No. 17-5410

United States Court of Appeals

for the

Sixth Circuit

UNITED STATES,

Plaintiff-Appellant,

– v. –

RICHARD E. PAULUS, M.D.,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES, DISTRICT COURT FOR THE EASTERN DISTRICT OF KENTUCKY, JUDGE DAVID BUNNING, NO. 15-CR-15

BRIEF OF THE NATIONAL ASSOCIATION OF CRIMINAL DEFENSE LAWYERS AS *AMICUS CURIAE* IN SUPPORT OF APPELLEE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Sixth Circuit Rule 26.1, amicus curiae National Association of Criminal Defense Lawyers certifies that it is a nonprofit entity that does not have parent corporations. No publicly held corporation owns 10 percent or more of any stake or stock in amicus curiae.

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INTEREST OF AMICUS CURIAE[1]

The National Association of Criminal Defense Lawyers ("NACDL") is a nonprofit voluntary professional bar association that works on behalf of criminal defense attorneys to ensure justice and due process for those accused of crime or misconduct. NACDL was founded in 1958. It has a nationwide membership of many thousands of direct members, and up to 40,000 with affiliates. NACDL's members include private criminal defense lawyers, public defenders, military defense counsel, law professors, and judges. NACDL is the only nationwide professional bar association for public defenders and private criminal defense lawyers. NACDL is dedicated to advancing the proper, efficient, and just administration of justice. NACDL files numerous amicus briefs each year in the U.S. Supreme Court and other federal and state courts—including this Court—seeking to provide amicus assistance in cases that present issues of broad importance to criminal

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[1] Pursuant to Federal Rule of Appellate Procedure 29(a), counsel for amicus curiae certifies that all parties have consented to the filing of this brief. Pursuant to Rule 29(c)(5), counsel for amicus curiae states that no counsel for a party authored this brief in whole or in part, and no person other than amici curiae, its members, or its counsel made a monetary contribution to its preparation or submission.

defendants, criminal defense lawyers, and the criminal justice system as a whole.

As an association concerned with the fair administration of criminal justice, NACDL has a compelling interest in preventing the creation of judicial precedents that may erroneously criminalize legitimate professional activity. In the present case, NACDL's interest is implicated by the government's attempt to turn a professional disagreement between the defendant and the government's expert witnesses over decisions involving a high degree of medical judgment into conclusive evidence of guilt with respect to health care offenses.

INTRODUCTION

SUMMARY OF ARGUMENT

Overturning the judgment below would create a precedent allowing the government to obtain criminal convictions against physicians making difficult, highly subjective medical decisions primarily on the basis of the testimony of a single expert with a contrary view. At best, this type of evidence can establish good faith medical error or perhaps negligence, which Congress did not intend to criminalize and are already appropriately dealt with by other legal means.

ARGUMENT

I. Contrary expert opinion, taken alone, is insufficient to establish false statements or fraudulent intent beyond a reasonable doubt with respect to medical decisions that are inherently a matter of subjective professional judgment.

The present case underscores an evidentiary issue faced in much of the litigation involving health care: how should factfinders attempt to *objectively* assess health care decisions, when the actual practice of medicine is often suffused with *subjectivity*? NACDL submits that in the criminal context the answer should be: "With great caution."

The court below correctly recognized that criminal liability for false statements relating to health care should not attach to statements regarding medical determinations—such as the degree of stenosis—that involve a high degree of subjective medical judgment. The nature of certain medical determinations simply does not allow them to be established as false when the only evidence of their falsity is the disagreement of a sole expert witness.

As the record in this case shows, the interpretation of angiograms is a highly subjective act. The court below found that "cardiologists frequently disagree with one another regarding the degree of stenosis." Order R.318, #12207. The government itself acknowledges that cardiologists may in good faith disagree on the degree of stenosis. (Gov. Br. 22-23, ECF No. 15.) Yet the government attempts to circumscribe with precision an "acceptable" degree of subjectivity for this exercise of medical judgment, proposing that inter-observer variability of the degree of stenosis should never exceed 20%. While this proposed bright-line rule regarding inter-observer variability is itself highly dubious (*see* Brief for the Mid-Atlantic Innocence Project

2-4, ECF No. 17-1.), even more alarming is the erosion of the government's burden of proof that such a bright-line rule would entail.

In the prosecution below, the government essentially cherry-picked diagnoses from among the thousands of patients that Dr. Paulus has treated and, for all but one of those diagnoses, asked a single one of its two experts whether he agreed with Dr. Paulus.[2] The subjective disagreement of that expert with Dr. Paulus' assessment by more than 20% should, according to the government, be sufficient to establish falsity. To accept this position would turn a professional disagreement over a subjective exercise of medical judgment between a defendant and a single, carefully-selected government expert into evidence beyond a reasonable doubt of a false statement. NACDL views this as an unacceptably low evidentiary bar for criminal liability, which could potentially subject physicians to criminal liability in all areas of medicine that call for subjective judgments.

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[2] The government had more than one expert testify as to the degree of stenosis for only a single patient whose diagnosis by Dr. Paulus was called into question: an individual referred to as "D.C." Order R.318, #12205.

