Case No. 18-10500-AA

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

UNITED STATES OF AMERICA, *et al.*,
ex rel. ANGELA RUCKH,

Plaintiff–Appellant,

v.

SALUS REHABILITATION, LLC, *et al.*,

Defendants–Appellees.

On Appeal from the United States District Court
for the Middle District of Florida
Case No. 8:11-cv-1303-SDM-TBM

BRIEF OF AMICI CURIAE AARP, AARP FOUNDATION, CALIFORNIA ADVOCATES FOR NURSING HOME REFORM, CENTER FOR MEDICARE ADVOCACY, JUSTICE IN AGING, THE LONG TERM CARE COMMUNITY COALITION, THE NATIONAL CONSUMER VOICE FOR QUALITY LONG-TERM CARE, AND THE NATIONAL HEALTH LAW PROGRAM IN SUPPORT OF PLAINTIFF-APPELLANT

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to FED. R. APP. P. 26.1 and 11TH CIR. R. 26.1-1 & 26.1-2, amici curiae AARP, AARP Foundation, California Advocates for Nursing Home Reform, the Center for Medicare Advocacy, Justice in Aging, the Long Term Care Community Coalition, The National Consumer Voice for Quality Long-Term Care, and the National Health Law Program submit the following certificate of interested persons:

AARP and AARP Foundation

The Internal Revenue Service has determined that AARP is organized and operated exclusively for the promotion of social welfare pursuant to Section 501(c)(4) of the Internal Revenue Code (1993) and is exempt from income tax. AARP is also organized and operated as a non-profit corporation pursuant to Title 29 of Chapter 6 of the District of Columbia Code (1951).

Other legal entities related to AARP include AARP Foundation, AARP Services, Inc., Legal Counsel for the Elderly, and AARP

Insurance Plan, also known as the AARP Health Trust. AARP has no parent corporation, nor has it issued shares or securities.

California Advocates for Nursing Home Reform

The Internal Revenue Service has determined that California Advocates for Nursing Home Reform (CANHR) is organized and operated exclusively for charitable purpose pursuant to Section 501(c)(3) of the Internal Revenue Code and is exempt from income tax. CANHR is also organized and operated as a non-profit corporation pursuant to the California Revenue and Tax Code § 2370d (1949). It has no parent corporation, nor has it issued shares or securities.

Center for Medicare Advocacy

The Internal Revenue Service has determined that the Center for Medicare Advocacy Inc. (Center) is organized and operated exclusively for charitable purpose pursuant to Section 501(c)(3) of the Internal Revenue Code and is exempt from income tax. The Center has no parent corporation, nor has it issued shares or securities.

Justice in Aging

The Internal Revenue Service has determined that Justice in Aging is organized and operated exclusively for charitable purpose pursuant to Section 501(c)(3) of the Internal Revenue Code and is exempt from income tax. Justice in Aging is also organized and operated as a non-profit corporation pursuant to Title 29 of Chapter 6 of the District of Columbia Code (1951). It has no parent corporation, nor has it issued shares or securities.

Long Term Care Community Coalition

The Internal Revenue Service has determined that Long Term Care Community Coalition (LTCCC) is organized and operated exclusively for charitable purpose pursuant to Section 501(c)(3) of the Internal Revenue Code and is exempt from income tax. LTCCC is also organized and operated as a non-profit corporation pursuant to the N.Y. Not-For-Profit Corp. Law § 201. It has no parent corporation, nor has it issued shares or securities.

The National Consumer Voice for Quality Long-Term Care

The Internal Revenue Service has determined that The National Consumer Voice for Quality Long-Term Care (Consumer Voice) is organized and operated exclusively for charitable purpose pursuant to Section 501(c)(3) of the Internal Revenue Code and is exempt from income tax. The Consumer Voice is also organized and operated as a non-profit corporation pursuant to Title 29 of Chapter 6 of the District of Columbia Code (1951). It has no parent corporation, nor has it issued shares or securities.

National Health Law Program

The Internal Revenue Service has determined that the National Health Law Program Inc. (NHeLP) is organized and operated exclusively for charitable purpose pursuant to Section 501(c)(3) of the Internal Revenue Code and is exempt from income tax. NHeLP is also organized and operated as a non-profit corporation pursuant to the California Revenue and Tax Code § 2370d (1949). It has no parent corporation, nor has it issued shares or securities.

Counsel

Furthermore, counsel for the above-listed amici curiae certifies that, to the best of his knowledge, the Certificate of Interested Persons and Corporate Disclosure Statement included in Appellant's Opening Brief is complete. In addition to the individuals and entities listed on that certificate, the following counsel also have an interest in this case under 11TH CIR. R. 26.1-2:

1. BAGBY, Kelly – an attorney with AARP Foundation, Washington, DC, representing amici curiae.

2. GRENADIER, Meryl D. – an attorney with AARP Foundation, Washington, DC, representing amici curiae.

3. GRIFFIN, Rosie Dawn – an attorney with Constantine Cannon LLP, Washington, DC, representing amici curiae.

4. GYAMFI, Maame – an attorney with AARP Foundation, Washington, DC, representing amici curiae.

5. RIVERA, William A. – an attorney with AARP Foundation, Washington, DC, representing amici curiae.

6. SU, Henry C. – an attorney with Constantine Cannon LLP, Washington, DC, representing amici curiae.

7. VOLDMAN, Max – an attorney with Constantine Cannon LLP, Washington, DC, representing amici curiae.

Dated: July 20, 2018

/s/ Henry C. Su

Henry C. Su

Counsel for Amici Curiae AARP, AARP Foundation, California Advocates for Nursing Home Reform, the Center for Medicare Advocacy, Justice in Aging, the Long Term Care Community Coalition, The National Consumer Voice for Quality Long-Term Care, and the National Health Law Program

