UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

UNITED STATES OF AMERICA and THE STATE OF NEW MEXICO, ex rel. SALLY HANSEN, Plaintiffs, v. DEMING HOSPITAL CORPORATION d/b/a MIMBRES MEMORIAL HOSPITAL, COMMUNITY HEALTH SYSTEMS, INC., COMMUNITY HEALTH SYSTEMS PROFESSIONAL SERVICES CORP., and JERRY BOSSELL Defendants.	)	Case No. 2:11-cv-00566-WPL-CG

DEFENDANTS DEMING HOSPITAL CORPORATION d/b/a MIMBRES MEMORIAL HOSPITAL, COMMUNITY HEALTH SYSTEMS PROFESSIONAL SERVICES CORP., AND JERRY BOSSELL'S REPLY MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS

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INTRODUCTION AND SUMMARY OF ARGUMENT

In our opening memorandum, Deming Hospital Corporation d/b/a Mimbres Memorial Hospital, Community Health Systems Professional Services Corporation, and Jerry Bossell (collectively, "Mimbres" or the "Hospital") explained why the CLIA regulations here are materially identical to the Medicare regulations that the Tenth Circuit in *Conner* held were conditions of participation, and therefore cannot give rise to False Claims Act ("FCA") liability as a matter of law. *United States ex rel. Conner v. Salina Regional Health Center, Inc.*, 543 F.3d 1211 (10th Cir. 2008). Like the regulations in *Connor*, (1) the CLIA regulations are enforced through a comprehensive administrative scheme; (2) when a laboratory is noncompliant, the federal agency uses its expertise and discretion to choose a sanction that is appropriate in the circumstances; (3) withholding Medicare payments is a remedy of last resort; and (4) even when that sanction is imposed, the agency applies it only prospectively, and does not require the laboratory to return payments it has received for tests already performed, even though those tests were noncompliant with CLIA. For the same reasons, here as in *Conner*, "[r]eading the FCA" as Hansen does "would undermine the government's own administrative scheme for ensuring that hospitals remain in compliance and for bringing them back into compliance when they fall short." *Id.* at 1220.

Hansen disputes none of this. She does not claim that Mimbres misreads a single regulation. She does not point to any regulation (or policy or procedure or judicial or administrative interpretation) that Mimbres fails to consider. And, most tellingly, she does not respond *at all* to Mimbres's argument that this lawsuit exemplifies *Conner*'s concern about misusing "the FCA, a statute intended to protect the government's fiscal interests, to undermine the government's own regulatory procedures." *Id.* at 1222.

Instead, Hansen resorts to two strategies, both of which fail. The first is to all but ignore *Conner*. Indeed, her only substantive discussion of the case is nestled in a single paragraph on page 24 of her brief. *Conner*, however, is binding Tenth Circuit law that specifically addresses how the FCA applies (and does not apply) in the health care context—the exact scenario here. Second, rather than confront *Conner*, Hansen tries to evade it by using a "throw everything at the wall" approach. Her thirty-two page brief invokes a host of different theories of FCA liability in the hope that one will stick. But however she styles her claims—whether as false certification or fraudulent inducement or (she claims for the first time) worthless services—each of her theories rests on the same allegation: That Mimbres is liable under the FCA because it violated CLIA regulations in connection with its laboratory tests. Because CLIA regulations are quintessential conditions of participation—a point Hansen does not seriously deny—the appropriate remedy, assuming *arguendo* the truth of her allegations, is to allow the agency to act in its expertise and discretion, not to hijack that process by "stretch[ing]" the FCA beyond its intended reach. *Id.* at 1214. Accordingly, ***Count I*** should be dismissed.[1]

Count III, alleging retaliation under the FCA, also fails to state a claim. Hansen alleges that she investigated and reported to Mimbres what she believed were CLIA violations. She does not allege, however, that she ever investigated—much less reported to Mimbres—that the Hospital was receiving improper Medicare reimbursements or was engaging in any sort of fraud (let alone that she was contemplating an FCA lawsuit). Hansen's only response is that such

[1] Hansen finds it significant that Mimbres does not argue for dismissal of her amended complaint under Rule 9(b). Brief in Opposition 2 (Doc. 69). This is misguided. While the Hospital continues to believe her complaint does not satisfy Rule 9(b), there is no need to argue these pleading deficiencies when it is so clear that the amended complaint fails under *Connor*. Moreover, it plainly does not follow, as Hansen erroneously implies, that Mimbres concedes that her allegations are accurate. To the contrary, the decision of the United States and New Mexico twice to decline to join Hansen's lawsuit strongly signals that her allegations lack merit.

allegations are not necessary to state a retaliation claim under the 2009 amendments to the FCA. But the authority she cites for that proposition explicitly refutes it.

