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Exclusive Coverage

California & Quest Diagnostics Settle Discount Price Lawsuit for $241 Million!

Also... Similar Lawsuits in Six Other States!

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THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

What Future for Deeply-Discounted Lab Prices?

IN THE LABORATORY TESTING INDUSTRY, there is probably no single issue that causes more rancor than the regular use of deeply-discounted pricing of laboratory tests by a certain cohort of laboratory companies.

This fault line in our industry is quite distinct. Those managers and pathologists in lab organizations that refuse to use low cost pricing as a way to win new customers and retain market share have a certain disdain for those lab companies and anatomic pathology companies that do. Because of the corrosive financial effects that such deep price discounting has across the entire laboratory industry, it is a constant and regular sore spot for those laboratories which don't discount in this manner—but must compete against lab companies that do.

This deep division involving either the willingness or the refusal to use deeply-discounted pricing for lab tests is the emotional dynamite that is associated with the whistleblower lawsuit in California. This lawsuit accuses multiple laboratory companies operating in California of violating a state law that, when a provider gives a lower price to another provider that is less than the Medi-Cal fee for that service, that provider must also give Medi-Cal that same lower price.

Now regulatory agencies in California—after several decades without effective enforcement of the state laws that address "comparable pricing"—are attempting to enforce their interpretations of these laws. The process has not been easy, either for state regulators or the lab companies that have been targeted for enforcement action. It has also been disruptive to the lab testing marketplace across all of California.

Further, it is still unclear if those lab companies which rely on deeply-discounted lab test prices to capture and hold market share will emerge from these court cases and regulatory enforcement actions with some type of competitive advantage intact, due to the specific terms of the settlement agreement they are able to negotiate with government officials in California.

On the other hand, California's enforcement efforts may cause Medicaid officials in other states to revisit enforcement of their own state's "comparable pricing" laws. If that happens, it could trigger a regulatory change in attitude toward the use of deep discounted lab test prices. In a perfect world, it might even cause Medicare officials to reassess the "fairness" of labs that often give favored customers lab test prices that are 40% to 60% of Medicare Part B lab test fees, but continue to bill Medicare at full price. TDR

Will Medi-Cal Price Case Bring More Enforcement?

Certainly California is poised to pursue labs for discounted pricing that it says violates 51501(a)

CEO SUMMARY: It was on May 19 that the California Attorney General and Quest Diagnostics Incorporated signed an agreement to settle allegations that Quest Diagnostics overcharged Medi-Cal, the state's Medicaid program. It is expected that the California Attorney General will now move to resolve the whistleblower case against the remaining lab company defendants. Meanwhile, similar whistleblower suits are ongoing in at least six other states across the nation.

FOR BETTER OR FOR WORSE, the long-running whistleblower lawsuit in California has produced a settlement agreement between the California Attorney General and the nation's largest laboratory testing company.

On May 19, national news outlets were quick to report that **Quest Diagnostics Incorporated** agreed to sign an agreement and pay $241 million to settle the case—even as Quest defiantly declared that it still denies all the allegations in the complaint.

By any measure, this settlement is a major milestone in the flow of events that was unleashed back in 2005. That's when **Hunter Laboratories, LLC**, and Chris Riedel filed, under seal, a *qui tam* lawsuit in a California court.

This original whistleblower lawsuit named seven laboratory companies as defendants. The plaintiffs claimed that, going back as far as 1995, these lab firms had violated several state and federal laws by giving favored clients a discounted price for a laboratory test that was less than the price they charged Medi-Cal, the state's Medicaid program, for that same test.

Now there is a settlement of these claims by one defendant. It involves payment of almost one-quarter billion dollars. On the surface, that may indicate there was substance to the allegations made by the plaintiffs in the whistleblower lawsuit.

On the other hand, the settlement payment represents only a portion of the maximum exposure Quest faced if it lost at trial. In the sixth version of the *qui tam* lawsuit that named Quest Diagnostics as a defendant, plaintiffs alleged that Quest

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

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Diagnostics had, for a 15-year period beginning in 1995, billed for, and was paid, more than $726 million by the Medi-Cal program. Plaintiffs asserted that this was a 90% overcharge to Medi-Cal, due to alleged violations of various state and federal laws. Plaintiffs sought to have the overcharges of $509 million returned to the State of California. With respect to certain claims, plaintiffs also sought treble damages and attorneys' fees. And, of course, Quest had to foot the bill for its own attorneys' fees regardless of the outcome.

As will be noted in the following pages, Quest Diagnostics emphatically denied all of the allegations asserted against it. Ultimately, Quest agreed to settle and pay $241 million—an amount that is only 47.3% of the full $509 million of alleged overcharges identified in the *qui tam* lawsuit.

With a potential exposure of one-half billion dollars, at a minimum, and a settlement that requires a payment of one-quarter billion dollars, it should be obvious to all pathologists and lab administrators that this story has important dimensions that need to be fully understood. This is particularly true for clinical laboratory executives who operate in California.

Moreover, there is evidence in the public record that similar whistleblower actions are taking place in as many as six other states, including the populous state of Florida. These whistleblower lawsuits are believed to center upon the common practice of offering discounted laboratory test prices to some providers while billing that state's Medicare program at a higher price for the same tests, allegedly in violation of relevant state statutes.

Monitoring The Outcome

For this reason, laboratory administrators and pathologists across the nation will want to monitor how authorities in California resolve the *qui tam* court case with the remaining defendants. As well, **California's Department of Health Care Services** (DHCS) will likely base its enforcement policies on the legal precedents that result from the collective body of settlement agreements that result from negotiations between the California Attorney General and the seven or more defendant laboratory companies.

Because this is a major lab industry story for California—and because this case has the potential to trigger similar enforcement actions in other states across the nation, this entire issue of THE DARK REPORT provides detailed information about different aspects of this situation.