TABLE OF CONTENTS

Page

TABLE OF CITATIONS

Page

CASES

STATUTES

REGULATIONS

RULES

OTHER AUTHORITIES

STATEMENT OF THE ISSUES

This appeal asks whether the district court misapplied the materiality requirement under the False Claims Act (FCA), 31 U.S.C. §§ 3729–33 (2016), and *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). The court granted judgment as a matter of law against the relator, concluding that the jury couldn't reasonably have found the defendants' statutory and regulatory failures relating to therapy and care assessments, *see* 42 U.S.C. §§ 1395i-3(b)(2) & 1396r(b)(2) (2016); 42 C.F.R. § 483.20(k) (2016)[1]; FLA. STAT. ANN. §§ 409.913 & 409.919 (2016); FLA. ADMIN. CODE § 59G-4.200 (2016), material to the Centers for Medicare and Medicaid Services' (CMS) and the State of Florida's Agency for Health Care Administration's (AHCA) decision whether or not to reimburse.

[1] The relevant regulation was revised and re-designated in November 2016. *See* 42 C.F.R. § 483.21(b) (2017) (replacing section 483.20(k)); Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 81 Fed. Reg. 68,688, 68,736 (Oct. 4, 2016) (final rule). For consistency with the Appellant's opening brief, this brief cites to the pre-November 2016 version.

STATEMENT OF THE IDENTITIES AND INTERESTS OF AMICI CURIAE[2]

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering Americans 50 and older to choose how they live as they age. With nearly 38 million members and offices in every state, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, AARP works to strengthen communities and advocate for what matters most to families, with a focus on health security, financial stability, and personal fulfillment. AARP's charitable affiliate, AARP Foundation, works to end senior poverty by helping vulnerable older adults build economic opportunity and social connectedness.

Among other areas, AARP and AARP Foundation fight on behalf of older people for access to affordable healthcare and control

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[2] Amici curiae certify that no party or party's counsel authored this brief in whole or in part, or contributed money intended to fund its preparation or submission. Amici curiae further certify that no person, other than themselves, their respective members, and their undersigned counsel, contributed money intended to prepare or submit this brief.

Both the Appellant and the Appellees have consented to the filing of this brief. FED. R. APP. P. 29(a)(2).

of healthcare costs without compromising quality. Through its charitable affiliate, AARP Foundation, AARP has filed amicus curiae briefs in courts throughout the country in support of whistleblowers and other parties who reveal false claims filed by healthcare providers, especially when those providers' fraudulent activities expose vulnerable people to harm.

California Advocates for Nursing Home Reform (CANHR) is a non-profit organization that represents the interests of approximately 100,000 California nursing home residents and their families. Since 1983, CANHR has been advocating for the rights of long-term care residents. CANHR and its 3,000 members have a substantial interest in ensuring that quality care be provided to persons living in nursing facilities. CANHR's efforts include aiding residents and their families in obtaining legal services for long-term care issues; working to impose tougher sanctions on nursing homes that abuse or neglect residents; providing consumers, attorneys, and social workers with accurate information on long-term care; and continually working to determine the root causes of poor care and developing legislation and policies to address them.

The Center for Medicare Advocacy (Center) is a national, private, non-profit law organization, founded in 1986, that provides education, analysis, advocacy, and legal assistance nationwide, primarily to assist the elderly and people with disabilities to obtain necessary healthcare, therapy, and Medicare. The Center focuses on the needs of Medicare beneficiaries, people with chronic conditions, and those in need of long-term care, and provides nationwide training regarding Medicare and healthcare rights. It advocates on behalf of beneficiaries in administrative and legislative forums, and serves as legal counsel in litigation of importance to Medicare beneficiaries and others seeking healthcare coverage.

Justice in Aging is a national, nonprofit law organization that uses the power of law to fight senior poverty by securing access to affordable healthcare, economic security, and the courts for older adults with limited resources. Justice in Aging conducts Medicare and Medicaid training and advocacy, and provides nationwide technical assistance to attorneys and others on how to address problems arising under these programs. Justice in Aging frequently

appears as amicus curiae in cases involving healthcare access for older Americans.

The Long Term Care Community Coalition (LTCCC) is a nonprofit organization dedicated to improving quality of care, quality of life and dignity for elderly and disabled people in nursing homes, assisted living and other residential settings. LTCCC focuses on systemic advocacy, researching relevant national and state policies, laws, and regulations in order to identify relevant issues and develop meaningful recommendations to improve quality, efficiency, and accountability. In addition to providing a foundation for advocacy, LTCCC uses this research and the resulting recommendations to educate policymakers, consumers, and the general public. Consumer, family and LTC Ombudsman empowerment are fundamental to its mission.

The National Consumer Voice for Quality Long-Term Care (Consumer Voice) was formed as NCCNHR (the National Citizens' Coalition for Nursing Home Reform) in 1975 due to public concern for substandard care in nursing facilities. The Consumer Voice has since become the leading national voice representing consumers in issues

relating to long-term care and is the primary source of information and tools for consumers, families, caregivers, ombudsmen, and other advocates to help ensure quality care for all residents. Consumer Voice is dedicated to advocating for quality care, quality of life, and protection of rights for all individuals receiving long-term services and supports.

