# United States Court of Appeals
## For the First Circuit

No. 25-1110

UNITED STATES, ex rel. OMNI HEALTHCARE INC.,

Plaintiff, Appellant,

STATE OF ALASKA, ex rel. Omni Healthcare, Inc.; STATE OF CALIFORNIA, ex rel. Omni Healthcare, Inc.; STATE OF COLORADO, ex rel. Omni Healthcare, Inc.; STATE OF CONNECTICUT, ex rel. Omni Healthcare, Inc.; STATE OF DELAWARE, ex rel. Omni Healthcare, Inc.; DISTRICT OF COLUMBIA, ex rel. Omni Healthcare, Inc.; STATE OF FLORIDA, ex rel. Omni Healthcare, Inc.; STATE OF GEORGIA, ex rel. Omni Healthcare, Inc.; STATE OF HAWAII, ex rel. Omni Healthcare, Inc.; STATE OF ILLINOIS, ex rel. Omni Healthcare, Inc.; STATE OF INDIANA, ex rel. Omni Healthcare, Inc.; STATE OF IOWA, ex rel. Omni Healthcare, Inc.; STATE OF LOUISIANA, ex rel. Omni Healthcare, Inc.; STATE OF MARYLAND, ex rel. Omni Healthcare, Inc.; STATE OF MASSACHUSETTS, ex rel. Omni Healthcare, Inc.; STATE OF MICHIGAN, ex rel. Omni Healthcare, Inc.; STATE OF MINNESOTA, ex rel. Omni Healthcare, Inc.; STATE OF MONTANA, ex rel. Omni Healthcare, Inc.; STATE OF NEVADA, ex rel. Omni Healthcare, Inc.; STATE OF NEW JERSEY, ex rel. Omni Healthcare, Inc.; STATE OF NEW MEXICO, ex rel. Omni Healthcare, Inc.; STATE OF NEW YORK, ex rel. Omni Healthcare, Inc.; STATE OF NORTH CAROLINA, ex rel. Omni Healthcare, Inc.; STATE OF OKLAHOMA, ex rel. Omni Healthcare, Inc.; STATE OF RHODE ISLAND, ex rel. Omni Healthcare, Inc.; STATE OF TENNESSEE, ex rel. Omni Healthcare, Inc.; STATE OF TEXAS, ex rel. Omni Healthcare, Inc.; STATE OF VERMONT, ex rel. Omni Healthcare, Inc.; STATE OF VIRGINIA, ex rel. Omni Healthcare, Inc.; STATE OF WASHINGTON, ex rel. Omni Healthcare, Inc.,

Plaintiffs,

v.

MD SPINE SOLUTIONS LLC, d/b/a MD LABS INC.; DENIS GRIZELJ; MATTHEW RUTLEDGE; DOE HEALTHCARE PROVIDERS 1 - 100,

Defendants, Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Patti B. Saris, U.S. District Judge]

Before

Montecalvo, Lynch, and Thompson,
Circuit Judges.

Evan Bianchi, with whom Thomas M. Kenney and Spiro Harrison & Nelson LLC were on brief, for appellant.

Seth B. Orkand, with whom Julianna M. Charpentier, Danielle H. Tangorre, Edward J. Heath, Scott T. Garosshen, and Robinson & Cole LLP were on brief, for appellees.

December 1, 2025

**THOMPSON, Circuit Judge.** Today, we're reckoning with a qui tam Medicare fraud case arising under the False Claims Act ("FCA"), 31 U.S.C. § 3729 et seq. On its face, this appeal has a bit of everything: a labyrinthine regulatory structure, a fraud-hunting doctor, an alleged "smoking gun" email exchange, and a lot of information -- perhaps more than most readers would care to know -- about urinary tract infection ("UTI") tests.

But behind all that fanfare, the question we face is straightforward: did OMNI Healthcare (our relator/appellant) produce enough evidence that MD Labs (our main defendant/appellee) "knowingly" submitted false Medicare claims to avoid the summary judgment scythe?[1] See 31 U.S.C. § 3729(a)(1)(A). The district court said "No." We agree. Read on to see why.

## HOW WE GOT HERE

### A.

As our opening line intimated, this case sits at the intersection of the Medicare Act and the FCA. For now, we'll

[1] We'll take a second to get the parties straight. Because this is a qui tam case, OMNI isn't serving as a plaintiff in its own right. See United States ex rel. Schutte v. SuperValu Inc., 598 U.S. 739, 743 (2023). Instead, it's a relator (a private party litigating on the government's behalf) suing while standing in the shoes of the United States, 29 states and commonwealths, and the District of Columbia. And we'll note here that MD Labs (formally known as MD Spine Solutions LLC) isn't the only defendant/appellee; so, too, are its co-founders Denis Grizelj and Matthew Rutledge, as well as 100 unnamed healthcare providers. But unless more specificity is necessary, we'll use MD Labs for all of the appellees to save keystrokes.

provide the reader with some context about the Medicare Act, 42 U.S.C. § 1395 et seq., and our breakdown of the FCA will come later.

Signed into law during the administration of President Lyndon B. Johnson, the Medicare Act established "a national health insurance program for the elderly and the disabled." Warder v. Shalala, 149 F.3d 73, 75 (1st Cir. 1998). It's a sprawling and serpentine statute that we've reckoned with on many different occasions and in many different circumstances.[2]

Yet our focus today is on a narrow -- but important -- part of it. Generally, Medicare can reimburse medical providers for expenses incurred while providing services to patients. See 42 U.S.C. § 1395x(s)(2)(C) (defining diagnostic services covered by Medicare Part B); see also 42 C.F.R. § 410.28 ("Medicare Part B pays for hospital or [other] diagnostic services furnished to outpatients, including drugs and biologicals required in the performance of the services[.]"). But there's some qualifications to that rule. The one our parties key in on is that "no payment may be made" for "any expenses incurred for items

[2] See, e.g., Hosp. Amerimed Cancun S A DE C V v. Martin's Point Health Care, Inc., 149 F.4th 82, 85 (1st Cir. 2025) (considering a Medicare administrative exhaustion requirement); Medicaid & Medicare Advantage Prods. Ass'n of P.R., Inc. v. Emanuelli Hernández, 58 F.4th 5, 7-10 (1st Cir. 2023) (considering the relationship between Puerto Rico's Act 90 and a federal Medicare plan); Warder, 149 F.3d at 75 (considering an administrative ruling interpreting Medicare Part B).

or services" that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Or, paraphrasing, to secure a Medicare reimbursement, the expense must be "reasonable and necessary."