Likewise, evidence establishing only a professional disagreement is insufficient to establish knowledge or intent under the provisions relating to health care fraud, 18 U.S.C. § 1347, and false statements, 18 U.S.C. § 1035(a)(2). The fact that another physician, or even several other physicians, would have exercised their judgment differently does not establish beyond a reasonable doubt knowledge of false statements or intent to commit health care fraud. In areas of medicine calling upon a doctor's personal experience and subjective judgment, idiosyncratic views about how best to proceed are not suggestive of criminal intent. Indeed, "most clinicians' practices do not reflect the principles of evidence-based medicine but rather are based upon tradition, their most recent experience, what they learned years ago in medical school, or what they have heard from their friends." John M. Eisenberg, *What does evidence mean? Can the law and medicine be reconciled?*, 26 J. HEALTH POL. POL'Y L. 369, 369-70 (2001). The precedents cited by the government appear to recognize this fairly obvious fact, since they feature convictions on the basis of a record containing greater evidence of intent than in the present case.[3]

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[3] *See United States* v. *Persaud*, 866 F.3d 371, 384-85 (6th Cir. 2017)

II. Overturning the judgment below could lead to criminalizing legitimate exercises of medical judgment by physicians.

A. Congress did not intend to criminalize legitimate, good faith medical practice.

Congress took great care to craft health care fraud statutes that would not "make criminals out of good doctors," 142 CONG. REC. H9785-02, at H9792 (1996), or "unleash an army of intrusive investigators trying to entrap innocent doctors." 142 CONG. REC. S6116-01, at S6116 (1996). Lawmakers acknowledged and agreed with the American Medical Association's statement that "honest mistakes should not make physicians or any other citizens candidates for incarceration." *Id.*

(Defendant transferred $250,000 from his business account to his wife's name after the investigation became public and consistently "upcoded" the medical services for which he billed.); *United States* v. *McLean*, 715 F.3d 129, 139-40 (4th Cir. 2013) (Circumstantial evidence of fraud included misrepresentation of patient symptoms, an attempt to shred subpoenaed patient files, and statements by the defendant implying he was aware that the procedures were unnecessary.); *United States* v. *Patel*, 485 Fed. App'x 702, 709 (5th Cir. 2012) (Circumstantial evidence of fraud included misrepresentation of patient symptoms and suspicious conduct and statements by the defendant prior to and during trial.). And to the extent that these cases suggest that the testimony of a single expert, without more, can establish falsity or intent to commit health care fraud, NACDL submits that they were wrongly decided.

In light of those concerns, during the drafting of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), lawmakers added explicit knowledge and willfulness requirements to the health care fraud provisions. These requirements were intended to serve as crucial bulwarks against convictions of doctors for medical decisions—and even errors—made in good faith:

> The addition of willful in this standard is essential to ensure that inadvertent or accidental conduct is not deemed criminal. . . . Without this clarification, legitimate disagreements regarding a physician's medical judgment and treatment decisions could have been the basis for imposing criminal penalties.

142 CONG. REC. S9501-01, at S9524 (1996).

Legislators expected that "[p]rosecutors would continue to have an extremely high burden to prove that the violations were committed knowingly and willfully," *id.* at S9511, and that the use of the health care fraud statutes would be limited to "prosecut[ing] egregious, intentional acts of fraud." 142 CONG. REC. S6116-01, at S6116 (1996). The HIPAA health care fraud provisions were therefore drafted to ensure that they did not transform idiosyncratic or sub-standard medical practices into criminal activity.

Finally, Congress recognized that it was legislating within the context of a well-developed regulatory framework for addressing non-criminal misconduct by medical providers. Even prior to the passing of HIPAA, Congress was well aware that it had a role to play in "providing a full array of enforcement tools against health care fraud," 140 CONG. REC. S11341-04, at S11353 (1994), but its role in that regard is not exclusive.

B. Disagreements among medical professionals in areas of medicine involving a significant degree of medical judgment can form the basis for civil liability or disciplinary sanctions, rather than criminal liability.

Affirming the court below will not create a precedent that there is no remedy for reckless or negligent medical decisions. Several state and federal laws allow public and private litigants to combat over-diagnosis and over-treatment by the medical profession, restore improperly obtained federal health care funds to the public, compensate patients for harms suffered, and hold medical professionals accountable. Where, as in this case, the government cannot prove falsity or intent beyond a reasonable doubt, these laws are the most appropriate enforcement tools. Any suggestion that unnecessary medical

procedures will go unpunished without a criminal judgment against individual physicians is false.

The government can avail itself of the Stark Law, 42 U.S.C. § 1395nn (prohibiting certain financial relationships between health care institutions and referring professionals), and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (prohibiting compensation in exchange for health care referrals), to bring actions against medical providers to reclaim inappropriately spent public funds.[4] In negotiating a May 2014 settlement with King's Daughters Medical Center ("KDMC"), where Dr. Paulus worked, the government used the threat of prosecution under these statutes to recover a substantial amount of state and federal funds from the hospital in connection with allegedly unnecessary heart procedures.[5] The Anti-Kickback Statute also permits the Secretary of

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[4] NACDL refers to other proceedings against or settlements with KDMC and/or Dr. Paulus as illustrations of alternatives to the present criminal proceedings, but takes no position as to the merits of the actions brought in these proceedings or allegations relating to these settlements.