The National Health Law Program (NHeLP) protects and advances the health rights of low-income people and people with disabilities. For nearly fifty years, NHeLP has worked to help individuals and advocates overcome barriers to healthcare, including lack of affordable services.

SUMMARY OF THE ARGUMENT

This Court should reverse the district court and reinstate the jury's verdict. Doing so will ensure that the FCA continues to be a vital and effective tool in enforcing the 1987 Nursing Home Reform Act's (NHRA) quality-of-care objective for the benefit of nursing facility residents, who are generally elderly, frail, and otherwise vulnerable; and correct the district court's misapplication of *Escobar's* holistic materiality analysis.

Whistleblowers play a critical role in exposing fraud that places people in nursing facilities at risk of dangerous conditions. Through relator-initiated FCA lawsuits, the government annually recovers billions of federal and state dollars that would otherwise be lost to fraud. Such recoveries help ensure the continued viability of federal healthcare programs, including Medicare and Medicaid, on which millions of Americans depend for part or all of their healthcare needs.

Here, the defendants' abject failure to develop and maintain comprehensive care plans mandated by federal and Florida statutes and regulations, and their efforts to conceal that failure, imperil the Medicare/Medicaid Programs' fundamental objective that nursing facilities provide services enabling each resident "to attain or maintain the highest practicable physical, mental, and psychosocial well-being." 42 U.S.C. §§ 1395i-3(b)(2) & 1396r(b)(2) (2016). In enacting the NHRA, which enshrined this fundamental objective,[3] Congress determined that quality care is best achieved and ensured

[3] The NHRA was passed as part of the Omnibus Budget Reconciliation Act (OBRA) of 1987, Pub. L. No. 100–203, tit. IV, subtit. C, §§ 4201–18, 101 Stat. 1330-160–1330-221 (Dec. 22, 1987).

through the development, maintenance, and use of "a written plan of care which . . . describes the medical, nursing, and psychosocial needs of the resident and how such needs will be met." *Id.* An essential element of this requirement is that care plans be devoid of misrepresentations and accurately reflect resident care needs.

Viewed even under *Escobar*'s "demanding" and "rigorous" lens, a comprehensive care plan is material because it goes to the "very essence of the bargain" between the government and the defendants for the provision of quality care to residents. Under Medicare/Medicaid, the government paid the defendants a per-diem rate to provide each eligible resident at their nursing facilities with all needed care and services based on the acuity of their illness(es) or condition(s). Per this payment scheme, where a fixed amount covers an individualized bundle of services needed by a given resident, care plans are fundamental not only to ensuring the well-being of each resident, but also to enabling the government to assess whether it is getting what it bargained for.

In view of the trial record and the additional authorities discussed herein, the defendants' failure to develop and maintain

comprehensive care plans unquestionably should have been recognized by the district court as material to CMS' and AHCA's decisions to reimburse the defendants for the care their facilities were required to provide residents. By statutory and regulatory design, these care plans are the contracts between the facilities and the government, as they define the scope and nature of the services that the United States and Florida purchased from the defendants for each eligible resident. The jury rightly found the defendants liable under the FCA for failing to develop and maintain these care plans and covering up that failure, and this Court should therefore reverse.

ARGUMENT AND CITATIONS OF AUTHORITY

I. Introduction

This case impacts the health and welfare of 1.4 million nursing facility residents in America, some of the most vulnerable members of our society. Many residents suffer both physical and cognitive impairments. *See, e.g.,* CTRS. FOR MEDICARE & MEDICAID SERVS., NURSING HOME DATA COMPENDIUM 185 (11th ed. 2015) (finding over 80% of residents censused in 2014 had at least one impairment in an activity of daily living—e.g., bed mobility, dressing, eating,

transferring, toileting—and over 60% had moderate to severe cognitive impairment, including Alzheimer's disease and other dementias). Given their vulnerabilities, it is imperative that residents get the care and services that meet their specific needs.

Many nursing facilities are operated as for-profit entities. NURSING HOME DATA COMPENDIUM 30 (finding that 69.8% of nursing facilities in 2014 were for-profit). A growing body of evidence indicates that for-profit entities often engage in business practices that increase their bottom line at the expense of resident health, safety, and well-being, including reduced staffing levels. *See, e.g.*, Charlene Harrington et al., *Nursing Staffing and Deficiencies in the Largest For-Profit Nursing Home Chains and Chains Owned by Private Equity Companies*, 47:1 HEALTH SERVS. RES. 106, 120 (Feb. 2012); U.S. GOV'T ACCOUNTABILITY OFFICE, NURSING HOMES: CMS'S SPECIAL FOCUS FACILITY METHODOLOGY SHOULD BETTER TARGET THE MOST POORLY PERFORMING HOMES, WHICH TENDED TO BE CHAIN AFFILIATED AND FOR-PROFIT 30–31 (Aug. 2007) (No. GAO-09-689), https://bit.ly/2NnCqKL. Residents are often powerless to prevent for-profit entities from taking advantage of them by

providing substandard care, or worse, causing them harm or jeopardy.