Hansen's state law claims in ***Counts II and IV*** should be dismissed for the same reasons her federal claims should be. In addition, Hansen does not deny that she fails to satisfy the statutory prerequisite for bringing a claim under the New Mexico Medicaid False Claims Act.

ARGUMENT

I. Count I Fails Rule 12(b)(6) Because It Alleges Only Regulatory Violations, And Not False Claims

A. Hansen's "False Certification" Theory Is Foreclosed By *Conner*

Conner rejected the same false certification theory that Hansen alleges. There, the Tenth Circuit explained the "significant distinction" between a condition of payment and a condition of participation. 543 F.3d at 1220. Conditions of participation "are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program." *Ibid.* In contrast, conditions of payment "are those which, if the government knew they were not being followed, might cause it to actually refuse payment." *Ibid.* Only conditions of payment can form the basis of FCA liability. *Id.* at 1220–21. Applying this framework, *Conner* analyzed the Medicare regulations at issue, and concluded they were conditions of participation in light of "the fact that the government has established a detailed administrative mechanism for managing Medicare participation." *Id.* at 1221. Accordingly, *Conner* affirmed the dismissal of the relator's complaint under Rule 12(b)(6).

In its opening memorandum, Mimbres explained why the CLIA regulations are the same as the *Conner* regulations in every relevant way. Mem. 10–17 (Doc. 63). In response, Hansen makes no effort to distinguish the two. Instead, she tries to avoid *Conner* at every turn. We address her arguments below, each of which is meritless.

1. Hansen asserts that *Conner* has no bearing on her implied false certification claim. Brief in Opposition ("Opp.") 24 (Doc. 69). Hansen provides no support for this assertion, and it is totally wrong. *Conner* stated unequivocally that implied false certification claims are viable only if compliance with the regulation at issue is a condition of receiving payment: "Under an implied false certification theory, by contrast, courts do not look to the contractor's actual statements; rather, the analysis focuses on the underlying contracts, statutes, or regulations themselves *to ascertain whether they make compliance a prerequisite to the government's payment*." 543 F.3d at 1218 (emphasis added). Hansen does not acknowledge this unambiguous statement, let alone explain how her assertion could be correct in light of it.

2. Hansen asserts that *Conner* is "easily distinguished" because there the relator's claim arose from a statement the defendant made in an annual cost report. Opp. 24. We do not understand this argument. To evaluate the relator's claim in *Conner*, the Tenth Circuit undertook "review of the scheme for managing Medicare participation." 543 F.3d at 1220. The court analyzed the applicable regulations in detail to determine whether they were conditions of participation or payment, using the criteria outlined above. *Id.* at 1220–21. Mimbres does the same here, analyzing the regulations and demonstrating why the CLIA regulations are conditions of participation. Mem. 10–17. Far from being "easily distinguished," *Conner* is directly on point, and Mimbres does no more than apply it.

3. Hansen asserts that the relevant question is not whether CLIA regulations are conditions of payment or participation, but whether they are "material" to the government's decision to provide Medicare reimbursement. Opp. 22. Again, we are at a loss to understand this argument. The condition-of-payment/condition-of-participation framework is not Mimbres's invention. It comes directly from *Conner* (and also from every other federal circuit

court that has addressed the issue, see Mem. 10 n.4 (collecting cases)). Hansen's suggestion that the framework is somehow invalid is no more than a request to overrule *Conner*.