Proper Compliance

For clinical laboratory executives who want to act in ways to keep their laboratories in proper compliance with state and federal laws, this issue of THE DARK REPORT presents information and analysis on several important aspects of this unfolding story. Our coverage is organized as follows:

Pages 5-7: basic facts about the settlement agreement announced by the California Attorney General and Quest Diagnostics on May 19, 2011.

Pages 8-11: the legal claims and positions of each party are identified, using information from the press releases and the "Settlement Agreement and Release." Among the legal issues in dispute, the California Code of Regulations, title 22, Section 51501(a) is most prominent.

Pages 12-13: a description of the steps that Quest Diagnostics has agreed to take, as described in the "Settlement Agreement and Release," including its reporting requirements to DHCS through November 1, 2013.

Pages 14-15: Analysis of how the California AG and the remaining defendant labs in this *qui tam* lawsuit may resolve their individual cases, given the terms negotiated by Quest Diagnostics in the "Settlement Agreement and Release."

Pages 16-18: An overview of the potential for other state and federal *qui tam* lawsuits to alter legal interpretations of when the use of discounted lab test prices violates existing state and federal laws involving Medicaid and Medicare claims. TDR

Quest Diagnostics Settles Medi-Cal *Qui Tam* Case

Press releases issued by both parties indicate it was a toe-to-toe legal slugfest to get a settlement

CEO SUMMARY: On May 19, the California Attorney General announced a $241 million agreement with Quest Diagnostics Incorporated that represents the largest settlement in the history of California's False Claims Act. At issue in this whistleblower lawsuit were allegations that Quest Diagnostics, along with multiple other defendant lab companies, had overcharged Medi-Cal, which is California's Medicaid program. In its public statements, Quest Diagnostics, denied any wrongdoing.

SAYING IT IS THE LARGEST RECOVERY in the history of California's False Claims Act, on May 20, California Attorney General Kamala D. Harris trumpeted news that **Quest Diagnostics Incorporated** would pay $241 million in a settlement over what the state alleged were illegal overcharges to Medi-Cal, the state's medical program for the poor.

One day earlier, Quest Diagnostics had issued a press release about the settlement stating that: "In the lawsuit, the plaintiffs alleged, among other things, that the company did not comply with California's 'comparable charge' regulations, resulting in overpayments for laboratory testing services by Medi-Cal, California's Medicaid program."

The Quest press release then addressed the allegations, declaring that:

"Our laboratory testing services for Medi-Cal were priced appropriately, and we deny all allegations in the complaint," said Michael E. Prevoznik, Senior Vice President and General Counsel of Quest Diagnostics. "Quest Diagnostics operates with the highest standards of integrity and fairness. California's interpretation of the Medi-Cal 'comparable charge' regulations created uncertainty and resulted in an intolerable business environment for us. This agreement allows us to put the lawsuit behind us and provides for an orderly process for resolving any remaining interpretation issues. We also intend to pursue other avenues, including legislative action, to ensure clear regulatory standards in California for the clinical laboratory industry."

That feisty statement indicates how Quest Diagnostics drew the battle lines in its legal defense. Also, it indicates that the nation's largest laboratory testing company may be prepared to push the state legislature to take legislative action and revise or rewrite the existing statutes which lie at the heart of this legal dispute.

'Dueling Press Releases'

In fact, the press releases issued by both parties to the settlement agreement demonstrate that there are two widely-divergent views on the matter.

In her press release, Harris stated that, "In a time of shrinking budgets, this historic settlement affirms that Medi-Cal

exists to help the state's neediest families rather than to illicitly line private pockets. Medi-Cal providers and others who try to cheat the state through false claims and illegal kickbacks should know that my office is watching and will prosecute."

Attorney General's View

Harris' press release also described the attorney general's view about the case, which read as follows:

The settlement with Quest is the result of a lawsuit filed under court seal in 2005 by a whistleblower and referred to the Attorney General's office. The lawsuit alleged that Quest systematically overcharged the state's Medi-Cal program for more than 15 years and gave illegal kickbacks in the form of discounted or free testing to doctors, hospitals and clinics that referred Medi-Cal patients and other business to the labs.

California law states that "no provider shall charge [Medi-Cal] for any service more than would have been charged for the same service to other purchasers of comparable services under comparable circumstance." Yet, Quest charged Medi-Cal up to six times as much as it charged some other customers for the same tests. For example, Quest charged Medi-Cal $8.59 to perform a complete blood count test, while it charged some of its other customers $1.43.

California law also prohibits Medi-Cal providers from soliciting and receiving "any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in valuable consideration of any kind [in] return for the referral, or promised referral, of any individual for the furnishing of any service" paid for by Medi-Cal.

An investigation revealed that Quest systematically offered doctors, hospitals and clinics low prices for lab tests in return for referrals to Quest of patients, including Medi-Cal patients. Quest then charged Medi-Cal a higher price to make up the difference—resulting in the loss of millions of dollars to the Medi-Cal program.

A review of the 21-page settlement agreement shows that, within 20 business days of May 20, Quest Diagnostics must make these payments: $171 million to the state of California, $69.89 million to the attorney for the whistleblower, **Hunter Laboratories, LLC,** of Campbell, California, and Chris Reidel. Quest Diagnostics must also pay reasonable fees and costs for the attorneys representing Hunter Laboratories and Chris Riedel, although the settlement agreement said the exact amount of this payment is under dispute.

Also, the settlement requires Quest Diagnostics to report information to assist the state in determining Quest's future compliance with Medi-Cal's pricing rules. Under the terms of the settlement, Quest must decide by August 31 whether to charge what California calls a Transitional Rate of 85% of Medi-Cal's fee schedule for claims dating through July 31, 2012. Or, Quest could decide to send written "Exception Reports" to the state every quarter until Nov. 1, 2013, for certain tests. Quest Diagnostics also must designate a compliance officer at Quest who would ensure that Quest complies with the terms of the settlement agreement.

