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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE EDWARD M. CHEN, JUDGE

UNITED STATES OF AMERICA, ex rel. RONDA OSINEK, Plaintiffs, VS. KAISER PERMANENTE, FOUNDATION HEALTH PLAN, INC., and THE PERMANENTE MEDICAL GROUP, INC., Defendants.	Consolidated Case No. 13-cv-03891-EMC And Related Cases Nos. 16-cv-1558-EMC 16-cv-5337-EMC 18-cv-1347-EMC 21-cv-3124-EMC 21-cv-3894-EMC

San Francisco, California
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TRANSCRIPT OF PROCEEDINGS

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(Appearances continued, next page)

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Tuesday - November 16, 2021 **2:46 p.m.**

P R O C E E D I N G S

THE COURTROOM DEPUTY: Osinek, et al. versus Kaiser Permanente, Case No. 13-3891. Counsel, please state your appearances for the record, beginning with plaintiffs.

MR. CHOE: Good afternoon, Your Honor. Shiwon Choe behalf of the United States

THE COURT: All right, thank you, Mr. Choe.

MR. MOSKOWITZ: Good afternoon, Your Honor. David Moskowitz on behalf of the United States.

THE COURT: Thank you.

MS. ZEMAN: Good afternoon, Your Honor. Amy Zeman on behalf of relator Osinek.

THE COURT: Good afternoon, Ms. Zeman.

MR. VOLDMAN: Good afternoon, Your Honor. Max Voldman on behalf of relator Taylor.

THE COURT: Thank you, Mr. Voldman.

MR. LEWIS: Good morning, Your Honor. Roger Lewis on behalf of relators Bryant and Hernandez.

THE COURT: Thank you, Mr. Lewis.

MR. PORTNOI: Good afternoon, Your Honor. Dimitri Portnoi on behalf of the defendants.

THE COURT: All right. Thank you.

MR. BLALACK: Good afternoon, Your Honor. Lee Blalack on behalf of defendants.

THE COURT: All right, thank you Mr. Blalack.

All right. We have a series of motions. Why don't we start with the government's -- motion to dismiss the government's complaint and intervention. And obviously I'm not going to be able to cover everything today, but I want to cover some issues that would be helpful to me to get some clarification on.

So, with respect to the falsity question and the theory of falsity based on inaccurate diagnoses as distinguished from the diagnosis that were not related to doctor visits, the question is whether or not there's been enough here under *Twombly* and *Iqbal* to establish a pattern or practice to add non-existence diagnoses to patient records.

There are some examples given -- Paragraphs 338, 339, 210 through 211 -- of sort of three anecdotes about various examples. But it's not until you get to the -- I'm not sure how it's pronounced, "Kechetsia?" I'm probably pronouncing it wrong.

MR. PORTNOI: I believe it is "Kekeksia."

THE COURT: How's it pronounced?

MR. PORTNOI: I believe it's "Kekeksia."

THE COURT: Okay. It's not until we get to there that it seems to me that there is more of a -- more allegations about systemic, you know, system-wide non-anecdotal kind of evidence. So, that's my take. But I want to hear from the

government whether I've missed something here. Whether there's more to establish a pattern or practice beyond cachexia.

MR. MOSKOWITZ: Thank you, Your Honor.

So I would like to start off at the outset, because only in the reply brief did they raise this idea that you have to establish a scheme, and I think to begin with, they misstate the law.

And that's the ***Ebeid*** case that they cite, it's addressing an issue about what you do if you don't actually have allegations about specific claims that have been submitted that were false. There's no dispute that when you have specific example claims of what has been false, that establishes the falsity of those claims.

And so this is actually an issue before the Supreme Court that is going up. Can you just allege a scheme? Or do you need to allege specific examples? But there's never been a court that says when you have specific examples, that, alone, is not sufficient.

And if you go back to the statute, the provisions in the statute itself, 3729, they talk about whoever knowingly presents or causes to be presented a false claim. It can be a single claim. It doesn't have to be a scheme. Whoever makes or uses or causes to be made or used a false record or statement, that's another basis for a claim.

And so to start off with, the scheme requirement is not

actually a requirement in the statute. It doesn't exist.

THE COURT: Well, all right, I understand that you -- it's actionable to have it on a specific claim, but the scope of the complaint and the relief may turn on how widespread --

MR. MOSKOWITZ: Sure. But we would demonstrate then based on these examples, these examples demonstrate what they were doing.

So, to go further, though, we have actually alleged a single scheme. And that scheme is this. Kaiser Permanente, they systematically mind patient data for diagnoses. They then pressed physicians to add these diagnoses. A large part of this involves diagnoses that just simply had nothing to do with the visit at all. In fact, all of them covered that. But many times, when those diagnoses, themselves, also didn't exist.

And this pattern or practice was a reckless conduct where there was no significant concern that existed to show that we should only be pressing physicians to add these if we've confirmed that the diagnosis exists.

And the cachexia example -- because we could have spent, you know, hundreds of pages here going through different types of conditions, but the cachexia example is a perfect example of what was going on. In cachexia, they created an algorithm that was completely flawed. It was searching for patients who were merely thin. It is not remotely what cachexia is.

The doctors were warning Kaiser, this is going to cause us

to submit a whole bunch of false claims; we're just going to be picking up thin patients who don't have cachexia. Kaiser ignored that warning. Kaiser did an audit. When Kaiser did that audit, it showed that 90 percent of what they were adding via addenda was not appropriate.

THE COURT: No, I get you. That's why I said that there is systematic --

MR. MOSKOWITZ: Yes.

THE COURT: You do that for at least the one example of cachexia.

MR. MOSKOWITZ: Sure.

THE COURT: I didn't see similar ones for other --

MR. MOSKOWITZ: We didn't do it for similar ones. But the point is, like with the obesity ones, and there's a couple of examples here, is that the patient isn't obese, and yet they're asking the providers to add diagnoses that, you know, involve -- they's are asking providers to add obesity-related diagnoses. And that's reckless. You shouldn't be asking a provider to add a diagnosis for obesity related conditions when the record shows they weren't obese.

THE COURT: So what suggests that that was more than a one-off on -- on the obesity thing, as an example?

How do we know that wasn't just one example that's not necessarily indicative of the large iceberg underneath?

MR. MOSKOWITZ: So we've shown -- there's actually --

we've given at least two examples in this complaint, alone. We've given a whole bunch of examples of how they were using the queries improperly, that there was not attention paid to whether or not that condition actually existed or not, or sufficient attention.

And so, you know, I am not going to suggest that this is the primary focus of our case. The primary focus is the first problem. But the second problem exists.

And, and I think it's also important, Your Honor, to note that these two issues are completely intertwined. And that's shown through the examples. You know, when the physicians are pressed to add a diagnosis that's contradicted by the record, there isn't two schemes going on here. It's a single query.

And there are two problems with the query. One, the condition didn't exist. And two, it didn't have anything to do with the visit. And those things are intertwined, right? Because also, whether or not something required or affected patient care, treatment or management at that visit, it turns in part on whether or not the condition existed. If the condition didn't exist, then the second part is not true.

And so, no matter what, all of these things are going to stay in the case, because when the medical records show the patient didn't have that condition, well, that also means that it didn't require or affect patient care, treatment or management.

So this is largely Kaiser rewriting our complaint from what we allege, which was a single scheme, to being two schemes about two different parts of the exact same guideline.

THE COURT: All right. So in other words, to put it differently, some of this other misconduct, this so-called first scheme which you say is part of the second scheme can be inferred from both cachexia example, the unrelated to visit press which came from the same kind of inquiry, together with the anecdotes, from that you could infer that this was -- this was systemic on both fronts.

MR. MOSKOWITZ: Yes, it's systemic. It's not as widespread as the first problem. But it is a significant problem that existed throughout.

THE COURT: All right. Let me hear the response to that.

MR. PORTNOI: Well, Your Honor, thank you. The government has -- has been trying to have its -- to eat its cake and have it too, as I recently learned is the way we're supposed to say it.

The government wants to put everything in the legal falsity bucket, but then wants to focus on examples of clinical falsity and wants to leave that door a little bit ajar, so that if down the line its legal falsity claim fails, they can keep those clinical falsity claims in.

