No. 22-1463

In the United States Court of Appeals for the Sixth Circuit

SHANNON MARTIN, M.D., Relator, ex rel. UNITED STATES OF AMERICA;
DOUGLAS MARTIN, Relator, ex rel. UNITED STATES OF AMERICA,

Plaintiffs-Appellants,

v.

DARREN HATHAWAY, M.D.; SOUTH MICHIGAN OPHTHALMOLOGY; and
ELLA E. M. BROWN CHARITABLE CIRCLE, d/b/a Oaklawn Hospital,

Defendants-Appellees.

On Appeal from the United States District Court
for the Western District of Michigan, Southern Division
Case No. 1:19-cv-915
Honorable Jane M. Beckering

BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, MICHIGAN HEALTH & HOSPITAL ASSOCIATION, KENTUCKY HOSPITAL ASSOCIATION, OHIO HOSPITAL ASSOCIATION, AND TENNESSEE HOSPITAL ASSOCIATION IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE

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CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Amici make the following disclosures under Sixth Circuit Rule 26.1:

1. Is any *amicus* a subsidiary or affiliate of a publicly owned corporation?

No. The American Hospital Association, Michigan Health & Hospital Association, Kentucky Hospital Association, Ohio Hospital Association, and Tennessee Hospital Association are nonprofit corporations. No entity has a parent company and none has issued stock.

2. Is there a publicly owned corporation, not a party to the appeal or an *amicus*, that has a financial interest in the outcome?

None known.

Dated: December 5, 2022

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INTEREST OF *AMICI CURIAE*[1]

The American Hospital Association ("AHA") represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations. AHA members are committed to improving the health of the communities they serve and to helping ensure that care is available to and affordable for all Americans. The AHA educates its members on healthcare issues and advocates on their behalf so that their perspectives are considered in formulating health policy. One way in which the AHA promotes the interests of its members is by participating as *amicus curiae* in cases with important and far-ranging consequences for its members, including cases arising under the False Claims Act ("FCA"). *E.g.*, *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016) ("*Escobar*"); *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401 (2011); *Rockwell Int'l Corp. v. United States*, 549 U.S. 457 (2007).

The AHA is joined in this *amicus* brief by the state hospital association for each of the four states in the Sixth Circuit. The Michigan Health & Hospital Association, established in 1919, represents the interests of its members on key issues and supports their efforts to provide quality, cost-effective, and accessible

[1] Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), *amici* state that no counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution toward the preparation or submission of this brief. No person other than *amici* and their counsel made a monetary contribution to its preparation.

care in Michigan. The Kentucky Hospital Association, established in 1929, represents hospitals, related health care organizations, and integrated health care systems in Kentucky. It is dedicated to sustaining and improving the health status of Kentucky's citizens. The Ohio Hospital Association, established in 1915, helps its members meet the needs of the Ohio communities they serve by influencing health policy, driving healthcare quality improvements, and advocating for economic sustainability among hospitals. And the Tennessee Hospital Association, founded in 1938, is the premiere organization that promotes and represents the interests of Tennessee hospitals, health systems, and the patients they serve.

The issues presented here are of manifest importance to the AHA and this Circuit's state hospital associations. The core mission of *amici*'s members is to provide patient care and improve community health. Meritless *qui tam* suits divert scarce resources from this core mission, and the harm such suits impose on hospitals would be magnified by watering down the pleading standards that provide crucial guardrails against such litigation. Relaxing the standards of causation and remuneration required under the Anti-Kickback Statute ("AKS") and False Claims Act ("FCA"), as Relators ask, would embolden the relators' bar to assert more meritless claims based on decisions that hospitals and their governing boards must make every day in managing their finances and operations.

The consequence of overturning the district court's well-reasoned opinion would be to vastly expand hospitals' exposure to FCA suits, which are tremendously expensive to defend throughout a government investigation and litigation even when the suit is meritless. *Amici* therefore have a strong interest in ensuring that this Court maintains the appropriate pleading standards for FCA claims and adheres to reasonable limitations on the meanings of remuneration and causation in this context of AKS-based FCA claims.

INTRODUCTION

This case sought to turn one doctor's disappointment in not being hired by a hospital as an employed physician into an FCA suit for Medicare fraud. But a hospital's decision not to develop a new service line is precisely the sort of decision that hospitals must have discretion to make when running their day-to-day operations. The mere fact that a hospital's decision to employ (or not employ) a specialty physician directly impacts whether the hospital continues referring patients to local physicians cannot be a hook for launching costly FCA litigation that diverts resources from patient care.