In any event, *Conner* discussed both concepts in adjacent paragraphs and explained that they are "related"—a condition of participation is, by definition, not material to the government's decision to dole out funds. 543 F.3d at 1220. Accordingly, *Conner* dismissed the relator's complaint because the Medicare regulations there were "condition[s] of ongoing Medicare *participation*," and hence not material. *Id.* at 1221 (emphasis in original). Hansen does not explain how these standards could differ and, if they do, why *Conner* would have articulated two inconsistent standards in adjacent paragraphs.[2]

4. Quoting *Conner*, Hansen claims that CLIA regulations are conditions of payment because their violation "might" cause the government to withhold Medicare payments. Opp. 23. This is exactly backwards. In *Conner*, the agency *might* have used its discretion to terminate the defendant's Medicare participation and billing privileges. But that discretion and administrative mechanism were precisely what *Conner* held made the regulations conditions of *participation*. 543 F.3d at 1220–21. Likewise, in *Conner*, participation in the Medicare program "is a prerequisite to ever receiving payment," and revocation of participation "always" leads to cancellation of payments. Opp. 22. Indeed, every argument Hansen levels against CLIA applies just as much to the regulations in *Conner*. If her logic were correct, then *Conner* is wrongly

[2] In support of her materiality argument, Hansen also cites to *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163 (10th Cir. 2010). Yet that case expressly affirms the condition-of-payment requirement for false certification claims. *Id.* at 1168 ("Claims arising from legally false requests, on the other hand, generally require knowingly false certification of compliance with a regulation or contractual provision *as a condition of payment*.") (citing *Conner*) (emphasis added)).

decided, and the "significant distinction" (543 F.3d at 1220) between conditions of payment and conditions of participation is meaningless.[3]

5. Lacking any substantive argument that CLIA regulations are conditions of payment, Hansen retreats to the favorite argument of plaintiffs at the motion to dismiss stage: asserting that the issues here are too "complex" and too "factbound" to decide now, and that if only the Court would permit her to proceed to discovery, she could develop a stronger case. Opp. 25.

Again, Hansen's argument runs headlong into *Conner*. That case was decided on a motion to dismiss, as condition-of-participation cases routinely are.[4] Indeed, where (as here) a relator alleges FCA liability based on a regulatory violation, *Conner* states that courts "must look to the underlying statutes to surmise if they make the certification a condition of payment." 543 F.3d at 1218. *Conner* did just that, through a detailed analysis of the applicable Medicare regulations, and dismissed the relator's claim under Rule 12(b)(6). *Id.* at 1220–21. Hansen provides no reason why the same cannot be done here.

The Medicare regulations specifically provide that compliance with CLIA is a condition of participation. See 42 C.F.R. § 482.27(a). Compliance with CLIA is placed in the part of the Medicare regulations entitled "Conditions of Participation for Hospitals." 42 C.F.R. Part 482.

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[3] Hansen also argues in a footnote that Mimbres unduly emphasizes the fact that CLIA regulations do not permit CMS to recover payments retroactively. Opp. 23 n.12. Yet *Conner* specifically instructs courts to consider this factor when determining whether a regulation is a condition of participation. 543 F.3d at 1221 (finding significant that relator could not identify any authority "indicating that the government normally seeks retroactive recovery of Medicare payments for services actually performed on the basis that the noncompliance rendered them fraudulent"). Here, Hansen does not deny that CLIA does not permit retroactive recovery of payments.

[4] See, *e.g.*, *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295 (3d Cir. 2011); *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262 (5th Cir. 2010); *United States ex rel. Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601 (7th Cir. 2005); *United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791 (8th Cir. 2011); *Maa v. Ostroff*, No. 12-cv-200, 2013 WL 1703377 (N.D. Cal. Apr. 19, 2013); *Foglia v. Renal Ventures Mgmt., LLC*, 830 F. Supp. 2d 8, 19–20 (D.N.J. 2011).

CLIA is nowhere mentioned in the part of the Medicare regulations entitled "Conditions for Medicare Payment." 42 C.F.R. Part 424. The CLIA regulations provide for a range of sanctions, including directing the laboratory to take corrective action, requiring on-site government monitoring, imposing a civil monetary penalty of up to $10,000 per day of noncompliance, and suspending, limiting or revoking a laboratory's CLIA certificate. 42 C.F.R. §§ 493.1806, 493.1834(d)(2). But no CLIA regulation authorizes CMS to cancel a laboratory's billing privileges retroactively or to order the laboratory to disgorge Medicare payments it received for noncompliant testing. See generally 42 C.F.R. Part 493. Thus, the regulations themselves could not be clearer in establishing that CLIA is a condition of participation, and nothing that Hansen could learn in discovery can possibly change this.

