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False Claims: The Coordinated Exploitation of the United States Government by the Healthcare Industry

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FALSE CLAIMS:
THE COORDINATED EXPLOITATION OF THE UNITED STATES GOVERNMENT BY THE HEALTHCARE INDUSTRY

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I. THE AMERICAN PREMIUM FOR HEALTHCARE

Healthcare prices in America have been on the continual rise for several years, constantly surpassing prior all-time highs.[1] These soaring costs have led to an increase in individuals filing for bankruptcy due to medical debt.[2] To combat this phenomenon, Americans have turned to their communities to help alleviate their medical costs through crowdsourcing platforms like GoFundMe.[3] These increasing prices have imposed a tremendous financial burden on suffering families who face the possibility of losing a loved one or potentially crippling financial debt.

For the past two years, the world has been engulfed by a global pandemic that has stretched the capabilities of public health systems.[4] The stress placed on the public health system by COVID-19 has awakened the United States to the difficulties of obtaining accessible and affordable healthcare.[5] Throughout the pandemic, hospitals have struggled with sourcing personal protective equipment (PPE), ventilators, and other necessary products to care for patients who have contracted COVID-19.[6] In the second year of the pandemic, hospitals were faced with the new challenge of finding enough staff to attend to the enormous number of patients in need of attention.[7] The nurse and doctor shortage occurred because many medical professionals have elected to leave the profession. Some opted to have children or retire early, and others left the profession due to burnout and low wages.[8]

During the Civil War, the federal government established the False Claims Act (FCA) to protect the Army from being exploited by merchants.[9] Today, the FCA has been applied to multiple pharmaceutical companies for price-fixing and kickback schemes they have employed.[10] These actions have held pharmaceutical companies accountable by levying billion-dollar fines.[11] The

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[1] Rabah Kamal et al., *How has U.S. Spending on healthcare changed overtime?*, PETERSON-KFF (Feb. 25, 2022), https://www.healthsystemtracker.org/chart-collection/u-s-spending-healthcare-changed-time/#item-usspendingovertime_4.
[2] David U. Himmelstein et al., *Medical Bankruptcy in the United States, 2007: Results of a National Study*, 122 AM. J. MED. 741, 741-46 (2009).
[3] Dr. Shamard Charles, *What the rise of GoFundMe's to pay medical bills says about US health care system*, THE GRIO (Sept. 23, 2021), https://thegrio.com/2021/09/23/gofundme-medical-bills-health-care-system/.
[4] Sukrit Dogra, *COVID-19: Impact on the hospitality workforce*, EHL INSIGHTS, https://hospitalityinsights.ehl.edu/covid-19-impact-hospitality-workforce (last visited Nov. 16, 2022).
[5] Eileen K. Fry-Bowers, *The Affordable Care Act, COVID-19, and Health Care Insurance for Children*, 35 J. PEDIATRIC HEALTH CARE 639 (2021).
[6] *Id.*
[7] Amanda Plasencia, *Need for Nurses as Hospitals Struggle With Staffing Shortages*, NBC 6 SOUTH FLORIDA (Oct. 12, 2021), https://www.nbcmiami.com/news/local/need-for-nurses-as-hospitals-struggle-with-staffing-shortages/2572194/.
[8] Peter I. Buerhaus et al., *Impact Of The Nurse Shortage On Hospital Patient Care: Comparative Perspectives*, 26 HEALTH AFF. 853 (2007).
[9] U.S. DEP'T OF JUST., THE FALSE CLAIMS ACT (Feb. 2, 2022), https://www.justice.gov/civil/false-claims-act.
[10] Press Release, U.S. DEP'T OF JUST., *Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs* (Oct. 1, 2021).
[11] *Id.*

FCA has also been applied to large hospital networks for participating in kickback schemes and charging patients for care they did not receive.[12]

On June 26, 2003, the Department of Justice and HCA (a healthcare group), reached a record-setting $1.7 billion settlement for damages arising from the false claims submitted to Medicare and other federal healthcare plans.[13] This was the single largest example of Medicare fraud accounted for, and it was settled under the FCA.[14] HCA plead guilty to keeping two sets of books, one for accurately reporting the services the group provided, and another set that was submitted to the federal government.[15] The set of books provided to the federal government included charges for services not provided to patients, shifted salary costs to increase reimbursement from federal healthcare programs and showed inflated costs for services provided and participation in kickback schemes.[16]

Since the early 2000s, large hospital networks have exponentially increased their leverage over the market.[17] To match the growing price-setting power of large hospital networks, the federal government should expand the current interpretation of the FCA to allow for the review of prices that healthcare networks are charging Medicare, Medicaid, and other insurance plans that receive subsidies from the federal government through the Affordable Care Act.[18]

Promoting accountability of large hospital networks will prevent fraudulent overcharging of patients, which could prevent patients from amassing unnecessary medical debt. Using the FCA to establish a threshold for acceptable payments for treatments and other services provided by large hospital networks would help to level the imbalance of power between private insurance providers and hospital networks. If implemented effectively, this price establishment could have a ripple effect across the healthcare market, reducing the costs of treatments to all patients, regardless of their health insurance provider.

II. THE AMERICAN HEALTHCARE SYSTEM & THE FALSE CLAIMS ACT

a. Healthcare Landscape

Healthcare spending in America has increased "thirty-one times over the span of the last four decades."[19] According to the Center for Medicare and Medicaid Services, national healthcare expenditures "grew [by] 4.6%

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[12] Press Release, U.S. DEP'T OF JUST., *Hospital Chain Will Pay Over $260 Million to Resolve False Billing and Kickback Allegations; One Subsidiary Agrees to Plead Guilty* (Sept. 25, 2018).

[13] Press Release, U.S. DEP'T OF JUST., *Largest Healthcare Fraud Case in US History Settled HCA Investigation Nets Record Total of $1.7 Billion* (June 26, 2003); 42 USCS, Ch. 7, XVIII USCS.

[14] *Id*.

[15] *Id*.

[16] *Id*.

[17] Karyn Schwartz et al., *What We Know About Provider Consolidation*, KAISER FAM. FOUND. (Sept. 2, 2020), https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation/.

[18] 42 U.S.C. § 1396; Patient Protection and Affordable Care Act; Elder Justice Act, 111 P.L. 148, Part 1 of 3, 124 Stat. 119.

[19] Kamal, *supra* note at 1.

[increasing spending to] $3.8 trillion" in 2019. [20] This astronomical increase in the cost of healthcare coverage led many patients to make tough decisions involving whether they can undergo a test or treatment. According to the Kaiser Family Foundation (KFF), "21% of adults ages 18-64 reported they have not undergone a medical test or treatment that was recommended by a doctor because of cost, [and] 32% of adults have postponed receiving medical care because of the cost."[21]

As the COVID-19 pandemic continued to burden health care systems, the pandemic also heavily impacted Americans' finances. A KFF study analyzing how the pandemic impacted Americans found "half of U.S. adults say they put off or skipped some sort of health care or dental care in the past year because of the cost."[22] The same study found that high health care costs "disproportionately affect uninsured adults," resulting in uninsured patients delaying or foregoing prescribed medical procedures.[23] Rising health care prices also affected Americans who were covered by health insurance. "Nearly half - 46% - of insured adults reported difficulty affording their out-of-pocket costs and about one in four - 27% - reported difficulty affording their deductible."[24]

The cost of healthcare is a major factor patients weigh when determining whether they will undergo a procedure.[25] As the health care system currently operates, consumers do not have access to healthcare providers' negotiated prices for treatments. Enabling customers to understand the billing process, prices for treatment, and how much of the treatment their insurance will cover could increase transparency. This will allow patients to make more informed decisions while also inspiring competition between healthcare providers.

Transparency in healthcare pricing was recently addressed by the federal government. In 2019, a rule was promulgated by the Department of Health and Human Services requiring hospitals to publish gross charges for treatments, payer-specific negotiated prices, and other information, or be subject to a fine and audit.[26] This rule faced tremendous pushback from hospitals refusing to comply with its' disclosure requirements. A study found that 83% of hospitals are not complying with the finalized rule, citing that the fine of $300 a day is minimal, while the potential cost and loss from disclosure is far greater.[27]

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[20] *National Health Expenditure Fact Sheet*, CTR. FOR MEDICARE & MEDICAID SERVS. (Dec. 1, 2021), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-andReports/NationalHealthExpendData/NHE-Fact-Sheet.
[21] *Id*.
[22] Alex Montero et al., *Americans' Challenges with Health Care Costs,* KAISER FAM. FOUND. (July 14, 2022), https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/.
[23] *Id.*
[24] *Id.*
[25] *Id*.
[26] 45 C.F.R. § 180.50 (2022).
[27] Rebecca Pifer, *Majority of hospitals not complying with price transparency rule: JAMA,* HEALTHCARE DIVE (June 15, 2021), https://www.healthcaredive.com/news/majority-of-hospitals-not-complying-with-price-transparency-rule-jama/601810/.