According to Relators' theory, if a physician who has previously performed surgical procedures at a hospital voices opposition to the hospital providing those services through an employed physician, the die is cast. If the hospital elects not to proceed with an employed physician model, then *every referral* from the

complaining physician would be viewed through the lens of the AKS as unlawful remuneration, with the result being that the complaining physician *could never again perform a surgical procedure at the hospital* without subjecting himself and the hospital to scrutiny under the AKS—a felony statute—and to liability for causing false claims to be submitted any time the patient's care is covered by Medicare or Medicaid.

If that sounds nonsensical, it's because it is. Under Relators' theory, echoed by the Government in its *amicus* brief, once Dr. Hathaway suggested he would move his practice elsewhere, Oaklawn had only two options for avoiding an AKS violation. Option one is that Oaklawn could have *approved* a new in-house ophthalmology practice, regardless of its financial viability as a business decision. Option two is that if Oaklawn *declined to approve* that new service line, Oaklawn was required to disallow Dr. Hathaway from performing any more surgeries at the hospital and was required to never again refer a hospital patient to him, even though Dr. Hathaway had long provided valuable patient care to Oaklawn patients and performed surgeries on his patients at Oaklawn. This nonsensical result is the direct consequence of an absurd theory that converts the ordinary flow of patients between hospitals and physicians who practice at those hospitals into unlawful "remuneration" under the AKS. Such misuse of the FCA threatens the independent judgment and autonomy of hospitals everywhere to decide, every day, how best to

manage their own finances and operations to most effectively serve their communities.

Particularly for rural hospitals, like Oaklawn, operational decisions about whether to provide certain types of specialty patient care through employed physicians or through community physicians with hospital privileges require a careful balancing. Hospitals must allocate their limited available resources while accounting for concerns about chronic staffing shortages and the ongoing challenge of attracting and retaining specialists to serve their patients and communities. Indeed, hospitals must consider, accept, and reject business proposals, employment applications, patient and employee complaints, requests, threats, and all manner of information from impossibly varied sources in their constant effort to make financial and operational decisions that ultimately inure to the benefit of their patients and communities. Hospitals make these difficult cost-benefit analyses every day, throughout this Circuit and across the country. Neither the FCA nor the AKS dictates how these decisions are to be made.

Relators' operative complaint—the fourth iteration of their allegations—was deficient in numerous ways. It did not satisfy Rule 9(b)'s particularity pleading standard. It did not plead remuneration under the AKS. And it did not plead a

sufficient causal nexus between the alleged kickback and any claim for payment.[2] This Court should affirm.

ARGUMENT

I. Relators Must Plead All Elements Of Their FCA Claim With Particularity, Including Any Alleged Causal Connection Between An Asserted AKS Violation And Purportedly False Claims.

FCA claims allege fraud, and under Federal Rule of Civil Procedure 9(b) they must be pled with particularity. Rule 9(b) shields defendants from "spurious charges of immoral and fraudulent behavior." *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006) (citation omitted). This Court has explained that "Rule 9(b) requires relators to adequately allege the entire chain—from start to finish—to fairly show defendants caused false claims to be filed." *United States ex rel. Ibanez v. Bristol-Meyers Squibb Co.*, 874 F.3d 905, 914 (6th Cir. 2017). When a FCA suit is premised on an alleged AKS violation, the entire chain includes that the allegedly false claims are "link[ed]" to the asserted kickback. *Miller v. Abbott Labs.*, 648 F. App'x 555, 562 (6th Cir. 2016). That is because, based on a 2010 amendment to the AKS, a Medicare claim that "includes items or services *resulting from* a violation

[2] Oaklawn's appellee brief additionally offers an alternative ground for affirmance based on one relator's misconduct in violating HIPAA by accessing patient information that he had no authority to access. Although *amici* offer no argument on this ground for affirmance, *amici* urge the Court not to reward a relator's misconduct in violating patients' privacy rights.

of" the AKS is a false claim for purposes of the FCA. 42 U.S.C. § 1320a-7b(g) (emphasis added).

