False Claims

CALIFORNIA LEGAL HISTORY WAS MADE LAST MAY WHEN THE ATTORNEY GENERAL'S OFFICE and a medical testing company agreed to settle a false claims dispute for a record-setting $241 million. During our roundtable, counsel for both the whistleblower and the accused companies debated the impact of *Hunter Labs* on false claims cases. ((*State of California ex rel. Hunter Labs. v. Quest Diagnostics, Inc.*, No. CIV 34-2009-00048046 (Sacramento Cny. Super. Ct.).)

Our panel of experts also discussed the role of the relator, and state versus federal FCA cases. They are Shawn Hanson of Akin Gump Strauss Hauer & Feld, counsel for LabCorp; Niall McCarthy and Justin Berger of Cotchett, Pitre & McCarthy, counsel for Hunter Laboratories; Frederick Herold of Dechert, counsel for Quest Diagnostics; Robert Nelson of Lieff Cabraser Heimann & Bernstein; and Sara Winslow of the U.S. Attorney's Office. The roundtable was moderated by *California Lawyer* and reported by Krishanna DeRita of Barkley Court Reporters.

EXECUTIVE SUMMARY

MODERATOR: How has the *Hunter Laboratories* case, as well as other cases, affected false claims cases and policy issues in California?

McCARTHY: The *Hunter Labs* case—despite having highly skilled defense counsel—resulted in a significant monetary recovery. But more importantly from our perspective, the case exposed a flaw in the medical billing system where, as a result of referral agreements, the government pays several times more than what private companies pay for the exact same service. As a result of the light shed on that case, we are seeing changes in the billing practices for medical services.

BERGER: There is renewed focus on low-price laws—many of which have lain dormant for years if not decades—and not just in the health care industry. We also see renewed focus on more subtle violations of the anti-kickback laws. There's been a tendency in the past to focus only on anti-kickback violations that deal with nothing more subtle than envelopes stuffed with cash.

NELSON: Are you pursuing those?

BERGER: Yes. For example, one case just came out from under seal in the Central District dealing with the lab industry and a swapping arrangement for Medicare services. (*United States v. Kan-Di-Ki, LLC dba Diagnostic Laboratories and Radiology*, No. 10-CV-965 (C.D. Cal. order unsealing file issued Nov. 15, 2011).) It's being prosecuted largely as a kickback case. Another effect of the *Hunter Labs* litigation in coming years may be a shift from people focusing solely on the federal act while forgetting the state acts and the very capable state government attorneys. We may experience more state-only false claims.

WINSLOW: In California, Medi-Cal is half federally funded so those claims can also be brought under the federal FCA. Particularly when you are dealing with more than one state, it can be helpful to also bring it to federal court, and then you can assert both a federal and state FCA claim.

HEROLD: I represented Quest Diagnostics in the *Hunter Labs* case and a few things need to be very clear before we talk about how it's influenced behavior. First, there was no finding of liability or wrongdoing during the entire course of the case. There was no admission of liability. There was a settlement. The reason the dollars get so big in Medicaid cases is the long statute of limitations in the False Claims Act and the very large volume of Medicaid business over time for a lab like Quest Diagnostics—the largest clinical lab in the world.

The *Hunter Labs* case is not about the amount of settlement dollars, but how the FCA is a very bad substitute for clear regulation. What Justin [Berger] described as a lowest-price regulation, which it is really not at all, is a regulation that requires clinical labs and other providers to give the same low price to Medi-Cal that it gives to others under "comparable circumstances." What is a "comparable circumstance?" There's been very little case law on that since the regulation was issued in the late 1960s, and so the entire lab industry has been struggling with how to define "com-

parable circumstances" for years. Several labs went to the agency years before the lawsuit and asked for clarification and basically received none. The DOJ of California intervened in the *Hunter Labs* case without talking to the agency about their interpretation of this ambiguous regulation. When the agency found out about the lawsuit, it finally took a position on the regulation by sending letters to every lab in California threatening suspension if they didn't immediately change their billing to comply with the interpretation of the regulation set forth in the *Hunter Labs* complaint.

When defending a public health care company that's received a suspension letter from Medi-Cal and is facing an FCA case with the usual large penalties, it's difficult to do anything but go to the settlement table. The settlement amount, although large, was a fraction of the claimed damages in this case. Worst of all, despite the litigation, the key legal issues have still not been resolved. The Quest and LabCorp settlement agreements are very explicit that both the labs and the regulators can litigate about the meaning of the regulation through declaratory judgment or recoupment actions without threat of suspension or an FCA case for a period of years. We are finally trying to clarify this regulation so that the industry and the regulating agency can be on the same page with respect to future behavior.