But Your Honor hit the nail on the head in the sense that

there is no scheme to put in, to have a false -- to have clinically false diagnoses submitted to CMS. And simply holding onto the idea that we can maybe keep a clinically false -- clinical falsity claim here, that is not the way to litigate a False Claims Act case. And it doesn't comport with Rule 9(b).

A clinical falsity scheme, Your Honor, is a dangerous indictment of a company. Part of the reason we have heightened pleading standards is so that defendants don't spend years with the title of an alleged fraudster. There's valid reason to have these standards, when you're accusing a company in a public document filed by the government of something so drastic.

And to understand, Mr. Moskowitz said -- said that part of the scheme was not having attention by doctors. But doctors are the ones making the diagnosis. And what is a query, but a request to a doctor to consider a diagnosis?

And to understand the scheme the government is proposing, they'd like to say that the complaint adequately alleges a scheme where hundreds, if not thousands, of doctors sat at their desks, looked at a medical chart, knew that a patient did not have a medical condition, and knowingly lied about that.

THE COURT: Well --

MR. PORTNOI: And that's not just --

THE COURT: What about -- what about with respect to

cachexia? I mean, there's a lot of systemic stuff there. You're not saying there was not -- there weren't allegations of a systemic data-mining query sent to doctors finding, cachexia added via addenda 120 times more than physicians in southern California that didn't have this initiative. Audits finding that the -- these diagnoses were invalid. I mean, that sounds pretty systematic to me.

MR. PORTNOI: Well, Your Honor, first off, if that were the case, then the clinical falsity would be limited there. But the cachexia data-mining initiative allegations don't show falsity.

What they show is that TPMG identified cachexia as a medical condition that could increase revenue if diagnosed. That TPMG created a data-mining algorithm to identify those potential cachexia diagnoses. That providers were sent those results to see if they should add potentially missed cachexia diagnoses to medical records, and that some providers expressed concern the algorithm incorrectly identified cachexia diagnoses.

What we don't have, Your Honor, after eight years of investigation, is one patient diagnosed with cachexia who did not have cachexia. Not one, Your Honor. And after eight years of investigation, we should be able to put that into a complaint, even as a conclusory allegation. But they don't even say that there's an unidentified person -- an unidentified

person --

THE COURT: Not one instance of an alleged misdiagnosis?

MR. PORTNOI: Nowhere in this complaint, Your Honor. What we have is an allegation that we took profit-driven steps to identify these diagnoses. But the Ninth Circuit said in *Integra* that CMS has acknowledged that there is nothing inappropriate, unethical or otherwise wrong with healthcare providers taking full advantage of coding opportunities to maximize the Medicare payment that is supported by documentation in the medical record.

And that's all this shows, is something that has already been described by the courts --

THE COURT: So what about -- what about Paragraph 321? As part of the audit, the internal audit, found that over 90 percent of the time, a physician added cachexia diagnosis based on the query from Kaiser, but the documentation was either, quote, "lacking, or contradicted the definition of cachexia."

MR. PORTNOI: Your Honor, we don't know what that means to say documentation is lacking or -- or not. That could -- documentation being lacking doesn't say that a patient did not have the diagnosis. It could be that a name was transposed. It could be that dates are wrong. There are many documentation errors that can exist that have nothing to do

with the patient not having cachexia.

If the government wants to say --

THE COURT: So 90 percent of the time, you think it was a mistyped name?

MR. PORTNOI: There's no reason to believe -- if the government believes that somebody was diagnosed with cachexia who doesn't have it, why can't they allege that?

THE COURT: All right, let me stop you right there. Let me get the government response to that.

What about that?

MR. MOSKOWITZ: So there have been a lot of misstatements there about our complaint.

First off, in Paragraph 346, we specifically alleged one of the examples of cachexia. And it was a person who had the flu. And they lost a few pounds. That's not cachexia.

Cachexia is a complex syndrome involving an underlying condition that is causing the body to physically waste away. You get $6,000 from Medicare to pay for that, because it's an extremely significant condition. It's not somebody having the flu who lost a couple of pounds. And the record shows exactly what happened.

And this record, not only did it say this person wasn't wasting away, it says they had no general disability. They're well appearing. He's clear that the weight loss is just a temporary issue related to the flu. That's not cachexia. But

that's one example of what is going on here.

Second, we are not saying that the doctors are sitting around being liars. That's not the allegation. The allegation is that the company was generating these. That the company was pressuring physicians to do things. That the company told these physicians "Don't spend more than a minute on this. We've already looked at this for you. Just go ahead and add this."

If you're going to spend a minute or less per diagnosis, you're not going through the records to look at them. You're just adding the diagnosis. And that's the problem here. There's pressure and -- from the company. The company is driving this, not the doctors.

If the doctor added the condition during the original visit, if all we had here was: Hey, Kaiser wants doctors to pay attention to cachexia, and if they actually see it in the visit then that's -- you know, please make sure to diagnose it, that would be one thing. What we have here is a systematic adding of these conditions after the fact, when the doctor saw the patient, and didn't diagnose them with it.

And that's similar problems with these other things. That the doctors aren't actually doing any work to do the check, because they were told: We, Kaiser -- Kaiser's already done this. You need to get through however many hundreds of addenda through the year that you're supposed to look at. It became a

problem. And especially a problem because the doctor has to then -- if they want to say no, they have to justify it. If they just do what Kaiser wanted them to do, it gets added.

And so all --

THE COURT: I understand the theory. I understand the theory. The question is --

MR. MOSKOWITZ: Okay, but it's all a reckless scheme. And it's one scheme.

THE COURT: And the question, I think ultimately, is under *Twombly* and *Iqbal*, is there enough specificity here to put meat on the bones, to show that there was this practice? And it seems to me that, cachexia, there's a number of systemic allegations here about the audit, about the communications, about the results, supplemented by anecdotes.

It's the area outside of that where I'd have to look twice to see whether there's enough there, frankly, to meet the *Twombly* kind of standard.

MR. MOSKOWITZ: And I think, Your Honor, you should look, because they've never been able to point to a case that actually gave examples that was not sufficient to move forward. And their argument is essentially it wasn't as systematic as the other parts of the claim. And that may bear out, and may be something that's addressed at summary judgment.

But even if it turns out that only, you know, 10,000 of the claims had this problem, as opposed to hundreds of

thousands of the claims having the other problem, well, those are still all false claims. And we'll have to prove that they were done knowingly, but that's a different question than whether it's false.

THE COURT: Well, you'll also have to prove it's more than one area, and more than three anecdotes outside the area of cachexia.

MR. MOSKOWITZ: Sure, right. But we would prove that. But there's not been a case where we provide specific examples of what happened, specific examples that, themselves, are false claims, but the court dismissed it because we didn't provide enough examples. And that's -- that is what, you know, at least, you know, Kaiser has not pointed to those cases. I'm not aware of them.

And, and so, the main issue has been: Do you need to point to examples? Or can you rely on other indicia to establish that false claims were submitted? And that's what's before the Supreme Court. That's what the ***Ebeid*** decision that they rely on says.

But, what is covered by this act is very broad amounts of, you know, any type of false claim or false statement. And so the fact that these are alleged to have been false is enough to show that they were false.

THE COURT: Let me get to the second group. I know there's a lot to be said.

MR. PORTNOI: Your Honor, may I be very brief --

THE COURT: Very brief, and then I want to get to the second category.

MR. PORTNOI: The first thing I want to note with respect to the example that's given on Paragraph 346, at cachexia, again, that paragraph does not allege that the patient did not have cachexia. It says that there's inconsistent data in the file. And they don't state what clinical indicator is necessary to show cachexia.

That's because on Paragraph 295 -- and we have to treat this as true -- the government alleges that cachexia is based on clinical judgment, not clinical indicators. It is something that is more or less subjective to the doctor. Which, again, not only means that to prove cachexia you have to show that the doctor --

THE COURT: Well, the allegation says that the health plan was not entitled to this risk adjustment, because cachexia did not exist. Now, you may take some issue. I guess you're saying now, to back that up we'd have to have more specific evidence of clinical indicators to show that it did not exist.

I'm not sure if *Twombly* and *Iqbal* go that far. I don't have to necessarily see medical records on a 12(b)(6) to make a conclusion. There's a specific allegation that it didn't exist.