No particularized pleading of any link between an asserted kickback and claim exists in Relators' pleading. As to Relator Dr. Martin's patients, the operative complaint says she was unaware of the asserted kickback agreement with her employer. *See* SAC, RE 64, Page ID # 839, at ¶ 126. Thus, her decision to perform procedures at Oaklawn on her own patients could not possibly have "resulted from" the asserted kickback. As to Dr. Hathaway's patients, the operative complaint offers no facts linking Dr. Hathaway's decision to perform these patients' procedures at Oaklawn to any improper inducement he received. And as to the claims submitted by South Michigan Ophthalmology, P.C., which were supposedly based on a referral from someone at Oaklawn after October 26, 2018, the operative complaint likewise does not meet the minimum requirement of stating "the 'who, what, when, where, and how' of the alleged fraud." *Sanderson*, 447 F.3d at 877 (citation omitted). It never details, for example, who referred a patient to South Michigan Ophthalmology, whether the referring medical provider had any knowledge of the alleged kickback, or how the referring medical provider's referral was related to the alleged kickback.

Oaklawn's appellee brief carefully details all of the Rule 9(b) pleading deficiencies, *see* Brief of Appellee Oaklawn 18-27, and it is telling that the

Government's *amicus* brief *entirely* ignores Rule 9(b). But, as this Court has held repeatedly, Rule 9(b) plays a crucial gatekeeping role in weeding out FCA litigation that amounts to a fishing expedition, will cause unwarranted reputational harm, and requires defendants to expend financial resources to defend against. Relators were obligated to plead with particularity a causal chain demonstrating that any Oaklawn medical provider who made a referral to South Michigan Ophthalmology did so *because of* the Board of Directors' decision not to establish a new ophthalmology service line. Relators were likewise obligated to plead with particularity a causal chain showing that Dr. Martin's and Dr. Hathaway's decisions to perform specific patients' procedures at Oaklawn were *because of* that same Board of Directors' decision. Were the Court to allow Relators to evade application of Rule 9(b)'s standard to the entire chain, such a decision would make hospitals and healthcare organizations even more attractive targets for opportunistic relators.

Given the complexity of the rules and regulations to which they are subject and the way they do business with the government through federal healthcare programs, hospitals and healthcare organizations are *already* frequent targets of opportunistic relators bringing meritless claims under the FCA's bounty hunter provisions. As further detailed below, *infra* pp.20-21, approximately two-thirds of FCA *qui tam* cases filed in the past two years involved healthcare defendants. *See* U.S. Dep't of Justice, *Fraud Statistics—Overview: Oct. 1, 1986-Sept. 30, 2021*, at 2,

5 (2022), *available at* https://www.justice.gov/opa/press-release/file/1467811/download (showing 847 of 1273 *qui tam* suits filed in 2020 and 2021 involved healthcare defendants). The costs of defending FCA suits are immense; every dollar spent defending against deficient complaints is an unnecessary diversion of resources needed to provide patient care.

Rule 9(b) is a vital check against this wasteful diversion of resources. But Relators here failed to satisfy Rule 9(b)'s pleading standard. The decision of the District Court should be affirmed on that ground alone.

II. Relators' "Taint" Theory Is Inconsistent With The Plain Meaning Of The AKS, Which Requires A Claim "Resulting From" An Unlawful Kickback, And Proximate-Causation Under The FCA.

Relators' brief and the Government's *amicus* brief take the position that a FCA plaintiff alleging an underlying AKS violation need not plead, or apparently ever prove, a causal connection between the AKS violation and any claim to the government because a relator can just label all claims from that provider "tainted." This position conflicts with the relevant statutory text.

Congress amended the AKS in 2010 to expressly state that a claim for items or services "resulting from" an AKS violation is a false claim for purposes of the FCA. *See* 42 U.S.C. § 1320a-7b(g). Prior to this statutory amendment, courts had taken varying positions on whether a violation of the AKS rendered claims false, and, if so, what universe of claims would be considered false for purposes of the

FCA. *See, e.g.*, *United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 901–02 (5th Cir. 1997); *see also United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 694 F. Supp. 2d 48 (D. Mass. 2010), *rev'd*, 647 F.3d 377, 386 (1st Cir. 2011). Congress resolved the uncertainty of these different standards by choosing a specific term—"resulting from"—to delineate the universe of claims that a kickback could render false. This unambiguous language has an "ordinary meaning": it requires but-for causation. *Burrage v. United States*, 571 U.S. 204, 210-11 (2014); *United States v. Jeffries*, 958 F.3d 517, 521 (6th Cir. 2020) ("the phrase 'results from' is not ambiguous.").