HANSON: As a lawyer for LabCorp your views are well taken, but the future of cases like *Hunter Labs* is interesting to consider. One, the U.S. Chamber of Commerce wants to cap relator awards at $15 million. That would provide sufficient economic incentive for relators, but leave more dollars in the government's pocket than in the relator's pocket. You may see those initiatives both federally and on a state level.

A recent case out of Virginia has some similarities to *Hunter Labs* in that the violation was of DME regs and there was a lot of historical back and forth between the regulatory agency and the providers. In that case, the District Court acknowledged the remarkable nature of the civil penalties. It held that they likely violated the eighth amendment. Some cases have looked at alternatives to per claim civil penalties and proposed penalties driven by the overall nature of the relationship. (*United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, 2010 WL 4688977 (E.D. Va order on summary judgment Nov. 10, 2010).)

McCARTHY: The Chamber's proposed caps on relators is preposterous unless the Chamber wants to put a cap on how much fraud its members commit by taking taxpayers' money, which I'm sure they're not willing to do. The Chamber's proposal shouldn't get any substantive review in Congress. On the issue of *Hunter Labs*,

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the defense contended there was no liability. We contended there was, and I agree with Fred [Herold] that the settlement says there's no liability finding. Putting aside the *Hunter Labs* case, and speaking generally, the needed reform is more prosecutions of company executives. You have CEOs and CFOs who are aware that taxpayer money is being misappropriated and do nothing about it. Right now it's just a cost of doing business. If you take $200 million and you pay back a hundred million, you are still doing pretty well if no one goes to jail. I'd like to see more criminal enforcement in cases involving a misappropriation of funds.

HANSON: The proposal with respect to the cap will leave the teeth as they are. It's just who gets the benefit of those teeth, whether it's the relator or the government.

NELSON: Perhaps as a result of *Hunter Labs* any regulatory ambiguities that may have existed will be cleared up. That's a positive.

HEROLD: It *is* a positive when the government decides to clarify ambiguous regulations, but it's a tough pill to swallow for clients who have to go through years of litigation in order to get these reforms. Especially when the client did the responsible thing years ago by going to the agency and saying, "This is ambiguous. This is how we interpret it. Can you tell us if it's okay?"

In a lot of the state DHCS employee depositions, the DHCS folks said, "We don't provide clarification. That's not what we do." We should take the *Hunter Labs* case as an illustration that the system needs change. Relators initiate around 85 percent of the cases that go forward. It didn't used to be that way. The system is set up so that there's no formal opposition on the other side—other than a meeting with the government without the benefit of any discovery of the regulatory agency—prior to the government's decision to intervene.

WINSLOW: I can't think of a situation in 15 plus years of litigating these cases where my office has intervened without first getting a partial unsealing and talking to the defendant if they want to talk to us. There have been times when we have met with defense counsel and they've convinced us—because of something that we didn't know and the relator didn't know—it's not a case to proceed on.

HEROLD: But often the government has spent years hearing one side. It has subpoena or CID power and obtains documents to build its case. It's an unbalanced situation. The government and a relator who have invested a lot of time and are seeking a lot of money, have an incentive to say they were unconvinced by the defendant.

WINSLOW: It works the same way when it's not a qui tam. When a plaintiff brings a case, the defendant generally doesn't get discovery until after the complaint is filed and served.

HEROLD: The difference is that in the qui tam case, the government gets discovery of the defendant through the issuance of CID's and the defense does not get discovery of the regulators until very late in the game. It's worth having a debate about whether this is a good system. Often all we hear about is how much the government has recovered in qui tam cases. Pull out any article and they always start with the same thing: settlement recoveries. But that doesn't tell me anything about the merits of any case.

McCARTHY: Initially, I disagree that there's no correlation between money paid and liability. It's very common for corporations to say, "It was just the cost of doing business." That's just corporate spin. Next, the system is set up so the government and the plaintiff can get some discovery into this non-public fraud before the government decides whether it wants to intervene. By definition, the defendant has all the information with respect to the charging allegations. The defendant has an advantage and the government and the relator are trying to put the pieces of the puzzle together.