MR. PORTNOI: And if so, Your Honor, then that's one

claim. And it goes no further. It doesn't show a scheme. And -- I'm not saying that there need to be more examples. That's a distortion of our argument.

But, there hasn't been a case that has said: We gave you three examples, now let's go forward on 10,000 claims because we believe that there's -- with no allegation of the scheme. There are usually allegations.

And again, after eight years of investigations, it's usually not hard to find them. Meetings in which people talked about: Hey, let's get diagnoses, even though they're false. As opposed to: Let's send queries to doctors. That is simply not in the complaint. And after eight years of investigation, you would think it could be, by this time.

THE COURT: All right. Let me get to the next group that the government asserts.

Is the government asserting, besides sort of the legally false claim of compliance with ICD guidelines, is there a claim also of just factual falsity in this regard?

MR. MOSKOWITZ: Yes. So, all of these claims are factually false. Right? Each and every one of these false claims entails an ICD code that is inaccurate. It's inaccurate, according to the ICD guidelines. And that fact, in and of itself, makes it factually false. It's inherently a misrepresentation to use ICD codes but disregard the guidelines, the standard that gives those codes some meaning.

Right?

So Kaiser is not submitting diagnoses. If they submitted a diagnosis to CMS, they said: Patient X has cancer. They would get zero dollars for that.

What they're submitting is encounter-level data. This is data for a particular patient who saw a particular provider on a particular date. And a list of the ICD codes, numbers that have no meaning other than against the ICD standard. Right? So instead of "aortic atherosclerosis" they're submitting "I70.0." That means nothing. What it means and what gives it meaning is the ICD standards. And when you are not complying with the ICD standard, with the ICD guidelines that give the meaning to that code, you are misrepresenting the code.

And that was decided directly in the *Moncrief* case, in completely identical circumstances, where the Court says: If you're going to submit a CPT code, then you need to comply with the CPT manual. Because the CPT manual is what gives the meaning. It says what that CPT code means.

And so, yes, they're both factually and legally false.

THE COURT: And the non-compliance is that it's unrelated to a doctor visit. Is that the --

MR. MOSKOWITZ: So, right. It's actually that that ICD guideline has two requirements. It has to coexist at the visit, so it needs to be a condition that existed at the visit, and it needed to have required or affected patient care,

treatment or management. Both of those conditions have to be met in order to report it. If you don't have both of those conditions, you can't report it.

And that same rule applies across Medicare. It applies to traditional Medicare, and it applies to Medicare Advantage. And that's really important, because the way that the Medicare Advantage model works is it uses the data from traditional Medicare to calculate the payments in Medicare Advantage.

And the whole idea of this is that the same standards apply. Because you use that for the model to calculate one to the other. And it is factually false, on its own, when you misrepresent an ICD code that doesn't comply with the ICD guidelines.

THE COURT: So how is that distinguished from the legally false claim of assertion of compliance with the ICD guidelines, when in fact, there wasn't -- seems like that's two sides of the same coin.

MR. MOSKOWITZ: So in this case, they both apply. And we've never -- we've never -- this wasn't our argument, right, this was something that the plaintiff -- or that Kaiser Permanente came up with in their briefing, right? Our point is they are both factually and legally false. Something that is factually false is, it appears on the face of the claim, that is an incorrect description of the code, itself.

And that's what *Moncrief* said, right? *Moncrief* said that

was -- CPT codes that were inaccurate were both factually and legally false. Something that's legally false is, if you're relying on some other thing that's not on the face of the complaint but you're saying they certified compliance with that, and our point is for this case it's a distinction without a meaning. It is both factually false and legally false.

THE COURT: All right. So let me hear the response to the -- to that.

MR. PORTNOI: Well, Your Honor, first off, the distinction between clinically false and legally false is not something that Kaiser created. This is something that exists across the case law.

The court in *Moncrief* was clear to point out that the type of falsity at issue in that case was factual falsity, whether the defendants actually performed the service that they billed for. The Court concluded that sub-regulatory guidance was relevant to help answer that question.

Here, DOJ's theory with respect to what we're calling legally false claims is that defendant's right to payment is premised on his complete compliance with the ICD guidelines. That was not the argument in *Moncrief* at all, and that's not the argument that's being made here.

THE COURT: Why isn't it analogous, though? The idea is that you've rendered an ICD code that requires coexistence and effect, effect --

MR. PORTNOI: Well --

THE COURT: -- in management. And if the code were in fact rendered without even a visit, why isn't that factually false?

MR. PORTNOI: Because, Your Honor, there's not -- there's nothing here to say that -- we don't have a certification, for instance, here, that says that with each diagnosis, every time we sent it in, that we said this requires or affects care. What we're doing is we're incorporating by reference something into a contract that then incorporates by reference another level.

This, this is -- this is classic legal falsity, because what we're -- what the government is alleging is that -- is that what we have is a scheme where the contract requires something. And so there's an implicit statement when diagnoses are sent, that this subsequent -- that this subsequent -- what is in the ICD guidelines, which is not referenced in the contract, is going to be followed in every single of the 115 pages, and every line.

And that's just not plausible, in reading the contract in this case to show that that's something that represents the statement. You have to figure out, Your Honor, what is the false statement that Kaiser made? And --

THE COURT: The false statement is that: This diagnosis was rendered in connection with an actual visit for a

condition that co-existed and was a condition that was subject to -- affected the course of treatment and management.

MR. PORTNOI: But that's not something that Kaiser ever said. And that's the problem. Kaiser --

THE COURT: You have to use those words? You're saying there's no falsity unless they use those exact words? Is that your theory?

MR. PORTNOI: What I'm saying is that when we render a diagnosis we're, of course, representing that the diagnosis exists. But what we -- what we are denying is that the contract or any regulation requires Kaiser to follow every inch of the ICD guidelines, much less the Medicare managed care manual, such that it renders every diagnosis false, if you hadn't followed every page in the 800 pages of the Medicare care manual or the ICD guidelines, themselves.

There's simply -- the contract doesn't support that interpretation, and they don't compel compliance with the require-or-affect requirement. It doesn't reference the requirement that --

THE COURT: Well, maybe this goes to materiality. Maybe this overlaps with materiality. But isn't -- this is not every inch. This is, like, pretty important. Right?

If it says you've got to -- in order to render this kind of diagnosis, you've got -- it's got to be based on something that's concurrent. And, current.

I mean, that's not rocket science. That's not searching a manual for some footnote. It's pretty central. It's common sense.

MR. PORTNOI: Well --

THE COURT: And, Kaiser's own internal documents recognize the need to comply with ICD guidelines. So surely, surely, Kaiser can't feign ignorance of that requirement, can it?

MR. PORTNOI: Well, Your Honor --

THE COURT: That's not plausible, counsel.

MR. PORTNOI: Your Honor, a few answers to those questions. First off, the fact --

THE COURT: Yeah, give me a few answers, will you?

MR. PORTNOI: First off, the fact that Kaiser's internal documents talk about complying with the ICD guidelines -- and with a lot of guidance that isn't issued by the government, as the ICD guidelines isn't -- isn't something that goes to whether our statements to the government are false.

Second --

THE COURT: Well, yes, it does. It indicates that this is not, quote, your words, "every inch of the guidelines." This is something that's important, material, and central. If Kaiser recognized it, that's pretty good evidence that this is pretty important stuff, isn't it?

MR. PORTNOI: Well, Your Honor, it's not -- that simply -- that simply isn't the case.

And also, part of the response, too, to note, is that what the ICD guidelines state is simply that you must diagnose all conditions that co-exist and that require or affect care. They don't state any -- there is no prohibition in there, in the negative, just to be clear on that point. And as a result, that's part of what is there.

But, again, what we are talking about here is what does -- and the fact that something is a requirement doesn't make every time we submit a diagnosis a false statement, Your Honor. There are many -- there are many situations where that simply -- where that simply isn't the case. And what we have here is: Did we believe every time, or was it the case that every time we submitted a diagnosis, it was clear on its face that we were making a statement that every single diagnosis required or affected care?

All -- what the government relies on is the fact that in the contract, the MA organizations agree to follow the Medicare managed care manual, which is an 800-page document itself, which references in one instance the ICD guidelines which later has the "require or affect care."