The government is the primary payer of nursing facility services. *See* Infographic, Kaiser Family Found., *Medicaid's Role in Nursing Home Care* (June 2017) (noting Medicaid paid $55 billion in 2015 and covered 62% of residents), https://kaiserf.am/2zpEk6L. The FCA is an essential weapon to combat substandard care. For each eligible resident, the government contracts with a nursing facility to provide the services identified in the comprehensive care plan. The government pays the facility with the clear expectation that this care plan exists. If it doesn't exist, then the government has been defrauded because it has no way to verify that taxpayer dollars paid for the services it contracted for. Absent care plans, residents may suffer harm either from not receiving certain needed services, or from receiving inappropriate or unnecessary services.

II. *Qui Tam* Lawsuits Help Ensure Quality Care and Continued Viability of Federal Healthcare Programs

FCA lawsuits, including those initiated by relators, have proven to be a powerful weapon in uncovering fraud, ensuring that nursing

facility residents, the government, and taxpayers receive the full benefit of the bargain. Where federal and state monies are paid to nursing facilities for resident care, the intended benefit is twofold: first, the provision of identified necessary care to residents as dictated by care plans; and second, the continued viability of government healthcare programs funding such care, paying only for claims free of misrepresentation. Although defendants brazenly denied the nursing facility residents, government, and taxpayers these public benefits, the jury verdict in this FCA lawsuit was dismissed with apparent animus for the FCA and relators. Amici curiae are concerned that this perspective may have inappropriately colored the district court's application of the materiality requirement and influenced its decision to set aside the verdict.

A. The FCA and Relators Play a Key Role in Combating Fraud and Chronically Substandard Care

The district court's opinion is imbued with disdain for whistleblowers and FCA lawsuits: "The judgments effect an unwarranted, unjustified, unconscionable, and probably unconstitutional forfeiture—times three—sufficient in proportion and

irrationality to deter any prudent business from providing services and products *to a government armed with the untethered and hair-trigger artillery of a False Claims Act invoked by a heavily invested relator*." *United States ex rel. Ruckh v. Salus Rehabilitation, LLC*, 2018 WL 375720, at *5 (M.D. Fla. Jan. 11, 2018) (Doc. 468) (emphasis added). This Court should not allow this inaccurate assessment of the FCA and relators to stand.

The FCA has served to ensure the long-term financial viability of federal healthcare programs, including Medicare/Medicaid. In fiscal year 2017 alone, federal FCA recoveries totaled over $3.7 billion, $2.4 billion of which involved healthcare fraud. *See* Press Release, U.S. Dep't of Justice, *Justice Department Recovers Over $3.7 Billion from False Claims Act Cases in Fiscal Year 2017* (Dec. 21, 2017) (noting federal healthcare-related FCA recoveries topped $2 billion for eight consecutive years), https://bit.ly/2mcgqX2 [hereinafter, FY2017 FCA Press Release].

The FCA has also proven instrumental in exposing fraudulent conduct that harms or endangers Medicare/Medicaid-eligible residents, thereby serving a key protective function for a vulnerable

and often voiceless population. For example, in 2014, Extendicare Health Services entered into a five-year Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General (HHS-OIG) and agreed to pay $38 million to resolve government charges that it provided medically unnecessary rehabilitation therapy and nursing care so deficient the services were worthless. Press Release, U.S. Dep't of Justice, *Extendicare Health Services Inc. Agrees to Pay $38 Million to Settle False Claims Act Allegations Relating to the Provision of Substandard Nursing Care and Medically Unnecessary Rehabilitation Therapy* (Oct. 10, 2014), https://bit.ly/2zAPNW2. The grossly substandard care was pervasive, persisting from 2007 to 2013 in 33 facilities. *Id.*

In healthcare settings, whistleblowers contribute substantially to the government's record of success. Although the FCA provides the federal government with broad powers to combat healthcare fraud, public enforcement can be limited. Resource constraints, including budgetary restrictions, often prevent the Department of Justice (DOJ) and other law enforcement from investigating potential instances of healthcare fraud. *See* David Freeman Engstrom, *Private*

Enforcement's Pathways: Lessons from Qui Tam Litigation, 114 COLUM. L. REV. 1913, 1986–87 (2014). Furthermore, the high degree of automation in the federal government's processing of reimbursement claims makes uncovering healthcare fraud particularly difficult for regulators. MALCOLM K. SPARROW, LICENSE TO STEAL: HOW FRAUD BLEEDS AMERICA'S HEALTH CARE SYSTEM 29–30 (2000) (discussing the ease with which healthcare fraud can be perpetrated because of Medicare's automated billing scheme).

Amid these complications and constraints, whistleblowers armed with a private right of action, i.e., relators, uncover wrongdoing by helping regulators overcome an information asymmetry problem in healthcare, where employees of regulated providers have more information about internal operations and activities than regulators. This imbalance can stifle the government's ability to identify and remedy wrongdoing. *See* Pamela H. Bucy, *Information as a Commodity in the Regulatory World*, 39 HOUS. L. REV. 905, 940 (2002). Relators, however, compensate for this imbalance because as insiders they are uniquely situated to expose fraud concealed from reimbursement claims processors and law

enforcers. *See* S. Rep. No. 99-345, at 3 (1986) ("Detecting fraud is usually very difficult without the cooperation of individuals who are either close observers or otherwise involved in the fraudulent activity."); FY2017 FCA Press Release (quoting Acting Asst. Atty. Gen. Chad A. Readler ("Because those who defraud the government often hide their misconduct from public view, whistleblowers are often essential to uncovering the truth.")).