The Supreme Court's decision in *Burrage*, 571 U.S. at 211, solidifies this conclusion. In *Burrage*, the Supreme Court interpreted the term "results from" as used in the Controlled Substances Act to require proof of but-for causation. Since the statute at issue did not define the term, the Court explained that it should be given its ordinary meaning and that the ordinary meaning "imposes . . . a requirement of actual causality." *Id.* To show that one thing "results from" another "requires proof 'that the harm would not have occurred' in the absence of—that is, but for—the defendant's conduct." *Id.* (quoting *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 346 (2013) (interpreting Title VII)); *see also United States v. Samayoa*, 827 F. App'x 967, 970 (11th Cir. 2020) ("The phrase 'resulted in' imposes a causation

requirement."); *Brief for the United States*, *Burrage v. United States*, 571 U.S. 204 (2014), 2013 WL 5461835, at *13-15 ("That language plainly requires proof of causation.").

The Eighth Circuit recently applied this reasoning to the "resulting from" language of the 2010 amendment to the AKS. The court had "little trouble concluding that, in common and ordinary usage, the participle phrase 'resulting from' also expresses 'a but-for causal relationship.' " *United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 834 (8th Cir. 2022) (quoting *Burrage*, 571 U.S. at 213). Therefore, *Cairns* explained, "[t]racking the textbook definition, the government had to prove here that the defendants would not have included particular 'items or services' absent the illegal kickbacks." *Id.* at 835. This Court, like the Eighth Circuit, should confirm that but-for causation is "an 'essential element' " of AKS-based FCA liability "that must be proven, not presumed." *Id.* (citation omitted).

By choosing "resulting from" as the causal standard, Congress chose an unambiguous phrase that requires proof of a clear causal nexus between kickbacks and claims. Here, as always, a court must "assum[e] that the ordinary meaning of th[e] [text] accurately expresses the legislative purpose." *Gross v. FBL Fin. Servs. Inc.*, 557 U.S. 167, 175 (2009) (citation omitted). Interpreting "resulting from" to authorize FCA claims based on some sort of nebulous "taint" theory for some vague

period of temporal proximity, as Relators and the Government argue, would run afoul of Congress's chosen text.[3]

Relators and the Government apparently want this Court to replace Congress's "resulting from" language with the phrase "happening after." *E.g.*, Brief of *Amicus* Department of Justice at 22-23 ("*[A]fter* defendants provided remuneration 'to induce' referrals, and received that remuneration 'in return for' referrals, the referrals in fact *happened* …. That is sufficient for items or services provided in the course of those referrals to 'result[] from' the AKS violation.") (emphases added). But the AKS expressly contemplates a claim being false only if it covers products or services actually *resulting from* kickbacks.

Congress's choice of words in amending the AKS for the specific purpose of linking it to the FCA marks another critical distinction that Relators and the Government simply ignore. The Government's argument falls flat where it requires this Court to disregard the fact that Congress chose the phrase "resulting from" for the standard linking AKS violations to FCA violations when that phrase appears

[3] Even in the sole appellate decision on which Relators and the Government rely, the Third Circuit rejected the notion that mere temporal proximity between an alleged kickback and an alleged FCA claim is enough. *See United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 98 (3d Cir. 2018) (holding it is insufficient for a plaintiff to argue the defendant paid kickbacks and submitted claims in the same time period without evidence "link[ing]" the claim to a kickback). Relators' and the Government's "taint theory" fails this lesser standard because the supposed "taint" theory has no defined duration or endpoint, so there is not even a temporal-proximity limitation.

nowhere in the FCA. As numerous courts have held, proximate cause applies where Congress chose the word "caused" to define violations of the FCA, *see United States v. Hodge*, 933 F.3d 468, 475 (5th Cir. 2019); *United States v. Luce*, 873 F.3d 999, 1012-13 (7th Cir. 2017); *United States ex rel. Sikkenga v. Regence BlueCross BlueShield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006), which is consistent with the Supreme Court's admonition in *Escobar*, 136 S. Ct. at 1999, that Congress intended to import common law concepts into the FCA. But Congress did *not* include the word "caused" in the AKS amendment. It chose an entirely different term—"resulted from"—which is a statutory phrase that the Supreme Court has made clear requires more than a simplistic "one thing follows another." Holding that the AKS amendment requires anything less than but-for causation would re-write the statute that Congress enacted in favor of a more relaxed standard that Congress rejected.