Resolution to Lawsuit

This agreement resolves the *qui tam* case against Quest Diagnostics. In its May 19 press release, the company wrote:

The company agreed to the settlement to resolve claims pertaining to the 'comparable charge' allegations. The company also agreed to reporting obligations regarding its pricing for a limited time period and, in lieu of such obligations for a transitional period, to provide Medi-Cal with a discount until the end of July 2012. The company received a full release of all the claims alleged in the lawsuit.

For its part, the California Attorney General stated that similar cases are pending against four other clinical lab defendants, including **Laboratory Corporation of**

America. A trial in the LabCorp case is scheduled for early next year. Like Quest, the other labs also deny the suit's allegations.

Also in the press release, the attorney general noted that, in 2005, when Hunter Laboratories and Riedel filed the *qui tam* action under seal, they stated in the legal filings that they could not compete in a significant segment of the marketplace when major medical laboratories offered lower rates for laboratory tests to doctors, hospitals, and clinics than they charged the Medi-Cal program.

Can Bill For Medi-Cal Testing

In addition to stipulating how Quest Diagnostics must bill DHCS for serving Medi-Cal patients going forward, the settlement explained that Quest Diagnostics can now bill DHCS for the months when it continued to provide lab testing services to Medi-Cal but had not billed DHCS.

On September 28, 2010, Quest and DHCS had a "Stipulation and Settlement Agreement Between the California Department of Health Care Services and Quest Diagnostics Incorporated" in which Quest Diagnostics agreed not to bill DHCS for testing services for Medi-Cal patients, pending resolution of the whistleblower lawsuit and related issues. Suspension of billing for a government health program by a publicly traded clinical laboratory is a rare event.

In its financial report for fourth quarter 2010, Quest Diagnostics disclosed that, as of December 31, 2010, its unpaid balance with the Medi-Cal program was $25 million. This represented the unbilled claims for laboratory testing services performed on behalf of Med-Cal patients since the start of the temporary billing suspension earlier in 2010.

Billing Suspension Ends

To the $25 million from 2010 that went unbilled by Quest Diagnostics, there will also be added the amount that was unbilled for the first five months of 2011. With the end of this billing suspension, Quest Diagnostics may collect as much as $50 million from the Medi-Cal program for these claims.

Quest Diagnostics Denies "Liability and Wrongdoing"

IN THE "SETTLEMENT AGREEMENT AND RELEASE" negotiated between the California Attorney General and attorneys for **Quest Diagnostics Incorporated**, the nation's largest laboratory testing company was direct in denying all the allegations made in the whistleblower lawsuit originally filed by **Hunter Laboratories** and Chris Reidel back in 2005.

This language can be found in Section II-D, where it is stated that:

The Quest Defendants specifically deny any and all liability and wrongdoing. The Quest Defendants contend that:

(a) their billing practices were at all times in material compliance with Section 51501(a), industry practice, and all other applicable laws and regulations,

(b) several of the Quest Defendants specifically advised DHCS' predecessor agency of their interpretation of Section 51501(a) both in writing and in oral discussions starting in the late 1990s,

(c) their interpretation and application of Section 51501(a) was correct.

It is Quest's position that the Settlement Amount described in III-A below represents a compromise settlement under 51501(a). The Quest Defendants further contend that their conduct was at all times lawful and in compliance with applicable statutory and regulatory requirements, regulatory safe harbors, and the requirements of their Medi-Cal Provider Agreements.

As shown here, the "dueling press releases" issued by the California Attorney General and Quest Diagnostics over the same matter indicate that each party views this case from very different perspectives. This could be a sign that each party is prepared to strenuously defend their respective interpretations of 51501(a) and related state and federal laws. TDR

Understanding the Deal With Medi-Cal and Quest

➤Settlement terms may be applied to other labs operating in California, with interesting consequences

➤➤CEO SUMMARY: It is now possible to see the specific language in the "Settlement Agreement and Release" document executed by the California State Attorney General and Quest Diagnostics Incorporated. For those clinical lab managers—and the attorneys who represent their laboratory companies—there is mixed news and guidance about 51501(a) from this agreement. That's because, while assenting to pay $241 million to resolve these allegations, Quest Diagnostics denies any "wrongdoing."

FOR CLINICAL LABORATORY COMPANIES in California, no single issue is more important at the moment than the correct interpretation of state laws that spell out how providers must bill Medi-Cal, the state's Medicaid program, when they offer other providers a price that is less than the Medi-Cal fee schedule.

However, there is mixed guidance to be found on this point in the "Settlement Agreement and Release" document executed last month between the California Attorney General (AG) and **Quest Diagnostics Incorporated**.

Many in the lab industry expected that the first settlement between the California AG and one of the two blood brothers would provide some type of template or road map that the AG and the California **Department of Health Care Services** (DHCS) would then bring to bear against other laboratories facing allegations that they had overcharged the Medi-Cal program, in violation of state laws, including the statute commonly known as 51501(a).

Thus, the lab testing industry watched with strong interest when, on May 20, California Attorney General Kamala D. Harris issued her press release to announce a deal with Quest Diagnostics. What got most of the national press headlines was the fact that, under terms of the settlement agreement, Quest Diagnostics would pay $241 million. According to the press release, this would allow California "to recover illegal overcharges to the state's medical program for the poor."

➤Settlement Document

Along with the press release from the AG's office, a copy of the 21-page "Settlement Agreement and Release" document was made public. The document makes for interesting reading, and begins to open a window on some of the specific approaches that are likely to be used by either the California AG or the DHCS in their ongoing efforts to enforce 51501(a) and related state laws.

THE DARK REPORT contacted a number of attorneys knowledgeable about the general circumstances of the whistleblower lawsuit and the DHCS enforcement actions during 2010 with a request to discuss the specifics in the settlement agreement. However, as of press time, no

attorney was willing to go on the record with their observations or comments.

