UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	
LABORATORY CORPORATION OF AMERICA	**Docket No. 9345**
and	**PUBLIC**
LABORATORY CORPORATION OF AMERICA HOLDINGS, corporations.	

RESPONDENTS' SUPPLEMENTAL BRIEF IN FURTHER SUPPORT OF THEIR MOTION TO COMPEL DOCUMENT PRODUCTION

Respondents submit this supplemental brief pursuant to this Court's February 24, 2011 Order ("Order"). Complaint Counsel has failed to provide an adequate privilege log and has failed to meet its burden of establishing the government deliberative process privilege, the attorney work-product doctrine, and the government informant privilege.[1] Moreover, Complaint Counsel still has not produced responsive communications with the Commission or included them on its privilege log and has not responded to Respondents' arguments on this topic or this Court's mention of it in its Order.

ARGUMENT

I. Complaint Counsel's Privilege Log Is Facially Inadequate

Complaint Counsel's latest attempt at a privilege log does not comply with the Order in that it does not include information to show that "*each and every document*" sought to be

[1] Complaint Counsel repeatedly and incorrectly implies that the burden falls on Respondent. *Compare* Supp. Opp. at 2 *with Coastal States Gas Corp. v. Dep't of Energy,* 617 F.2d 854, 862 (D.C. Cir. 1980) ("We remind the agencies, once again, that the burden is on them to establish their right to withhold information from the public and they must supply the courts with sufficient information to allow us to make a reasoned determination that they were correct.").

withheld, including "each page and portion thereof, is in fact protected from disclosure." Order at 5 (emphasis added); *see also Grinnell Corp. v. ITT Corp.*, 222 F.R.D. 74, 78 (S.D.N.Y. 2003) (finding that proponent of privilege must establish elements as to "each document individually"). Instead, Complaint Counsel grouped documents together in large batches, thereby preventing Respondents from understanding whether *each* document was properly withheld. Complaint Counsel apparently is withholding "approximately" 759 documents, but there are only 69 Log entries, many of which include entirely different types of documents, such as emails, attachments, and voicemails. *See, e.g.*, Log at 1, 2, 3. In many instances, the group of documents spans several *months*. *See, e.g.*, Log at 4 ("7/23/2010 – 2/10/2011"). Lumping groups of documents and ascribing dates that cover almost the entire period between the acquisition and the close of discovery renders those entries and dates meaningless.

Moreover, Complaint Counsel *approximated* the number of documents in each group. The first entry of the Log, for example, is for "emails and voicemails (approx. 10)." Log at 1. The approximate nature of the number of documents about which the FTC is claiming privilege highlights the problem. How can Respondents adequately evaluate the privilege claims without knowing the number of documents to which the claim purports to apply?

Complaint Counsel also lists several possible authors "and/or" recipients for each Log entry. *See, e.g.*, Log at 1. Respondents, thus, cannot tell who authored and received each document and cannot evaluate the privileges claimed – particularly the deliberative process privilege.[2] *See Coastal States*, 617 F.2d at 868 ("The identity of the parties to [a] memorandum is important; a document from a subordinate to a superior official is more likely to be

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[2] Remarkably, one entry simply describes the following "Author/Recipient": "LabCorp/Westcliff Investigatory Team, Antitrust Law Section of the California Department of Justice, Office of the Attorney General." Log at 3.

predecisional."). Respondents cannot even identify whether the individuals are FTC employees or not.

Complaint Counsel also provides extremely vague descriptions of the groups of documents. For instance, the Log describes a group of "emails, attachments and voicemails" that are purportedly privileged because they "[r]eflect[] notes, impressions, or analyses" prepared in anticipation of litigation. Log. at 3. Without more information, Respondents must guess how voicemails and attachments sent to third parties reflect "notes, impressions, or analyses." *See SEC v. Beacon Hill Asst Mgmt. LLC*, 231 F.R.D. 134, 145 (S.D.N.Y. 2004) (compelling production for failure to provide sufficient information as to any document withheld as an attachment). This provides no clue as to whether emails are forwarding attachments containing attorney work product or whether the emails themselves constitute work product, and if so, on what basis.

That Complaint Counsel failed to provide the very information it demanded from Respondents is particularly telling. Among other instructions, Complaint Counsel requested that "[a]ttachments to a document should be identified as such and entered separately on the log," and that the log state each person's title and employer or firm, the number of pages of *each document*, a description of *each document*, addresses, and the document's date. *See* Complaint Counsel's First Set of Document Requests, at 12-13. Indeed, the FTC regularly includes such instructions and expects respondents to comply. For instance, in this case, Respondents' first privilege log included over 15,000 entries (one for every document about which it claimed privilege, including dates, descriptions, and author and recipient information regarding every document), and it is preparing another log with nearly 7,500 entries pending this Court's ruling on the present motion. In contrast, Complaint Counsel chose not to comply with Respondents' requests for the same

details. Instead, out of apparent self-serving convenience, Complaint Counsel compressed those "approximately" 759 entries (less than 4% of the entries Respondents' counsel is logging) to 69 entries.