Of course, that prompts an important question: what expenses are "reasonable and necessary"? The Act doesn't tell us, but it does vest the Secretary of Health and Human Services with the power to decide. See 42 U.S.C. § 1395ff; see also Heckler v. Ringer, 466 U.S. 602, 617 (1984). Still, the Secretary isn't making those decisions all alone; the Centers for Medicare and Medicaid Services (or "CMS") helps, too. See Health Care Financing Administration; Statement of Organization, Functions, and Delegations of Authority, 46 Fed. Reg. 56911, 56911-34 (Nov. 19, 1981) (establishing the Health Care Financing Administration, which was later renamed CMS); see also Kort v. Burwell, 209 F. Supp. 3d 98, 102 (D.D.C. 2016) (describing this history). And CMS also "contracts with private entities to which healthcare providers and suppliers submit their claims for reimbursement." Kort, 209 F. Supp. 3d at 102. These contractors (somewhat akin to our regional circuit courts) are each "responsible for a particular region of the country." Odell v. U.S. Dep't of Health & Hum. Servs., 995 F.3d 718, 720 (9th Cir. 2021). (Keep those contractors in mind, because we'll run into one later.)

Zooming back out, the Secretary can determine whether an expense is reasonable and necessary either "by promulgating a generally applicable rule or by allowing individual adjudication." Heckler, 466 U.S. at 617. As for the "generally applicable" rules, there are two kinds. Id.; see Odell, 995 F.3d at 720 (describing this framework).

The first are "National Coverage Determinations," or "NCDs." Those are decisions "with respect to whether or not a particular item or service is covered nationally." Kort, 209 F. Supp. 3d at 102 (quoting 42 U.S.C. § 1395ff(f)(1)(B)). The Secretary, through CMS, issues NCDs. Id. And these are binding on Medicare contractors nationwide. Odell, 995 F.3d at 720.

Along with NCDs are "Local Coverage Determinations," or "LCDs." And that's where our private contractors come in. If there isn't a clear national coverage decision, Medicare coverage decisions are left to local contractors. See 42 U.S.C. § 1395ff(f)(2)(B); Willowood of Great Barrington, Inc. v. Sebelius, 638 F. Supp. 2d 98, 106 (D. Mass. 2009). And a local contractor can issue general determinations in the form of LCDs about whether services are "reasonable and necessary" within its jurisdiction. See 42 U.S.C. § 1395ff(f)(2)(B).

But if there isn't an on-point LCD or NCD, that isn't the end of it. Contractors can also make case-by-case determinations. See Odell, 995 F.3d at 720 ("Absent a regulation,

a national coverage determination, or an LCD, the Medicare contractor proceeds on a case-by-case basis to determine whether a service is reasonable and necessary."). That's important to our case today, as the reader will see, because no NCDs or LCDs governed the issue that our parties faced. Instead, the case concerns how a group of providers and a lab grappled with medical necessity absent those more generalized guiding determinations.

**B.**

That's an adequate introduction to Medicare, but we need a bit more table-setting. As the reader will soon learn, much of this case is about different methods for UTI testing -- and whether some are medically "necessary" under the Medicare reimbursement provision that we just discussed. So now's as good a time as any to tee up the debate.[3]

We'll start with some basics: the human urinary tract (the "UT" in "UTI") includes the bladder, the urethra, and the kidneys. See U.S. Ctrs. for Disease Control and Prevention, *Urinary Tract Infection Basics* (Jan. 22, 2024), https://www.cdc.gov/uti/about/index.html [https://perma.cc/Q8TB-NKHZ]. And a UTI is a "common" infection, normally happening when "bacteria, often from the skin or rectum, enter the urethra and infect the urinary tract." Id. It's so common, in fact, that one

[3] Disclaimer: this opinion is not intended to provide medical advice.

study estimates that UTIs affect more than 10 million patients in the United States each year.

Doctors test for UTIs in two ways relevant to our case.[4] For decades, the "gold standard" test for UTIs has been the bacterial urine culture ("BUC") test. That test requires placing a urine sample on a growth medium (think: petri dish) and waiting between twenty-four and seventy-two hours to see if certain bacteria grow. The growth of that select bacteria leads to the diagnosis.

But medical advancements have expanded options for UTI testing. Now there's the PCR test, and that one uses polymerase chain reaction (thus, "PCR") technology to amplify copies of a DNA segment in the urine sample.[5] Our understanding is that PCR tests somehow lock into a segment of DNA in a urine sample, allowing the scientist to identify the genetic material present belonging to a particular biological origin -- like a pathogen. These tests can apparently pinpoint what's wrong 24 hours faster than BUC tests, given the time those BUC tests need for the bacteria culture to grow. That faster diagnostic turnaround naturally lends itself to faster appropriate treatment of infections, too. So PCR testing

[4] There may be more ways to test for UTIs that we don't know about, but they aren't relevant for our discussion.

[5] The reader might remember PCR testing becoming prominent during the COVID-19 pandemic.

is by some considered more efficient and accurate but (and here's the kicker) also much more costly than BUC testing.

**C.**

All the prelims explained, we can get into the facts of today's case. We'll start with our alleged fraudsters: MD Labs, an independent clinical laboratory in Reno, Nevada, founded in 2011 by Matthew Rutledge and Denis Grizelj.