That's not enough to get to a place where the state -- where the diagnoses that we're making are statements that are indicating every single time that every diagnosis requires or

affects care.

THE COURT: All right, because it's a reference to a reference, it is incorporation by reference two degrees away, it is part of 800 pages, it's too minute to be implied as part of the representation.

MR. PORTNOI: Sure.

THE COURT: What's the response to that? Let me hear the government's response to that.

MR. MOSKOWITZ: First off, I want to correct one thing, because we actually say that there are three things here that make the ICD guidelines and make this a false claim.

First, it is correct that that contract requires Kaiser to follow the ICD guidelines.

Second, the Medicare Advantage regulations require Kaiser to follow the ICD guidelines.

But, third, even if they didn't exist, when you use an ICD code, that, in and of itself, is a misrepresentation if you haven't complied with the standard. And this is exactly what's involved in *Moncrief*; it's what happened in *Escobar*.

In *Escobar*, they were using MPI codes, and they were using payment codes that were half-truths. Were misleading. They didn't have to make an express statement because, in context, the statement is: I'm reporting what are the ICD codes that are reportable for this patient visit that happened here.

It is a significant misrepresentation and half-truth in

context to not -- to reveal -- to use codes to submit them for payment that didn't comply with the standard. But the --

THE COURT: What if one of the standards is one of 800 standards? Any, any, any, any not-compliant --

MR. MOSKOWITZ: That's certainly not what we have here, right? So we have -- this is -- as you hit right on the point, this is the central standard for an outpatient encounter.

So I want to be clear here. Kaiser -- Kaiser didn't just like get lucky and identify this particular standard. They were hit over the head with it along with every other MAO, who were trained on it, who were given participant guides and all sorts of other guidance that identifies this particular standard as the number-one standard they need to look out for. So it's not just a: They got lucky. They had this in their own internal guidance, because CMS pointed it out to them.

But, the contract is clear. Right? The contract says that they have to operate in compliance with the Medicare managed care manual. Doesn't say Chapter 1. It says all of the Medicare managed care manual.

Now, they make a big deal about this Medicare managed care manual being 800 pages long. The vast, vast, vast majority of this are about how CMS is going to run the program.

So if you take Chapter 7, for example, that is the only chapter on risk adjustment payments, which is a huge part of

the program. Kaiser gets tens of billions of dollars a year from risk adjustment payments.

And in Chapter 7 -- it's 70 pages long. But of that chapter, if you look at the first couple of pages, that identifies specifically for the MAOs what their obligations are. And it couldn't be clearer.

That obligation, the first obligation they have, it says (As read):

> "MAOs must ensure the accuracy and integrity of risk adjustment data submitted to CMS."

And it says:

> "The diagnosis must be coded according to the international classification of diseases, modification guidelines for coding and reporting. The ICD guidelines."

It couldn't be clearer that every diagnosis has to be in compliance with that.

They also make a big deal about how long the ICD guidelines are. Well, the actual guidelines for an outpatient visit happen to be about four pages long. And this is the most important guideline.

They take advantage of the fact that the vast majority of the ICD guidelines involve specific guidance about how to treat particular conditions. What do you do with COVID? What do you do with West Nile Virus? What do you do in a hurricane? All

sorts of random things that just don't have anything to do with it.

The outpatient rules are simple and clear, and they went over them in all of the participant guides. Kaiser attached that guide. In Chapter 6, you can see for yourself how this particular guide is the first -- or this particular guideline is the first one identified for it.

And the participant guide also noted to each MAO that the guiding principle of risk adjustment has four different parts which happen to mirror exactly what Kaiser's own internal advisory shows. And one of those four key parts is that diagnoses must be coded according to the ICD guidelines. This was the most -- up there among the most crucial requirements.

But, second, they also were required by the regulations to comply with the ICD codes. The regulations, the Medicare Advantage regulations, specifically require them to submit equivalent data to traditional Medicare. Right?

So traditional Medicare submits encounter-level data, including ICD diagnoses, coded according to the ICD guidelines. MA organizations must submit data that conforms to these data requirements for equivalent Medicare fee-for-service data and to all relevant national standards.

And, obviously, when you're submitting ICD codes, the relevant national standard is the ICD standards. The ICD guidelines.

The idea that you can submit data that -- ICD codes that don't comply with the standard and that you've complied with all relevant national standards is nonsensical, and it undermines the entire merits -- the entire system, in and of itself. And there is nothing in that regulation that says "only according to data form."

And finally, I would note that we have pointed to numerous authoritative guidance from the agency, including statements in the Federal Register that identify the ICD standard as the chief standard that applies to this regulation.

And under ***Kisor v. Wilkie***, what the Court's job to do in interpreting this regulation is, first, you use the ordinary tools of construction to identify that. To identify what it means.

We think unambiguously it shows this is not limited to data form. Kaiser's been able to point to no case or any law that would support their position. But even if Kaiser were correct that there was some ambiguity, at that point in time, then the Court defers to the authoritative position of the agency about its specific views on the statute.

And in ***Kisor v. Wilkie*** they say: What are those? Those are the -- the positions that emanate from those actors using those vehicles understood to make authoritative policy.

And no one has ever suggested that statements, policies from the Secretary of HHS in the preamble to rules is not, in

fact, authoritative positions of the agency. This has been the position of the agency for decades. No one has ever challenged this before, in two decades, until Kaiser did it.

We've litigated numerous cases like this. No one has ever suggested that the ICD guidelines don't apply. In fact, many parties outright come out and say: We acknowledge the ICD guidelines apply. Because they do.

THE COURT: And in that regard, are you advocating *Chevron*? *Auerbach*? What kind of deference are you suggesting?

MR. MOSKOWITZ: Yeah. So the deference, because it is a regulation, would be under ***Kisor v. Wilkie***. And the first -- it's basically a two-step process similar to *Chevron*, but it's not *Chevron* because it's not an interpretation of a statute.

And so the first is you look at this regulation and say: Using all the tools of construction, what's the right interpretation? And we think our interpretation is -- is clearly correct, because it is related to all relevant national standards, not relevant to national standards related to data format.

This was -- the rule at issue was about substantive data that's submitted to CMS that is equivalent to traditional Medicare data.

And in order to take Kaiser's position to be correct, you would need to add words or limitations that don't appear in the text, itself. If CMS wanted to limit it, they would have done

that.

But if the Court determines that there is ambiguity, then it looks to the authoritative statements of the agency in the Federal Register and elsewhere.

THE COURT: All right. Let me -- I'll give you a brief chance to respond, and then I have got to go on to the next motions.

MR. PORTNOI: Thank you, Your Honor. I have just a few points here to make.

First off, there's nothing in the complaint that makes clear that this particular provision that appears three pages before the appendix of the ICD guidelines is the central provision.

In fact, there's another provision in the general -- near the general coding guidelines that states that (As read):

> "The assignment of a diagnosis code is based on the provider's diagnoses statement that the condition exists; the provider's statement that the patient has a particular condition is sufficient."

And that is the more general statement. There's nothing in here -- there's nothing here to state that this particular "require or affect" sentence is the key sentence in the entire ICD guidelines or that it's -- or that somehow it is the key thing incorporated into the Medicare managed care manual, into

the contract, or into these regulations.

If CMS wanted -- I just heard Mr. Moskowitz start a sentencing that way. If CMS wanted to make clear that the second of the ICD guidelines or the ICD guidelines as a whole were required, they could do so, in the contract, itself. And they could also cite this particular provision in regulations.

I also want to respond briefly to the issue regarding the regulations, because the regulations, very clearly, we don't have to get to deference. They very clearly don't apply. The two sets of regulations are cited in the opposition.

Part 162 states:

> "Part 162 applies only when covered entities are conducting a transaction covered by this part."

In a footnote -- in our brief, we noted that there are nine transactions that are covered by this part. And we listed the nine transactions covered by this part.

We asked the government to state which of these nine transactions does it believe occur in this case. And the government, in their opposition, chose to not respond. To simply ignore that statement, entirely.

And when we go to the regulatory history -- this is also cited in our briefs -- it also makes clear the dataset from a private managed-care organization to a state agency equivalent to an MAO setting CMS data does not need to be a standard

transaction.