The importance of relators in combating healthcare fraud is underscored by the amount of taxpayer money their claims recoup and the oversight they provide for vulnerable populations. Financially, relators have helped the federal government recover billions of dollars. *See* FY2017 FCA Press Release (reporting that $3.4 billion of the $3.7 billion in settlements and judgments in fiscal year 2017 related to *qui tam* lawsuits). Relator-initiated FCA cases trigger systemic reform when healthcare providers knowingly and repeatedly fail to meet legal and regulatory requirements—or flaunt them to advance fraudulent schemes. Often regulators are unaware of or simply cannot adequately address the dangerous conditions that result from serious fraud without help from whistleblowers. *See*

OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., PROTECTING PUBLIC HEALTH AND HUMAN SERVICES PROGRAMS: A 30-YEAR RETROSPECTIVE 32 (2006) (crediting "the use of [FCA] suits to recover money and enforce systemic improvements in the quality of care in long term care settings") https://bit.ly/2NpfBGE.

B. Relator Enforcement Can Effectively Target Nursing Facility Noncompliance That Causes Resident Harm or Jeopardy

Relators play a critical role in exposing wrongdoing in nursing facilities, where regulation alone proves ineffective in stopping continuing and pervasive noncompliance. *See, e.g.* Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., *Special Focus Facilities (SFF) Initiative* 1 (updated June 21, 2018) (identifying nursing facilities with "yo-yo" or "in and out" compliance histories), https://go.cms.gov/2LnXVu6.

In 2016, over one in five U.S. nursing facilities received a deficiency for causing actual harm or jeopardy to residents. *See* CHARLENE HARRINGTON ET AL., KAISER FAMILY FOUND., NURSING FACILITIES, STAFFING, RESIDENTS AND FACILITY DEFICIENCIES, 2009 THROUGH 2016 16 (Apr. 2018), https://kaiserf.am/2L2qMs5. Sadly,

that picture wasn't much different from a decade before. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, NURSING HOME REFORM: CONTINUED ATTENTION IS NEEDED TO IMPROVE QUALITY OF CARE IN SMALL BUT SIGNIFICANT SHARE OF HOMES 9 (May 2007) (No. GAO-07-794T). (testimony before Congress that "[a] small but significant proportion of nursing homes nationwide continue to experience quality-of-care problems—as evidenced by the almost 1 in 5 nursing homes . . . cited for serious deficiencies in 2006") https://bit.ly/2moSvnQ. Serious deficiencies "cause actual harm or place residents in immediate jeopardy," *id.* at 3, and those found in facilities cycling in and out of compliance include inadequate treatment of pressure sores, medication errors, poor accident supervision, and resident abuse, *see* U.S. GOV'T ACCOUNTABILITY OFFICE, NURSING HOMES: EFFORTS TO STRENGTHEN FEDERAL ENFORCEMENT HAVE NOT DETERRED SOME HOMES FROM REPEATEDLY HARMING RESIDENTS 26, 68 (Mar. 2007) (No. GAO-07-241), https://bit.ly/2Ju67HF.

In this case, the relator's unique position inside the defendants' facilities enabled her to expose rampant fraud that escaped the

attention of spot surveys. Her lawsuit not only helped identify hundreds of millions of federal and state dollars that shouldn't have been paid to the defendants, it also exposed that many residents did not receive services from the defendants as required by federal law and their individualized care plans. In reinstating the verdict, this Court would reaffirm the importance of the FCA in exposing serious, costly healthcare fraud that harms both nursing facility residents and the government programs that pay for their care.

III. Defendants' Knowing Misrepresentations in Care Plans (and Concealment of Those Misrepresentations) Was Material to the Government

In *Escobar*, the Supreme Court did not redefine "materiality" under the FCA. On the contrary, the Court observed that the FCA's definition ("having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property"), 31 U.S.C. § 3729(b)(4), is consistent with the term's usage in other federal fraud statutes and familiarly "descends from 'common-law antecedents.'" 136 S. Ct. at 2002 (quoting *Kungys v. United States*, 485 U.S. 759, 769 (1988)). "Under any understanding of the concept, materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the

alleged misrepresentation.'" *Id.* (quoting 26 R. LORD, WILLISTON ON CONTRACTS § 69.12, at 549 (4th ed. 2003)).

Furthermore, in declaring the FCA's materiality requirement "rigorous" and "demanding," *Escobar*, 136 S. Ct. at 1996, 2002, 2003 & 2004 n.6, the Court sought to prevent the FCA from becoming "a vehicle for punishing garden-variety breaches of contract or regulatory violations," *id.* at 2003 (further noting "[m]ateriality . . . cannot be found where noncompliance is minor or insubstantial"); *see also id.* at 2004 (emphasizing that the FCA "is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations"). By contrast, a misrepresentation is material if it goes "to the very essence of the bargain." *Id.* at 2003 n.5 (quoting *Junius Constr. Co. v. Cohen*, 257 N.Y. 393, 400, 178 N.E. 672, 674 (1931)); *accord Marsteller for the use and benefit of United States v. Tilton*, 880 F.3d 1302, 1313 (11th Cir. 2018) (acknowledging distinction).

Although the Court declared the analysis rigorous and demanding, it stressed that materiality determinations require careful consideration and weighing of various evidentiary factors, and

no single factor—not even "the government's consistent refusal to pay claims in the mine run of cases"—is dispositive. *Escobar*, 136 S. Ct. at 2003–04. Other Circuits have duly recognized and applied *Escobar's* holistic, multi-factor materiality analysis. *See United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 831 (6th Cir. 2018); *United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh, Pa.*, 2018 WL 1517159, at *5 (3d Cir. Mar. 28, 2018); *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 906 (9th Cir. 2017); *United States ex rel. Escobar v. Univ. Health Servs., Inc.*, 842 F.3d 103, 109 (1st Cir. 2016) (on remand) [hereinafter, *Escobar II*].