b. Health Insurance Coverage in America

Historically, Americans have primarily relied on their employers for their health insurance.[28] With an aging population in need of health care coverage, President Lyndon B. Johnson signed Medicare into law in 1965.[29] Medicare was founded to provide health insurance for older Americans who were no longer in the workforce and who otherwise would not have healthcare coverage.[30] Those eligible for Medicare are "age 65 or older, younger people with disabilities and people with End Stage Renal Disease."[31] Medicare is made up of four parts: Part A, Part B, Part C, and Part D. Part A covers inpatient care in hospitals, nursing facility care, hospice care, and home health care.[32] Patients are eligible for premium-free Medicare Part A at age 65 or older if they or their spouse have paid Medicare taxes for a minimum of 10 years.[33] Part B's coverage includes ambulance services, mental health services, and limited prescription drugs.[34] Medicare Part C is also referred to as Medicare Advantage plans. These plans are offered by private companies who have their plans approved by Medicare. [35] Medicare Advantage Plans offer the same coverage provided by Part A and B but also include extra coverage such as "vision, hearing, dental, and/or health and wellness programs. Most also include prescription drug coverage."[36] Medicare does not cover long-term (custodial) care, dental care, or eye exams.[37] Lastly, Medicare Part D covers a wide range of prescription drugs for people on Medicare.[38] Part D covers generic prescription drugs for a low copayment and name-brand drugs for higher copayment.[39] Part D is accessible only to patients enrolled in Part A and Part B or patients enrolled in a Medicare Advantage Plan.[40]

Like Medicare, Medicaid was signed into law in 1965 by President Johnson in the Social Security Act.[41] Medicaid requires states to provide coverage for low-income families, pregnant women, people with disabilities, and people who need long-term care.[42] Specific Medicaid eligibility is established by a citizen's state of residence.[43] The Affordable Care Act (ACA) allowed states to expand their Medicaid coverage to increase eligibility for children and

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[28] *Health Insurance Coverage of the Total Population,* KAISER FAM. FOUND., https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Nov. 17, 2022).

[29] *A brief history of Medicare in America*, MEDICARERESOURCES.ORG, https://www.medicareresources.org/basic-medicare-information/brief-history-of-medicare/ (last visited Nov. 17, 2022).

[30] *History of Medicare,* NAT'L ACAD. SOC. INS., https://www.nasi.org/learn/medicare/the-history-of-medicare/ (last visited Nov. 17, 2022).

[31] *Who is eligible for Medicare?* U.S. DEP'T OF HEALTH & HUM. SERVS.

[32] *Id.*

[33] *What Part A covers,* U.S. CTRS. FOR MEDICARE AND MEDICAID SERVS.

[34] *What Part B covers,* U.S. CTRS. FOR MEDICARE AND MEDICAID SERVS.

[35] *What is Medicare Part C?* U.S. DEP'T OF HEALTH & HUM. SERVS.

[36] *Id.*

[37] *What's not covered by Part A & Part B?,* U.S. CTRS. FOR MEDICARE AND MEDICAID SERVS.

[38] *What Medicare Part D drug plans cover?,* U.S. CTRS. FOR MEDICARE AND MEDICAID SERVS.

[39] *Drug plan coverage rules,* U.S. CTRS. FOR MEDICARE AND MEDICAID SERVS.

[40] *How to get prescription drug coverage,* U.S. CTRS. FOR MEDICARE AND MEDICAID SERVS.

[41] *Program History,* U.S. CTRS. FOR MEDICARE AND MEDICAID SERVS.

[42] *CMS History,* U.S. CTRS. FOR MEDICARE AND MEDICAID SERVS.

[43] *Medicaid Eligibility,* U.S. CTRS. FOR MEDICARE AND MEDICAID SERVS.

adults who have income at or below 138% of the federal poverty level.[44] Medicaid "benefits include inpatient and outpatient hospital services, physician services, laboratory and x-ray services, and home health services, among others. Optional benefits include services including prescription drugs, case management, physical therapy, and occupational therapy."[45] Medicaid entitlement is based on two principles. First, all Americans who meet Medicaid eligibility are guaranteed coverage.[46] Second, states are guaranteed federal matching funds, without a cap, for qualified services provided.[47]

Currently, 38 states and Washington, D.C. have adopted the Medicaid expansion; 12 states have not adopted the expansion.[48] States that have expanded their Medicaid programs can cover more eligible citizens than states that have not expanded. Florida is an example of a state that has not expanded its Medicaid program, while Ohio has expanded Medicaid.[49] Ohio's Medicaid program covers an individual whose income is below $17,131 and a household of four whose income is below $35,245.[50] In states that have not adopted the Medicaid expansion, income-based eligibility is capped at an annual income of $8,905 for a household of four, with single and childless adults remaining ineligible.[51]

In 2010, the passage of the Affordable Care Act changed the healthcare market. The ACA had 3 main objectives: "(1) to reform the private insurance market—especially for individuals and small-group purchasers, (2) to expand Medicaid to the working poor with income up to 133% of the federal poverty level, and (3) to change the way that medical decisions are made."[52] The ACA has largely been successful at achieving these goals. The ACA has provided coverage to "about 20 million [previously uninsured] Americans" since it was enacted.[53] The ACA has impacted how Americans receive their health insurance through state programs which have expanded Medicaid access. The Census Bureau's American Community survey showed that nearly 160 million Americans obtain their health insurance through their employer, while 63 million receive coverage from Medicaid and another 45 million are covered under Medicare.[54]

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[44] *Status of State Medicaid Expansion Decisions: Interactive Map*, KAISER FAM. FOUND. (Nov. 9, 2022), https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/.

[45] *Benefits*, U.S. CTRS. FOR MEDICARE AND MEDICAID SERVS., https://www.medicaid.gov/medicaid/benefits/index.html.

[46] Robin Rudowitz et al., *10 Things to Know about Medicaid: Setting the Facts Straight*, KAISER FAM. FOUND. (Mar. 6, 2019), https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-setting-the-facts-straight/.

[47] *Id.*

[48] *Id*.

[49] *Id.*

[50] *Ohio Medicaid*, U.S. DEP'T HEALTH & HUMAN SERVS., https://www.benefits.gov/benefit/5940.

[51] Rachel Garfield et al., *The Coverage Gap: Uninsured Poor Adults in States that Do Not Expand Medicaid*, KAISER FAM. FOUND. (Jan 21, 2021), https://www.kff.org/medicaid/issue-brief/the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-expand-medicaid/.

[52] J. B. Silvers, *The Affordable Care Act: Objectives and Likely Results in an Imperfect World*, 11 ANNALS OF FAM. MED. 402, 402-05 (2013).

[53] Nicole Rapfogel et al., *10 Ways the ACA Has Improved Health Care in the Past Decade*, CTR FOR AM. PROGRESS (Mar. 23, 2020), https://www.americanprogress.org/issues/healthcare/news/2020/03/23/482012/10-ways-aca-improved-health-care-past-decade/.

[54] Schwartz et al., *supra* note 17.

Exponential increases in costs have led to record-setting profits in the healthcare industry. In 2019 alone, top health insurance providers reported profits that "topped $35 billion."[55] According to a market research survey completed by Bain & Company, healthcare providers (hospitals, doctors, and care centers) recorded $180.7 billion in profits in 2019.[56] The same market research survey found that pharmaceutical companies also made record-setting profits in 2019 totaling $125.9 billion.[57]

c. False Claims Act Overview

The False Claims Act was enacted by Congress in 1863 in response to concerns that merchants supplying goods for the Union Army during the Civil War were defrauding the government.[58] When first passed, "the FCA provided that any person who knowingly submitted false claims to the government was liable for double the government's damages, plus a penalty of $2,000 for each false claim."[59] The FCA was adjusted in 2010 to increase the penalty to a range from $5,000 to $10,000, plus three times the amount of the government's damages resulting from the person's act.[60]

The FCA allows private persons to file claims on behalf of the federal government. These suits are known as "qui tam" actions.[61] The person filing the complaint on behalf of the federal government is known as the relator.[62] The complaint must include a written disclosure of all the relevant facts and information privy to the relator.[63] The complaint must be served to the U.S. Attorney for the judicial district where the qui tam was filed and must be filed by the United States Attorney General. [64] If the government intervenes in a qui tam action, "the relator is entitled to receive between 15 and 25 percent of the amount recovered."[65] If the government declines to intervene, "the relator's share is increased to 25 to 30 percent."[66]

The FCA defines a claim as a "demand for money or property made directly to the federal government or other recipient if the money is spent on the government's behalf and if the federal government provides any of the money demanded or if the federal government will reimburse the contractor or grantee."[67] A violation under the FCA occurs when a person knowingly submit a false claim to the government. To have knowledge of the falsity of the claim,

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[55] Paige Minemyer, *Health insurers' profits topped $35B last year. Medicare Advantage is the common thread,* FIERCE HEALTHCARE (Feb. 24, 2020, 12:01 AM), https://www.fiercehealthcare.com/payer/big-name-payers-earned-35-7-billion-2019-here-s-one-common-thread-their-reports.

[56] Tim van Biesen & Joshua Weisbrod, *US Healthcare Profit Pool to Rise at a Healthy Pace*, BAIN & CO. (Mar. 2, 2020), https://www.bain.com/insights/healthcare-profit-pool-expected-to-rise-at-healthy-pace-snap-chart/.