MD Labs got its start by processing urine drug tests. But in 2017, it began offering PCR UTI testing. It decided to get into UTI testing because, in processing drug tests, a lot of patient specimens came in "resembling having the characteristics of an infection" (co-founder Rutledge's words). Yet because many specimens that MD Labs received were from patients on certain pharmaceuticals, the patients' UTI symptoms were concealed. The concern? In Rutledge's phrasing, there "might be a lot of undiagnosed urinary tract infections coming through the lab" that better testing could fix. So MD Labs entered the UTI testing business to help solve that patient-care gap.

One email exchange at MD Labs early into their PCR testing days is (at least in OMNI's view) critical, so that's where we'll turn next.[6] In January 2018, as MD Labs began rolling out

[6] Like most readers, we typically loathe long block-quotes. But because OMNI puts a lot on this email exchange, and MD Labs argues that OMNI's taking it out of context, we figured it best to include the whole thing in our discussion.

PCR UTI testing, Rutledge drafted an email to Noridian, the private Medicare contractor overseeing MD Labs' region, and shared his draft email with his co-founder Grizelj for review. Rutledge wrote to Grizelj, in an email titled "Noridian Email on UTI billing & coding," as follows:

> Hey Dude,
>
> What do you think about this letter to Dr Lurvey at Noridian to give them a heads-up on our new molecular diagnostic testing? I think it would be a prudent move to at least document that we told CMS of this new technology and advised them to modify their billing and coding. I think it's our duty, in a way.
>
> Lemme know what you think of this first draft...

Below that last line, Rutledge included a draft email to Dr. Lurvey. Here it is:

> Hi Dr Lurvey,
>
> Happy New Year. I hope this email finds you well.
>
> I'm writing to let you and Noridian know of some new clinical laboratory testing we are now offering which is becoming very popular in the area of urinary tract infections (UTI's).
>
> Genetic analytical technology is now allowing us to pinpoint DNA signatures from various infectious pathogens in order to positively identify them with almost 99% certainty very quickly and relatively affordably. We couple this with antibiotic susceptibility testing here at the lab and the result is a report provided to physicians that positively identifies the infecting agent and what

> antimicrobials will be most effective at killing it and treating the infection.
>
> We are finding physicians are excited about this test and starting to order it in greater numbers. Thus, you will be seeing an increasing number of claims submitted by our laboratory and labs around the country for this testing in 2018 and beyond.
>
> But... the current CPT coding system doesn't adequately describe this testing very well and the fee schedule payment is quite robust for the work being performed. New technology is able to do this work much more affordably than it could in the past.
>
> I'd recommend we have a discussion on how to best change the current payment system to best accommodate this new testing technology so that CMS can develop a fair compensation system and simplified coding system that makes billing easy and avoids future overpayments to labs.
>
> I'd strongly advise having this discussion sooner, rather than later. Let me know when you are available.
>
> - Matthew Rutledge
> President
> MD Labs[7]

Later that day, Grizelj wrote back to Rutledge. Here's that email, too:

> I think we should wait on this and instead of asking them to modify their rates, we should ask them to give us guidance on medical necessity instead. I don't think we are going to a significant amount of testing that would reach Millennium-like levels so we may still end up being a blip. I am not sure how many

[7] We've omitted only Rutledge's proposed post-script about Dr. Lurvey being the Contractor Medical Director for Noridian.

> Pathnostics is currently doing but I am hoping that they are at least aware of this testing currently.[8]
>
> The other reasons I want to wait are 1) I want some time to leverage this on some of the commercials carriers we are not in network in yet to hopefully backdoor a tox contract and 2) I would like for them to re-visit looking at Rxight and adopting a similar model that Pathway Genomics (or whoever it was) has in their Medicare jurisdiction.
>
> I get what you are trying to do but I would like to wait at least 6 months if that's cool with you. We haven't even made a dent yet.
>
> Denis Grizelj

And that's the entire email exchange relevant here. It's uncontested that Rutledge and Grizelj did not follow up with Noridian about the things they discussed in their exchange. Instead, MD Labs continued to roll out PCR UTI testing. And that's how it encountered OMNI, our fraud-hunting relator.

Owned by Dr. Craig Deligdish, OMNI is a broad-spanning medical practice, boasting seven offices with more than twenty medical professionals across Brevard County, Florida.[9] As a

[8] We've inserted an extra line between paragraphs here for readability, but otherwise (aside from the omission noted in the last footnote) left the text of the emails entirely unaltered.

[9] The careful reader will note that we've said OMNI's in Florida and MD Labs is based out of Nevada. It isn't exactly clear to us how the two, in practice, worked together -- for instance, was OMNI shipping every urine sample practically cross-country just to have MD Labs test it? -- but the parties don't give us any insight into those logistics that, by our lights, are immaterial to today's case anyway.

medical practice goes, OMNI professionals see patients and diagnose them. And when an OMNI provider determines that a patient needs a particular test, the provider selects the test in the patient's electronic medical record, and a medical assistant completes the form for a lab (like MD Labs) to do the requested test. Afterward, the lab can submit a claim to Medicare (via the local contractor) to reimburse or subsidize the test. As long as the service is covered, the claim is paid. See 42 U.S.C. § 1395*l*(a); Odell, 995 F.3d at 720.

Between 2017 and 2019, that process played out repeatedly between our parties here: OMNI sent MD Labs nearly 600 requisition forms and samples for UTI testing, MD Labs ran those tests and reported back the results, and Medicare reimbursed MD Labs for at least some of those tests.[10]

Here's the twist. The whole time, Dr. Deligdish instructed his OMNI medical assistants to order only PCR UTI testing from MD Labs, even if the provider had requested the older BUC test. The reason is that, as Dr. Deligdish later admitted, he wanted to beef up a Medicare fraud case against MD Labs.[11] It's

[10] The parties don't provide us a precise figure of how many tests were submitted for Medicare reimbursement.