II. The Government Deliberative Process Privilege Does Not Apply

Even with the opportunity to submit additional information and briefing, Complaint Counsel failed to meet its burden to demonstrate the applicability of the privileges it claims.[3]

A. Complaint Counsel failed to properly invoke the Deliberative Process Privilege

An agency head must personally review *each* document *before* invoking the deliberative process privilege. *In re McKesson Governmental Entities Average Wholesale Price*, 264 F.R.D. 595, 601 (N.D. Cal. 2009) (holding that privilege may be invoked "only by the agency head after personally reviewing the documents for which the privilege is asserted"). Complaint Counsel's declarant, Richard Feinstein, admitted that he originally did not review every document listed in Complaint Counsel's privilege log. Feinstein Decl. ¶¶ 19, 24. He even admitted that Complaint Counsel wrongly asserted the privilege with respect to many documents (while claiming that they were still protected attorney work product). Supp. Opp. 1 n.1. This admission casts serious doubt on Complaint Counsel's other assertions of privilege especially given the fact that those claims were grouped and described generically. Also, neither Respondents' counsel nor this Court can tell from the Log or Feinstein's declaration the specific documents about which the Commission has changed its claims.

Additionally, allowing staff attorneys to cherry-pick certain documents for an agency head's review completely undermines the purpose of the rule, which exists to "deter governmental units from too freely claiming a privilege that is not to be lightly invoked . . . by

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[3] Of course, Respondents' arguments regarding whether Complaint Counsel has carried its burden are largely based on guesswork as to the factual circumstances surrounding the withheld documents because of the deficient nature of the Log.

assuring that someone in a position of high authority could examine the materials involved from a vantage point involving both expertise and an overview-type perspective." *McKesson*, 264 F.R.D. at 601 (citations omitted). Courts have even determined that the failure to take this step in the first instance waives the privilege. *See L.H. v. Schwarzenegger*, 2008 WL 2073958, *7-8 (E.D. Cal. May 14, 2008).

B. Communications With The California Attorney General Are Not Privileged

The California Attorney General ("CAAG") is not an unbiased consultant to the FTC, and therefore the CAAG communications are not protected by the deliberative process privilege.[4] *See People for the Am. Way Found. v. U.S. Dep't of Educ.*, 516 F. Supp. 2d 28, 37 (D.D.C. 2007). Although the CAAG may not have concluded its investigation, it chose not to join the FTC's lawsuit, suggesting that the CAAG and the FTC did not see eye-to-eye on the transaction. Moreover, the CAAG's ongoing *qui tam* action against numerous labs, including LabCorp, indicates that the state agency "represent[s] an interest . . . of its own" and does not represent the interests of the FTC. *Dep't of the Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 11 (2001).

Indeed, contrary to Complaint Counsel's purported goals in this case, the CAAG's *qui tam* action and the parallel enforcement action by California's Department of Health Care Services ("DHCS") would likely *raise* capitated contract rates. One industry report recently concluded that if the CAAG and DHCS succeed, "federally qualified health centers, independent practice associations, private payers, and patients will pay more – and the bill will likely exceed an additional $100 million per year in higher lab test fees." *Who Wins and Who Loses With*

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[4] Complaint Counsel wrongly asserts that the cases interpreting FOIA exemption 5 do not apply to the deliberative process in non-FOIA contexts. *See, e.g., CACI Field Servs., Inc. v. United States,* 12 Cl. Ct. 680, 687 n. 7 (Cl. Ct. 1987) ("The only distinction between the deliberative process privilege when arising under FOIA and the privilege when invoked in this court is that in the context of FOIA no affidavit from the agency head is necessary to invoke it.").

51501 Enforcement, The Dark Report at 9 (Dec. 27, 2010) (detailing the history and likely effects of the CAAG *qui tam* action and DHCS' enforcement action and noting the connection between those actions and the FTC's pending lawsuit) (attached as Exhibit A). The CAAG cannot be an unbiased consultant when at least some of its interests diverge so sharply from those of Complaint Counsel.