[57] *Id.*

[58] U.S. DEP'T OF JUST., *supra* note 9.

[59] *The False Claims Act: A Primer*, U.S. DEP'T OF JUST., https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.

[60] False Claims Act, 31 U.S.C. § 3729 (1986).

[61] *Id.*

[62] *Id.*

[63] *Id.*

[64] *Id.*

[65] *Id.*

[66] *Id.*

[67] *Id.*

a person must have (1) actual knowledge, (2) deliberate ignorance of the truth or falsity of the information, or (3) reckless disregard of the truth or falsity of the information.[68]

Civil actions for false claims are handled by the United States Attorney General, who is required by § 3729 to investigate all violations reported to and uncovered by their office.[69] If the Attorney General finds such a violation exists, they may bring a civil action against the suspected party. If the government elects not to proceed with a qui tam action, "the person who initiated the action shall have the right to conduct the action."[70]

III. UTILIZING THE FALSE CLAIMS ACT TO CURTAIL HEALTHCARE COSTS

a. Large Network Hospitals Leveraging the Market

Whenever an individual receives medical care from a new source, the question "will my insurance cover this?" is often in the back of their mind. This question lingers because health insurance companies have established a system of in- and out-of-network doctors.[71] This system determines whether the care provided will be covered by your insurance. In- and out-of-network doctors exist because health insurance companies only cover a limited number of doctors at each hospital.[72]

Hospitals and other healthcare providers have the luxury of price setting for their treatments and services. Health insurance companies negotiate with network hospitals to determine rates for specific procedures and treatments for patients covered on their programs.[73] However, since the early 2000s, hospitals have increased their influence over contracts with insurance companies.[74] Hospitals have been more willing to use the negotiating leverage they possess because of increased consolidation and the movement toward large hospital networks.[75]

Consolidation has allowed hospitals to increase their negotiation leverage through their increased regional presence.[76] Large network healthcare providers have emerged by purchasing local hospitals and healthcare providers and placing these hospitals and providers under their unified network.[77] The network healthcare providers have established control over large metropolitan areas, monopolizing coverage in their locations.[78] For example, in Ohio, Cleveland is home to the Cleveland Clinic and Cincinnati has Tri-Health. In Florida, the Tampa and Orlando areas have Advent Health.[79] These providers

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[68] *Id*.
[69] *Id*.
[70] *Id*.
[71] *In-Network vs. Out-of-Network Providers*, CAREFIRST BLUECROSS BLUESHIELD, https://individual.carefirst.com/individuals-families/health-insurance-basics/understanding-your-coverage/in-network-vs-out-of-network.page (last visited Nov. 17, 2022).
[72] *Id*.
[73] Schwartz, *supra* note 17.
[74] *Id*.
[75] *Id*.
[76] *Id*.
[77] *Id*.
[78] *Id*.
[79] *Cleveland Clinic Main Campus*, CLEVELAND CLINIC, https://my.clevelandclinic.org/locations/directions/231-cleveland-clinic-main-campus; *Find a*

have expanded their control over these large metropolitan areas to increase the standard of care while attempting to reduce costs.[80] However, this expansion has had the added effect of increasing providers' negotiating power with insurance companies, leading to increased pricing for care.[81]

In 2002, this progression toward consolidated large network healthcare providers enabled hospitals to break their established contracts with insurance companies.[82] Hospitals were emboldened to take more aggressive negotiating stances, such as "demanding price increases two to three times more than plans offered" and "seeking other favorable contract changes."[83] Insurance companies who lost leverage to these large healthcare providers were forced to accept the providers' price hikes.[84]

Large network providers indicated that the increase in their contracts with insurance companies was the result of three major changes in the market. First, healthcare plans were subject to increased regulation at the state level. The legislation sought to "reduce plans' ability to selectively contract and to aggressively manage utilization, increasing hospitals' negotiating leverage with plans."[85]

Second, employers who were purchasing health insurance from insurance providers were more sensitive to their employees' concerns about plans that offered greater consumer choice.[86] Essentially, there was an increased demand for insurance plans that provided consumers with more opportunities to choose their own doctors. This increased large network providers' leverage because insurance companies' client bases were more widespread, making it increasingly difficult to funnel patients to a small number of healthcare providers.

The last change that favored network providers was the declining number of people covered by Medicare and Medicaid.[87] Because Medicare and Medicaid programs are controlled by negotiations with the government, health insurance providers had more individuals they needed to cover.[88] This change favored network providers because insurance companies had more capital from more individuals covered.[89] Coupled with the increased amount of capital and number of individuals insurance companies were required to cover, large hospital networks were afforded the ability to hold out for higher rates.[90]

Because large network hospitals have increased prices for insurance companies, prices for government-backed plans like Medicare and Medicaid have increased. According to KFF analysis of Medicare spending data,

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Location, TRIHEALTH, https://www.trihealth.com/hospitals-and-practices/; *Find a Location*, ADVENTHEALTH, https://www.adventhealth.com/find-a-location.

[80] Schwartz, *supra* note 17.

[81] *Id*.

[82] *Id*.

[83] Kelly J. Devers et al., *Hospitals Negotiating Leverage with Health Plans: How and Why Has It Changed?*, 38 Health Servs. Res. 419, 427 (2003).

[84] *Id.*

[85] *Id.* at 426.

[86] Sally Trude et al., *Employer-Sponsored Health Insurance: Pressing Problems, Incremental Changes*, 21 HEALTH AFF. (2002).

[87] *Id.*

[88] *Id.*

[89] *Id.*

[90] *Id.*

Medicare's expenditures have increased 22% for Part A and B coverage.[91] In 2008, Medicare spent $462 billion on Medicare Part A and B, Medicare Advantage Plans, and Part D benefits.[92] Ten years later, in 2018, Medicare spent $731 billion on the same services with a growth of enrollment by 2% annually.[93] Over the next 10 years, KFF projects Medicare expenditures will reach $1.27 trillion.[94] This projected 75% growth in spending will be driven mainly by the increasing costs of healthcare procedures, specialty drug use, and an aging population.[95] The heightened negotiating leverage large network hospitals have employed over insurance providers, Medicare, and Medicaid has led to record high insurance costs for nearly every service provided by network hospitals.

b. Network Hospitals' Record-Setting Prices

Americans are accustomed to the idea that identical surgeries and procedures cost significantly more in the United States than in other nations providing a similar level of surgery.[96] In 2015, the KFF conducted a survey of healthcare costs for similar surgeries in similar countries, and the results of the survey showed just how much of a premium Americans are burdened with when compared to other nations.[97]

Examples of the staggering differences in costs are exhibited in appendectomies, knee replacements, MRIs, and other non-elective procedures. In the United States, the average price of an appendectomy was $15,930.[98] The United Kingdom has the next highest average price, charging $8,009 for the procedure. This is about half the price for the same surgery in the United States with the "American Premium."[99]

The "American Premium" was also evident in knee replacement surgeries. An average knee replacement surgery in the United States costs $28,184.[100] Switzerland has the next highest average price of $20,132, and this is still 40% more than the next closest country.[101] However, this same knee replacement surgery costs less than $16,000 in Australia, the fourth most expensive nation surveyed. This demonstrates there is an "American Premium" of 77% for the same surgery.[102]

MRI usage also shows how healthcare providers are intentionally setting the market for their services higher than they should be. "The U.S. has more MRI units available per million population than most comparable countries have on average, and it performs more MRI examinations per 1,000 people

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[91] Juliette Cubanski et al., *The Facts on Medicare Spending and Financing*, KAISER FAM. FOUND. (Aug. 20, 2019), https://www.kff.org/medicare/issue-brief/the-facts-on-medicare-spending-and-financing/.
[92] *Id.*
[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] Rabah Kamal & Cynthia Cox, *How do healthcare prices and use in the U.S. compare to other countries?,* PETERSON-KFF (May, 8, 2019), https://www.healthsystemtracker.org/chart-collection/how-do-healthcare-prices-and-use-in-the-u-s-compare-to-other-countries/.
[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] *Id.*
[101] *Id.*
[102] *Id.*

than the comparable country average."[103] Despite the high accessibility of MRIs, the average price of an MRI in the United States is still the highest at $1,119.[104] The United Kingdom, the second most expensive nation, has an average price that is 42% lower.[105] The least expensive nation providing MRIs was Australia, with an average price that is 420% less than the United States.[106] These disparities in price show that the amount of capital (equipment, staff, or trained professionals) is not a viable rationale for why the United States pays exponentially more for similar services.