Nor do the out-of-circuit cases Hansen cites support her. She quotes principally from a Texas case, but fails to disclose that the relator there *conceded*—at the motion to dismiss stage, no less—that his claims would be foreclosed in the Tenth Circuit under *Conner*, which he urged the Texas court to disregard. See *United States ex rel. Porter v. HCA Health Servs. of Okla.*, No. 3-09-CV-0992 (N.D. Tex. Mar. 25, 2011), Doc. 44 at 11 ("Because [*Conner*] stands at odds with [Fifth Circuit precedent], it should not be afforded any weight.").[5]

6. Finally, Hansen makes passing reference to her express false certification theory. Opp. 21. Her complaint quotes four different certifications the Hospital allegedly made. First Amended Complaint ("Compl.") ¶¶ 44–46, 48 (Doc. 50). Our opening memorandum explained why each certification could not, as a matter of law, form the basis of FCA liability, even if it

[5] The other two cases Hansen cites do not involve the condition-of-payment/condition-of-participation distinction, and do not remotely suggest that this issue cannot be resolved on a motion to dismiss—a position that *Conner* refutes in any event. *United States ex rel. Loughren v. Unum Group*, 613 F.3d 300 (1st Cir. 2010); *United States ex rel. Bidani v. Lewis*, No. 97 C 6502, 2001 WL 1609377 (N.D. Ill. Dec. 14, 2011).

were false. Mem. 18 & n.8. Hansen now "acknowledge[s]" (in a footnote) that three of the four certifications "do not form the basis for an express false certification claim." Opp. 22 n.10. Instead, she relies solely on the certification contained in CMS Form 1500. *Ibid.* Our opening memorandum explained that this certification, along with the others, fails under *Conner* because (among other things) "it contains only general sweeping language and does not contain language stating that payment is conditioned on perfect compliance with any particular law or regulation." 543 F.3d at 1219; Mem. 18. Hansen does not respond to this dispositive argument.

* * *

In short, *Conner* is controlling law that specifically addresses the application—and misapplication—of the FCA in the field of health care regulations. Yet Hansen does everything she can to evade *Conner* on its terms. For the reasons above, these efforts are unavailing. So, too, is her other attempt to circumvent *Conner*: by re-styling her allegations as a "fraudulent inducement" theory. We address that argument now.

B. Hansen Cannot Evade *Conner* By Re-Labeling Her Theory As One Of "Fraudulent Inducement"

Hansen's fraudulent inducement theory rests on exactly the same alleged CLIA violations as does her false certification theory. The only difference is the point in time when Mimbres allegedly concealed the violations. Under the false certification theory, Mimbres concealed the alleged violations from CMS when seeking Medicare reimbursement (Opp. 21–22); under the fraudulent inducement theory, Mimbres concealed the violations from the Joint Commission when seeking CLIA certification (*id.* at 15–18). Even though the violations are the same under both theories, Hansen claims that this distinction makes all the difference, because a laboratory must have a CLIA certificate to receive Medicare reimbursement (even if the laboratory does not have to maintain perfect compliance with CLIA to receive reimbursement once the certificate is

obtained). Therefore, according to Hansen, the same conduct that cannot state a false certification claim—because CLIA regulations are conditions of participation—states a fraudulent inducement claim.

The Court should reject this approach, which would make *Conner* a nullity by allowing a relator to transform a condition of participation into an actionable false claim merely by using the fraudulent inducement label. Almost by definition, every non-disclosed violation of a "condition of participation" would allow the defendant to be improperly eligible to submit the claim for payment to the government and therefore "fraudulently induce" the payment. If Hansen were correct, then *Connor* and the numerous other cases discussing at length the critical distinction under the FCA between conditions of participation and conditions of payment were all engaged in an unnecessary waste of time since any plaintiff can avoid dismissal by merely recasting her complaint as a fraudulent inducement case. This is simply not the law.

Rather, courts have made clear that the fraudulent inducement theory, whatever its proper application elsewhere, cannot be imported into the health care context because doing so would impede agencies' enforcement efforts and nullify the purpose of distinguishing conditions of participation from conditions of payment in the first place. Indeed, the key statement on this issue comes from the same Seventh and Ninth Circuit cases that Hansen relies on, but from which she quotes selectively. *United States ex rel. Hendow v. University of Phoenix*, 461 F.3d 1166 (9th Cir. 2006); *United States ex rel. Main v. Oakland City University*, 426 F.3d 914 (7th Cir. 2005). In each case, the relator alleged that a university knowingly made false statements when applying to become eligible for federal funding. The Seventh Circuit held that these allegations stated a claim that the funding the university later received was fraudulently obtained.