So we don't have something there. And when we come to 42 C.F.R. 422.310, this provides rules for risk adjustment data formatting. It is not about MAO's right to payment, nor does it restrict healthcare providers' ability to diagnosis medical conditions.

It is simply talking about that the data has to -- has to -- that the data has to be formatted in a particular way in order to enable data to be able to upload to the system.

In no way, based on simply the use of the word "national standards" when we're talking about data formatting do we get the elephant in a mouse hole, that every inch of the ICD guidelines -- which is not even mentioned in the regulation -- is referenced there.

THE COURT: So are you suggesting that the guidelines with respect to the co-existence and the doctor visit and the diagnoses having to do with -- having to affect treatment, does not apply at all? Is that your position?

Not that it's not important and not noticeable, but not -- not even applicable? Is that what you're arguing?

MR. PORTNOI: The Court doesn't need to reach whether it's there, because the fact is, Your Honor, if the ICD guidelines apply but there's no false statement, CMS has many other tools in its toolbox to enforce the ICD -- to enforce the ICD guidelines, or to enforce the Medicare managed care manual.

It's not the case that the government cannot do anything when a claim is based on sub-regulatory --

THE COURT: Well, but if I have to explore the limits of your argument, the law to the extent of your argument, if you're saying the regulations of 42 C.F.R. only applies to form of data, has nothing to do with actual outpatient visits and all that, that suggests there are no regulations requiring what the government says is required.

MR. PORTNOI: The regulations can require it, but without it being a pre-condition for payment, Your Honor. And that's what we're talking about here. That goes to falsity and it goes to materiality, when we're talking -- when what we're dealing with is a sub-regulatory requirement that isn't placed directly into the contract or into regulations.

THE COURT: The hour is late. Let me get to the -- I want to address the Taylor --

MR. MOSKOWITZ: Can I make one small point on the HIPAA rules?

THE COURT: Quickly, yeah.

MR. MOSKOWITZ: So we have not argued that the HIPAA rules are what applies. We said the Medicare Advantage rules are what require Medicare Advantage -- MAOs to comply with the standard. What CMS has said is that the providers have to comply with the ICD guidelines when they transmit stuff.

So Kaiser's argument is actually: The ICD guidelines

apply when the providers transmit the codes to the MAOs. But then when the MAOs get it, all rules are off. There literally is nothing, that they could submit anything as long as it's, quote, "clinically accurate." Which also doesn't appear in the regulations.

And so our argument is that the MA regulations, those specifically require the MAOs to submit the data that conforms to the relevant national standard. And if you're submitting ICD codes, the relevant national standard is the ICD standard, the ICD guidelines.

THE COURT: All right. Thank you. Let me go to the Taylor question here. And I guess one of the questions is what the basis of liability is for Kaiser Foundation Health Plan. Especially in terms of the wider breadth of error claimed.

And so let me hear from the relator exactly where -- what's the basis here --

MR. VOLDMAN: Thank you.

THE COURT: -- of broader liability.

MR. VOLDMAN: Thank you, Your Honor.

So as our opposition laid out, KFHP employees ran these -- set goals and ran the projects that led to the violation of FCA. For example, Mr. Tholen set goals for financial targets that were unattainable, without the schemes that Kaiser decided to implement to attain them.

It's true that there's nothing wrong with setting

financial goals, and that for-profit healthcare companies are welcome to do everything legal to make money. But the reaction wasn't to do everything legal to make money. It was to design something like a (Inaudible) team of external providers to hit artificially high goals that Mr. Tholen presented. He was a KFHP employee in Colorado. Similarly, Diane Morissette, a KFHP employee not based in Colorado, was aware, and as KFHP generally was aware that the external providers had extraordinarily high error rates.

Kaiser did nothing to address the error rates, except in the direction that helped them financially, and ignored the downside of these error rates that would -- that the correction of which would have hurt them financially. These were driven from the parent health plan. It's true that some of these schemes were implemented in the Colorado region, but that's not where they initiated. And that's not why they initiated, either.

THE COURT: Well, what are the allegations that, one, the action and knowledge of these, two, can be attributed and a basis to find essentially a nationwide policy of the organization itself?

And, and exactly, besides sort of ignoring, for instance, high error rates, is there anything affirmative here that's alleged?

MR. VOLDMAN: So, Kaiser was aware of high error rates

and external providers, yet they did nothing to correct them. Instead, only correcting the upside for them. With the knowledge of high error rates in external provider coding, that is definitionally knowledge of false claims, as our external chart review scheme lays out. Because when there were mismatches in the data, correcting one way means the other way that's not corrected is false claims.

And --

THE COURT: How did they know that these wrong-way error rates were the result of inappropriate diagnoses or violations of ICD guidelines, or the result of false diagnoses, et cetera, et cetera?

MR. VOLDMAN: Sure. So we allege that Kaiser, in blind chart reviews -- meaning that Kaiser coders didn't know what providers previously submitted -- were told to follow coding guidelines as required by the ICD and the industry. And that the result of them following coding guidelines were mismatches between its provider-submitted codes and Kaiser coder-generated codes. Those mismatches were, again, only submitted when they benefited Kaiser, and not deleted from CMS systems when they would have cost Kaiser money.

With the combination of knowing that external providers -- which is the chart review program's focus -- were extraordinarily high error rates from various audits, including year-to-year audits in several regions and Ms. Morrissette's

KFHB audit that went back as early as 2009, that is a violation of the False Claims Act.

It's true that Kaiser could have not matched up those two sets of data, but that is a classic example of an ostrich burying its head in the sand.

THE COURT: So the systemic behavior is doing something about under-reporting errors, and ignoring over-reporting errors, even though they were clearly extant.

MR. VOLDMAN: Correct. And that is FCA's scheme recognized by the courts in ***Anthem***, ***Poehling***, ***Ormsby*** and ***Swoben***.

THE COURT: Is there anything more in terms of recognizing what the cause of the -- the downside error rates were?

MR. VOLDMAN: Sure. So we allege that the cause of all the downside error rates was non-compliance with ICD guidelines, and lack of support in the medical record. That is the reason they're false; that is the reason that Kaiser audits, year after year, identified this set of codes as false.

It's correct that there's a myriad of specific ways that these codes could be false. They could be not clinically supported, as Kaiser pointed out. They could be typos, which is the same thing, because if it's the wrong ICD code, it's not clinically supported.

But it could be the wrong provider type. It could be a

not face-to-face visit. It could be a provider excluded from Medicare. It could be someone that's not a doctor diagnosed it, or an NP, or anything else like that. It could be something that didn't affect patient care.

It's true there's going to be a myriad of reasons. But audit after audit identified this set of codes as having downside risk for Kaiser, and they chose to ignore it.

THE COURT: So, so you call it this sort of willful blindness, essentially, that's the basis of culpability and attribution to KFHP here.

MR. VOLDMAN: Yes. Despite knowing of high error rates and this set of data, they did nothing to fix them, and they kept signing attestation after attestation saying that their risk adjustment data was accurate, complete and truthful. Something that *Swoben* said, when a scheme like this was running, is impossible to attest to truthfully.

THE COURT: Is it necessary that KFHP had to know what the error rates were of, let's say, external providers versus internal, or any more details as to what percentage of the errors were due to certain causes?

MR. VOLDMAN: Not necessarily. But the fact here is they did do specific audits of external providers, and then did -- set up a chart review program designing a review of those external providers, while not fixing any of those downside errors, as you put it.

And, but, like the *Swoben* court recognized in its collective pleading allegation, like, these -- KFHB and Kaiser Health Plan of Colorado are in the same business. They run health plans that try to maximize profit and maximize revenue generation from CMS. They are in the same business, much like the *Prime* case recognized, of running health plans. They are identical actors in terms of running health plans.

THE COURT: What about on the question of materiality, especially under *Escobar*? Wouldn't it be necessary to establish materiality to know what the -- what the basis of errors were?

MR. VOLDMAN: So the basis of the errors is the fact that the diagnosis codes aren't supported. It's true that the underlying reason for their lack of support could vary from code to code, and most likely, does. But the basis of the errors, that they did not meet medical record documentation support as required by the ICD guidelines, the contract and other CMS regulations.

And in case after case -- *Swoben*, *Poehling*, *Ormsby*, *Anthem* -- the government or relators that have been allowed to proceed past the pleading stage do not list out a code-by-code or even a bucket-by-bucket reasoning of why every code isn't true. The health plan has that information. They identified this as a universe of codes that isn't supported, and refused to correct it.