Under *Escobar's* holistic, multi-factor analysis, comprehensive care plans required of nursing facilities by the government delineate the terms of the bargain because they enumerate the scope and nature of services for which the government is paying. The jury therefore properly found materiality in the defendants' failure to develop and maintain such plans for many of their residents, and their cover-up of that failure by creating plans after-the-fact and backdating them to mislead surveyors.

A. Statutes and Regulations Governing Nursing Facilities Expressly Make Care Plans a Condition of Participation and Payment

Healthcare providers voluntarily participate in state and federally funded healthcare programs, but their participation is conditioned on compliance with state and federal law. Nursing facilities must comply with the NHRA and implementing regulations that set forth minimum standards of care for long-term care facilities that receive federal funding. *See* 42 U.S.C. §§ 1395i-3, 1396r (2016); 42 C.F.R. §§ 483.1–.95 (2017). Here, the plan-of-care requirements are plainly material to both program participation and reimbursement. *See Escobar*, 136 S. Ct. at 2002 (declining to draw an artificial distinction, for purposes of FCA liability, between conditions of payment and conditions of eligibility for participation in a federal program).

In order to be reimbursed, nursing facilities are required to "provide services [and activities] to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care which . . . describes the medical, nursing, and psychosocial needs of the resident

and how such needs will be met." 42 U.S.C. §§ 1395i-3(b)(2) & 1396r(b)(2) (2016).[4] CMS regulations specify that facilities must develop, based on a comprehensive assessment, a care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, mental, and psychosocial needs. 42 C.F.R. § 483.20(k) (2016). The plan must describe all services to be furnished to attain or maintain the resident's highest practicable well-being. *Id.* § 483.20(k)(1)(i).

Congress charged CMS and the States with surveying and certifying nursing facility compliance with the plan-of-care requirement, 42 U.S.C. §§ 1395i-3(g)(1)(A) & 1396r(g)(1)(A), and armed them with a range of sanctions and remedies, including partial and full denial of payment to the noncomplying facility, to address identified defaults and deficiencies, *id.* §§ 1395i-3(h)(1) & 1396r(h)(1).[5]

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[4] Bracketed words in the quoted text appear in the Medicaid statute but not the Medicare statute.

[5] The denial-of-payment remedy appears in subsection (h)(2)(B)(i) of the Medicare statute and in subsections (h)(2)(A)(i) and (h)(3)(C)(i) of the Medicaid statute.

Through AHCA, Florida likewise makes the plan-of-care requirement integral to its Medicaid regulatory and enforcement scheme for nursing facilities. Notably, the Florida statute governing Medicaid Program integrity imposes "an affirmative duty" on providers, when presenting claims for payment, to ensure that claims are true and accurate, are for goods and services provided in accordance with applicable laws, regulations, rules, and policies, and are "documented by [contemporaneous] records . . . demonstrating the medical necessity for the goods or services rendered." FLA. STAT. ANN. § 409.913(7)(e) & (f) (2016). "*The agency shall deny payment or require repayment for goods or services that are not presented as required in this subsection.*" *Id.* (emphasis added).

Exercising its rulemaking authority to adopt regulations ensuring provider compliance with Medicaid Program requirements, FLA. STAT. ANN. § 409.919 (2018), AHCA requires nursing facilities to adhere to its Florida Medicaid Nursing Facility Services Coverage Policy. FLA. ADMIN. CODE § 59G-4.200(2) (2016), https://bit.ly/2uulk6N. Under section 4.2 of that policy, nursing facility providers "must provide or arrange for the provision of

necessary care and services required for each recipient to attain, or maintain, the highest practicable physical, mental, and psychosocial well-being, in accordance with 42 CFR 483, Subpart B and section 400.022, F.S." Fla. Medicaid Nursing Facility Servs. Coverage Pol'y § 4.2 (May 2016), https://bit.ly/2uup3Bl. AHCA's coverage policy thus points nursing facilities right back to CMS' own regulation implementing the plan-of-care requirement, 42 C.F.R. § 483.20(k)(1), as well as to Florida's nursing facility residents' bill of rights, which includes "[t]he right to receive adequate and appropriate health care and protective and support services . . . and therapeutic and rehabilitative services *consistent with the resident care plan* . . . " FLA. STAT. ANN. § 400.022(*l*) (2016) (emphasis added).

Taken together, the relevant federal and Florida statutes and regulations uniformly prescribe that a comprehensive care plan is a foundational requirement for nursing facilities participating in government healthcare programs and seeking government reimbursement. And with good reason—Congress intended such plans to be the central document for comprehensively identifying each resident's specific needs, the means by which state surveyors

evaluate whether the facility is meeting those needs, and the tool through which changed circumstances are identified and accommodated. 42 C.F.R. § 483.20(k)(2) (2016) (requiring comprehensive care plan preparation by an interdisciplinary team including a physician, a registered nurse, the resident and her family, and plan revision when needs change).