But even if this Court were to look to proximate cause as instructive, the "taint" theory does not meet that standard either. Under that theory, an alleged kickback between parties under the AKS supposedly renders false every claim subsequently submitted by those parties to Medicare or Medicaid, for an undefined period of time, without the need to plead a specific factual causal nexus between the alleged kickback and the alleged subsequent false claim. The taint theory also allows an FCA plaintiff to avoid making any showing that CMS would have declined to

pay claims for that undefined time period, or that a defendant knew CMS would have declined to pay claims for that undefined time period.

To be clear: Relators are asking this Court to radically depart from existing case law by holding that FCA plaintiffs can unilaterally replace the requirement of causation evidence with never-ending FCA liability apparently applicable to all claims after October 26, 2018 (the date of the decision they attack) through at least the present day. Even worse, in cases like this one, the purported kickback is not alleged to have resulted in any change *at all* to the way a hospital, a defendant physician, and his practice worked together—and thereby fails entirely to provide a factual basis to allege proximate cause.

Finally, the "taint" theory also fails on its own terms because, as any reputable statistician or scientist knows, *temporal correlation does not equate to causation of any kind.* Courts across the country agree. *See Peters v. AstraZeneca LP*, 224 F. App'x 503, 507 (7th Cir. 2007) (affirming summary judgment for defendants where the evidence was sufficient to prove, at most, correlation); *In re JFD Enters., Inc.*, 215 F.3d 1312 (1st Cir. 2000) (unpublished) (same); *Pennington v. Bd. of Trs. of Univ. of Ark.*, No. 4:10-CV-1071-DPM, 2012 WL 2254247, at *2 (E.D. Ark. June 15, 2012) (granting summary judgment to defendants where plaintiff presented no evidence to raise an inference of causation beyond correlation), *aff'd sub nom. Pennington v. Univ. of Ark. Bd. of Trs.*, 500 F. App'x 567 (8th Cir. 2013). Relators'

complaint rests on temporal correlation, which—if accepted—would make meritless lawsuits against hospitals and health care systems in this Circuit available whenever a hospital or health system's operational decision happened to be aligned with a position articulated by a physician who treats patients at that facility.

III. Relators' "Remuneration" Arguments Would Unduly Hamstring Hospitals From Exercising Their Business Judgment In Employment Decisions.

Amici are particularly concerned about the practical consequences of a decision adopting an overly broad definition of remuneration under the AKS that would preclude hospitals from making rational operational decisions about whether patient needs should be met by employing physicians or by the traditional model of granting privileges to physicians in private practice. A holding that a hospital board's decision not to hire an in-house physician confers AKS-triggering remuneration on one—or every—private practice physician of the same specialty would be truly unprecedented and, frankly, shocking. It would create a lose-lose situation for hospitals: anytime a hospital's management even *considers* directly employing a physician, the hospital would thereafter be unable to reject the applicant and also unable to allow any private-practice physician of the same specialty to continue treating patients at the hospital without the specter of an AKS violation. Most notably here, there is no allegation that (1) the hospital made any commitment to Dr.

Hathaway, or (2) Dr. Martin or other private practice physicians had a lesser opportunity than Dr. Hathaway to treat their own patients or Oaklawn's patients.

Similarly, a holding that a physician like Dr. Hathaway provides remuneration to a hospital by simply continuing the same patient treatment practices before and after a hospital's staffing decision—without making any binding commitment to do so now or in the future—would stretch the relevant statutes beyond reason and recognition. Such a distorted interpretation would harm hospitals and patient care alike, as hospitals would be effectively prevented from engaging in discussions with specialists about the costs and benefits of private practice versus hospital employment. This, in turn, would inhibit efforts to attract and retain specialists and secure the availability of specialty care in their patient communities.