Rather, higher administrative costs are the predominant theory for why healthcare prices are exponentially higher in the United States, as compared to the rest of the world.[107] Estimates suggest 20% to 30% of all healthcare spending goes to administrative costs.[108] "Administrative costs refer to back-end functions of the healthcare system, including medical billing, scheduling appointments, managing staff, and investing in quality improvement efforts."[109] Healthcare providers explain that the complexity of the billing process is the reason for these high administrative costs.[110] This is explained by the fact health insurance companies try to reduce costs, while healthcare providers attempt to maximize their collections.[111]

c. Establishing a Baseline for Healthcare Costs Using the False Claims Act

The False Claims Act has been applied to pharmaceutical companies, and the government has held these companies responsible for overcharging for drug prices.[112] However, the FCA has rarely been applied to healthcare providers. Even when applied to healthcare providers, the FCA has primarily been used to address the fraudulent billing of treatments or procedures patients did not receive.[113] Expanding the FCA would help combat the price-setting power wielded by large hospital networks. Completing a comprehensive review of the price-setting strategies employed between health insurance providers and large network providers would balance the disparity in negotiation leverage and will allow for fair market pricing.

To establish a standard for acceptable prices submitted to federal healthcare plans, the federal government should conduct a review of the largest hospital networks with the highest revenue or profits. These top earners recorded more

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[103] *Id.*
[104] *Id.*
[105] *Id.*
[106] *Id.*
[107] Joshua D. Gottlieb & Mark Shepard, *How Large a Burden are Administrative Costs in Health Care?*, ECONOFACT (Sept. 8, 2018), https://econofact.org/how-large-a-burden-are-administrative-costs-in-health-care.
[108] *Id.*
[109] *Id.*
[110] *Id.*
[111] *Id.*
[112] Press Release, *supra* note at 4.
[113] Press Release, U.S. Dept. of Just. *Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020* (Jan. 14, 2021), https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020.

than $300 million in profits in 2016 and have continued to grow.[114] Reviewing the most profitable hospitals will establish a range of acceptable prices for other hospital networks to work within. Failure to do so would result in the non-complying hospital to be subject to an FCA action.

To establish appropriate price ranges for treatments, a standard for review must be established under the FCA. First, the review board must be comprised of doctors, healthcare administrators, health insurance experts, representatives from federal government-backed healthcare plans, and representatives from the Department of Justice. This review board should be able to ascertain a reasonable price that would not reduce the overall level of care provided.

The primary factor this review board should consider when evaluating these prices is the average cost for that treatment around the world. There should be a focus on countries that provide the same level of care to their patients. Comparing prices of other countries will allow hospitals and other healthcare providers to see that providing treatments at this level is achievable and will not result in diminished care for their patients.

The next factor for the board to consider is the range of prices in the United States. Amino, a consumer healthcare company, found that the price of an MRI can range from $444 to $3900, depending on the state you live in. [115] This disparity in price for an MRI—in the same country—displays how healthcare providers price the market. Establishing a price ceiling will prevent this monopolistic behavior employed by large healthcare providers and curb price gouging.

Another factor to be considered is the administrative costs associated with providing this treatment. Identifying average administrative costs for certain procedures will allow for more honest accounting and billing to patients. Establishing a threshold for acceptable administrative costs will be vital to the success of the implementation of this agreement. Large hospital networks and other healthcare providers will look to increase their administrative costs to offset their losses on healthcare-related pricing, attempting to maintain their level of profitability.

The last factor for the board to consider when establishing an acceptable charging range for homogenous treatments is the amount that large hospital networks and health insurance companies agree the price should be. The networks have an interest in the prices being high; however, their costs should be factored in when determining the price of these treatments. It is imperative to remember the objective of this review of healthcare pricing is to prevent fraudulent price setting and systemic overcharging of the United States government. Furthermore, the objective is to ascertain the "fair market value" of treatments, not prevent large hospital networks and other healthcare providers from turning profits.

d. Adjudicating Large Hospital Networks for Price-Fixing

Despite the longevity of the FCA, there have been few adjudications levied against healthcare providers for non-fraudulent practices. However, the DOJ

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[114] John Commins, *7 of 10 Most Profitable Hospitals are NFPs*, HealthLeaders – HCPro (May 4, 2016), https://www.healthleadersmedia.com/finance/7-10-most-profitable-hospitals-are-nfps?page=0%2C1.

[115] Lydia R. Pflanzer, *The cost of an MRI can vary by thousands of dollars depending on where you go*, Business Insider (Mar 28, 2017 at 11:12 AM), https://www.businessinsider.com/how-much-an-mri-costs-by-state-2017-3.

has entered into multiple settlement agreements with pharmaceutical companies for engaging in price-fixing behavior, in violation of the FCA and the Sherman Anti-Trust Act. On October 1, 2021, the DOJ announced they had reached a settlement with Taro Pharmaceuticals USA, Inc., Sandoz Inc., and Apotex Corporation for "a total of $447.2 million to resolve violations of the FCA arising from conspiracies to fix the price of various generic drugs. [This scheme] resulted in higher drug prices for federal health care programs and beneficiaries." [116]

Ven-A-Care of the Fla. Keys., Inc. v. Abbott Labs., Inc. exemplifies the process followed by the DOJ and multiple pharmaceutical companies when the companies are alleged to have violated the FCA. Abbott Labs and other pharmaceutical companies were alleged to have inflated the price of their drugs to receive increased reimbursement from Medicare plans.[117] The defendants' made arguments that the prices were not false, nor inflated, and certain terms were ambiguous.[118] However, the Court was not persuaded and denied the defendants' motion for summary judgment.[119] Abbott Labs elected to enter into a $126 million settlement with the DOJ, two years after their motion for summary judgment was denied.[120]

A relator can bring a qui tam action against a large hospital network alleging the hospital was violating the FCA by charging patients with federally backed insurance plans, through the Medicaid expansion, increased prices beyond the Medicaid rate. Under 31 U.S.C. § 3279(a)(1), the plaintiff must establish the defendant made "(1) a false claim (2) which the defendant presented or caused to be presented to the United States for payment (3) knowing that the claim was false."[121] To establish a case under § 3729(a)(1), the plaintiff must first prove that the hospital group made a false claim.[122] The plaintiff would prove this by establishing that the hospital group engaged in price setting of homogenous services. Courts have ruled that pharmaceutical companies "do not have free reign to [manipulate] numbers" to compute the best price for their reimbursement.[123] The Court in *Abbott Labs* went on to rule that the average wholesale price of a drug was the proper method to determine the "fair" price of the drug.[124] The plaintiff could prove the large hospital network engaged in price setting by comparing the price of the homogenous service to the average price in the region and nationwide. If there is a significant discrepancy between the prices, Courts have found using inflated

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[116] Press Release, U.S. Dept. of Just. *Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs* (Oct. 1, 2021), https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability.

[117] *Cal., ex rel. Ven-A-Care of the Fla. Keys., Inc. v. Abbott Labs., Inc*. (*In re Pharm. Indus. Average Wholesale Price Litig.),* 478 F. Supp. 2d 164 (D. Mass. 2007).

[118] *Id*.

[119] *Id*.

[120] Press Release, U.S. Dept. of Just. *Pharmaceutical Manufacturers to Pay $421.2 Million to Settle False Claims Act Cases* (Oct. 1, 2021), https://www.justice.gov/opa/pr/pharmaceutical-manufacturers-pay-4212-million-settle-false-claims-act-cases.

[121] *Abner v. Jewish Hosp. Health Care Servs*., No. 4:05-cv-0106-DFH-WGH, 2008 U.S. Dist. LEXIS 61985 (S.D. Ind. Aug. 13, 2008).

[122] False Claims Act, 31 U.S.C. § 3729 (1986).

[123] *Cal., ex rel. Ven-A-Care of the Fla. Keys., Inc. v. Abbott Labs., Inc. (In re Pharm. Indus. Average Wholesale Price Litig.),* 478 F. Supp. 2d 164 (D. Mass. 2007).

[124] *Id*. at 174.

or misleading prices constitutes making a false claim for the prices. [125] Applying the element established in pharmaceutical cases would cause hospital networks to determine their "wholesale" costs for homogenous services. This wholesale price would likely be significantly lower than the price billed to individuals on Medicaid expansion health insurance plans.

Next, the plaintiff would have to prove the defendant presented the false claim to the United States government for payment. The plaintiff must assert their health insurance plan was offered through Medicaid expansion. Courts have not issued a ruling on whether federally subsidized Medicaid expansion-backed policies qualify. However, the DOJ defines a claim as qualifying "if the Federal Government provides any of the money demanded."[126] By this definition, federally subsidized health insurance programs would qualify. Thus, Plaintiff would be able to satisfy the second prong of the FCA by introducing evidence of the bill delivered to their insurance company.

The last element the plaintiff must establish for an FCA violation is that the defendant knew the claim was false. This could be proven by introducing evidence of price-setting between large hospital networks. Price-setting could be established by providing evidence of how large hospital networks have systemically increased the price of healthcare while their costs have not continued to rise.

When considering the above, it appears that large hospital networks have knowingly engaged in price-setting to falsely increase the price of healthcare in the United States, violating the False Claims Act.

e. Leveling the Healthcare Market

As previously mentioned, the FCA has led to some of the largest settlements in the history of the federal government.[127] This case would likely exponentially shatter the previous records. This FCA action would be brought against multiple large hospital networks that have engaged in price-fixing, violating both the FCA and the Sherman Anti-Trust Act. Proving the duration of the conspiracy would be difficult and computing the damages required under the FCA would be equally so. Further, there is a public health interest in ensuring that healthcare providers, especially during the ongoing pandemic, have the resources necessary to continue their operations. Coupling these factors, a settlement between the networks and the government would be in the best interest of all parties.