[11] This is perhaps unsurprising when considered alongside the fact that OMNI, by its own account, is a frequent flyer in the qui tam world, having recovered tens of millions of dollars on behalf of the government in other similar cases.

undisputed that all the PCR UTI tests that MD Labs delivered for OMNI patients resulted from this instruction. But nothing in the record suggests that MD Labs knew the inner workings of OMNI's qui tam side-tactics -- all it knew was that a doctor's office had ordered UTI tests for its patients.

**D.**

OMNI then sued MD Labs on behalf of the governmental coalition we described in Footnote 1 for a host of claims, including Medicare fraud under the FCA. The relevant Medicare fraud theory? PCR tests are far more expensive yet confer no greater benefit than BUC tests, and thus (in OMNI's view), are medically unnecessary. So MD Labs, in recouping payment for PCR tests, submitted claims that didn't comply with Medicare's "reasonable and necessary" standard; by doing so, it "knowingly" submitted false claims. (More on what "knowingly" means shortly.)

Some other claims in the case (claims whose details are immaterial here) must have had teeth, because MD Labs entered a settlement agreement with OMNI and the federal government to resolve them. As part of the settlement, OMNI retained the right to pursue this claim against MD Labs about unnecessary test submissions.

So that aspect of the case carried on. Complaints were amended, motions to dismiss were filed but largely denied (and not on appeal), and discovery ensued all in the usual course.

Following the close of discovery, each party moved for summary judgment, although in different ways. MD Labs wanted summary judgment on all of OMNI's remaining claims. OMNI sought partial summary judgment on three questions of law relating to the FCA standard.

The district court granted summary judgment to MD Labs in full (and thus denied it to OMNI). OMNI only appeals the district court's decision as to one issue -- the "medically unnecessary" theory of FCA liability that we've described above -- so we skip detailing the district court's reasoning as to the others.

In its summary judgment filing below, MD Labs sought judgment for the "medically unnecessary" theory of FCA liability on three grounds: (1) because the claims for reimbursement were not false because the tests were not medically unnecessary; (2) because Dr. Deligdish broke the causal chain by ordering the PCR tests himself; and (3) because MD Labs and its employees did not know that MD Labs was performing medically unnecessary tests.

The district court determined summary judgment should be granted on the third argument (what it christened the "scienter" argument) alone, so it didn't address the other two arguments we just mentioned. As for scienter, the district court reasoned that MD Labs offered evidence showing how it believed PCR testing was "superior" to BUC testing for diagnosing UTIs. And the district

court explained that none of OMNI's evidence to the contrary raised a triable issue of fact about MD Labs' purported knowledge that the tests were unnecessary. (OMNI now puts all that evidence in front of us and asks us to draw the opposite conclusion, so we'll save any further explanation for later.) Largely relying on its holding that OMNI's federal FCA claims failed, the district court also granted summary judgment on OMNI's analogue state-law claims.

OMNI timely appealed the above-described part of the district court's summary judgment order. And that led to the appellate task now before us.

**OUR TEST**

"We review an order granting summary judgment de novo." Irobe v. U.S. Dep't of Agric., 890 F.3d 371, 377 (1st Cir. 2018). The standard is a familiar one: a court can grant summary judgment "only if the record, construed in the light most amiable to the nonmovant, presents no genuine issue as to any material fact and reflects the movant's entitlement to judgment as a matter of law." Id. (cleaned up); see Fed. R. Civ. P. 56(a).

A word also on the mechanics of summary judgment, as they drive our decision. The party "seeking summary judgment must, at the outset, inform the court of the basis for its motion and identify the portions of the pleadings, depositions, answers to interrogatories, admissions, and affidavits, if any, that demonstrate the absence of any genuine issue of material fact."

Irobe, 890 F.3d at 377 (cleaned up). As long as the movant "crosses this modest threshold," it becomes the nonmoving party's duty to, "with respect to each issue on which it would bear the burden of proof at trial, demonstrate that a trier of fact could reasonably resolve that issue in its favor." Id. (cleaned up). To avoid the axe, the nonmovant must identify "significantly probative evidence favoring" its position. Id. (cleaned up).

**OUR DIAGNOSIS**

Like we said at the start, the question on appeal is rather narrow: did OMNI produce enough evidence that MD Labs "knowingly" submitted a false claim to survive summary judgment? See 31 U.S.C. § 3729(a)(1)(A). Like the district court, we think not. We'll start with a primer on FCA scienter and then explain why OMNI's case can't go on.

**A.**

The FCA "permits private parties to bring lawsuits in the name of the United States . . . against those who they believe have defrauded the Federal Government." United States ex rel. Schutte v. SuperValu Inc., 598 U.S. 739, 743 (2023).

Relevant here, the FCA imposes liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the federal government. 31 U.S.C. § 3729(a)(1)(A). So for a successful FCA claim under this part of the statute, the relator needs to show:

(1) that there's a "false or fraudulent claim" made to the government, (2) that the defendant "presents, or causes to be presented," that claim, and (3) that the defendant did so "knowingly." See id. Our appeal today centers on that third element, "knowingly," so we'll next turn to what that means.

Thankfully, the FCA defines it for us, and the term encompasses "three mental states." SuperValu, 598 U.S. at 749. It reaches: (1) a person who "has actual knowledge of the information," (2) one who "acts in deliberate ignorance of the truth or falsity of the information," and (3) one who "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(i)-(iii).[12] But what do those three states of mind mean? We can tell you. Actual knowledge "refers to whether a person is aware of information" about the claim's falsity. SuperValu, 598 U.S. at 751 (cleaned up). Deliberate ignorance instead "encompasses defendants who are aware of a substantial risk that their statements are false, but intentionally avoid taking steps to confirm the statement's truth or falsity." Id. And reckless disregard "similarly captures defendants who are conscious of a substantial and unjustifiable

[12] We'll note here, as the Supreme Court did, that "proof of specific intent to defraud" is not necessary. SuperValu, 598 U.S. at 750 n.3 (quoting 31 U.S.C. § 3729(b)(1)(B)).

risk that their claims are false, but submit the claims anyway." Id.