I also disagree that regulation involved in *Hunter Labs* was ambiguous. In fairness to California, their position was that they didn't need to provide clarification because the statute was clear on its face. We have seen a very creative defense emerge in the past five years. No matter what the statute says, the defense argues the statute is ambiguous and if it's ambiguous, there can be no intent, and if there's no intent, there can be no false claims violation.

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NELSON: In my last three major qui tam cases, the alleged ambiguousness of a regulation has played a major part in the company's defense. And each case settled for significant monies. If there really is ambiguity, then you've got a good defense. But I would assume that in part because you didn't feel confident in that defense in *Hunter Labs*, you settled. You may not want to admit it and your client may not want to admit it because you need to say what you need to say publicly, but the reality is there has to be scienter to be liable under the FCA. My experience is that companies make a judgment as to settlement based on how confident they are in that defense. Your client likely knew that its conduct could have been perceived to cross the line and its decision to settle reflected that judgment.

WINSLOW: This ambiguity defense has been around forever. It's an argument in the defense counsel's arsenal, and they probably ought to make it whenever there's any potential ambiguity.

HANSON: It's getting renewed interest because more cases are getting filed based on contract terms or regulatory issues and it's part of the FCA expansion into those areas. There's a recent case from Mississippi (*United States ex. rel. Jamison v. McKesson Corp.*, 784 F. Supp.2d 664 (N.D. Miss. 2011) that speaks to this objective standard in both a regulatory and contractual setting. The court held that an FCA violation could not rest on the government's subjective interpretation of its regulations and its contract, but there had to be an objective determination that there was a false claim. It granted judgment on the FCA based on that theory. We are going to see that case law getting a lot of focus.

It's hard for defendants now, in light of both cases, regarding what to do when you send a letter to the regulator and don't get a response. Historically, if you call the issue to the regulator's attention and they continue to do business as usual, you got your answer. Now people will be wondering, "Do I conduct business as usual or do I have to file a declaratory relief action?" That would have the benefit of working things out on the merits by a court without the pressures of the FCA case.

NELSON: It seems to me that if a defendant files a declaratory relief action to seek clarification of a regulation, then it would be very difficult to bring an FCA action against that company.

WINSLOW: It's going to depend on the facts, too. Did they ask the right office? Is it the same people who are paying them? These are very fact specific inquiries.

BERGER: Who the letter is addressed to is of key importance. Some of these departments and agencies get literally dozens or hundreds of letters of inquiry, and if it's not directed to the right person, and if there's no follow up, naturally there's not going to be a substantive response.

HANSON: If that's the state of affairs, then is it right to bring the full force and effect of the FCA against anybody? It is pretty draconian, and emerging case law will look at what transpired between the regulator and the company.

WINSLOW: I would want to know before deciding whether to intervene if the company contacted the wrong office on purpose to cover their butts or were they really trying to get an answer and the agency was being obstinate? If I were advising a company in that situation, I would ensure they had contacted the part of the agency that deals with payment and said, "This is what we are doing. Is there a problem?" in writing. If they don't get a response, do it again and maybe a third time. In a case like that, I would think the government would not be likely to intervene.

McCARTHY: The key to Sara [Winslow]'s point is what was disclosed to the government, and in *Hunter Labs* we disagree as to the scope of the disclosure.

HEROLD: That's a fair statement. Also before it intervenes, the government has some obligation to ask the agency, "What's your interpretation of this regulation? What's the history? Has the industry come to you with their point of view?"

BERGER: The government has done that in all of my cases. To their credit, the government is very careful with these intervention decisions. They only intervene in around 20 percent of the cases, and that includes intervention after the unsealing or on the verge of settlement.

WINSLOW: There's no one here from the state of California to tell us what they did, but my office and the U.S. DOJ would always consult the agency. We can't not consult the agency. We don't get authority to intervene unless the agency weighs in.

HEROLD: When representing corporate defendants, the calculus is not simple and includes all the uncertainty in litigation often involving a jury. In an FCA health care case, a company can go out of business because of the volume of claims and the threat of suspension. As a result very few corporate FCA cases go to trial, but a settlement does not mean the company secretly thinks there is liability. It's a balancing of the risks.

What corporate FCA cases do go to trial? Very few. I can think of several cases where the government and a corporation settled, but when the government went to try individuals for similar fraud claims, they all got acquitted, the most prominent being the TAP Pharmaceutical "AWP" litigation in Boston. (*United States v. MacKenzie*, 01-CR-10350 ECF 705-720 (D. Mass jury verdicts July 15, 2004).)