426 F.3d at 916–17. The Ninth Circuit adopted the Seventh Circuit's reasoning. 461 F.3d at 1174.[6]

In doing so—and in language Hansen (understandably) does not acknowledge—the Ninth Circuit emphasized that its reasoning does *not* translate into the Medicare context. The *Hendow* court explained that its holding made sense in "the context of Title IV and the Higher Education Act," because without the threat of FCA liability, "an educational institution could flout the law at will." *Id.* at 1176. But, the court cautioned, the Medicare context is "completely distinguishable from the case before us" because compliance with health care regulations is "ensured by peer review and extensive monitoring." *Id.* at 1177.

The Tenth Circuit reaffirmed this point in *Conner* itself, again in key passages Hansen does not acknowledge. In *Conner*, this circuit explicitly addressed and distinguished these education cases as inapplicable in the highly regulated health care context. *Connor* pointed to *Hendow* as a "telling contrast to the present case." 543 F.3d at 1122. Like the Ninth Circuit, *Conner* underscored that *Hendow* "completely distinguish[ed]" itself from the Medicare context, "where relevant regulatory compliance is ensured by peer review and extensive monitoring." *Ibid.* (internal quotation marks omitted)[7]; see also *United States ex rel. Willard v. Humana Health Plan of Texas Inc.*, 336 F.3d 375, 386 n.2 (5th Cir. 2003).

Hansen ignores these distinctions and would turn *Conner* on its head. The entire reason *Conner* distinguished conditions of payment from conditions of participation is that the latter are

[6] Hansen's fraudulent inducement argument relies entirely on these two cases from the Seventh and Ninth Circuits and several district court cases from the Seventh Circuit. It certainly is questionable whether the Tenth Circuit would go as far as these two circuits in permitting plaintiffs to proceed under a fraudulent inducement theory in the education context. However, as discussed above, this Circuit has already ruled in *Connor* that these education cases do not apply in the health care context.

[7] The relator in *Conner* tried to assert a fraudulent inducement claim for the first time on appeal, which the Tenth Circuit declined to address. 543 F.3d at 1220 n.7.

appropriately enforced administratively, and subjecting them to the FCA would interfere with that process. 543 F.3d at 1220. Yet this concern applies just as much whether the relator styles her claim as one of false certification or fraudulent inducement. Either way, a court would be enforcing through the FCA the same condition of participation that *Conner* says is for the agency to enforce through its own extensive administrative scheme—a scheme that allows for the use of expertise and discretion that courts institutionally cannot provide. Indeed, if anything, Hansen's fraudulent inducement theory would be far *more* disruptive to agencies than would the false certification theory *Conner* rejected. The certification theory is at least limited because it attaches liability only to the particular reimbursement request containing the false certification. But under the fraudulent inducement theory, according to Hansen, *every payment* received for *every laboratory test* performed since October 2009 (when the first alleged fraudulent inducement occurred) is *automatically* a false claim, even if the result is "damages far in excess of the entire value of Medicare services performed by [the] hospital." *Id.* at 1221.[8]

Hansen does not address the above points at all, even though they are *Connor*'s gravamen. Instead, the total of her analysis is to assert that *Main* and *Hendow* are "perfectly analogous" to this case and can be "superimposed directly onto" it. Opp. 18. But for the reasons above, and in light of *Conner*'s and *Hendow*'s direct statements to the contrary, that assertion is just wrong.[9]

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[8] The implications of Hansen's fraudulent inducement theory are staggering. If CLIA (or another statute) had called for renewal of the certification every 5 years or maybe even 10 years, then Hansen's theory would transform every payment to the hospital for 5 or 10 years into FCA violations. Along with causing unreasonably massive damages (surely plaintiffs' aim), this theory leads to litigation focused on wrongful conduct far removed in time and place from the purportedly false claim, the claim for reimbursement for performing the lab test.

[9] Hansen also cites to an inapposite Illinois decision involving the Medicaid anti-discrimination statute. See *United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719 (N.D. Ill. 2007). There is no indication that this statute is enforced by means other than withholding payment, and certainly not

Finally, Hansen asserts that Mimbres's position would make laboratories "immune" from liability. Opp. 2. This fundamentally misunderstands *Conner*. It is *always* true under *Conner* (and under every other circuit that has addressed this subject) that where a condition of participation is at issue, the defendant will be "immune" from FCA liability. But that is because the defendant already is subject to an existing administrative regime with its own set of enforcement mechanisms and sanctions, so imposing FCA liability in that circumstance would "undermine the government's own administrative scheme." *Conner*, 543 F.3d at 1220. It is also because the FCA "was not designed for use as a blunt instrument to enforce compliance with all medical regulations." *Wilkins*, 659 F.3d at 307 (internal quotation marks omitted). At bottom, Hansen's objection is not to how Mimbres has applied *Conner* to CLIA, but to the condition-of-payment/condition-of-participation framework itself—that is, to *Conner*.