In the antitrust context, decades of case law has repeatedly upheld hospitals' discretion to choose their own providers and referral arrangements—even exclusive arrangements—as permissible, pro-competitive, and good for patients. *See Beard v. Parkview Hosp.*, 912 F.2d 138, 145 (6th Cir. 1990) ("Parkview [Hospital] and Bucholz explained that their [exclusive radiological services] contract is necessary to enhance the quality of care its patients receive as well as improve the efficiency of the hospital."); *Balaklaw v. Lovell*, 14 F.3d 793, 799, 802 (2d. Cir. 1994) ("[T]he Hospital is not required to open its operating rooms to any and all anesthesiologists who wish to practice there.") (citation omitted); *Imaging Ctr., Inc. v. W. Md. Health*

Sys., Inc., 158 F. App'x 413, 420 (2d. Cir. 2005) ("[E]xclusive arrangements are needed for control of quality, 'control of cost, provision of services, ensuring the availability of services 24/7, 365 days a year, to ensure that the practitioners are highly qualified, and to minimize the disruption of services.' ") (citation omitted). While remuneration under the AKS is a broad term, it is not so unbounded that decisions viewed as reasonable under the antitrust laws could be converted to felonies because they impact the flow of referrals among physicians practicing at a hospital.

Ensuring that hospitals can properly assess the costs and benefits of in-house employed physicians versus private practice physicians necessarily assumes that a hospital's decision as to which to choose should not be considered remuneration to one candidate or another—particularly where the candidate who was not chosen remains available to compete on equal footing for referrals. Relators' theory, however, is that to avoid an AKS violation, Oaklawn was required to allocate the approximately $2 million in limited discretionary resources it would take to get an unproven in-house ophthalmology practice up and running. No court has held that the AKS ties hospital purse strings in this way. This Court should not be the first.

Straining to save their novel theory of FCA and AKS liability, Relators recast the concept of remuneration in a manner that could, if adopted, impose tremendous risk, and burden, on hospital decisions that should be about patient care and resource

allocation. It cannot be the case that after Oaklawn's Board of Directors received a letter from Dr. Hathaway voicing his opposition to a potential in-house ophthalmology service line, the only way to avoid an AKS violation was either to approve the new in-house practice—regardless of its financial viability[4]—or sever all future business dealings with Dr. Hathaway. This nonsensical result would call into question every hospital's authority to make its own independent hiring decisions in the face of multiple competing options, in which some doctors may inevitably experience more lucrative outcomes than others. Hospitals instead must have the autonomy to manage their own operations in order to most effectively serve their patient communities.

IV. A More Lenient Standard Of Causation Or Remuneration Would Force Hospitals To Anticipate And Defend Against More Frivolous *Qui Tam* Claims, To The Detriment Of Patients.

If the District Court's decision is not affirmed, hospitals could face unprecedented levels of uncertainty regarding their routine business decisions and resultant exposure to would-be FCA relators. Hospitals are *already* at disproportionately higher risk than other government program participants to be targeted for frivolous FCA *qui tam* claims. A relaxed causation or remuneration

[4] And under Plaintiff's exceedingly low standard for remuneration, a decision to establish an in-house ophthalmology practice could have itself constituted a "kickback" to Dr. Martin, exposing Oaklawn to FCA litigation from Dr. Hathaway.

standard would only increase the incentive for frivolous claims against healthcare providers.

FCA lawsuits have increased tremendously in recent decades. This growth has been driven primarily by suits the government has investigated and declined—a strong indicator of their lack of merit. While the Government filed 150 or fewer FCA cases each year from 2017 to 2019, in each of those years *qui tam* relators filed more than four times as many cases—682 in 2017, 648 in 2018, 638 in 2019, and 675 in 2020. U.S. Dep't of Justice, *Fraud Statistics-Overview* at 2; *see* U.S. Dep't of Justice, *Deputy Associate Attorney General Stephen Cox Gives Remarks to the Cleveland, Tennessee, Rotary Club* (Mar. 12, 2019), *available at* https://www.justice.gov/opa/speech/deputy-associate-attorney-general-stephen-cox-gives-remarks-cleveland-tennessee-rotary ("*Qui tam* filings have been on the rise for many years.").

While the overall number FCA lawsuits have increased in recent decades, the number of *meritorious* FCA suits has not. According to a comprehensive empirical analysis of suits from 1987 to 2004, less than 10% of non-intervened private *qui tam* actions actually result in recovery, with more than 90% dismissed as frivolous or otherwise without merit. *See* Christina Orsini Broderick, Note, *Qui Tam Provisions and the Public Interest: An Empirical Analysis*, 107 Colum. L. Rev. 949, 974-75 (2007). That study concluded that the high rate of dismissal "lends strong support to

the conclusion that *qui tam* statutes result in many frivolous claims." *Id.* And the ratio of dismissals to recovery continues at essentially the same clip today, even with the increase in the number of new case filings observed in the Department of Justice's fraud statistics.