WINSLOW: But acquittal in a criminal case does not speak to whether the company is civilly liable or not.

HEROLD: Nor does a settlement.

WINSLOW: Right. In settlements, defendants don't admit liability, but just because an individual is acquitted doesn't mean that the same exact jury wouldn't find the corporation civilly liable.

McCARTHY: Criminal prosecutions are few and far between in these cases, and as a result you don't have the deterrent effect that you should with the false claims civil action standing alone.

MODERATOR: What is the role of the relator in the government's investigations and litigation?

WINSLOW: The role of the relator in qui tam cases is always interesting to me—as government attorneys, we hear from both relator's counsel and defense counsel. And relator's counsel always

wants to be involved in our investigation, and defense counsel always wants to tell us what a horrible person the relator is and why we can't trust him or her. Usually neither of those reflects the point of view of the government lawyer.

Whether the relator is a bad person or not is largely irrelevant to us because I can't imagine a situation where we would proceed with a case based on uncorroborated allegations by a relator. No matter how trustworthy they are, they are inherently biased and stand to make a lot of money. We would never litigate a case just based on the words of the relator. We would have to have corroborating evidence.

It may be something defense counsel does for its clients, but it's not a productive way to spend the time that you have with the government lawyers. But if you have information about why you think the relator is wrong, certainly we want to hear that.

On the relator's counsel side, I'm not very likely to rely heavily on the relator during the investigation. Sometimes we need to because the relator may be the only insider to whom we have access or we need someone to interpret something we don't understand. But really we need to make a determination as to whether we can corroborate the allegations outside of the relator.

McCARTHY: The majority of the time the government and relator work together, but a segment of government attorneys view the relator as someone who is going to get too much of the government's recovery. Yet the relator takes a tremendous risk by bringing the case. No matter what the industry, he or she will never work in it again. So unless they are independently wealthy, they are doing this to a large degree because they believe in the cause. In your office, Sara [Winslow], is it attorney by attorney or is there a general rule that, "Let's develop a case on our own away from the relator?"

WINSLOW: There's no rule, but I think that our preference is to develop the case independently of the relator because it makes for a better, more defensible case. As government attorneys, we make the same amount of money whether we decline our cases or get billion dollar recoveries. If I can have the government or a disinterested third party review it rather than your client, I trust that more, and not because I think you are untrustworthy, but because some studies have concluded that even a small amount of money can subconsciously skew someone's view. Both relators and defendants have an inherent bias because there's money involved.

BERGER: We've had a mixed experience with government attorneys. Some don't require much input, but others rely on us heavily, especially in the more complicated industries and schemes where literally only an insider would be able to interpret a particular document or spreadsheet or know what particular acronyms mean.

NELSON: It sounds like you [Winslow] have a predilection to develop your case independent of the relator. Is that because you believe that the case has a better likelihood of success or somehow the government will have more credibility vis-à-vis the defendant if you conduct your investigation independently?

WINSLOW: If I'm asking for authority to intervene, I need to be able to say that I think we will win before a jury. And I don't think that's true if all we have to support our case is a relator standing to make millions of dollars. We need an independent perspective—whether it's a government person or better yet a third-party expert consultant telling us the allegations are correct.

NELSON: It makes sense that the government would want to independently verify what is being presented, and such verification is essential for any case's success. Most relators and their counsel would agree with that kind of independent approach. But typically when we bring a case on behalf of a relator, we have done our homework and will support the relator's position with extensive documentation. The idea of course is to give you a disclosure statement that provides considerable independent verification and corroboration of the relator's allegations.

HEROLD: I applaud and agree with what Sara [Winslow] said—the government attorneys should be convinced that a case is meritorious before they intervene. That is absolutely critical to the system working. And I agree that it's usually not in the interest of a defendant to spend time and effort criticizing the relator. I also applaud your comment that no matter the outcome in the case, government lawyers get paid the same. It's critical for government lawyers to have that approach. Often there is a sort of contest in qui tam cases, "Can I get the biggest recovery and get my name all over the press." Many lawyers who have made very successful careers as government prosecutors, or civil qui tam lawyers, later end up in law firms and start out with large salaries.

HANSON: Is there an increase in the number of people coming back to the government after it has made a decision not to intervene?

WINSLOW: It's as it has always been and for me it is pretty rare. It's also rare for relators to go forward after we decline. It doesn't happen often that the cases actually proceed for a long time. When they do and when the relators develop new evidence that we haven't seen, it's always been common for them to come back to the government and say, "We have this new evidence. Do you want to change your mind?"