C. Hansen's "Worthless Services" Theory Is Not Properly Pled And Fails To State A Claim In Any Event

In her opposition brief, Hansen alleges for the first time that even if her CLIA allegations fail under a false certification or fraudulent inducement theory, they state a claim under a "worthless services" theory. The Court should reject this argument for any of three reasons.

First, the claim is not properly presented. Hansen's original complaint makes no mention of it. Nor does the operative First Amended Complaint. Instead, both complaints exclusively address her false certification and fraudulent inducement theories, which are identified by name.

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through an extensive regime, as is true of CLIA. See 42 U.S.C. § 1396b(m)(2)(A)(v) (providing that "no payment shall be made" to discriminating hospitals). Moreover, the defendants in *Tyson* did not argue that any alternative enforcement scheme existed. See 2006 WL 3604794 (Nov. 16, 2006) (Defendant's Memorandum of Law).

Hansen also quotes the statement of a single legislator that the FCA applies to both conditions of participation and conditions of payment. Opp. 19–20. The Court should give no weight to that statement, not only because it represents the view of one legislator, see *DeVargas v. Mason & Hanger-Silas Mason Co.*, 911 F.2d 1377, 1386–87 (10th Cir. 1990), but because it directly contradicts *Conner* and countless other circuit court decisions.

See, *e.g.*, Compl. ¶¶ 177–81 (under heading titled "THE FALSE CLAIMS," alleging that the Hospital "falsely certified" compliance with CLIA and "fraudulently induced" its CLIA certification). A complaint must "give the defendant fair notice of what the claim is and the grounds upon which it rests to prevent prejudice to the defendant." *Simantob v. Mullican Flooring, L.P.*, No. 12-4090, 2013 WL 2897882, at *7 (10th Cir. June 14, 2013) (internal quotation marks and alteration omitted). Here Hansen has not done so, with the "worthless services" theory not surfacing until she was faced with opposing Mimbres's motion to dismiss. Accordingly, the Court should not consider this theory. See, *e.g.*, *ibid.* ("We have warned that reading complaints too broadly to include any possible theory of recovery could create injustice by requiring defendants to infer every potential argument a plaintiff could later make." (internal quotation marks omitted)).

Nor should the Court grant Hansen leave to amend her complaint a second time to add this theory. Opp. 28 n.16, 31 n.19. Her request comes only in a footnote and should be deemed waived. *Hardeman v. City of Albuquerque*, 377 F.3d 1106, 1122 (10th Cir. 2004). In addition, Mimbres has already incurred substantial expense preparing two motions to dismiss; requiring it to prepare a third when Hansen offers no excuse (and has none) for not having pleaded this theory already in the two years since she commenced her lawsuit would unfairly prejudice Mimbres. Finally, for the reasons below, amendment would be futile anyway.

Second, even if the worthless services theory were fairly pleaded, it does not allege nearly the heightened detail required by Federal Rule of Civil Procedure 9(b). See *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 726–27 (10th Cir. 2006) (relators must "set forth the 'who, what, when, where and how' of the alleged fraud" (some internal quotation marks omitted)); *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245

F.3d 1048, 1051 (9th Cir. 2001) (dismissing worthless services claim under Rule 9(b)). Hansen's allegations relate to multiple laboratory tests dating back to June 2009. Compl. ¶ 8. That period would seemingly encompass thousands of tests. Yet Hansen does not identify a single test that was *actually* (and not merely hypothetically) inaccurate or worthless. Nor does she allege the date any such worthless test was performed, who performed it, what patient(s) it affected; and what the effect was. As a result, to defend this claim, Mimbres would have to mine the thousands of tests potentially at issue and guess which ones Hansen thinks are worthless. That is just what Rule 9(b) is meant to prevent. *Schwartz v. Celestial Seasonings, Inc.*, 124 F.3d 1246, 1252 (10th Cir. 1997).