MR. PORTNOI: Your Honor, may I be heard?

THE COURT: Yes.

MR. PORTNOI: So, a few things here, because you've covered a number of topics with Mr. Voldman just now.

The first is Mr. Voldman has said many times they did something or Kaiser did something, but the crux of your question is: What did KFHP do, versus what did Kaiser Colorado do.

And KFHP was not involved, was not -- is not alleged to have set up this one-way chart review program. And the actual allegations in Dr. Taylor's complaint made clear that there was very little actual knowledge or participation by KFHP.

Mr. Tholen presented a report about tracking risk score to capture as much revenue as possible. That's on Paragraph 88. But the allegation does not plausibly suggest that Mr. Tholen or KFHP engaged in fraud.

Ms. Diane Morrissette, who Mr. Voldman just referenced at Paragraphs 92 and 113, had one audit in 2004-2005, where there was no allegation about what the audit found. And, whether Ms. Morrissette knew about any actual improper data submissions to CMS following the audit.

Significantly, that audit took place before the risk adjustment system was fully implemented. Before any risk adjustment data was submitted to CMS.

And then in 2009, Ms. Morrissette simply stated that

external provider codes were less well-monitored than those of Kaiser internal physicians, and more likely to have higher error rates, which is just a truism. It's just a fact that when you are talking about external providers, providers that are not your employees, you are going to have less control over that, to begin with.

Turning, though, however, to more fundamentally the Taylor materiality and falsity issue with respect to external providers, there's really a remarkable statement Mr. Taylor has made in the briefs and has made here, which is that they don't -- is that relators don't have to describe anything about the false claims, including the basic facts about why there's an error, and why something is in error.

It's an essential statement that in a False Claims Act case, Rule 9(b) doesn't apply. You don't need to say how something was false. You don't need to say why something was false. You don't need to identify a false statement. You simply need to say: My opponent is a fraudster. They have the information in their files. They can go look for it.

That's not the way Rule 9(b) works. And that's not the way -- and that simply turns everything, not just with respect to the False Claims Act, but with respect to Rule 9(b), on its head.

THE COURT: Well, the assertion isn't quite that broad The claim is that there were -- as I understand it, that there

were submissions that were not -- that were not -- the diagnostic codes, themselves, were erroneous. There may be a variety of reasons why they're erroneous, such as not being diagnosed as a current condition, or misdiagnosed.

But, so I wouldn't say it was just saying: You're a fraudster. I mean, there's something to it. The question is what level of detail needs to be explicated in order to have a -- state a cause of action here.

MR. PORTNOI: Right. And some of those reasons ought to be alleged. That's the how of fraud. And at Footnote 13 of their brief, Mr. Voldman even goes so far as to say any typo, no matter how insignificant and regardless of how described, is enough to allege a False Claims Act case. I'm describing the theory that they are presenting.

And, that is simply not the case. There needs to be some understanding for both the external provider claims and the natural language processing claims about what is actually false when it comes -- so that we have some ability to defend against this.

And there -- you know, there's not a rule that one-way chart review is inherently wrong. And I agree that that is a practice that is more specific that is alleged in the Taylor complaint. But the holding in the Ninth Circuit's decision in *Swoben* upon which Mr. Voldman just relied was narrow. Because what it alleged was that the MAOs in that case "designed

retrospective reviews --" I'm quoting now, "of enrollees' medical records deliberately to avoid identifying erroneously-submitted diagnoses that might otherwise have been identified with reasonable diligence."

And doing so -- I finished the quotation -- with substantial error rates that were already present. And this is something that's very significant here, when we're talking about this, is that *Swoben* relies on the idea that the one-way chart review was designed after the defendant in that case had very poor -- what are called CMS risk adjustment validation audits or RADV audits, and error rates in excess of 20 percent. Having error rates in excess of 20 percent, they designed this program. And that's how you got to something that was false, knowingly false, materially false. Because -- in the face of that.

Now, RADV audits are conducted against every single MAO. And in almost any case I've ever seen, RADV audits are cited in the complaint of every relator and in every DOJ complaint. We're not -- and in this case, not a single -- not the DOJ, not any of the three relators that are here today, nor Ms. Osinek, nor the relators that were dismissed on first to file, chose to say anything about the RADV audits of Kaiser's.

And as a result, that's something that the Court can take in as an inference. That this is very different from *Swoben*, specifically because you don't have a program designed after

having these high error rates already placed at issue.

THE COURT: Instead, you have an after-the-fact turning a blind eye, is what is essentially alleged.

MR. PORTNOI: Well, if turning -- turning a blind eye, but we don't know what they are turning a blind eye to because we don't know what the errors are. And that's the issue, is that there has to be some allegation of in what way they were false. Otherwise, the requirement of how in Rule 9(b) has no meaning.

THE COURT: Does it matter?

If there's a wrong diagnostic code, if it's erroneous for one of a number of reasons, does it matter precisely why?

If you know that there are -- 40 percent of these codes are inaccurate, and that money is being -- and these are being submitted, and money is being paid by the federal government for erroneous codes, does it matter whether it's due to failure to comply with the existing condition requirement, or simply a misdiagnosis or something else?

MR. PORTNOI: Of course it does, Your Honor, because the False Claims Act only goes to preconditions for payment. It could be wrong because it violates an internal Kaiser standard. It could be wrong because it violates sub-regulatory guidance that isn't something that is seen as a condition of payment. This is -- this goes to falsity.

It also goes to materiality, Your Honor. This is exactly

the argument that the United States made in ***Escobar***, where a question was posed as a hypothetical there, and this made it into the opinion, where the -- where the Supreme Court, one of the justices asked: Well, what if the contract said that you -- that the company had to buy American-made staplers only? And they went out and they bought foreign-made staplers. And then they signed an attestation that stated that they've followed all the rules.

And the Supreme Court described this ex- -- and the United States said in a response: That would violate the False Claims Act. And that would give rise to a False Claims Act claim.

And the Supreme Court treated that as an absurd proposition. That there has to be some evidence, some facts at this stage that give rise to an inference that the government thought of this as material. And that the -- and, and in addition, that there was some way in which we know the error.

We can't get to materiality. We don't know the error. The question is: Does the government find this kind of error material? And we don't know what "this kind of error" is in the Taylor complaint.

THE COURT: Let me hear the response to that, that you need to know the nature of the error to know whether it's material.

MR. VOLDMAN: Sure. So first, as Mr. Portnoi pointed out, it's true that CMS does RADV audits. And when CMS asked

for money back in RADV audits, they asked for money back for a myriad of reasons, not making a distinguishment between which reason of violating ICD coding guidelines or other CMS guidance it's being asked back for.

Second, on the *Swoben* point, I just want to point out that this case -- *Swoben* controls this case. In Paragraph 107, we alleged that starting in 2007, high error rates were shown in Kaiser's internal audits.

It's true that RADV is not mentioned -- or Kaiser's RADV audits are not mentioned in that case. But it's also true that not every MAO, not every contract is RADV'ed every year, and these things are relatively rare occurrences.

So since 2007, we're showing error rates of 22 percent, 67 percent, 17 percent in the Colorado region with Kaiser's own audits.

Then, at Paragraph 119, we allege that they designed a retrospective chart review system, ignoring these error rates and only correcting the error rates that help them.

It's true, again, that the *Swoben* decision used the language that it's deliberate design. But that's not a standard False Claims Act. Intent is not a requirement. Knowledge is.

Kaiser, through its own audits, and through industry knowledge, knew of high error rates. They decided to correct only the ones that would help them. They decided to ignore the

ones that wouldn't.

And that's been held to be an FCA violation, nearly every time a court has seen this. Be it ***Poehling***, ***Swoben Ormsby***, or ***Anthem***, most recently.

THE COURT: What about the question of materiality? Why wouldn't the cause of those error rates -- you're saying it's irrelevant. As long as it's error, that's it?

MR. VOLDMAN: So I'm saying that as long as Kaiser knows that it violated CMS or ICD guidelines, it's true that there's going to be several reasons that is. Whenever that's true in a RADV audit, there's no distinguishment in whether they take money back because it was the wrong provider type, or whether it was a clinical condition, or whether it wasn't diagnosed in the medical record.