The district court, in skeptically viewing care plans as "*ostensibly* required by Medicaid regulation" and downgrading them to a "record-keeping" practice, *Ruckh*, 2018 WL 375720, at *1 (emphasis added), overlooked the NHRA's fundamental objectives carried out by these plans. As the determinative document governing each nursing facility resident's care, a false, inaccurate, or nonexistent care plan can dangerously impact care, as well as deprive the government of the benefit of its bargain—services that attain the highest practicable resident well-being. Contrary to the district court's characterization, this isn't the "system of government traps, zaps, and zingers" that *Escobar* eschews. *Id.* at *3 & *5. A missing care plan means that providers, however qualified, have no way of

ensuring a resident receives the care she has been assessed as needing.

B. Care Plans Delineate the Very Essence of the Bargain When the Government Purchases Nursing Facility Services

Apart from its status as a foundational requirement for Medicare/Medicaid program participation and reimbursement, a comprehensive care plan is also, as a practical matter, part and parcel of the bundle of nursing facility services the government purchases. As explained above, the NHRA requires nursing facilities to provide all services needed by a resident to "attain or maintain [his or her] highest practicable . . . well-being." 42 U.S.C. §§ 1395i-3(b)(2) & 1396r(b)(2) (2016). Unlike a patient who sees a healthcare provider for a specific problem (e.g., blurry vision) or a specific procedure, (e.g., insertion of a coronary stent), a nursing facility resident requires a variety of healthcare and psychosocial services (e.g., nursing, rehabilitative, medical, dental, pharmaceutical, dietary, mental health), *id.* §§ 1395i-3(b)(4)(A) & 1396r(b)(4)(A), determined through a comprehensive assessment, *id.* §§ 1395i-3(b)(3)(A) & 1396r(b)(3)(A), and delivered in accordance with a care plan tailored to the resident's

needs using the assessment results, *id.* §§ 1395i-3(b)(3)(D) & 1396r(b)(3)(D).

The contrasting examples furnished by *Escobar*—a misrepresentation that goes to "the very essence of the bargain" versus one that relates to a "garden-variety" breach or violation—are helpful guideposts in evaluating the nature and sufficiency of the evidence before the jury. *See, e.g.*, *Prather*, 892 F.3d at 834; *Escobar II*, 842 F.3d at 110. Here, the bargain a nursing facility provider strikes with the government is a commitment to provide whatever services a resident is determined to need under his or her comprehensive care plan in exchange for a per-diem payment. Unlike a fee-for-service payment model, in which the government directly reimburses a provider for specific healthcare services rendered, under the per-diem model the government has no way of knowing, absent a care plan, whether its dollars are being *properly* spent to provide *all* the services a resident needs. For this reason, care plans are integral to and inseparable from the bundle of services the government purchases.

The district court failed to see the problem with defendants' noncompliance, observing: "[t]he defendants in the present action used qualified providers who ably provided services in accord with orders issued by qualified professionals but who, for example, could not—years later—identify a 'comprehensive care plan' for each patient." *Ruckh*, 2018 WL 375720, at *7. This (faulty) observation illuminates the crux of the district court's misapplication of *Escobar*. Although services were rendered to each resident at the defendants' nursing facilities, and—let's assume—by qualified providers, CMS and AHCA couldn't tell, without accurate and contemporaneous care plans, whether those services in fact comprise the bundle a given resident needed to attain or maintain the NHRA-required highest practicable well-being. 42 U.S.C. §§ 1395i-3(b)(2) & 1396r(b)(2) (2016); 42 C.F.R. § 483.20(k)(1)(i) (2016). *See also* 42 U.S.C. §§ 1395i-3(b)(2)(A) & 1396r(b)(2)(A); 42 U.S.C. §§ 1395i-3(b)(4)(A) & 1396r(b)(4)(A); 42 C.F.R. § 483.20(k)(1).

Put differently, in the absence of a care plan, a resident might not receive needed services. For instance, a nursing facility, paid on a per-diem basis for each resident, might be tempted to cut corners and

withhold costly services such as rehabilitative therapy. Or a resident might not receive appropriate follow-up care for a medical condition such as a fracture. HHS-OIG's studies validate such concerns. OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., WEST CARROLL CARE CENTER DID NOT ALWAYS FOLLOW CARE PLANS FOR RESIDENTS WHO WERE LATER HOSPITALIZED WITH POTENTIALLY AVOIDABLE URINARY TRACT INFECTIONS 6 (June 2016) (No. A-06-14-00073), https://bit.ly/2JuUbFw; OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., NURSING FACILITY ASSESSMENTS AND CARE PLANS FOR RESIDENTS RECEIVING ATYPICAL ANTIPSYCHOTIC DRUGS 17 (July 2012) (No. OEI-07-08-00151), https://bit.ly/2L4Cane.

The district court characterized *Escobar* as "assum[ing] and enforc[ing] a course of dealing between the government and a supplier of goods or services that rests comfortably on proven and successful principles of exchange—fair value given for fair value received." *Ruckh*, 2018 WL 375720, at *3. That's right. And in the case of nursing facility services, a care plan ensures the government indeed receives fair value for taxpayer dollars. Charged with ensuring that elderly, frail, and vulnerable Americans in nursing facilities

receive necessary and appropriate quality care, the government does not pay for unnecessary or inappropriate care, nor for incomplete or deficient services.