BERGER: The government is also actively monitoring cases they don't intervene in, and not necessarily putting the case on the shelf if they don't have the initial ability to intervene. We are seeing more of that, where statements of interest are filed on briefs, and government attorneys coming to court on hearing dates even in the non-intervention cases.

HANSON: I haven't seen that as much.

WINSLOW: We do keep an eye on case law and sometimes some

bad law can be made in cases where the government doesn't intervene. So we like to weigh in on issues of law to monitor whether it's headed in an inappropriate direction. Sometimes we decline a case that we think has merit, but for reasons such as resources or policy we decide not to intervene. But we want to keep an eye on it.

BERGER: There is a body of case law developing where judges understand and assert that a government non-intervention should not have an impact on a court's ruling with respect to the merits of the case. For example, in *United States ex rel. Atkins v. McInteer*, (470 F.3d 1350, 1360n.17 (11th Cir. 2006)), the court of appeals emphasized that the United States' "absence from the fray" does not mean that the relator's claims lack merit. Similarly, in *United States ex rel. DeCarlo v. Kiewit/AFC Enterprises, Inc.*, (937 F. Supp. 1039, 1047 (S.D.N.Y. 1996)), the district court noted that, "Non-intervention does not necessarily signal governmental disinterest in an action."

HEROLD: I can give you many cases where the judges dismissed the case and probably will not say that they were influenced, but we all know they were.

MODERATOR: What are some of the new trends in false claims cases?

HANSON: We are going to see this year or next a broader set of cases brought by a broader set of relators in some interesting applications of the attorney-client crime fraud exception. There's not a lot of teaching about how that exception to the attorney-client rule overlaps with these issues, but those issues are going to ripen.

McCARTHY: There's a strong move towards filing cases in state court. Over half the states now have their own FCAs. A lot of states are trying to adopt the federal Fraud Enforcement and Recovery Act that was enacted in 2009, which made the federal law more conducive to plaintiffs. Washington state is trying to enact an FCA right now. I agree with part of what Fred [Herold] said—in these extraordinary budget times, due to the economic crisis in states, they are looking for sources of revenue and they are willing to expend time and energy prosecuting these cases.

NELSON: In California, we have an attorney general and insurance commissioner both very committed to whistleblower litigation, making this a particularly exciting time for those of us who represent whistleblowers. So I agree that we will see a good bit of activity state-side in the next few years, and much of it here in California.

BERGER: An issue that will change the landscape over the next few years is pressure on the government to decide more quickly whether or not to intervene. There will be shorter seal periods for cases as judges become more experienced with the False Claim Act and are less willing to rubber stamp a seal extension. Combine that with internal pressure in the DOJ and pressure from some U.S. senators to speed up things, there is going to be more pressure to shorten the investigatory period.

NELSON: Do you think this a good thing for relator's counsel or not?

BERGER: It's a mixed bag. In a lot of cases, we like that quick intervention decision, but at the same time we like the government to have plenty of opportunity to get comfortable with the facts and do their investigation. We don't want them declining something simply because they haven't been able to finish the last three months of their investigation.

HEROLD: There is a bill pending in the U.S. Congress called the Whistleblower Improvement Act (H.R. 2483) that relates directly to Dodd-Frank but has some interesting ideas that could apply more broadly, including a requirement that whistleblowers report alleged misconduct internally before going to the government. Other reforms might be making debarment harder for the government, strengthening the FCA intent requirement so that it applies only in egregious cases, and reforming the per-claim penalty provisions for health care fraud cases.

There are many health care FCA cases where the typical claim submitted by the provider is $50, but there are millions of claims. The $11,000 per-claim penalty exposure gets astronomical really fast, and as Shawn [Hanson] pointed out this raises constitutional issues. There's room for reform of the per-claim penalty provisions to get back to where the FCA originated—contracts with one or ten claims, not millions. It could be a carve-out or some separate treatment of penalties for high volume health care fraud cases.

WINSLOW: The Department of Justice now has civil investigative demand authority. We've always had it in the statute, but it was a non-delegable authority with the attorney general, so rarely used. You had to write this huge memo that went through a million people before it got to the AG and the AG has a lot of other things to do besides looking at your request to issue a civil investigative demand. But that's been delegated to the U.S. attorneys and the assistant attorney general. It's a much more streamlined procedure. We are able to use that authority and it's helping a lot in our investigations. ■