Calculating an adequate remedy for the systematic inflation of healthcare prices by large hospital networks that have burdened millions of Americans for years is a daunting task.[128] However, it is important to consider that only 20 million Americans have received health insurance from the Medicaid expansion.[129] A final consideration in determining the settlement would involve the theories of punishment. The appropriate theory of punishment to follow is the general deterrence approach which "aims to dissuade others from following [an] offender's example."[130] Utilizing the general deterrence theory

[125] *Id.* at 175.
[126] U.S. Dep't. of Just., *supra* note at 34.
[127] Press Release, *supra* note at 8.
[128] Himelstein, *supra* note at 2.
[129] Rapfogel, *supra* note at 28.
[130] *General Deterrence*, Encyclopedia Britannica, Inc., https://www.britannica.com/topic/punishment/General-deterrence.

of punishment is imperative because it looks to punish the offenders severely enough that other "would-be offenders" reconsider the criminal act.

The scope of the final settlement will depend on the number of hospital networks. However, it is reasonable to assess a $10 billion penalty on each large hospital network that has engaged in price-fixing behaviors. This penalty would be payable over the span of multiple years to prevent patients and employees of the hospital networks from suffering from the penalty. The severity of this penalty would deter other healthcare providers from overcharging their patients, with the end goal of reducing healthcare costs for all Americans.

IV. APPLYING THE FALSE CLAIMS ACT TO NETWORK HOSPITALS TO REDUCE COSTS

Healthcare costs in the United States have increased at a record pace throughout the last twenty years by way of the emergence of large hospital networks. These large hospital networks have engaged in price-fixing behaviors that have artificially increased the price of healthcare for Americans. Utilizing the FCA, the DOJ can prevent large hospital networks from continuing to engage in price-fixing behaviors.

Large hospital networks have violated the FCA by knowingly submitting false claims to the federal government at prices established through price-fixing practices. These violations should lead to a large financial settlement between the large hospital networks and the federal government. These sweeping changes would help reduce the price of healthcare in the United States, ending the "American Premium" citizens have grown accustomed to paying. While this approach to reducing the cost of medical procedures can be effective, it is imperative to consider litigation of individual cases involving unnecessary medical treatment to further alleviate the problem of medical debt.

V. WHAT MAKES A TREATMENT UNNECESSARY?

a. Overtreatment in America

The objective of this note is to suggest a systemic change through a legal framework to drastically reduce the incidence of medical debt of Americans and ensure reasonable, efficient, and transparent healthcare billing practices. To accomplish this objective, laying a foundation to protect patients at an individual level is necessary. Fraudulent medical debt can be litigated through the FCA when healthcare providers prescribe unnecessary treatments or procedures. Research has already demonstrated the economic impact of unnecessary treatments and procedures and has provided recommendations for how to alleviate these financial burdens, as discussed below.

In 2010, the Institute of Medicine ("IOM") examined strategies healthcare providers could use to reduce medical costs and ultimately concluded the best remedy was for healthcare providers to reduce unnecessary services.[131]

[131]Heather Lyu, Daniel Brotman, Brandan Mayer-Blackwell, Tim Xu, Michol Cooper, Michael Daniel, Elizabeth C. Wick, Vikas Saini, Shannon Brownlee, and Martin Makary *Overtreatment in the United States*, Nat'l Lib. Of Med. (Sept. 6, 2017) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5587107/.

Ultimately, the IOM found that in 2010, unnecessary spending accounted for "approximately $210 billion of the estimated $750 billion in excess spending."[132]

Further research conducted by the American Medical Association ("AMA") highlighted this trend of unnecessary medical care. A 2017 survey of over two thousand physicians conducted by the AMA found that "20.6% of overall medical care was unnecessary, including 22.0% of prescription medications, 24.9% of tests, and 11.1% of procedures."[133] These physicians cited the primary motivation for performing unnecessary procedures was profit, with over 70% of physicians agreeing.[134] To combat this problem, the surveyed physicians believed there should be a shift away from fee-for-service physicians, who they believe are the primary culprits of prescribing unnecessary treatments.[135] Fee-for-service healthcare is a system of health insurance where a doctor or other healthcare provider is paid a fee for each service rendered.[136] This system incentivizes doctors and other healthcare providers to increase the volume and quantity of services provided regardless of the outcome or necessity.[137] While reducing fee-for-service health insurance would reduce unnecessary medical treatments and spending, there is still a systemic overtreatment problem in the United States that keeps millions in medical debt.

Patients have a vested interest in receiving less treatment beyond financial motivations. Studies have found "overtreatment is directly associated with patient harm as evidenced by studies of antibiotic overuse leading to resistance and Clostridium difficile infection, [8] overuse of diagnostic testing, such as pap smear and colonoscopy, [9, 10] and the inherent postoperative complications from unnecessary surgical procedures.[11]"[138] As extraordinarily high as the financial impact of unnecessary care can be, unnecessary care can be even more significant in terms of the physical costs to the body.

Given the reality of both financial and possible physical harms created by unnecessary treatments and procedures, the law plays, and will continue to play, a vital role in attempting to eliminate these harms. Applying the FCA to reduce unnecessary treatments is one potential solution to address this growing concern. However, a string of recent cases involving the FCA demonstrate the current challenges in this area, both at the federal appellate level and eventually in the U.S. Supreme Court.

b. Split Decision

As previously established, the FCA requires a claim to be submitted to the United States government that is knowingly false.[139] However, the FCA does not lay out a legal framework to determine when a claim is false.[140] The lack

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[132] *Id.*
[133] *Id.*
[134] *Id.*
[135] *Id.*
[136] *What is fee-for-service?*, healthinsurance.org, https://www.healthinsurance.org/glossary/fee-for-service/.
[137] *Id.*
[138] Lyu *supra.* 133
[139] U.S. Dep't of Just., *supra* note at 4.
[140] *Id.*

of a specific method for determining whether a claim is false has required courts to develop analytical frameworks to determine when a claim qualifies as false. Courts have been successful at creating a framework to distinguish factual falsity (when a person submits a claim to the U.S. government for services not preformed), and legal falsity (when a claim does not meet the required legal standards).[141] However, the framework established by the courts has resulted in perceived inconsistencies. As the framework currently exists, the FCA does not have established processes to review claims involving subjective opinions. This lack of clear guidance has led to a circuit split between the Third, Ninth, and Eleventh circuit courts over when differences in medical opinions can constitute a false claim under the FCA.[142] Courts have differed over whether a subjective opinion of a medical professional can be evidence of a false claim under the FCA, while others have held that medical opinions can be a factual or legal falsity.

i. The Eleventh Circuit: Reasonable Difference of Medical Opinions Insufficient to Establish a False Claim

The issue of determining falsity under the FCA was brought to the forefront when the Eleventh Circuit held that a reasonable difference of medical opinion is insufficient to establish a claim as false.[143] In *United States v. AseraCare, Inc.*, three former AseraCare employees alleged AseraCare had knowingly submitted unsubstantiated Medicare claims, violating the FCA.[144] The employees alleged AseraCare was intentionally hiding information about patients to obtain false certification of hospice eligibility for patients who were not terminally ill.[145] Upon obtaining the certification of hospice, AseraCare would then submit the certification to Medicare for hospice services provided to patients who were allegedly not terminally ill. The government argued the patients were not terminally ill at the time of certification, which meant the claims were false under the FCA.[146] The government never alleged AseraCare's doctors relied on medical documentation that was "too thin, vague, or lacking in detail to reasonably substantiate their clinical judgment of terminal illness."[147] Rather, the question before the jury was whether a doctor's interpretation of the medical records submitted to obtain the certification of hospice was a factual falsity.