And when OIG does similar audits, they ask for money back for the same reasons. Because they didn't meet the type of guidance and documentation standards set up by CMS.

MR. PORTNOI: Your Honor, briefly?

THE COURT: Yeah, briefly. Then I'm going to move on to the next --

MR. PORTNOI: Absolutely.

THE COURT: Yeah.

MR. PORTNOI: Your Honor, Mr. Voldman's complaint doesn't match what he just said. There is no allegation that the errors necessarily were violations of CMS guidelines or ICD

guidelines. They're just errors.

They're just: We don't -- far from what ought to be there, which is that they violate a particular kind, they -- they instead are -- they simply are error rates without any subsequent, subsequent explanation.

And keep in mind, Dr. Taylor was effectively the director of coding. He knows what these errors are. He states that he looked personally at 100 claims, and found that ten of them had errors. He knows what they are. He just does not want to allege them, for reasons that I don't know. But this complaint has already been amended before. There was the opportunity to do so.

So Your Honor, there needs -- there does need to be an allegation regarding the why of falsity, and the error.

MR. VOLDMAN: I'm sorry, Your Honor --

THE COURT: In particular, you're saying that there is no allegation of, for instance, an ICD guideline violation. Or the reg.

MR. PORTNOI: When they're talking about error rates, they don't explain anything about what those error rates mean.

THE COURT: All right. Brief response to that.

MR. VOLDMAN: Sure. In the complaint, we explain the CMS rules, the CMS need for accuracy, and the attestation standard for accuracy. And then, it's true, we reference errors obviously against that standard.

It's true if you pick it apart paragraph by paragraph, we don't redefine what "error" means in each paragraph. But the complaint, seen as a whole, clearly lays out a standard for accuracy as required by CMS. And "error" means a violation of that standard of accuracy.

MR. PORTNOI: But Your Honor, they're quoting -- they're quoting supposed Kaiser employees, whether it's KFHP or Kaiser Colorado, and saying that there's an error here. But they don't -- they're not saying that that error that the person is talking about in some audit relates to a CMS or ICD guideline. They don't know.

They do know that Dr. Taylor reviewed some of these charts, and they know what Dr. Taylor thought when he reviewed those charts, and what kind of errors were there. They just don't allege it.

THE COURT: Let me ask counsel for Taylor, can you identify it so I can look at it later, what are the paragraphs that state that these high error rates, these one-sided error rates that weren't adjusted for, were those that violated, for instance, ICD guidelines or regs?

MR. VOLDMAN: So beginning at Paragraph 93, we state that a lot of these audits were simulated RADV audits, which is clearly the same standard as Mr. Portnoi pointed out that is pled in other complaints.

And then, by Paragraph 107, we go on and -- 106, we go on

to compare internal versus external providers against that standard. "Error" clearly means in a hypothetical practice RADV audit here.

It doesn't mean -- and Mr. Portnoi, of course, isn't laying out what else it could mean. He's just saying that we didn't define "error" every time we used it.

THE COURT: I mean, it has error rates, but where does it say that the error rates were for -- were the result of, for instance, non-compliance with ICD guidelines?

MR. VOLDMAN: So the RADV standard is the standard that CMS puts out for plans to comply with CMS standards, and that's discussed in Paragraph 93 as what the probe audits are preparation for. And then, the results of the probe audits, or least amalgamations of them to show year-by-year trends, come in Paragraphs 106 and 107, for example.

And there are other places in the complaint as well where specific hospitals, for example, in 109, show that the probe audit found very high error rates. In, for example, St. Joseph, one of the hospitals in the chart review program.

But probe audits begins to be defined in Paragraph 93 as the reason -- they match RADV standards, or are meant to simulate RADV standards.

THE COURT: All right. I'll take a closer look at that. Thank you.

MR. VOLDMAN: Thank you.

THE COURT: Let's go on to the Bryant and Hernandez motion here.

Let me make sure I understand what the scope of the complaint is in this particular instance. There's a lot of focus on aortic atherosclerosis, and vent dependence.

Is that the focus in terms of the problem areas here? Or is it a broader focus on all sorts of other things?

MR. LEWIS: It is a broader focus, Your Honor. I think when we were pleading the Medicare Advantage part of our case, or actually amending our complaint to plead it, we recognized that we weren't the first to file on a number of diagnoses, so we pleaded it, AA and vent dependence in particular, as to Medicare Advantage.

But now that we're limited by the first-to-file order to Affordable Care Act, certainly those two diagnoses are relevant to the Affordable Care Act, as well as are all our other allegations that there was systemic fraud on the ACA program -- and on Medicare Advantage, frankly, but obviously Your Honor has limited our claims at this point to ACA -- arising from Kaiser's, you know, systemic over-coding, over-documenting, over-submitting, of a whole bunch of codes impacting their risk adjustment portfolio and rating relevant to the Affordable Care Act.

THE COURT: So your complaint under the ACA is not restricted to AA and vent dependence; those are just examples?

MR. LEWIS: Those are just examples, Your Honor. And the vent dependence is a particularly good one for the Affordable Care Act, because it was a scheme that was implemented particularly on newborns, a population that would not be relevant to Medicare Advantage, but is certainly relevant to Affordable Care Act

Risk adjustment of newborns is a -- and gaming that system would be an Affordable Care Act issue, in particular. It was migrated eventually to Medicare Advantage as well, so it's relevant there. But, certainly as to Affordable Care Act.

THE COURT: All right. Let me hear defendant's response.

MR. PORTNOI: Your Honor, the main issue here is that we don't have -- we don't have -- as said in our papers, the relators don't identify a single allegedly fraudulent code or a single attestation that was submitted to HHS under the ACA's risk adjustment program.

Your Honor recognized in the first-to-file order that the ACA claims state causes of action entirely different and distinct from the Medicare Advantage claims. It's not enough to simply describe conduct that mostly related to the Medicare Advantage program -- as Mr. Lewis just described, the amendment was made to migrate, to bring it over to the Medicare Advantage program -- and then simply allege that the fraud on the ACA program was the same. That we have simply tacked on

allegations that fail to satisfy both Rules 8 and 9.

And so, no, Your Honor, I don't -- it simply doesn't work. And especially, for instance, doesn't work for materiality allegations. We don't have any statement here that HHS finds these materials. We don't have a statement that HHS has ever brought a single enforcement action or sought a single refund from anyone for an ACA claim. And that makes good sense. There's a reason that it would be different.

The materiality analysis would be different, Your Honor. And that's because the government doesn't keep the money. The money goes to HHS, and then HHS distributes it to other providers.

In fact, Your Honor, with respect to the ACA commercial risk adjustment program, some -- some -- some companies receive funds out of this, and some companies give funds in. The complaint doesn't even allege that for any particular year, Kaiser received a penny out of this program.

THE COURT: Well, net. I mean, net-wise. But there is -- there is some transfer of payment. There is payment, is there not?

MR. PORTNOI: If your population in a particular state, Your Honor, is -- is less healthy than the average, then you -- then you are -- then you are a recipient. If you are more healthy, then you -- then you provide -- then you pay -- then you pay money in.

There simply isn't even that allegation to allege that Kaiser made a claim, much less a false claim, here. And that's simply -- that's fatal to this complaint.

With respect to AA and vent dependence, Your Honor, it's important to note that what the complaint is alleging is not in this case a violation even of the ICD guidelines. What we're talking about is a HEMA guidance, guidance of a third party, often in emails that were simply sent on, not in something that was published.

This would require -- under the relators' theory, the company could be sued under the False Claims Act for violating any standard posted to the internet by anybody. And that similarly does not get you to a False Claims Act claim with respect to either aortic atherosclerosis or vent dependence.

THE COURT: Let me hear the response, that given the ACA context, there are lots of elements missing here. Payment, materiality.

MR. LEWIS: Yes, Your Honor. Thank you.

Well, first of all, Kaiser would have the Court ignore all the details in our complaint that are true-up and apply to both ACA and Medicare Advantage fraud.

You know, while we are foreclosed at this time by the Court's first-to-file order from pursuing claims based on Medicare Advantage fraud, the mechanics of the fraud is essentially the same. Committed by the same Kaiser personnel,

corporate entities, and the same --

THE COURT: But the payments, it's a different source, and a different submission source.