A couple more points. The scienter standard turns on the defendant's "knowledge and subjective beliefs -- not [on] what an objectively reasonable person may have known or believed." Id. at 749. And the relevant inquiry focuses us on "what the defendant thought when submitting the false claim -- not what the defendant may have thought after submitting it." Id. at 752.

So "in short, either actual knowledge, deliberate ignorance, or recklessness" regarding the claim's falsity "will suffice" to show scienter. Id. at 750.

**B.**

Scienter summarized, we'll now examine the merits.[13] OMNI makes two main arguments for reversal. First, in its view,

[13] One more minor point as we begin to forge through the merits. Despite OMNI's suggestion that summary judgment was inappropriate because it was a scienter-heavy analysis, it's long been good law in our circuit that scienter can be decided on summary judgment. See, e.g., Stepanischen v. Merchs. Despatch Transp. Corp., 722 F.2d 922, 928-29 (1st Cir. 1983). It's true that because "the state of mind of one of the parties is crucial to the outcome of the case, resort to summary judgment is vested with more than usual difficulty" in these types of cases. Id. at 928. "But the presence of issues involving state of mind, intent, or motivation does not automatically preclude summary judgment." Id. at 929. Of course a party "against whom summary judgment is sought is not entitled to a trial simply because [it] has asserted a cause of action to which state of mind is a material element." Id. (cleaned up). A party with a state-of-mind-based claim still must "produce the requisite quantum of evidence to enable [it] to reach the jury with [its] claim." Id. (cleaned up). And particularly here, where OMNI's theory is paper-based, a summary

the record shows how MD Labs and its founders recognized and ignored the risk of PCR UTI testing being medically unnecessary. Second, it submits that the district court relied on what OMNI dubs "irrelevant and inapposite evidence" in drawing the very conclusion that OMNI sought to avoid.

But we think the natural place to start is not OMNI's briefing, but MD Labs'. And MD Labs opens by contending that it had no reason to override OMNI's orders for PCR tests or OMNI's certifications that those tests were medically necessary. To support that point, MD Labs directs us to United States ex rel. Groat v. Boston Heart Diagnostics Corp., 296 F. Supp. 3d 155 (D.D.C. 2017). That court held that "a laboratory cannot and is not required to determine medical necessity, but rather is permitted to rely on the ordering physician's determination that the laboratory tests billed to Medicare are medically necessary." Id. at 158. We agree.

In making that holding, the Boston Heart court drew largely from the Office of the Inspector General ("OIG") for the Department of Health and Human Services' ("HHS") Publication of

judgment determination on scienter was fair game. See, e.g., United States ex rel. Phalp v. Lincare Holdings, Inc., 857 F.3d 1148, 1152 (11th Cir. 2017) (affirming a district court's summary judgment order in a false claims case where the relators' "best evidence of scienter" only "consisted of two emails," which when read together "did not allow a reasonable jury to conclude that [the defendants] knowingly submitted false claims" (cleaned up)).

OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45076, 45079 (Aug. 24, 1998). See Bos. Heart, 296 F. Supp. 3d at 158-63. (We'll call it the "OIG Guidance" or just "the Guidance.") And we find the Boston Heart court to be particularly persuasive in making sense of the Guidance, the role of laboratories in the patient-care process, and most importantly for our purposes, how that all relates to FCA cases. We'll recount what we see as necessary.

In 1998, HHS issued the Guidance "to refine and build on the original model guidance plan for clinical laboratories," published in 1997 to "engage the private health care community in combating fraud and abuse[.]" OIG Guidance, 63 Fed. Reg. at 45076; see Bos. Heart, 296 F. Supp. 3d at 158 (quoting OIG Guidance, 63 Fed. Reg. at 45077). More specifically, the Guidance aimed "to assist clinical laboratories in developing effective internal controls that promote adherence" to the law and to "advance the prevention of fraud, abuse, and waste in the clinical laboratory[.]" OIG Guidance, 63 Fed. Reg. at 45077; see Bos. Heart, 296 F. Supp. 3d at 158.

And there's a whole section of the Guidance dedicated to "medical necessity." OIG Guidance, 63 Fed. Reg. at 45079; see Bos. Heart, 296 F. Supp. 3d at 158-59. Central to our case, HHS recognized that "laboratories do not and cannot treat patients or make medical necessity determinations." OIG Guidance, 63 Fed.

Reg. at 45079. But it laid out "steps that such facilities can take to assure compliance with the applicable statutes, regulations, and the requirements" of Medicare and other health plans. Id. Those enumerated steps (along with other federal regulations) relate largely to requisition forms, billing practices, and recordkeeping. Id. at 45079-80; see Bos. Heart, 296 F. Supp. 3d at 158-63 (discussing the OIG Guidance as well as another regulation on clinical laboratory recordkeeping). We'll spare the reader the finer details to avoid straying too far from the task at hand.

The lesson we learn from Boston Heart and the OIG Guidance is this: while it's of course true that a clinical laboratory has a "legal duty to ensure that it is not submitting false or incorrect claims to [g]overnment and private payors," neither "the Medicare statute nor [current regulations] regarding laboratories require laboratories to independently determine the medical necessity of the tests billed." OIG Guidance, 63 Fed. Reg. at 45077 (first quote); Bos. Heart, 296 F. Supp. 3d at 162 (second quote).