The Eleventh Circuit held "a properly formed and sincerely held clinical judgement is not untrue even if a different physician later contends that the judgment is wrong."[148] Further, the Court required "the government [to] show something more than the mere difference of reasonable opinion concerning the prognosis."[149] The Eleventh Circuit required "the government [to] be able to link this evidence of improper certification practices to the specific 123 claims

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[141] *Supreme Court Declines to Resolve Circuit Split on Falsity Under the FCA*, Jones Day, (April 2021) https://www.jonesday.com/en/insights/2021/04/supreme-court-declines-to-resolve-circuit-split-on-falsity-under-the-fca
[142] *Id.*
[143] *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1297 (11th Cir. 2019).
[144] *Id.*
[145] *Id.*
[146] *Id.*
[147] *Id.*
[148] *Id.*
[149] *Id.*

at issue in its case."[150] The Eleventh Circuit stated that "such linkage is necessary to demonstrate both falsehood and knowledge."[151] The Eleventh Circuit's holding established that the government or any plaintiff alleging false certification (or unnecessary treatment) "must identify facts and circumstances surrounding the patient's certification that are inconsistent with the proper exercise of a physician's clinical judgment. When no such facts or circumstances are shown, the FCA claim fails as a matter of law."[152]

ii. The Third Circuit: Difference of Medical Opinions Enough to Create Triable Dispute of Fact Regarding Falsity

The split developed in March 2020, when the Third Circuit ruled in *U.S. ex rel. Druding v. Care Alternatives*—contrary to the Eleventh Circuit—that a "difference of medical opinion is enough evidence to create a triable dispute of fact regarding FCA falsity."[153] The Third Circuit's ruling is distinguished from the Eleventh Circuit's ruling on a similar issue. In *U.S. ex rel Druding v. Care Alternatives,* the false claims cause of action was brought by former employees of Care Alternatives, alleging the healthcare provider admitted ineligible patients and "directed its employees to alter Medicare certifications to increase the number of eligible patients."[154]

Like *AseraCare* in the Eleventh Circuit, Care Alternatives was submitting patients for hospice certification without documents required for the certification or with documents that did not support the need for certification.[155] On appeal, the central question was whether a hospice provider's claim for reimbursement is considered false under the FCA if expert medical testimony determines that a patient's certification did not match the patient's prognosis of a terminal illness. The appellants' expert, Dr. Jayes, reviewed the documentation Care Alternatives submitted for hospice certification.[156] In the one-year period Dr. Jayes reviewed, he found that 53% of the claims Care Alternatives submitted for hospice certification did not contain the necessary documentation to support a need for hospice care.[157] In Dr. Jayes report, he stated that in his view "any reasonable physician would have reached the same conclusion he reached."[158] Care Alternatives called their expert, Dr. Hughes, who disagreed with Dr. Jayes, and found these hospice certifications arguably necessary. Dr. Hughes stated that "a physician could have reasonably determined that the prognosis for each patient was six months or less."[159] After hearing these arguments, the District Court granted summary judgment in favor of Care Alternatives. However, appeal was granted to the Third Circuit.

The Third Circuit Court reversed the District Court's grant of summary judgment in favor of Care Alternatives, disagreeing with the District Court's

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[150] *Id.*
[151] *Id.*
[152] *Id.*
[153] U.S. ex rel. Druding v. Care Alternatives, 952 F.3d 89, 100 (3d Cir. 2020).
[154] *Id.*
[155] *Id.*
[156] *Id.*
[157] *Id.*
[158] *Id.*
[159] *Id.*

view that "a medical expert's opinion is false for purposes of FCA liability only when there is evidence of factual inaccuracy."[160] By taking this position, the Third Circuit recognized both factual and legal falsity as methods which create liability under the FCA.[161] The Third Circuit ultimately required under legal falsity that "appellants must show that Care Alternatives failed to meet at least one of the two regulatory requirements: (1) that a physician certified the patient is terminally ill and (2) that the certification is in accordance with § 418.22[162], which requires that "[c]linical information and other documentation that support the medical prognosis and accompany the certification . . . ."[163]

The Third Circuit's ruling on legal falsity on its face differed from the Eleventh Circuit Court's ruling on factual falsity, but substantially did not. In *AseraCare,* the Eleventh Circuit recognized that for the claim to be successfully determined a false claim, the government "must show something more than a mere difference of reasonable opinion concerning the prognosis."[164] Alternatively, the Third Circuit's holding in *Care Alternatives* that a "difference in medical opinion is enough evidence to create a triable dispute of fact regarding FCA falsity" does not conflict. In *Care Alternatives,* the question before the Third Circuit was whether the case could survive a motion for summary judgment. The Third Circuit's holding demonstrates that while potential liability could arise when there is a reasonable difference in opinion of a prognosis, it does not determine a claim is false merely because there is a difference in opinion.

iii. The Ninth Circuit: Distinguishing False Certification of Medical Necessity Can Establish FCA Claim

Shortly after the Third Circuit's ruling in *Care Alternatives,* the Ninth Circuit issued a similar holding in *Winter ex rel. U.S. v. Gardens Reg'l Hosp. & Med. Ctr.* In the Ninth Circuit case, relator Jane Winter, the former Director of Care Management at Gardens Regional Hospital brought a qui tam action alleging Gardens Regional submitted Medicare claims "falsely certifying that patients' hospitalizations were medically necessary."[165] Winter further alleged not only were the admissions not medically necessary, but that the patients' own medical records and the hospital's own admissions criteria showed that the patients' admissions were not medically necessary.[166]

The Ninth Circuit concluded that a "false certification of medical necessity can give rise to FCA liability."[167] The Ninth Circuit cited to a Fifth Circuit reversal in *United States ex rel. Riley v. St. Luke's Episcopal Hospital,* that a false claim exists "for services that were… not medically necessary," and that the defendants had ordered medical services "knowing they were unnecessary" and not simply errors.[168] According to the Ninth Circuit's holding, FCA

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[160] *Id.*
[161] *Id.*
[162] *Id.*
[163] 42 C.F.R. § 418.20.
[164] U.S. ex rel. Druding v. Care Alternatives, 952 F.3d 89, 100 (3d Cir. 2020).
[165] *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc*., 953 F.3d 1108, 1113 (9th Cir. 2020).
[166] *Id.*
[167] *Id.*
[168] *United States ex rel. Riley v. St. Luke's Episcopal Hospital,* 355 F.3d 370, 376 (5th Cir. 2004).

liability could be established when a false certification of medical necessity is submitted for reimbursement to Medicare.[169]

The Ninth Circuit referenced the Eleventh Circuit's opinion in *AseraCare*, asserting it did not view *Winter* as creating a split between itself and the Eleventh Circuit.[170] The Ninth Circuit viewed the Eleventh Circuit's holding in *AseraCare* to be a difference in medical opinion regarding terminal illness as not enough to deem a claim as false under the FCA when there is no other evidence to prove the claim is false.[171] The Ninth Circuit found that *Winter* did not conflict with *AseraCare* because the Eleventh Circuit was not asked whether a medical opinion could be false or fraudulent and that the Eleventh Circuit recognized its "objective falsehood requirement did not apply to physician's certification of medical necessity."[172]

iv. The Supreme Court Declines to Rule

In September 2020, Care Alternatives filed a petition for certiorari with the United States Supreme Court, arguing the Third Circuit ruling had created a split in rulings between the circuits.[173] In Care Alternative's petition, they stated that the circuits had differed on how a reasonable difference in physicians' clinical judgments could allow their diagnosis to be false under the FCA. In an amici curiae brief filed by the AMA, the National Hospice and Palliative Care Organization, the U.S. Chamber of Commerce, and Pharmaceutical Research and Manufactures of America outlined the detrimental consequences the split would have on hospice providers, physicians, and subsequently patients. First, the amici curiae brief argued that the split undermined national uniformity by creating different standards in different jurisdictions. The group argued that with many healthcare providers operating across multiple jurisdictions, the differences in application of the FCA would lead to difficulties providing treatments to patients. Citing the increased demand for hospice care, along with the "the False Claims Act's hard hammer…. [that] exposes providers to treble damages, statutory penalties, attorneys' fees, and other consequences, including severe reputational harm and debarment from government programs" required the creation of a uniform standard.[174] Next, the decision lowers the standard of review on physicians' medical opinions, making it easier for courts to find that a false statement was made. Lastly, with the standard for a false claim being lowered, patients' access to care will be affected because physicians will attempt to mitigate legal exposure to the FCA by being more conservative with their treatments.

Respondents from the Third Circuit case, Victoria Druding, Barbara Bain, Linda Coleman, and Ronni O'Brien filed an amici curiae brief in opposition of the writ of certiorari. Respondents first argued that a physician must certify the patient is terminally ill and that the patient has less than six months to live

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[169] *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc*., 953 F.3d 1108, 1113 (9th Cir. 2020).
[170] *Id.*
[171] *Id.*
[172] *Id.*
[173] Petition for Writ of Certiorari, Care Alternatives v. U.S. *ex rel*. Druding, No. 20-371, 2020 WL 5657690 (*certiorari denied*).
[174] *Id.;* https://www.justice.gov/civil/page/file/1080696/download.

before Medicare will reimburse hospice providers for services rendered.[175] Further, if a patient survives the original six-month prognosis, a physician must periodically recertify the patient's continued eligibility for hospice care.[176] For the hospice certifications to be valid, they must be accompanied with documentation that supports the physician's prognosis. The respondents argued that these robust requirements are in place because hospice care means a patient is no longer receiving curative care, and they act to counter fraud in healthcare systems. The respondents' argument stated that a failure to submit all of the required materials to support a physicians' prognosis does not question the physicians' prognosis but the lack of sufficient medical documentation to support that prognosis. The respondents further stated that there is not a genuine issue over the standard for review of a physician's prognosis because the question was about the sufficiency of the supporting documents. Lastly, the respondents echoed the sentiment of the Ninth Circuit, which held that there was not a material split within the circuits. Both respondents and the Ninth Circuit stated that the cases dealt with different aspects of the False Claims Act and applied the correct standard on each occasion.