Neither were any attorneys with direct knowledge of this case willing to speak off the record about the document. In many cases, this was because these lawyers represent lab companies operating in California who are either defendants in the whistleblower lawsuit or are currently in negotiation with DHCS because of enforcement action notices sent by the state agency in 2010.

Key Points In Settlement

What follows are observations about the "Settlement Agreement and Release" document that should be useful in helping clients and regular readers of THE DARK REPORT understand key points. In future issues, we expect to have one or more attorneys provide their analysis of how certain legal issues were addressed in this document, which was signed by the California AG and lawyers representing Quest Diagnostics.

The first observation about this agreement and release is that Quest Diagnostics emphasizes that it denies "any and all liability and wrongdoing." The sidebar on page 7 reproduces the specific language from the settlement agreement that describes Quest Diagnostics' denial and its position on these legal points.

Is There A Legal Precedent?

It appears that the California Attorney General, in choosing to settle and not allow this case to go to trial, has missed the opportunity to possibly obtain a court verdict that supports the state's interpretation of 51501(a) and similar state laws that address pricing for Medi-Cal claims.

Thus, this important legal point seems to still be a contested issue, as confirmed in clause II-F of the agreement, which reads thusly:

This Settlement Agreement shall constitute neither an admission of liability by the Quest Defendants nor a concession by California or the Qui Tam Plaintiffs that any part of the Complaint lacks merit, and it does not constitute or contain any statement or interpretation of law. No one other than a Party to this Settlement Agreement is intended to receive any right or benefit under it or to have standing to enforce any of its provisions.

In the preamble of the agreement between the California AG and Quest Diagnostics, the specific acts in dispute were described in the language that is reproduced below. This information can help pathologists and clinical laboratory managers understand the nature of the actions that the state considers to be violations of the law:

II-C. California and Qui Tam Plaintiffs allege that the Quest Defendants submitted or caused to be submitted false claims for payment to the California Medical Assistance Program, which is California's Medicaid program ("Medi-Cal"), by allegedly engaging in the following conduct (hereinafter referred to as the "Covered Conduct"):

1. During the period from November 7, 1995, through the Effective Date of this Settlement Agreement (as defined in Section III-W below), the Quest Defendants (including the Quest Releasees as defined in Section III-F below) allegedly charged Medi-Cal more for laboratory tests than they charged other purchasers of "comparable services" under "comparable circumstances," in violation of California Code of Regulations, title 22, Section 51501(a) ("Section 51501(a)"), other regulations governing Medi-Cal, including without limitation, title 22, Sections 51480 and 51529, and the requirements of their Medi-Cal Provider Agreements.

2. During the period from November 7, 1995, through the Effective Date of this Settlement Agreement, the Quest Defendants (including the Quest Releasees) allegedly offered and gave capi-

tated and fee-for-service discounts on laboratory tests for non-Medi-Cal services in order to induce purchasers to refer Medi-Cal laboratory test business to the Quest Defendants, in violation of 42 U.S.C. § 1320a-7b, Section 650 of the California Business and Professions Code and Section 14107.2 of the California Welfare and Institutions Code, regulations governing Medi-Cal, and the requirements of their Medi-Cal Provider Agreements.

II-3. During the period from November 7, 1995, through the Effective Date of this Settlement Agreement, the Quest Defendants (including the Quest Releasees) allegedly engaged in the conduct that is alleged in the Complaint.

➤Useful Description

This description of alleged violations is helpful to laboratory executives because it identifies the specific laws and regulations—both state and federal—which the California AG argued were violated by the defendant laboratory company's use of discounted prices for laboratory testing. These are longstanding and widespread practices in California's intensively-competitive laboratory testing marketplace.

The list of laws that were alleged to have been violated is extensive. Not only does it reference 51501(a), but it also mentions Sections 51480 and 51529 of the California code, and inducements in exchange for Medi-Cal referrals in violation of 42 U.S.C. § 1320a-7b.

The other statutes referenced include Section 650 of the California Business and Professions Code and Section 14107.2, The California Welfare and Institutions Code, the regulations governing Medi-Cal, and the requirements of the Medi-Cal Provider Agreements.

The next clause in this section is II-D. This clause contains Quest Diagnostics' denial of these allegations. It is reproduced in full in the sidebar on page 7.

Having set out the allegations of wrongdoing, along with the denials of these allegations by Quest Diagnostics, the agreement next addresses actions that Quest Diagnostics must take. This includes payment of the $241 million, plus timely reporting and other requirements. These required actions are detailed in the following story, which is found on pages 12-13.

At the heart of the whistleblower lawsuit was the issue that the defendant laboratory companies failed to give the Medi-Cal program the same lowest price for a laboratory test that these defendant lab companies offered to other providers. Language in the "Settlement Agreement and Release" document indicates that the two parties still differ in their interpretation of that state law. It is mentioned in two clauses.

Each clause reserves the rights of one party. In the case of the California Attorney General and the DHCS, the clause is III-17, which states:

Nothing in this Settlement Agreement has any effect or impact on California's ability to pursue actions, claims, or remedies that are not explicitly renounced by Sections III.C.15, III.C.16, and III.C.19 of this Settlement Agreement. Without limitation, nothing in this Settlement Agreement shall preclude California from:

(a) initiating a proceeding to recover alleged Medi-Cal overpayments for an asserted violation of Section 51501(a) based on pricing disclosed in an Exception Report, or that is not required to be disclosed in an Exception Report (hereinafter a "Recoupment Action").

(b) withholding payments to a Quest Releasee, or (c) seeking or imposing temporary or permanent suspension, exclusion, debarment or deactivation of a Quest Releasee's Medi-Cal provider numbers on any grounds that may be authorized by law other than those explicitly renounced by Sections III.C.15, III.C.16, and III.C.19 of this Settlement Agreement.

...Without limitation, nothing in this Settlement Agreement shall preclude

California from seeking or imposing temporary or permanent suspension, exclusion, debarment, or deactivation of a Quest Releasee's Medi-Cal provider numbers for failure to pay or comply with a final order, judgment, or assessment that is made or affirmed by court or administrative tribunal of competent jurisdiction at the conclusion of the action or proceeding, including any appeals of the judgment, order, or assessment obtained.