MR. LEWIS: Yeah.

THE COURT: How do you deal with that?

MR. LEWIS: So, what -- what Kaiser benefited from, from its risk adjustment fraud, the same fraud as it relates to the ACA, is that it got more of the pool than it should have gotten.

Sometimes it got payments from the pool or sometimes it -- and those payments were too high. Sometimes it had to pay into the pool, but those payments were too low. Either way, it benefited. And that pool is populated in part by federal funds. In the form of premium -- premium contributions and tax breaks that the government provides to beneficiaries. That's the false claim. It happens at least every year when Kaiser submits what it's owed or not owed from the fund.

And frankly, Your Honor, it may be that there are many false claims that underlie it, every time, for example, they submit a risk adjustment code that's non-bona fide. But, at least those claims are false.

And they are also material, Your Honor. The ACA, itself, makes clear that payments under the ACA are subject to the False Claims Act. And it goes on to say in that same section, that payments are material. That -- I'm sorry -- that the idea

of qualification of the entity is material to payment.

So, defendants would say that's not a sufficient statement of materiality under the statute, and we would take issue with that. Because payments are subject to the False Claims Act, and are thus, per se, material.

We do allege in our complaint, Your Honor, in Paragraphs 152 and 154 that the United States, unaware of the falsity of the record statements and claims made, has paid money that it otherwise would not have paid.

In 154 we say that the risk adjustment attestation submitted by the Kaiser defendants each year are a reminder to the Kaiser defendants that -- their obligation to submit valid data and to promptly correct invalid data. They also have a direct impact on the government's risk adjustment payments.

Now, we use CMS and the Medicare Advantage program as examples in those paragraphs. It's true. But we were alleging more broadly that they're material to both programs.

THE COURT: What's an example of a false statement submitted to -- I guess it goes to HHS?

MR. LEWIS: Yes, Your Honor. Yeah.

THE COURT: Where do I see that in this -- I know you do it by analogy to CMS and Medicare Advantage, but that's by analogy. What -- where is you have to allege a false payment and false submission of a claim here to the funding agency?

Where do I find that?

MR. LEWIS: I think the best source, Your Honor, would be in some of the opening paragraphs. And if our language is inadequate, we can certainly amend.

Paragraphs 7 and 8, 10(b), and 49 and 50 all allege sort of the basic mechanics of how the ACA works. Including that the insurer makes claim into the pool for funds that it's owed, or less funds that it's not owed, based on its risk adjustment portfolio as --

THE COURT: What is the role of the ICD guidelines with respect to the ACA and submission to HHS?

MR. LEWIS: Yeah, the ACA makes clear in its regulations that they're incorporating ICD and the Medicare Advantage standards into the acts. And we cite the CFR sections for that proposition, Your Honor.

Let me get --

THE COURT: So that is the source of the falsity? I mean, that's the connection. That if it's false -- if it was a false claim -- would have been a false claim with respect to CMS, because the same requirements under the Medicare Advantage and the ICD standards apply, that submission in violation of those standards, HHS was also false claims.

MR. LEWIS: I think that's right, Your Honor.

THE COURT: There's no independent -- that's your bridge. The incorporation of Medicare Advantage and the ICD guidelines.

MR. LEWIS: At this time, Your Honor, that's what we have.

THE COURT: All right. So what's -- let me ask defendant, what's wrong with that?

MR. PORTNOI: Well, Your Honor, these regulations are not cited in the complaint as demonstrating the falsity, so this is something that -- and there's -- they don't say anything saying that there's an ACA regulation that applies the ICD guidelines, in total.

But going to materiality, which makes this a much easier case for you, Your Honor, *Escobar* stated that a threadbare recital that the government would not have paid a claim if it had known of the conduct is insufficient.

We don't have a threadbare recital, Your Honor. We don't have a single paragraph, we don't have a single sentence, we don't have a single word that says that HHS would not have done something, that HHS might not have done something, that HHS had the power not to do something. The latter of which would be far from sufficient.

Again, in all of those things, if that threadbare recital were present, the complaint would still be insufficient, because it would lack facts that meet what the Supreme Court called the very demanding standard of materiality. Facts that give rise to an inference that HHS, in fact, would not have paid the claim. Facts that would include situations where HHS

has asked for money back in the past, situations where HHS has taken enforcement actions, situations where HHS has issued advisories on this issue, or situations where there have been prior FCA actions on this.

And they don't have that. I'm not hearing that they plan to amend to add those in. And on that basis, any amendment would be futile.

MR. LEWIS: Your Honor, just to respond quickly?

THE COURT: Yeah, I take it your assertion is that: Well, if it's material under -- with respect to CMS, under, under Medicare Advantage program, it would be -- you can infer it would be material to HHS, under the ACA.

MR. LEWIS: If they're material under one program they're material to both, because the HHS, which by the way CMS is a division of, said at 45 C.F.R. 153.610 that it herits (Phonetic) to the criteria and methods of the Medicare Advantage program, are mandated for ICD compliance under the ACA.

So yes, the answer, in short, is yes. And in terms of amendment and futility, Your Honor, obviously if Your Honor finds what we have already alleged to be insufficient, which we don't believe to be true, we would certainly review contracts, language and the regs even more thoroughly, and find potentially some more things to put in the amendment.

THE COURT: I guess, you know, you're asking for an

inference and an equation, but how do we know that? I mean, we don't -- there's no history cited. There's no -- I don't remember if you cited a regulation from HHS.

MR. LEWIS: Yes, we do. We do in our brief, Your Honor, 45 C.F.R. 153.610.

THE COURT: That's not in the complaint.

MR. LEWIS: That's correct.

THE COURT: And you would cite that that reg enforces your equation, your ability to sort of import CMS/Medicare Advantage.

MR. LEWIS: That's a reg that gives the folks that are contracting with our issuers like Kaiser the ability to import ICD rules into their contracts, just like they do for Medicare Advantage. And if given the chance, I think we can establish that those terms, in fact, wound up in those contracts.

THE COURT: All right. Well, this is helpful. At least I understand the parties' position.

MR. PORTNOI: Your Honor, may I make a brief point?

THE COURT: Yeah, briefly.

MR. PORTNOI: Well, the first issue is, again, none of that -- even if the regs say what he says, again, having not been pleaded, that none of that gets to materiality. These are still two entirely different programs.

And critically, that is what got this complaint past the first to file, is the idea that these are different programs

that make different calculations, and that there are fundamentally different schemes that Kaiser engaged in for both.

And to be honest, there's a potential judicial estoppel problem here, and there's a problem where potentially what we have is that the first-to-file order may have been based on the premise that these are entirely different programs and entirely different schemes, and we may -- and that, as a result, that may be something based on these new representations that requires a different result for the first-to-file order.

MR. LEWIS: All we said, Your Honor, is they were entirely different victims. A risk adjustment scheme was perpetrated on two different government victims, in much the same way. And we said that in the prior briefing, and in this one.

THE COURT: Well, all right. I'm not sure I see a judicial estoppel question, but I do see a potential factual question, that you're presuming that what is material in one context is material to an agency in a different context. And perhaps that can be inferred, but it's -- that does take an inference here.

MR. PORTNOI: And Your Honor, we just heard, there are two completely different victims.

THE COURT: Well, different victims, but it may be a parallel program, so one could presume or infer that they might

act in the same way.

If, for instance, ICD, particularly the -- you would say it's not important, they would say important -- aspects of the IDC (sic) guidelines is central to documenting entitlement.

You know, whether it is as important to HHS as it is to CMS, you know, I guess they would say the regs indicate so. But I'm not sure. I'll have to take a closer look at that.

MR. PORTNOI: Thank you, Your Honor.

THE COURT: Thank you, counsel. I know there's a lot of other things we didn't cover, but this was very helpful in at least covering the high points. And I needed to hear from the parties. So I thank you for your input.

I'll take the matter under submission. Thank you.

(Counsel thank the Court)

(Proceedings concluded)

CERTIFICATE OF REPORTER

I, BELLE BALL, Official Reporter for the United States Court, Northern District of California, hereby certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/s/ Belle Ball

Belle Ball, CSR 8785, CRR, RDR

Monday, November 21, 2022