On February 22, 2021, the Supreme Court denied Care Alternatives petition for a writ of certiorari and did not issue an opinion.[177] The Supreme Court's denial of certiorari left the circuit split over whether a disagreement of clinical judgment can be a false claim under the FCA in place. With the issue remaining unsettled, future petitioners are likely to seek clarity regarding differing medical opinions as false claims under the FCA. In assuming the presence of a circuit split, which the U.S. Supreme Court failed to take on, establishing a framework to guide future FCA litigation will allow for increased understanding of FCA falsity and allow healthcare providers to readily comply with its regulations.

VI. SOLIDIFYING FALSITY REQUIREMENTS

As Americans look to reduce healthcare spending and debt, reducing the expenditures on unnecessary procedures is a strong first step. A majority of states have expanded their Medicare, allowing more citizens to enroll in government provided healthcare plans, which reduces healthcare spending for individuals. It has also allowed citizens to be protected by the FCA. With more patients eligible for protections under the FCA, a standard of review must be established by the Supreme Court to create guidelines for how courts should handle FCA falsity claims. Providing clarity of the standards surrounding FCA falsity will allow healthcare providers to better understand what documentation and procedures are necessary. Further, with an increased understanding of FCA falsity, healthcare providers will have the opportunity to establish policies which encourage compliance with the FCA, protecting themselves from potential litigation. This clarity will also allow healthcare professionals, nurses, and patients to have a better understanding of

[175] 42 C.F.R. §§ 418.20(b), 418.22(b)(1).
[176] 42 C.F.R § 418.22(a)(1).
[177] Petition for Writ of Certiorari, Care Alternatives v. U.S. *ex rel*. Druding, No. 20-371, 2020 WL 5657690, (*certiorari denied*).

requirements, empowering whistleblowers to speak out against healthcare providers when false claims are made.

If the Supreme Court were to make a ruling that established a standard for reviewing factual and legal falsity in physicians' prognoses, it would allow large hospital networks and multi-state healthcare providers to implement uniform policies to safeguard themselves from potential FCA liability. The primary objective of this ruling would be to create a standard for healthcare providers whose claims may be reviewed under the FCA. Additionally, such a ruling will have the added effect of self-enforced compliance, as healthcare providers will look to adhere to the standards created. This will have the trickledown effect of reducing unnecessary treatment.

The cases the circuit courts have heard dealt with different types of falsity, factual and legal. As previously established, factual falsity occurs when a person submits a claim to the U.S. government that is objectively false. A contractor who submits a claim to the federal government for the cost of 100 teddy bears, but only delivers 50 bears has submitted a factually false claim. Legal falsity exists when a claim does not meet the required legal standards. This type of falsity has inherently subjective qualities and a claim must be examined to determine if it meets the relevant legal standards. Although a circuit split exists on its' face, a split does not truly exist because factual and legal falsity both deal with different types of claims and should have different standards. However, it is important for the Supreme Court or Congress to proactively adopt standards to guide courts and allow FCA litigation to process without procedural challenges.

a. Factual Falsity Challenge

In *United States v. AseraCare, Inc*, the Eleventh Circuit dealt with the issue of factual falsity.[178] The Court held that a reasonable difference of medical opinion on a patient's diagnosis is not sufficient to rise to the level of a false claim.[179] The Eleventh Circuit required the government to show evidence of improper certifications or diagnosis practices to show knowledge of the falsehood.[180]

The Supreme Court should adopt a standard in line with the Eleventh Circuit's holding, as the Court correctly identified a proper standard for reviewing factual falsity. With factual falsity, the physician must have engaged in a practice that is objectively false. Factual falsity should be treated as a strict liability offense under the FCA, because it is within the legislative intent of the act. The legislative intent of the FCA is to require physicians and hospital groups who submit claims to have the proper supporting documentation to prevent fraud.

When a physician or hospital group submits incomplete or inaccurate documentary evidence, which is required to support their diagnosis to the federal government, they have knowingly submitted a false claim. Imposing a standard of strict liability upon healthcare providers who fail to submit the required supporting documents will allow for a universal standard that will have a trickledown effect of reducing unnecessary treatments and diagnostics.

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[178] *United States v. AseraCare, Inc*., 938 F.3d 1278, 1297 (11th Cir. 2019).
[179] *Id.*
[180] *Id.*

To determine if a healthcare provider or physician has not submitted the required documentation to support their diagnosis, the Court should rely on the testimony of a representative of the state medical board. The state medical board is the governing body that outlines procedures and requirements for doctors when treating patients.[181] The state in which the hospital is located will determine which state medical board will be controlling. There is not a federal medical board which oversees state medical boards, solely a federation of state medical boards.[182] As stated in the previous section, state medical boards offer objective testimony that is not biased for either party.[183] Further, allowing the state medical board to outline the procedures and required documentation necessary to support a diagnosis offers the best evidence for a judge and jury to understand the reporting requirements placed on healthcare providers and physicians.

Congress will be required to change FCA factual falsity to a strictly liable offense. Adjudication of a factual falsity claim will begin with a relator bringing an FCA claim against a healthcare provider. The relator will allege that a patient's diagnosis was not supported by the requisite documentation. The healthcare provider will contend that the physician submitted the necessary documentation to support their diagnosis.

To determine the required documentation and what the supporting documentation should state, the court will hear testimony from a representative from the state medical board. The state medical board will first testify about the standards and required procedures necessary to diagnose a patient with the prognosis asserted in the claim. Next, the state medical board representative will testify about the required documentation and the procedures required for the physician, and the healthcare provider must undertake to properly submit the materials. Lastly, the representative from the state medical board will be made available to both parties to be questioned about specifics of the case. In accordance with Federal Rules of Evidence, it will be important for the representative not to directly state whether the procedures were or were not adhered to, but rather to outline the standard procedures.

After the testimony from the state medical board representative has concluded, the Court will examine the documents and procedures the healthcare provider utilized to reach their prognosis. Should the Court find that the healthcare provider or physician did not adhere to the generally accepted or recommended procedures to support the diagnosis of a patient, the claim submitted to the federal government will be determined to be factually false. A claim will also be determined to be false if the healthcare provider or the physician submitted incomplete or insufficient documentation to support their diagnosis of a patient. Conversely, if the healthcare provider and the attending physician are determined to have properly adhered to the standards recommended by the state medical board, the claim will be valid.

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[181] Drew Carlson and James N. Thompson, MD, *The Role of State Medical Boards,* AMA Journal of Ethics (Apr. 2005), https://journalofethics.ama-assn.org/article/role-state-medical-boards/2005-04.

[182] *Fed'n of State Medical Bd., About FSMB, Federation of State Medical Boards (2018),* https://www.fsmb.org/about-fsmb.

[183] Thompson and Carlson, s*upra* note 181.

b. Establishing a Presumption for Physicians

Establishing guidelines that grant a heightened standard of review to healthcare professionals in cases which medical records have accurately been reported to the government is necessary. This presumption will only apply to cases involving a claim of legal falsity, as it will protect healthcare professionals who err on the side of caution when treating patients. First, when physicians and healthcare providers submit the necessary supporting information affirming their diagnosis as required by Medicare and other government-backed programs, a presumption should be afforded that the care was not fraudulent. This presumption should be afforded because the legislative intent of the documentation requirements was to prevent fraudulent requests for reimbursement. If a healthcare provider diagnosed a patient with a condition and included proper documentation to support their diagnosis, the physician should be afforded a presumption that their diagnosis was made with the best information available to them.

Second, this heightened standard would operate under the reasonable belief doctors are prescribing treatments that are in their patients' best interest. Further, this standard would protect doctors who are acting on information as provided to them at the time. While the current standard does afford physicians a level of protection against reviews in hindsight, the amici curiae brief filed by Care Alternatives correctly states that without an outlined standard, doctors could be more conservative with treatments which could negatively impact patients. Allowing doctors to have the authority to prescribe treatments with the information presented to them— without the looming threat of FCA liability—would be a mutually beneficial outcome to patients and doctors alike.

Establishing a presumption in favor of medical professionals is important. However, this presumption should be rebuttable, so as to not give healthcare professionals free reign any time "all the boxes are checked." Aligning with the Eleventh Circuit, a standard of reasonable difference of medical opinion is not enough to determine that a medical opinion by a healthcare professional was false. The standard the Supreme Court should adopt is one that reviews the information submitted by the healthcare professional at the time the prognosis was made and review with the state medical board. If the state medical board finds the medical professional reasonably relied on the information provided to them to make a diagnosis, and the information was the correct information to rely on, the claim will not be found to be legally false. However, if the state medical board finds that the healthcare professional incorrectly made a conclusion not supported by information provided to them at the time of the diagnosis, the presumption will be rebutted.

Establishing a standard that involves the state medical board will ensure that the review of the diagnosis remains objective, not biased by expert witnesses. Allowing a member of the state medical board to testify and break down the elements required to make a diagnosis will allow a jury or a judge to determine if the diagnosis was made in accordance with acceptable standards. Further, requiring the state medical board representative to testify will be in line with the Eleventh Circuit's requirement that "the government [must] show something more than the mere difference of reasonable opinion concerning the prognosis."[184]

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[184] *Id.*

The presumption that will be afforded to healthcare providers will function similarly to the current presumption in favor of treating physicians. In *Lipke v. Astrue* the Court explained, "a treating physician's opinion is presumed to be controlling only if it is not contradicted by any other substantial evidence in the record."[185] However, the court went on to state that "the opinion of a non-treating physician can constitute substantial evidence that rebuts the presumption."[186] To resolve the inevitable conflict between the treating physician and the non-treating physician, "[the judge] may decide whom to believe, so long as substantial evidence supports that decision."[187] This requirement means the presiding judge must make a written explanation of their ruling supported by evidence presented. This requirement has the added effect of creating a paper trail to understand the logical path of the judge's ruling.