And that lesson is edifying as we figure out this case. Recall that OMNI is a doctor's office that works on the frontlines with patients. And remember MD Labs is a clinical laboratory staffed with technicians who (as we understand it) lack both the expertise and the discretion to diagnose patients directly; their

role is instead to process tests that doctors (who presumably do interact with patients) order. See OIG Guidance, 63 Fed. Reg. at 45079 ("We recognize that laboratories do not and cannot treat patients or make medical necessity determinations.") Finally, recall that OMNI (the doctor's office) specifically ordered MD Labs (the laboratory) to conduct the very same UTI tests that OMNI's now saying are not medically necessary (insofar as BUC tests are cheaper), even though OMNI ordered PCR tests (and did so to gin up this very case).

So, truth be told, we struggle to make sense of OMNI's litigation position about medical necessity. We strain to see how MD Labs could know, be deliberately indifferent to, or reckless about a test being medically unnecessary when it has, in-hand, a requisition form from OMNI. See 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). At times there might be other problems undergirding "medical necessity" -- Boston Heart recognized one such instance in the very same decision that we endorse -- but, as we'll discuss below, this isn't one of them. See Bos. Heart, 296 F. Supp. 3d at 165.

Accepting OMNI's position to the contrary could also lead to dangerous consequences. Should laboratories start second-guessing a doctor's orders, delaying care to double-check the doctor's work (however that might get accomplished), or even providing different, less-expensive care than the doctor ordered

just to avoid FCA liability? And it seems to us that OMNI's "categorical" arguments might compel medical professionals not to order treatments as needed on an individualized basis. We don't think the FCA can be reasonably viewed as intending to expand labs' liability or to affect physicians' practices so significantly. Instead, like the Supreme Court, we read the statute to give "effect to Congress' efforts to protect the [g]overnment from loss due to fraud but also [to ensure] that a defendant is not answerable for anything beyond the natural, ordinary and reasonable consequences of [its] conduct." Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662, 672 (2008) (cleaned up) (considering 31 U.S.C. § 3729(a)(2)). And we don't see how it is "natural, ordinary and reasonable" to put labs on the hook for doctors' professional decisions, barring some other chicanery at play. Id.; see also Biden v. Nebraska, 600 U.S. 477, 512 (2023) (Barrett, J., concurring) (noting how "common sense" plays a role in statutory interpretation).

So we hold (as a matter of first impression in the First Circuit) that in FCA cases alleging Medicare fraud based on laboratory testing, generally a laboratory can rely on a doctor's order to show that the test is "reasonable and necessary" under 42 U.S.C. § 1395y(a)(1)(A). The burden then shifts to the FCA claimant to rebut this showing. See Bos. Heart, 296 F. Supp. 3d at 158-66 (working through that rule at the motion to dismiss

stage); United States v. Bertram, 900 F.3d 743, 750 (6th Cir. 2018) (explaining that, in a criminal health care fraud case, "a laboratory generally may rely on that doctor's order in submitting a claim for reimbursement as medically necessary"); OIG Guidance, 63 Fed. Reg. at 45079; see also United States ex rel. Allen v. Alere Home Monitoring, Inc., 334 F. Supp. 3d 349, 365 (D. Mass. 2018) (explaining that, absent a "specific basis to second-guess" a doctor's certification, a lab "is generally entitled to rely on the independent judgment of a medical provider"). To be clear: laboratories still have "a legal duty to ensure that they do not submit claims for medically unnecessary tests," Bos. Heart, 296 F. Supp. 3d at 166, and they can still be held liable under the FCA.[14] But -- and this is the critical point -- the doctor's order

[14] We provide more of the Sixth Circuit's reasoning to spell out at least one limit of this holding. As it explained:

> Laboratories, it is true, may not be well equipped to determine whether a doctor orders necessary services. But that practical reality means nothing when the laboratory acts in a way that makes the services unnecessary. When laboratories know that their own actions have made a medical service unnecessary, they should not be shielded by the independent determination of a physician, who never took -- who was never asked to take -- the laboratory's subsequent conduct into account.

Bertram, 900 F.3d at 750. And we further highlight the contours of the lab's independent duty identified by the OIG and discussed in Boston Heart. Labs should construct requisition forms carefully in compliance with federal law and regulation, ensure that doctors are not ordering unnecessary tests when reasonable suspicion arises about the propriety of the testing requested, not "alter the physician's order in any way either increasing or decreasing

for medical testing will generally offer a safe harbor of medical necessity that, once raised, a relator must rebut, discredit, or undermine to raise a genuine dispute of material fact as to the lab's scienter.[15] See Bos. Heart, 296 F. Supp. 3d at 162, 164-65; United States ex rel. Senters v. Quest Diagnostics Inc., No. 24-12998, 2025 WL 1951196, at *3 (11th Cir. July 16, 2025) (affirming dismissal of a case against a laboratory when "[r]elator provided no factual allegations to indicate that doctors later discovered, or even now believe, that they were tricked or confused [by the laboratory] into ordering medically unnecessary tests or

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the number of services performed without the express consent of the ordering physician," and require "that individuals with technical expertise in laboratory testing review the appropriateness of the codes [for services] before the claims are submitted" to avoid "upcoding," what the OIG describes as "the selection of a code to maximize reimbursement when such code is not the most appropriate descriptor of the service." See Bos. Heart, 296 F. Supp. 3d at 159 (quoting OIG Guidance, 63 Fed. Reg. at 45080).