[5] Justice Department Press Release, "King's Daughters Medical Center to Pay Nearly $41 Million to Resolve Allegations of False Billing for Unnecessary Cardiac Procedures and Kickbacks" (May 28, 2014). As part of the settlement, KDMC also entered into a Corporate Integrity Agreement with the U.S. Department of

Health and Human Services to exclude from federal health care programs an individual or entity that "furnished or caused to be furnished items or services to patients . . . substantially in excess of the needs of such patients." 42 U.S.C. § 1320a-7(b)(6)(B).

In appropriate cases, the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, would be available to the government and "does not require proof of specific intent to defraud."[6] *U.S. ex rel. Williams* v. *Renal Care Grp., Inc.*, 696 F.3d 518, 528 (6th Cir. 2012). Its knowledge requirement can be established by proving—by a preponderance of the evidence—"deliberate ignorance" or "reckless disregard," *id.* at 530, which would include "an aggravated form of gross negligence" of the duty to make a reasonable inquiry as to falsity. *Id.* at 531 (quoting *United States ex rel. Burlbaw* v. *Orenduff*, 548 F.3d 931, 945 n.12 (10th

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Health and Human Services Office of Inspector General, obligating it "to undertake substantial internal compliance reforms and to commit to a third-party review of its claims to federal health care programs for the next five years." *Id.*

6 Nearly thirty states and the District of Columbia have false claims acts of their own, many of which match or exceed in scope the federal Act. *See, e.g.*, 740 ILL. COMP. STAT. ANN. 175/1; IOWA CODE ANN. § 685; TENN. CODE ANN. § 4-18-101 *et seq.* Kentucky is not among those jurisdictions, but it does have laws governing Medicaid fraud and abuse. *See* KY. REV. STAT. ANN. §§ 205.8451-205.8483.

Cir. 2008). Therefore, FCA actions may be appropriate where prosecutions under the criminal health care fraud statutes are not, due to insufficient evidence of a physician's specific intent to defraud.

Patients who receive unnecessary cardiac and other procedures also have numerous state-law remedies available to them. Possible causes of action include:

> [B]attery; lack of informed consent; negligence; medical negligence; corporate negligence; *respondeat superior*; fraud; fraudulent concealment; negligent and/or intentional misrepresentation; civil conspiracy; negligent hiring, privileging, supervision and/or retention; negligent entrustment; violations of state unfair trade practices acts and state consumer protection laws; and loss of consortium.

Douglas Danner, *Unnecessary cardiac procedures—Plaintiff to defendant*, 3 MED. MALPRAC. CHKLSTS. & DISC. § 20A:20. Thus, patients who are injured as a result of medically unnecessary procedures can pursue—in addition to possible treble damages as relators under the FCA—any number of avenues to obtain monetary compensation under state law. Several such suits are currently pending against KDMC and Dr. Paulus.

In addition, the medical profession in the United States has long been afforded extensive self-policing authority. That authority

encompasses the power of state-level organizations of medical professionals to hold their members individually accountable for misconduct. In Kentucky, the Board of Medical Licensure ("KBML") has statutory authority to promulgate sanctionable violations, including "[e]ngag[ing] in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public or any member thereof," KY. REV. STAT. ANN. § 311.595(9), and making a false statement "in any document executed in connection with the practice of [the] profession." KY. REV. STAT. ANN. § 311.595(10). In the present case, Dr. Paulus and the KBML have entered into an Agreed Order of Retirement, the terms of which bar Dr. Paulus from the practice of medicine in Kentucky for a minimum of two years. R.23-2, #112. These disciplinary sanctions have a significant impact on physicians, and are commonly considered and imposed by state-level organizations like the KBML even in the absence of criminal convictions.

III. Conclusion

Reversing the district court's judgment of acquittal in this case would allow the government to convict doctors for complex, subjective decisions on the basis of the opinion of a single, hand-picked

expert who would have exercised his medical judgment differently than the defendant. Such a precedent would create an unacceptably high risk of criminal prosecutions of honest professionals who operate in areas of medicine requiring frequent judgment calls—precisely what Congress sought to avoid when crafting the health care fraud provisions of HIPAA. This Court should thus affirm the judgment of acquittal.

Dated: January 10, 2018

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

In accordance with Federal Rule of Appellate Procedure 32(a)(7)(C), the undersigned counsel certifies that this brief:

(i) complies with the type-volume limitation of Rule 29(a)(5) because it contains 2,209 words, including footnotes and excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Word 2010 and is set in Century 14-point font.

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CERTIFICATE OF SERVICE

I certify that on this Tenth day of January, 2018, I served the foregoing brief on counsel for the parties via the Court's ECF system:

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