C. A Failure to Develop and Maintain Care Plans Raises the Government's Concern About How Taxpayer Dollars Are Spent

The district court chastised the relator for failing to call witnesses to answer what it deemed "the controlling question," i.e., "the actual and expected conduct of the federal or state government when confronted with a record-keeping deficiency or any other deficiency by a health care provider engaged actively in providing qualified and essential health care to thousands of aged, infirm, and dependent patients at scores of residential facilities throughout the third largest state in the United States." *Ruckh*, 2018 WL 375720, at *7. In insisting that government witnesses answer this (loaded) question, the district court took an unreasonably and erroneously narrow view of the trial evidence, one that contravenes *Escobar's* holistic inquiry. *See Escobar II*, 842 F.3d at 109 ("The language that the Supreme Court used ["materiality cannot rest on 'a single fact or occurrence as always determinative'"] . . . makes clear that courts are

to conduct a holistic approach to determining materiality in connection with a payment decision, with no one factor being necessarily dispositive.") (quoting *Escobar*, 136 S. Ct. at 2001). *Accord Prather*, 892 F.3d at 831.

Escobar's rejection of a single-factor materiality test recognizes that many FCA cases, especially those involving healthcare fraud, present significantly more complex fact patterns than the simple, oft-cited example in which the government procures guns that don't shoot. *See Escobar*, 136 S. Ct. at 2001. In that example, the government is the direct purchaser, is immediately aware that the guns don't function, is able to reject the nonfunctioning guns and rescind the contract, and, presumably, has the freedom and opportunity to contract with a different supplier for functioning guns.

Withholding payment for nursing facility fraud on a service-by-service basis is rarely practicable in a case such as this, where the United States and Florida purchased care, not for themselves, but for vulnerable residents isolated in nursing facilities. Withholding payment, even on a clear finding of noncompliance, can disrupt care, a fact CMS makes clear to facility surveyors. *See* STATE OPERATIONS

MANUAL, CMS pub. 100-07, Ch. 7, § 7508.1 (Nov. 2017 rev.) (noting that denial of payment may be appropriate where "other remedies . . . have failed to achieve or sustain compliance"), https://go.cms.gov/QjlruI. Instead, the government has more effective remedies at its disposal to recover fraudulently obtained monies, like the FCA.

Publicly available information from HHS-OIG and CMS confirms the government's manifest concern about its pocketbook when nursing facilities receiving Medicare/Medicaid reimbursements fail to develop and maintain resident care plans. A February 2013 HHS-OIG study based on a medical record review of a stratified random sample of stays at skilled nursing facilities (SNFs) in 2009, found that in 37% of sampled stays, "SNFs did not develop care plans that met requirements or provide services in accordance with care plans." OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., SKILLED NURSING FACILITIES OFTEN FAIL TO MEET CARE PLANNING AND DISCHARGE PLANNING REQUIREMENTS 9, 16 (Feb. 2013) (No. OEI-02-09-0021), https://bit.ly/2mld2tE. The deficient stays represented $4.5 billion in Medicare payments, *id.* at 9, leading HHS-OIG to

remark that "[t]hese findings raise concerns about what Medicare is paying for," *id.* at 16, and to recommend that CMS "link SNF payments more closely to meeting the requirements," *id.* at 17. HHS-OIG reported that CMS concurred with its recommendations. *Id.* at 19. *See also Spotlight On . . . Skilled Nursing Facilities*, OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS. (2013), https://bit.ly/2LoynNL (summarizing study findings); Letter from Daniel R. Levinson, Inspector Gen., Dep't of Health & Human Servs., to Sen. Charles E. Grassley, Chmn., S. Comm. on the Judiciary Comm., App'x 1 at 5 (Mar. 15, 2016) (summarizing study findings in response to Senate inquiry), https://bit.ly/2uGrzE2.

That the defendants continued to receive payments from the government for care provided at their nursing facilities does not and cannot indicate government acquiescence or approval of a particular fraudulent business practice related to the claims—assuming the government had actual knowledge of that practice—or a finding that the claims are accurate and true. The jury was entitled to consider evidence regarding the entire regulatory scheme, which provides alternate mechanisms by which CMS and AHCA can obtain

compliance short of full denial of payment, and contemplates recovery of funds wrongfully disbursed as a consequence of the fraudulent scheme knowingly implemented by the defendants.

As the above-cited reports and statements demonstrate, HHS-OIG and CMS regard the written care-plan requirement as central to their bargain with the nursing facility and not as a mere "record-keeping" practice. *Escobar's* example of American-made staplers that had to be used by health care providers contracting with the government bears no resemblance to the defendants' failure to develop and maintain care plans that should have ensured residents received needed care and services and the government had the tools to evaluate facility performance. 136 S. Ct. at 2004. The care plan is so essential to the services the government intended to pay for that the defendants' misrepresentations about their development and implementation of such plans cannot be construed as anything but material.

CONCLUSION

For the foregoing reasons, amici curiae respectfully submit that the district court's judgment should be reversed and vacated, and the judgment reflecting the verdict reinstated.

Dated: July 20, 2018

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of FED. R. APP. P. 32(a)(7)(B) (as made applicable to amicus briefs by FED. R. APP. P. 29(a)(5)) because it contains 6148 words, excluding the parts of the brief exempted by FED. R. APP. P. 32(f) and 11TH CIR. R. 32-4.

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Dated: July 20, 2018

/s/ Henry C. Su

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CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2018, I electronically filed a true and correct copy of the foregoing document with the Clerk of this Court using the appellate CM/ECF system, which in turn effectuates service by sending a notice of electronic filing to all counsel participating in this appeal who are registered CM/ECF users.

Dated: July 20, 2018

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