end-false-claims-act-update.pdf> [<https://perma.cc/PMS4-YPHQ>] (explaining that "[d]espite the global pandemic, closed courts, and the realities of remote work," the government broke a record in 2020 by bringing more FCA cases than it ever had before).

225. See generally Newman, *supra* note 200 (pointing out that Third Circuit's opinion is not limited to hospice industry).

226. See McLetchie, *supra* note 205 (noting that businesses that received COVID-19 relief funds under the CARES Act face potential FCA liability in the future if the government can prove the funds were not necessary for the business to continue its operations).

227. See generally Partridge et. al., *supra* note 224 (noting that in 2020, health care FCA cases represented eighty-three percent of total recoveries).

228. See generally Thomas M. Burnett & Daniel G. Murphy, *Second Round of Pandemic Relief Revives Specter of False Claims Act Liabilities for Businesses*, REINHART BOERNER VAN DEUREN S.C. (Dec. 22, 2020), <https://www.reinhartlaw.com/knowledge/second-round-of-pandemic-relief-revives-specter-of-false-claims-act-liabilities-for-businesses/> [<https://perma.cc/48N9-RVKR>] (identifying steps businesses can take to minimize their FCA liability).

229. Cf. *id.*; Srere, *supra* note 77 ("While proponents laud the FCA as one of the most powerful tools in combating healthcare fraud, critics warn against the unintended consequences of FCA abuse, including costly investigations and litigation that ultimately result in employees and patients footing the bill.").

In sum, while *Druding* provided little guidance for future cases, it did illuminate a pre-existing condition: Congress, CMS, and the courts have yet to find the appropriate balance for FCA liability.²³⁰ Enforcement of the FCA is an important tool to safeguard taxpayer dollars; but over-enforcement creates undue FCA liability on health care providers and other entities receiving funding from the government.²³¹ Although a circuit split may not actually exist, the FCA liability imbalance may encourage Congress to pass legislation addressing the issue, or perhaps, in time, the Supreme Court will grant certiorari on a future FCA case where the truthfulness of an expert's opinion is once again questioned.

230. See Deborah R. Farringer, *From Guns That Do Not Shoot to Foreign Staplers Has the Supreme Court's Materiality Standard Under Escobar Provided Clarity for the Health Care Industry About Fraud Under the False Claims Act?*, 83 BROOK. L. REV. 1227, 1277 (2018) ("Although adoption of a bright line [rule] may have led to arbitrary results, there does need to be an increased emphasis on assisting government contractors, especially providers and suppliers who participate in federal health care programs, with a more clearly articulated position on the types of noncompliance that lie in the mysterious middle of 'material.'").

231. See generally Christopher Melton, *Medical Necessity and False Claims: The Intersection of Clinical Decisionmaking and Liability*, 22 J. HEALTH CARE COMPLIANCE 23, 23 (2020) (cautioning providers to "brace" for FCA liability, largely as a result of qui tam claims, on top of medical malpractice liability).