[15] We'll flag a couple of times that it's been overcome (although at earlier stages of the litigation) in the caselaw. See Bos. Heart, 296 F. Supp. 3d at 165 (holding that an FCA claim survived a motion to dismiss, even when a lab relied on a doctor's determination of medical necessity, when the lab allegedly "engaged in a scheme to encourage non-cardiology physicians to order medically unnecessary tests through a false marketing campaign and pre-printed test requisition forms"); United States ex rel. Allstate Ins. v. Phx. Toxicology & Lab Servs., LLC, No. 22-6303 (RMB/AMD), 2024 WL 2785396, at *9 (D.N.J. May 30, 2024) (holding that an FCA claim survived a motion to dismiss, even when a lab relied on a doctor's determination of medical necessity, when the lab allegedly "engaged in a scheme to conduct duplicative presumptive testing without regard to medical necessity and to encourage physicians to order additional screening tests as a matter of course").

tests that they did not intend to order"). Put differently, the doctor's determination of medical necessity (inherent, if not explicitly stated, in the order for the test) demonstrates "the absence of any genuine issue of material fact" about a lab's scienter of a false claim, such that it becomes the relator's problem to "demonstrate that a trier of fact could reasonably resolve" the claim (and, in particular, the necessary scienter element) in its favor despite the doctor's order. Irobe, 890 F.3d at 377 (cleaned up); cf. Bos. Heart, 296 F. Supp. 3d at 162, 164-65 (applying a similar rule at the motion to dismiss stage). (How this plays out will soon become clear.)

**C.**

That guiding principle now established, we can turn to the record. OMNI says that, in response to MD Labs' motion for summary judgment (which laid out the "medical providers' determination of medical necessity" argument, among others), it produced plenty of evidence showing how MD Labs and its founders deliberately ignored the risk of PCR testing being medically unnecessary. In particular, OMNI points to four buckets of evidence:

- the email exchange between MD Labs' co-founders discussing billing practices;
- medical literature about UTI testing;

- a lack of guidance from Medicare and its contractors on the question of medical necessity; and
- forms showing how MD Labs was "bundling" up tests to drive up costs.

In its view, that combination of evidence shows how a jury could reason that MD Labs "knowingly" submitted false claims, based on either deliberate indifference or recklessness theories.

Yet none of that evidence explains why MD Labs couldn't rely on OMNI's orders for its patients' PCR testing to show that such tests were medically necessary for FCA purposes. We see nothing here demonstrating why MD Labs should have had any reason to "second-guess" OMNI's determinations of its patients' medical needs. Allen, 334 F. Supp. 3d at 365. Nor do we see any basis for a jury to determine that, because of MD Labs' actions, "doctors later discovered, or even now believe, that they were tricked or confused into ordering medically unnecessary tests or tests that they did not intend to order." Quest Diagnostics Inc., 2025 WL 1951196, at *3.

We can be more specific, so we'll walk through the proffered evidence and why we don't think it undermines MD Labs' rightful reliance on OMNI's orders as evidence of medical necessity. First, the email exchange that OMNI ballyhoos. In OMNI's view, the emails between Grizelj and Rutledge showed three things: MD Labs' recognition that PCR testing was a novel

technology; MD Labs' recognition that it had a duty to inform its Medicare contractor; and MD Labs' recognition that it had a duty to seek more guidance before billing -- a duty that it never followed through on.

Yet we think OMNI's arguments about the email exchange are "all foam and no beer." United States v. Correia, 55 F.4th 12, 27 (1st Cir. 2022) (using the colorful phrase in a different context). For starters, Rutledge wanted to give Noridian a "heads-up on our new molecular diagnostic testing" because it "will be seeing an increasing number of claims" for it. He wanted "a discussion on how to best change the current payment system to best accommodate this new testing technology." But neither Rutledge's thoughts on the nitty-gritty of billing practices nor his acknowledgment that PCR tests are relatively new do anything to suggest that he thought they were medically unnecessary. See Patco Constr. Co. v. People's United Bank, 684 F.3d 197, 207 (1st Cir. 2012) ("A fact is material" only "if it has the potential of determining the outcome of the litigation." (cleaned up)). In fact, if he thought those tests weren't actually necessary, why would he be eager to raise the issue to the contractor and delve into those nitty-gritty billing details? We are baffled. See Lawton v. State Mut. Life Assurance Co. of Am., 101 F.3d 218, 222–23 (1st Cir. 1996) ("Though the district court must interpret the record in the light most hospitable to the nonmoving party,

reconciling all competing inferences in that party's favor, the nonmovant has a corresponding obligation to offer the court more than steamy rhetoric and bare conclusions." (cleaned up)).

As for Grizelj, all that OMNI seems to hang its hat on is one line: "instead of asking them to modify their rates, we should ask them to give us guidance on medical necessity instead." But we don't see how that statement reflects awareness "of a substantial and unjustifiable risk that their claims are false." SuperValu, 598 U.S. at 751 (emphases added); see, e.g., id. at 746-47 (noting, among other evidence, a direction to employees not to "put any of this in writing to stores");[16] see also United States v. Teva Pharms. USA, Inc., 682 F. Supp. 3d 142, 147 (D. Mass. 2023) (denying a company's motion for summary judgment in a similar FCA case because the company had, in its possession, legal analysis stating that its actions "would almost certainly violate" federal law). That's especially true given that MD Labs consulted its infectious disease doctor about the PCR tests, and he informed it of the tests' importance in patient care.

One last point on the email exchange: any inference that could be drawn from the co-founders' brief back-and-forth about

[16] The Court in SuperValu did not address "whether petitioners have made a sufficient showing under the correct legal standard to preclude summary judgment." 598 U.S. at 757. But we're just using the facts the Supreme Court identified as salient as a reference point for the appellees' far less suspicious actions.

general policy carries little weight against a specific order that MD Labs received from a specific doctor for a specific patient. Cf. Allen, 334 F. Supp. 3d at 365 (explaining that, absent a "specific basis to second-guess" a doctor's certification, a lab "is generally entitled to rely on the independent judgment of a medical provider"). Or, put differently, a past generalized remark about medical necessity should not fairly be considered an appropriate basis for liability in light of a specific present order from a doctor (that, in our view, shows that MD Labs believed the test was medically necessary), at least without evidence of more unscrupulous acts by the lab (which OMNI doesn't provide). See Bos. Heart, 296 F. Supp. 3d at 158.