Applying this presumption to a case, the issue at bar must involve legal falsity. The presumption will not apply to factual falsity. First, the healthcare provider will argue that the treating physician followed the necessary procedures and submitted the required documents which support the diagnosis. The healthcare provider will present evidence that the treating physician adhered to applicable medical standards and submitted the required documentation to support their diagnosis. Next, the party bringing the action will attempt to rebut the presumption by way of a consulting physician's testimony. The consulting physicians' testimony will offer evidence that the treating physician's documents did not support their diagnosis. Lastly, testimony will be heard from the state medical board. An individual representing the state medical board will outline requirements and standard procedures physicians must follow when making a diagnosis. Both parties will be allowed to cross-examine the state medical board expert to allow both sides the opportunity to solidify their argument with a non-biased witness.

After hearing testimony from both parties and the state medical board, the judge will determine whether the presumption will be granted to the physician or that the presumption has been rebutted. The judge will then be required to support their ruling in the form of a written statement to allow the parties to understand how the judge reached their conclusion. Requiring the judge to record their opinion in writing will allow reviewing courts to determine whether the judge followed the correct procedures when making their decision.

c. Action Arising Under Legal Falsity

The Third and Ninth Circuits dealt with cases involving doctors who sent claims for reimbursement to the federal government. In these cases, the issue at bar was whether the doctor's diagnosis was supported by the documents submitted in the claim for reimbursement. This left the Courts to decide when a doctor's opinion could become a false claim. In the Third Circuit case, *U.S. ex rel. Druding v. Care Alternatives*, the Court determined that a "medical expert's opinion is false for purposes of FCA liability only when there is evidence of factual inaccuracy."[188] While in the Ninth Circuit case, *Winter ex rel. U.S. v. Gardens Reg'l Hosp. & Med. Ctr.*, the Court held that a diagnosis

[185] Lipke v. Astrue, 575 F. Supp. 2d 970, 979 (W.D. Wis. 2007).
[186] *Id.*
[187] Carlson v. Shalala, 999 F. 2d 180, 181 (7th Cir. 1993).
[188] U.S. ex rel. Druding v. Care Alternatives, 952 F.3d 89, 100 (3d Cir. 2020).

"can be false or fraudulent for the same reasons any opinion can be false or fraudulent," such as "if the opinion is not honestly held, or if it implies the existence of facts … that do not exist."[189]

Although the fact patterns and the questions presented in the Third and Ninth Circuit cases are widely different, the two holdings regarding the standard of review for FCA claims involving objective falsity are extremely similar. The holdings of the Third and Ninth Circuits were correctly decided and create an important foundation for the Supreme Court or Congress that should be addressed when resolving the split. However, additions should be made to provide for better clarity of the expectations for healthcare providers, along with establishing a process for litigation of FCA claims based on objective falsity.

It is important for the Supreme Court or Congress to first establish that the record should be limited to what was submitted in the claim for reimbursement to the federal government. Limiting the record to that which was submitted with the claim has a multifaceted impact on the case. First, it allows the court to better understand the information the physician was presented with. Restricting the testimony to information that was contained in the claim prevents a party from introducing outside information that could suggest a different prognosis. However, an exception will be established to allow the introduction of tests or results that the physician had available or should have had available to them at the time of the diagnosis. Second, it ensures that physicians are following proper procedures when diagnosing patients. Barring outside information like a physician's hunch protects patients from being misdiagnosed or receiving treatment that is not necessary and ensures that physicians are taking the appropriate steps and measures when attending to their patients. Third, it prevents outside parties reviewing the physician's diagnosis from judging the diagnosis with the benefit of hindsight. It would be unfair to question a physician's prognosis in hindsight with test results that were not available to the physician at the time of their diagnosis. This would only be applicable if the testing methodology was unavailable to the physician based on reasons not related to their professional capacity. Capping the information at what was present at the time of the diagnosis will both protect physicians from questions involving the ultimate outcome but may also raise questions regarding the physician's decision to diagnose the patient.

To assist the Court in better understanding medical conclusions and how they were reached, a representative from the state medical board should testify on these issues. Requiring a representative of the state medical board to testify is of the utmost importance for cases involving objective falsity because it prevents expert witnesses from relaying viewpoint bias testimony to the court. Although the Third Circuit stated that a reasonable difference in medical opinions is sufficient for a dispute of fact, reliance on an expert witness to determine whether a physician's methods for diagnosis were accurate is not the best method for courts to engage in fact-finding. Having testimony from a state medical board representative allows factfinders to understand what typical procedures, examinations, and tests a physician is required to undertake before they can make their diagnosis. Having a neutral expert explain the requirements a physician is mandated to follow will eliminate the need for factfinders to wade through unnecessary information from expert witnesses

[189] Winter ex rel. U.S. v. Gardens Reg'l Hosp. & Med. Ctr., 953 F.3d 1108 (9th Cir. 2020).

testifying for the benefit of one party. With the case involving legal falsity, the appropriate standard of care will likely be a disputed issue that will have a major impact on the outcome of the case. The representative will also be able to testify on the standard of care required. This should resolve the disputes parties have over the required standard. The representative will explain information about the tests and results exhibiting how a physician should properly diagnosis the patient under the circumstances.

Lastly, a representative from the state Medicaid or Medicare program could outline the requirements that a healthcare provider must meet to file a claim for reimbursement with the federal government. Allowing a representative from the government to testify about the requirements for reimbursement will clearly articulate the standards imposed on medical professionals to be reimbursed for the care provided.

However, the representatives from the state medical board and state Medicaid or Medicare program must both be cautious when answering questions from both parties so as not to give their opinion on the issue at hand, in accordance with the Federal Rules of Evidence. It is important to note that the Federal Rules of Evidence do not prevent the witness from outlining the information necessary to make a diagnosis.

The presumption in favor of physicians would apply to cases involving legal falsity only. As previously outlined, the presumption would look to review the documentation and test results the treating physician had at the time of the diagnosis. Should the presumption be granted by the Court, it will most heavily be applied when the treating physician erred on the side of increased care for the patient. Essentially, if the treating physician was within the limits or on the fringe of accepted medical practices prescribed by the state medical board, the claim should be determined to be true. The presumption should grant the physician the benefit of the doubt that they were attempting to give their patient the best possible care. However, the presumption can be rebutted if the plaintiff can prove that the treating physician did not act within accepted medical practices.

When a Court is adjudicating an FCA claim, the Court must first determine if the case involves factual or legal falsity. As the Third Circuit held in *U.S. ex rel. Druding v. Care Alternatives*, an expert witness is enough to conclude that there is a reasonable difference in medical opinion.[190] Once a reasonable difference in medical opinion has been established, the Court then must review the contents of the claim the healthcare provider filed to the federal government for reimbursement. Examining the contents of the claim should demonstrate if the results of the examinations and tests met the necessary thresholds for the attending physician to make the diagnosis. To assist the fact-finders in determining the testing requirements and methods physicians are mandated to use before they can make a diagnosis, a representative of the state medical board should testify about these matters. Once the testimony from the representative has concluded, the Court will determine whether the physician followed the proper procedures to make their diagnosis. Should the Court determine the physician made the proper conclusions based on the information available to them, the claim will be determined to be valid. However, should the Court determine the physician incorrectly reached a conclusion that was

[190] U.S. *ex rel.* Druding, 952 F.3d 89, at 95.

not supported by the facts presented to them, the claim will be determined to be false, and the healthcare provider will be in violation of the FCA.

VII. REDUCING UNNECESSARY TREATMENTS THROUGH ADOPTION OF STANDARDS

The False Claims Act has a long-standing history of protecting the United States government from being defrauded by merchants and other parties submitting claims for repayment.[191] Affording Americans who have enrolled in Medicaid and Medicare expansion plans the same protection afforded to the federal government will allow for action to be brought to prevent large hospital networks from engaging in price-fixing behaviors. Implementing this change will have the effect of reducing healthcare prices for all Americans.

Applying the False Claims Act at the price-fixing level will have the largest affect, however it is still important to iron out procedures for individual claims involving factual and legal falsity. Although the different requirements established for the two types of falsity at first glance appear to be contradictory to each other, it is clear there is no overlap or split between factual and legal falsity. However, if large scale litigation were brought under FCA liability, it is important for Congress or the Supreme Court to offer lower courts guidance in applying these distinct standards. Establishing requirements for FCA liability under factual and legal falsity will allow for healthcare providers to make plans to adhere to the guidance. This change will have the effect of reducing unnecessary healthcare treatments and spending, passing on financial and physical health benefits to the American people.

[191] *Id.*