This description of alleged violations is helpful to laboratory executives because it identifies the specific laws and regulations–both state and federal–which the California AG argued were violated...

The rights reserved to Quest Diagnostics are described in clause III-18, which is reproduced below:

Nothing in this Settlement Agreement shall preclude a Quest Defendant from initiating any proceeding that may be authorized by law that seeks a declaratory judgment or damages sustained due to the withholding by California (including by DHCS) of any portion of a Medi-Cal reimbursement payment based on California's or DHCS's contention that Section 51501(a), Section 51529(a), or Section 51480(a) of Title 22 of the California Code of Regulations precludes payment, in whole or in part, due to information disclosed in an Exception Report (hereinafter a "Quest 51501(a) Action").

The Parties agree that such a Quest Section 51501(a) Action shall be deemed untimely and therefore barred unless it is commenced within one year from such a withholding by California. To the extent permitted by law, the Parties further agree that following such a withholding, Quest may commence such a Quest Section 51501(a) Action in court without first having to exhaust any otherwise applicable administrative remedies and that California will, to the extent permitted by law, expressly waive any defense of failure to exhaust administrative remedies with respect to such an action so that the Parties may obtain an expeditious judicial decision.

Quest agrees that if it brings more than one Quest 51501(a) Action, it will stipulate to such total or partial coordination, designation as related 13 cases, or consolidation of those Actions as DOJ or DHCS may request. Quest further agrees that if it chooses to commence a Quest Section 51501(a) Action in court without first having to exhaust any otherwise applicable administrative remedies, it will commence all such Quest Section 51501(a) Actions exclusively in Sacramento County Superior Court.

The Parties further agree that DHCS will not temporarily or permanently suspend, exclude, debar or deactivate any Quest Releasee (or its Medi-Cal provider number) due to the mere filing or pursuit of a Quest Section 51501(a) Action.

Quests' Right To Challenge

One way to read this clause is that Quest Diagnostics is keeping its legal powder dry and preserving its right to challenge decisions made by the California Department of Health Care Services that involve the agency's interpretation of 51501(a) and related laws.

These sections are followed by language in the "Settlement Agreement and Release" document that are a series of releases among the parties. Overall, this document illustrates how differently each party to the agreement viewed the issues in dispute. Because smaller laboratories typically cannot afford the legal resources deployed by Quest Diagnostics, it will be interesting to see if their settlements with the state turn out to have different conditions. TDR

Quest Diagnostics to File Regular Reports with DHCS

➤Exception reports and transition rates are described in the settlement agreement

➤➤CEO SUMMARY: Pathologists, clinical lab executives, and lawyers in California are going to find some surprises when they study the "Settlement Agreement and Release" that was recently signed by the California Attorney General and Quest Diagnostics Incorporated. Quest Diagnostics has indeed agreed to pay $241 million to resolve the allegations in the whistleblower lawsuit. But this agreement reveals that both parties continue to disagree on the interpretation and enforcements of 51501(a).

WHAT, EXACTLY, ARE THE TERMS of the "Settlement Agreement and Release" document, dated May 19, 2011, that was negotiated between the California Attorney General (AG) and **Quest Diagnostics Incorporated**?

This question is foremost in the minds of clinical laboratory executives in California and their attorneys. At the core of the *qui tam* case filed in 2005 by whistleblowers **Hunter Laboratories, LLC**, and Chris Riedel—and later joined by the California Attorney General (AG)—is California Code of Regulation, Title 22, section (22 CCR §) 51501(a).

➤Settling 51501(a) Allegations

The language of 22 CCR § 51501(a) describes how a provider, like a clinical laboratory, is to give the Medi-Cal program the same discounted price that it extends to other providers. 51501(a) states, in part that "Not withstanding any other provisions of these regulations, no provider shall charge for any service or any article more than would have been charged for the same service or article to other purchasers of comparable services or articles under comparable circumstances..."

In the "Settlement Agreement and Release" document, it is written that Quest Diagnostics specifically denies the allegations of the lawsuit, certain of which are repeated in the agreement. It is also written that "It is Quest's position that the Settlement Amount described in III-A below represents a *compromise settlement under 51501(a)*." (Italics by TDR.)

This statement likely describes one of the primary legal strategies adopted by the attorneys representing Quest Diagnostics. As its part of the "compromise settlement under 51501(a)," Quest Diagnostics must do the following:

a) It will pay a total of $241 million. The State of California will get $171 million. Whistleblowers Hunter Laboratories, LLC, and Chris Riedel will get $69.9 million.

b) Per California law, Quest Diagnostics will pay reasonable attorneys' fees and expenses to the *qui tam* plaintiffs. The specific amount is currently in dispute.

c) Starting August 1, 2011, and continuing through November 1, 2013, every

three months, Quest Diagnostics will send written "exception reports" for each of its five business units to the **California Department of Health Care Services** (DHCS). These exception reports are to identify instances, as defined in the agreement, where, during that three-month period Quest Diagnostics has offered a lower price to a provider than the Medi-Cal price for that test, along with the price that Quest Diagnostics billed Medi-Cal for that same test during that same time period.

d) As an alternative to filing the exception reports for the first five reporting periods identified in the settlement agreement, Quest Diagnostics can submit Medi-Cal claims "to DHCS at no more than eighty-five percent (85%) of Medi-Cal's then otherwise applicable published fee schedule for all otherwise eligible and proper Medi-Cal claims for tests or services with dates of service from May 1, 2011 through July 31, 2012." This is called the "Transitional Rate."

e) Quest Diagnostics "shall appoint and identify to the Settlement Compliance Contact an individual ("Compliance Officer") with the duty and authority to supervise and reasonably ensure compliance with all of the terms of this Settlement Agreement and to communicate with the Settlement Compliance Contact as required by this Settlement Agreement."