Third, even if Hansen's sparse allegations could clear the hurdles above (and they cannot), they fail to state a worthless services claim as a matter of law. The Tenth Circuit has not addressed this theory, but courts that have done so set a high bar. For a service that was actually provided to be deemed "worthless," it must be "so deficient that for all practical purposes it is the equivalent of no performance at all." *Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001); see also *United States ex rel. Badr v. Triple Canopy, Inc.*, --- F. Supp. 2d ---, No. 11-CV-288, 2013 WL 3120204, at *9 (E.D. Va. June 19, 2013) ("entirely devoid of value").

Here, Hansen cannot possibly meet this standard. She does not allege that a single particular laboratory test or machine produced a flawed result. She does not allege that Hospital physicians did not in fact use the laboratory tests to diagnose and treat patients. And she does not allege a single particular patient who was misdiagnosed, mistreated, or otherwise injured in any way on account of the alleged CLIA violations. She contends that CLIA regulations were violated because the lab's procedures manuals were outdated and that the director's credentials were supposedly lacking, but this is irrelevant to whether any particular lab test was inaccurate

and could not be used by doctors. Similarly, she charges that certain calibration or verification tests were not performed in a CLIA compliant manner, but (as noted) she does not identify a single lab test that was erroneous, let alone was "so deficient" that it was "entirely devoid of value." Courts have routinely dismissed comparable worthless-service allegations under Rule 12(b)(6). See, *e.g.*, *Sweeney v. ManorCare Health Servs., Inc.*, No. C03-5320RJB, 2005 WL 4030950, at *6 (W.D. Wash. Mar. 4, 2005); *United States v. Dialysis Clinic, Inc.*, No. 09-CV-00710, 2011 WL 167246, at *21 (N.D.N.Y. Jan. 19, 2011); *Badr*, 2013 WL 3120204, at *9.

II. Count III Does Not Satisfy Rule 12(b)(6) Because Hansen Does Not Allege She Investigated Or Reported Fraud

Mimbres's opening memorandum explained that Hansen's FCA retaliation claim fails as a matter of law because Hansen alleges only that she investigated and disclosed to her employer alleged CLIA violations, and not (as the case law requires) any improper billings or fraud, let alone a potential FCA lawsuit. Mem. 21–24 & n.12 (citing cases dismissing retaliation claims under Rule 12(b)(6) for this reason). In response, Hansen does not deny that she alleges only an investigation and reporting of regulatory violations. She also does not deny that, at least before the 2009 amendments to the FCA, her claims would therefore fail as a matter of law.

Instead, her sole argument is that, following the 2009 amendments, a relator can state a retaliation claim by reporting regulatory noncompliance to her employer, even if that report has no connection to fraud. Opp. 28–30. Yet the principal authority she cites for this assertion directly refutes it. In *Layman v. MET Laboratories, Inc.*, No. 12-2860, 2013 WL 2237689 (D. Md. May 20, 2013), the court stated (twice) unequivocally that, even after the amendments, the relator's investigation and report to her employer must involve fraud. See *id.* at *7 ("Nevertheless, to constitute protected conduct, an employee's internal report must specifically allege fraudulent claims for federal funds and not merely address concerns about general

misconduct." (internal quotation marks omitted)); *id.* at *9 ("Post-FERA [*i.e.*, the 2009 amendments], courts have continued to hold that internal reporting suffices to put the employer on notice as long as the employee specifically told the employer that he is concerned about fraud." (internal quotation marks and alterations omitted)). The *Layman* court denied the defendant's motion to dismiss because there, unlike here, the plaintiff "informed . . . his supervisor that the calculations [at issue] amounted to fraud on the government." *Id.* at *8. Here, Hansen does not allege she investigated or reported fraud, and her retaliation claim fails as a matter of law.

III. Counts II and IV Fail For The Same Reasons Under State Law

Hansen does not dispute that her state law counts should be dismissed if her corresponding federal counts are dismissed. Mem. 24; Opp. 31. She also does not deny that the New Mexico Department of Human Services has not provided a statement of substantial evidence of a violation, as is required for her claim to proceed under the New Mexico Medicaid False Claims Act. See N.M. Stat. § 27–14–7(C); Mem. 24–25; Opp. 32.

CONCLUSION

For all these reasons, the Court should dismiss the First Amended Complaint with prejudice.

[Signature page follows]

Respectfully submitted,

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