Qui tam suits disproportionately target healthcare entities. Of the 934 new FCA matters filed in 2020, for example, 581 involved healthcare defendants. U.S. Dep't of Justice, *Fraud Statistics-Overview* at 2, 5 (identifying number of FCA cases involving the Department of Health and Human Services as the primary client agency). That is nearly *two-thirds* of the new matters filed that year. The statistics are even more striking when comparing only relator-filed *qui tam* cases: nearly *seventy percent* of the 2020 relator-filed *qui tam* cases were filed against healthcare entities. *Id.* (459 of 675 cases). This stands in stark contrast to 1987, when only 15 of the total 371 FCA cases—a mere four percent—involved healthcare entities. *Id.*

Even when the Government declines to intervene in an FCA case, as it did in this case, targeted hospitals still must shoulder the burden and expense of defending themselves against a relator, and must constantly act in consideration of the reputational and financial costs of doing so. The costs of these lawsuits often times are tremendous, including internal investigations, government investigations while a case is under seal, and litigation itself. This case exemplifies those costs: even though the defendants prevailed at the motion-to-dismiss stage, they had to litigate

four iterations of the complaint before obtaining a judgment of dismissal—and now must face the expense of an appeal. Healthcare defendants disproportionately bear the burden of these expenses, while also facing different cost-benefit analyses than many other FCA defendants.

Hospitals must consider defense costs, the magnitude of potential liability, reputational harms, and the possibility of an adverse decision resulting in exclusion from participation in federal healthcare programs. *See* 31 U.S.C. §§ 3729(a)(1), 3730(d); 42 U.S.C. §§ 1320a-7, 1396a(a)(39); *see also* David A. Hyman, *Health Care Fraud and Abuse: Market Change, Social Norms, and the Trust "Reposed in the Workmen,"* 30 J. Legal Stud. 531, 552 (2001) ("Providers who believe they are blameless are under tremendous pressure to settle because of … the high probability of bankruptcy and professional disgrace if the jury does not see things the same way the provider does."); *Tex. Dep't of Hous. & Cmty. Affairs v. Inclusive Communities Project, Inc.*, 576 U.S. 519, 587 (2015) (Alito, J., dissenting) ("[T]he costs of litigation, including the expense of discovery and experts, may push cost-conscious defendants to settle even anemic cases. Defendants may feel compelled to abandon substantial defenses and … pay settlements in order to avoid the expense and risk of going to trial") (citations and internal quotation marks omitted). In light of these factors, *amici*'s members face the serious risk that any relaxation of the remuneration

or causation standards at issue in the AKS and FCA will disproportionately expose hospitals to even greater risk of being targeted by frivolous *qui tam* lawsuits.

The District Court did not err in its decision below, and the Sixth Circuit should not disturb its well-reasoned opinion. A reversal on any grounds is unwarranted, and would threaten the long-term financial sustainability of hospitals across this Circuit. After weathering a once-in-a-century global pandemic, health systems are already struggling with rising costs caused by inflation and labor shortages. Margins for all U.S. hospitals are "down 37% relative to pre-pandemic levels" and "[m]ore than half of hospitals are projected to have negative margins through 2022." KaufmanHall, *The Current State of Hospital Finances: Fall 2022 Update* at 1 (2022), *available at* https://www.kaufmanhall.com/sites/default/files/2022-09/KH-Hospital_Finances_Report-Fall2022.pdf. In this environment, every dollar is precious. Hospitals must not be forced to divert critical resources away from patient care and towards meritless *qui tam* lawsuits.

CONCLUSION

For the foregoing reasons and those in Appellees' briefs, the judgment of the District Court should be affirmed.

Dated: December 5, 2022

Respectfully submitted,

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CERTIFICATE OF BAR MEMBERSHIP

I hereby certify that I, Jessica L. Ellsworth, am admitted as an attorney and counselor of the United States Court of Appeals for the Sixth Circuit.

Dated: December 5, 2022

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitations of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) because this brief contains 5,165 words, excluding the parts of the brief exempted by the Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the type face requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in proportionally spaced type face using Microsoft Word in Times New Roman 14-point font.

Dated: December 5, 2022

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CERTIFICATE OF SERVICE

I hereby certify that on this date, I filed the foregoing with the Clerk using the Appellate CM/ECF system, which will automatically serve electronic copies upon all counsel of record.

Dated: December 5, 2022

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