How To Comply After 2013

It is these five basic elements in the settlement agreement that should be studied and understood by clinical laboratory executives and their legal counsel. It is notable that this document is silent on how, after November 1, 2013, Quest Diagnostics or any other medical laboratory should comply with the language of California's 51501(a) law.

Further, another section in the "Settlement Agreement and Release" document appears to confirm that the primary legal issue is 51501(a). In section III-C-4, it states that, per fulfillment of certain requirements and subject to specific exceptions, "California will not make any claim against or seek withholding from a Quest Releasee under Section 51501(a), or seek any discretionary suspension or exclusion of a Quest Releasee under Section 51501(a), on the grounds that a price charged before November 1, 2013, for a test performed on or before that date to a non-Medi-Cal purchaser or payor by a particular Reporting Business Unit was less than a price that was charged to Medi-Cal by a different Reporting Business Unit."

Denies The Allegations

In the settlement agreement and in its own press release about the signing of the settlement agreement, Quest Diagnostics has repeatedly denied the allegations of the *qui tam* lawsuit. It maintains that it has always conducted its affairs in full compliance with applicable state and federal laws. The complete statements on these points were covered earlier in this issue of THE DARK REPORT. *(See pages 5, 7, 9, and 11.)*

It is notable that, within this 21-page settlement agreement, there is no language where Quest Diagnostics agrees to comply with the California Attorney General's (and DHCS') interpretation of 51501(a). As noted in earlier pages, Quest Diagnostics denies all allegations and each party to the agreement is reserving its rights on issues relating to interpretation and enforcement of 51501(a).

In fact, language in the settlement agreement specifically describes that Quest Diagnostics considers the agreement to represent a "compromise settlement under 51501(a)." This language indicates that it can be expected that Quest Diagnostics intends to continue disputing how the State of California interprets and enforces 51501(a) and related statues. It may also signal that one consequence from this settlement agreement is that Quest Diagnostics continues to give lower prices for specific tests to some providers than what it gives to Medi-Cal, at least through November 1, 2013. TDR

Medi-Cal Deal Raises Interesting Questions

➤One interpretation of this settlement is that tough enforcement of 51501(a) only starts in 2013

➤➤CEO SUMMARY: From the perspective of the average citizen, it would appear that Quest Diagnostics scored two major "wins" over the California Attorney General in the negotiations as to how the whistleblower lawsuit was to be settled. Language in the settlement agreement would indicate that current lab sales and marketing practices involving deeply-discounted test prices that are not passed along to Medi-Cal will be tolerated by the state government, at least until November 1, 2013.

IF THERE IS ANY SINGLE "sword of Damocles" that hangs over the heads of clinical laboratory executives in the state of California, it is the question of appropriate prices for laboratory test claims submitted to Medi-Cal, the state's Medicaid program.

The risk of getting this issue wrong was demonstrated back in March 2009, when the California Attorney General unsealed a massive whistleblower lawsuit that claimed seven or more laboratory testing companies had "defrauded" the Medi-Cal program of hundreds of millions of dollars by systematically overcharging the state.

➤Comments At That Time

In his news conference at that time, then-Attorney General Jerry Brown stated: "In the face of declining state revenues, these medical labs have siphoned off hundreds of millions of dollars from programs intended for the most vulnerable California families. Such a pattern of massive Medi-Cal fraud and kickbacks cannot be tolerated, and I will take every action the law allows to recover what is owed." *(See TDR, April 6, 2009.)*

The next hammer to drop on some lab companies in California were letters sent by the California **Department of Health Care Services** (DHCS) to as many as 30 lab firms in the summer of 2010. DHCS informed these labs that, following an earlier audit to each lab's Medi-Cal claims, DHCS was suspending Medi-Cal payments, effective immediately. *(See TDR, December 26, 2010.)*

Collectively, these events caught the full attention of every laboratory company that provides testing to patients in California and submits claims to the Medi-Cal program. For this reason, the "Settlement Agreement and Release" that was recently negotiated between the California Attorney General, DHCS, and Quest Diagnostics is an important development. It provides insight into how 51501(a) is likely to be interpreted and enforced, at least relative to the claims involved in the whistleblower suit that covers the period of 1995 through the present.

As demonstrated in the preceding pages, certainly Quest Diagnostics will pay $241 million to resolve these allegations, even as it denies that it was guilty of any wrongdoing. But that $241 million must be viewed against the context that, during the

years since 1995, the whistleblower lawsuit says that Quest Diagnostics was paid $726 million by Medi-Cal. The plaintiffs alleged that $509 million of that $726 million were overcharges to the Medi-Cal program—based on 51501(a) and similar state and federal laws—and should be refunded.

So, it must be considered a "win" for Quest Diagnostics that it negotiated that number down to $241 million, or 47.3%, of the claimed $509 milion of alleged overcharges. In addition, Quest also faced claims for treble damages and attorneys' fees from the plaintiffs in the suit. For its part, the California Attorney General could claim that this $241 represented the largest state settlement ever for California.

Next, for the periods covering August 1, 2011, and continuing through November 1, 2013, every three months Quest Diagnostics must submit a report to DHCS which essentially requires it to identify each lab test and each customer which has gotten a price during that three-month period that is less than the price Quest Diagnostics charged to Medi-Cal during that period.

Compliance With 51501(a)

However, there is no language in the settlement agreement that requires Quest Diagnostics to comply with DHCS' interpretation of 51501(a) and thus extend that same lower price for that same test to Medi-Cal during that 28-month period. If this is a correct reading of the settlement agreement, then Quest Diagnostics is free to continue offering deeply discounted laboratory test prices to physicians, IPAs (independent physician associations), and managed care companies during this time.

Since this reporting requirement ends on November 1, 2013, it means that this settlement agreement allows Quest Diagnostics to continue its deep-discounted price strategy for at least the next 28 months. That must be considered another "win" for Quest Diagnostics in its high-stakes negotiations with the California Attorney General.