Similarly, contrary to OMNI's assertions, medical literature doesn't cast doubt on MD Labs' decision to rely on OMNI's requests. OMNI argues that guidance published by the American Urological Association ("AUA") in 2019 shows how PCR testing wasn't considered standard fare at the time. Though the district court didn't give this literature much weight because it post-dated most of the PCR tests at issue, OMNI says that it is probative for precisely that reason: even after MD Labs submitted false claims, a leading medical organization confirmed that the tests weren't all they were cracked up to be.

That line of argument flops for a couple of reasons. First, that generalized AUA guidance (presumably available to

urology specialists) again gives us no reason to think that MD Labs should have doubted the doctors' orders. See Allen, 334 F. Supp. 3d at 365. And we think the district court was wise to key in on the timing issue: scienter focuses on what "the defendant thought when submitting the false claim -- not what the defendant may have thought after submitting it." SuperValu, 598 U.S. at 752. So even if some later information surfaced and could grind against a determination of medical necessity, that shouldn't factor into scienter of the falsity of medical necessity at the time the tests were submitted. See id.

Next, OMNI observes that CMS (to remind, the federal agency determining what services are "reasonable and necessary") has never issued an NCD (to remind, "National Coverage Determination") about PCR UTI testing. Combined with the fact that there was no LCD (to remind, "Local Coverage Determination") on the issue at the time of the tests' submissions, that (in OMNI's view) shows that MD Labs should have known something was up.

But we need not tarry on this one: as the district court observed, OMNI specifically conceded that neither an NCD nor an LCD was required for a service to be deemed medically necessary. Individual adjudication, after all, can fill that stop-gap. See United States ex rel. Polukoff v. St. Mark's Hosp., 895 F.3d 730, 735 (10th Cir. 2018) (noting that determinations are made either "by promulgating a generally applicable rule or by allowing

individual adjudication" (quoting Heckler, 466 U.S. at 617)). So the lack of an LCD or NCD doesn't help OMNI prove scienter.

Finally, the "bundling" of tests. This one is a bit more complex but is still offered by OMNI as more evidence of MD Labs' scienter. One of the nuanced parts of PCR UTI testing is that it can test for many pathogens all at once, though each search for a specific pathogen, as we understand, is technically a separate test to run. OMNI argues that because MD Labs sometimes bundled up to nineteen pathogen tests into a single PCR test order -- via requisitions forms that in OMNI's view "forced" physicians to get either seventeen- or nineteen-pathogen panels with no other options -- it ran medically unnecessary tests. The allegedly unnecessary bundling is the purported hook for scienter here, says OMNI.

It's true that some courts have held that "bundled tests, ordered via a pre-printed form, can create FCA liability, provided the certifying entity is aware that one or more of the tests is medically unnecessary, or recklessly disregards such a risk." Allen, 334 F. Supp. 3d at 357 (collecting cases). Assuming that's right, we still don't think OMNI has presented evidence that MD Labs "knowingly" erred in its specific approach.[17]

[17] We say "assuming" because we don't have to grapple with that legal question today. That proposition's validity is pretty ancillary to our appellate work here, given that our decision turns on OMNI's evidentiary shortcomings.

Below, MD Labs offered an expert infectious disease doctor who stated in a report that the pathogens that MD Labs tested for "are reasonable" and "within the range endorsed" by a peer-reviewed article. The district court noted that OMNI "does not respond with any record evidence indicating that the make-up of the panels was unnecessarily broad."

On appeal, that hasn't changed. Instead, OMNI takes aim directly at the expert's opinions in its brief without any evidence to back up its attacks. For instance, OMNI fusses that the expert's opinion was based only on "a single study" issued in 2023 (thus post-dating the period in question) and that anyway, the expert didn't accurately interpret the study, so their conclusion's bunk. But we think OMNI's arm-chair scientist approach isn't consistent with its evidentiary obligations at the summary judgment stage to put up or shut up. See Corrada Betances v. Sea-Land Serv., Inc., 248 F.3d 40, 43 (1st Cir. 2001) ("We have held before, and today reaffirm, that statements contained in a memorandum or lawyer's brief are insufficient, for summary judgment purposes, to establish material facts.") Once MD Labs provided an expert backing its bundling position, it fell to OMNI as the non-movant to "point to materials of evidentiary quality" that could raise a genuine dispute for trial. Irobe, 890 F.3d at

377. It didn't then and still doesn't now.[18] See Corrada Betances, 248 F.3d at 43. OMNI "cannot defeat summary judgment by relying on speculation about the facts" laid out in MD Labs' expert's testimony. Lang v. Wal-Mart Stores E., L.P., 813 F.3d 447, 460 (1st Cir. 2016) (cleaned up). So the bundling issue is rather easily unbundled after all.

Those four buckets of evidence emptied, we see eye-to-eye with the district court in concluding that OMNI has failed to present any evidence through which a reasonable jury could find for it on the scienter issue. Because scienter is an essential element of the claim, that's dispositive. See 31 U.S.C. § 3729(a)(1)(A). We need go no further.[19]

[18] We don't see the 2019 AUA literature as relevant to this consideration because, by our understanding (and more importantly, OMNI's presentation of it), it doesn't address or concern bundling.

[19] Just a bit of housekeeping as we wrap up. Because we hold that OMNI hasn't presented enough evidence to survive summary judgment for the federal claims, we don't need to reach its alternative argument that the district court relied on what it calls "irrelevant and inapposite" evidence. That one, in our view, was settled by our holding that MD Labs could offer up OMNI's orders as evidence of medical necessity. Nor do we need to consider whether OMNI's state-law claims should be revived. The district court dismissed the state-law claims because it believed that they failed for the same reasons as the federal claims. On appeal, OMNI doesn't argue that they should be treated any differently, and because we think the only federal claim on appeal still fails, that settles the state-law claims too. And having found in MD Labs' favor on its main argument, we don't need to reach its alternative argument for affirmance about the causal chain, which the district court declined to address.

**(JURIS) DOCTOR'S ORDERS**

Our diagnosis is simple: we affirm. The parties shall bear their own costs.