This also raises an important question. If Quest Diagnostics is to be allowed to continue deep-discounted prices for tests—without having to extend those same low prices to Medi-Cal for the next 28 months—how will the California AG and DHCS enforce 51501(a) with other laboratory companies in the state?

Negotiate Comparable Terms

For example, attorneys representing **Laboratory Corporation of America** may want to negotiate comparable terms with the California AG in order to settle Labcorp's whistleblower suit. Similarly, the other remaining laboratory defendants may also want these terms as well.

If this proves true, then, for the next 2.5 years, California's market for laboratory testing services will continue to see deeply-discounted prices for lucky providers, IPAs, and managed care plans. But the state's Medi-Cal program will be reimbursing Quest Diagnostics and other laboratories at a price that, if the allegations of the whistleblower lawsuit are fully credited, is sometimes 90% greater than the cheapest price given by a laboratory to its preferred clients. Of course, California may well insist on an up-front settlement payment in exchange for allowing discount pricing practices to continue for the time being.

THE DARK REPORT reminds the reader that these insights are offered without the benefit of a knowledgeable attorney reviewing the *qui tam* lawsuit, the settlement agreement, and the press releases issued by the two parties to the settlement. In future issues of THE DARK REPORT, we hope to provide a more informed legal assessment of the "Settlement Agreement and Release."

At the same time, relevant language from the document has been presented on these pages. It is the first opportunity for laboratory executives in California and across the nation to get first-hand knowledge of what was negotiated between the two parties that led to this $241 million settlement. TDR

What Comes Next in Battle Over Discount Lab Prices?

➤ In California, this settlement agreement may create new complications for regulators

➤➤ CEO SUMMARY: Now that the settlement involving Quest Diagnostics Incorporated and the California Attorney General has been announced, attention turns to what comes next with the four remaining defendant lab companies in the whistleblower lawsuit. There are several different scenarios and it may be that California regulators face tough challenges before they can succeed in enforcing 51501(a) according to their interpretation. Similar lab test pricing cases are active in six other states.

NOW THAT A SETTLEMENT of the whistleblower lawsuit and related issues has been inked by the California Attorney General and **Quest Diagnostics Incorporated**, one question of great interest is: What happens next in California in regards to deeply-discounted lab test pricing and 51501(a) enforcement?

Several possible scenarios come to mind. For example, individually, the remaining four laboratory companies that are defendants in the *qui tam* lawsuit might work toward a resolution of their respective cases, perhaps settling on terms consistent with those agreed to by Quest.

➤ What's Next For AG?

It is likely that the California Attorney General will next focus on **Laboratory Corporation of America**. After all, claims against LabCorp represent the largest outstanding amount now that Quest Diagnostics Incorporated has signed a settlement agreement.

In the *qui tam* lawsuit that names LabCorp as a defendant, the allegation is that LabCorp, for 14 years beginning in 1995, billed and received $104 million from the Medi-Cal program. Of this amount, the lawsuit alleges that 79% of the amount paid to LabCorp represents overcharges due to the "systematic fraud committed by LabCorp against the State." The lawsuit seeks the return of this amount back to the State of California, which is approximately $72 million.

Like Quest Diagnostics, LabCorp denies these allegations. Last month, in public filings, LabCorp wrote that "The Company disagrees with the **Department of Health Care Services'** (DHCS) contentions and interpretation of its regulations and believes that it has properly charged the Medi-Cal program under all applicable laws and regulations."

Setting aside the expectation of settlements or trials involving four laboratory companies that remain as defendants in the whistleblower lawsuit, there is the practical problem of how the California Attorney General and the Department of Health Care Services will choose to enforce 51501(a), now that the settlement terms with Quest Diagnostics have been disclosed to the public.

As noted in earlier pages, the language of the settlement agreement between the California AG and Quest Diagnostics seems to define a period of time between now and November 1, 2013, when Quest Diagnostics will be free to continue to offer low prices for lab tests to its customers without a requirement that it submit claims to the Medi-Cal program for the same low prices for those same tests.

Lobby To Change Law

Is this a transition period to allow Quest Diagnostics to "wean" physicians, hospitals, independent practice associations (IPAs), and managed care plans away from deeply discounted lab test prices? Alternatively, given Quest Diagnostics' statement in its press release about this settlement, does the nation's largest laboratory company believe it can lobby the California state legislature and change or amend existing laws? *(See page 5.)*

In this scenario, Quest Diagnostics would probably like to lobby for changes to be made to the law that would allow it to continue offering rock-bottom laboratory test prices to some providers without a legal requirement that it extend those same low prices to the Medi-Cal program, as the California AG contends is required by the existing 51501(a) law.

Challenge For California AG

For its part, the State of California would appear to have its own unique challenge. It has agreed to give Quest Diagnostics a period of 28 additional months during which time Quest Diagnostics must simply report instances in which a provider got a lower price for a lab test than the (higher) price that was on claims submitted by Quest Diagnostics to the Medi-Cal program.

Thus, how will the AG and the DHCS regulate other lab companies in California relative to their interpretation of the 51501(a) law? If Quest Diagnostics now has a 28-month window which allows it to continue offering deeply-discounted prices to some providers while submitting claims to Medi-Cal at a higher price, will these same terms be offered to other clin-

Could Federal *Qui Tam* Cases Trigger Price Enforcement?

IT WOULD BE IRONIC if any unsealed or sealed *qui tam* action now wending its way through a federal court ended up moving on a parallel track as has the *qui tam* case of Hunter Laboratories, LLC, and Chris Riedel vs. seven lab companies in California state courts.

Remember, back in 2009, when this *qui tam* lawsuit was unsealed by then-California Attorney General Jerry Brown, most lawyers and lab executives in California scoffed at the possibility that the plaintiffs could prevail. They pointed out that no court rulings, nor enforcement actions, nor any strong legal precedents, relative to 51501(a), gave clear support to the legal arguments of the plaintiff. Indeed, the law had been on the books for years and California had seldom taken decisive action to assert its interpretation.

Now, just 26 months later, $241 million has been collected from one defendant and the remaining defendants could similarly settle in order to avoid a court case. Will this example motivate the federal **Department of Justice** (DOJ) to more energetically pursue *qui tam* case(s) involving allegations of deep discounted lab test prices which violate Medicare statutes for anti-kickback and false claims that are currently in federal court(s)? Will it motivate other individuals and companies to consider filing new *qui tam* suits?

Certainly the financial incentive is there, putting aside the legal merit of such claims, if any. Added together, the two blood brothers probably bill the Medicare program for a total that approaches $1 billion per year, maybe going back a decade. Recovering 10% of that amount, times ten years, would be a large recovery for DOJ and the Medicare program.

ical laboratories serving patients in California? Or will the same terms be offered only to labs that, like Quest, agree to settle claims about past billing practices and make a payment to the state?

This has the potential to become a complicated situation for state regulators. It could prove to be equally challenging for lab companies that compete daily against Quest Diagnostics in California.

At a minimum, these potential scenarios indicate that a host of legal issues are likely to come into play as California regulators take additional steps in coming weeks and months to enforce their interpretation of 51501(a) with other clinical laboratories operating in the state. Certainly at least some lab companies competing with Quest Diagnostics would want similar terms extended to them. Further, these same competing laboratories would have a motive to press their legal arguments through any channel possible, including the California court system.

National Implications

Setting aside these potential scenarios, the unfolding events in California are likely to have national implications. There are other states with similar laws that define how a provider must bill the state's Medicaid program in situations in which it has given a low price to another provider that is below the state's Medicaid price for that same service.

In recent years, both Quest Diagnostics and LabCorp have disclosed that they each received subpoenas regarding Medicaid billing practices involving six states. These states are Florida, Georgia, Virginia, Michigan, Nevada, and Massachusetts.

In the "Settlement Agreement and Release" document, one clause references these six state actions and notes that "the release also specifically excludes any governmental amendments to the previously brought actions in Florida, Georgia, Massachusetts, Michigan, Nevada, or Virginia, or amendments by Qui Tam Plaintiffs which do not assert new causes of action."

As California regulators either negotiate a settlement or go to trial with each of the four remaining defendant laboratory companies in the whistleblower lawsuit, it is possible that the outcomes of these efforts may establish precedents that find application in the individual *qui tam* cases apparently active in Florida, Georgia, Massachusetts, Michigan, Nevada, and Virginia.

Establish Legal Precedents

Were this to happen, then there would be a growing number of legal precedents at the state level affirming that the practice of laboratory companies offering deeply-discounted lab test prices violates those state laws that require a provider to give the state Medicaid program the same lowest price it gives other providers for that service.

In turn, such a series of similar decisions in multiple states could encourage the federal Medicare program to revisit this same subject. It is believed at least one federal *qui tam* lawsuit is still active that alleges that certain discounted pricing actions by Quest Diagnostics and LabCorp violate federal Medicare laws, including the anti-kickback statute and the false claims act. These lab companies deny the charges. Other unsealed whistleblower suits may also exist.

More Whistleblower Lawsuits

The point here is that this first settlement in California for $241 million can have a number of consequences. It may catch the attention of attorneys general in other states and encourage them to more aggressively enforce state laws that address "comparable pricing." It may also encourage a new wave of laboratory whistleblowers and their attorneys to file *qui tam* lawsuits against lab companies they believe have offered deep discounted lab test prices in violation of state or federal laws. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In coming weeks, **Agendia**, probably best known for its genetic breast cancer test, hopes to complete an initial public offering (IPO). Agendia is a company based in Amsterdam, The Netherlands with offices in Irvine, California. Its stock symbol will be "AGDX" and the shares will trade on the Euronext Amsterdam exchange. Plans are to raise €75 million (US $109 million). Financial documents filed by the company indicate that it had sales of €1.4 million (US $2.0 million) in 2009 and €4.7 million (US $6.7 million) in 2010.

MEDICAL DEVICE TAX REPEAL EFFORT GAINS MOMENTUM

Med City News reports that one Congressman's effort to repeal the 2.3% medical device tax is gaining wide support. This tax is mandated by the Patient Protection & Affordable Care Act which was passed in 2010. The new tax will become effective on January 1, 2013. *(See TDR, March 29, 2010.)* It is Representative Erik Paulsen (R-Minnesota) who is championing repeal of the medical device tax.

MORE ON: *Reform*

Paulsen's bill is titled the "Defend Medical Innovation Act." There are a reported 154 elected officials backing this bill, including four House Democrats. Paulsen says that implementation of this tax "unfairly penalizes entrepreneurship and innovation in an industry that makes up 2.7% of our nation's GDP."

TRANSITIONS

• Jacob "Jack" Kevorkian died on June 3, 2011, at the age of 83, at a hospital in Detroit, Michigan. A pathologist, Kevorkian became nationally-prominent in the 1990s for his advocacy of a "terminal patient's right to die via physician-assisted suicide." In 1991, his medical license was revoked by the State of Michigan. In 1999, he was convicted of second-degree murder for his role in an assisted suicide and was imprisoned until his parole in 2007. There are reports that Kevorkian was terminally ill with Hepatitis C, which he is said to have contracted while conducting research about blood transfusions.

• **ACM Laboratory**, of Rochester, New York, announced, on June 9, the appointment of Todd Meyers as Vice President of Sales and Marketing. Meyers' background is the pharmaceutical sector and includes positions with **i3 Global**, **Zitter Group**, and **Covance**.

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DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know ...

...how **IBM's** Watson supercomputer—winner over humans in a *Jeopardy* game show contest—was designed to help physicians assess patient data and develop a more accurate diagnosis.

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That's all the insider intelligence for this report. Look for the next briefing on Tuesday, July 5, 2011.