C. Communications With Shoemaker and Kane Are Not Privileged

Complaint Counsel has failed to provide any legitimate reason to treat communications with third parties Emmet Kane and Daniel Shoemaker as protected under the deliberative process privilege. Only in limited circumstances can the privilege extend to third parties not employed by a federal agency. *See Allocco Recycling, Ltd. v. Doherty*, 220 F.R.D. 407, 412-13 (S.D.N.Y. 2004) ("[T]here is obviously no rule that documents prepared by government consultants are necessarily deliberative. Rather, a court must consider the consultant's function in preparing the documents at issue."). Complaint Counsel has failed to demonstrate that any such exception applies here.

III. The Attorney Work Product Doctrine Does Not Apply

A. Complaint Counsel has not met its burden

Complaint Counsel argues that confidentiality agreements with Shoemaker and Kane shield communications with them under the work product doctrine. However, the mere existence of confidentiality agreements does not create work product protection; Complaint Counsel must first demonstrate that the withheld-documents were prepared by an attorney (or by the attorney's agent at the direction of the attorney) in anticipation of litigation. *See United States v. Nobles*, 422 U.S. 225, 238-39 (1974). Only once the documents qualify as such does the existence of confidentiality agreements become relevant. Complaint Counsel has failed to demonstrate that the withheld communications with Shoemaker and Kane contained only

information that was produced by or at the direction of an FTC attorney in anticipation of litigation, thus rendering the confidentiality agreements superfluous for this purpose.

Even assuming communications with Shoemaker contained work product (and could not be redacted), Complaint Counsel has waived any protection. Work product protection is waived by disclosure to a third party that "is inconsistent with maintaining secrecy against opponents or substantially increases the opportunity for a potential adversary to obtain the protected information." *Ricoh Co. Ltd. v. Aeroflex Inc.*, 219 F.R.D. 66, 70 (S.D.N.Y. 2003) (citations and quotations omitted). Here, Complaint Counsel sent its alleged work product to Shoemaker, an individual represented in his capacity as manager of LabWest by the same counsel as Respondents. While Complaint Counsel disputes the legitimacy of that representation, it has long been aware of it, and yet still claims protection regarding those communications.[5]

Complaint Counsel's work product claims are similarly overbroad with respect to Kane. In *United States v. Arthur Young & Co.*, 465 U.S. 805, 817-18 (1984), the Supreme Court refused to extend work product protection to independent auditors because an auditor has a "public responsibility" and "owes ultimate allegiance to the corporation's creditors and stockholders, as well as to the investing public." To shield the auditor's interpretations of the client's financial statements would "ignore the significance of the accountant's role as a disinterested analyst charged with public obligations." *Id.* Here, similar to an auditor, Kane is serving as the monitor whose ultimate allegiance is to the public. Accordingly, protection for any work product communicated to Kane has been waived.

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[5] Complaint Counsel's contention that Respondents *should* have sought the documents from the third parties, including Shoemaker, is disingenuous. For Respondents to have tried to circumvent the FTC's privilege claims pending this Court's ruling would have been improper. Indeed, even though Respondents' counsel represents Shoemaker, Respondents' counsel specifically did not attempt to review the documents in his files about which Complaint Counsel claimed protection.

B. Complaint Counsel's litigation hold undermines its work product claim

Complaint Counsel's stance on its discovery obligations contravenes its broad work product assertions. Respondents recently discovered that Complaint Counsel did not have all responsive materials from the outset of its investigation into this transaction because the FTC's document retention policy, including its auto-delete policies, remained in place until a litigation hold was implemented.[6] *See* Email from S. Wilkinson to C. Habeeb (Mar. 2, 2011) (attached as Exhibit B). Respondents assume that the FTC had not determined that litigation in this case was reasonably likely, and therefore that a litigation hold was not necessary, until on or after August 2, 2010 (45 days from the date of some of the missing responsive documents). Nonetheless, Complaint Counsel asserts that many documents were prepared in anticipation of litigation *months before* that date. Complaint Counsel cannot have it both ways. It cannot claim documents were prepared in anticipation of litigation in June and July while simultaneously claiming that it did not reasonably believe the matter was likely to lead to litigation until August (or later).

IV. Government Informant Privilege Does Not Apply

Complaint Counsel failed to respond to Respondents' claim that the government informant privilege does not apply, yet still asserts the privilege in its Log. Log at 2. This privilege is inapplicable where – as here – the identity of the informant has been revealed. *In re MSC.Software Corp.*, 2002 FTC WL 31433972 (May 7, 2002) (Chappell, J.). As a result, those third-party communications should be produced.

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[6] The litigation hold instituted by Complaint Counsel does not appear to have been produced and does not appear to be on the Log. Respondents' counsel has asked for the exact date the hold was implemented but has not received that information.

V. Complaint Counsel Must Produce Or Log Communications Between FTC Staff And The Commission

Complaint Counsel similarly failed to address Respondents' arguments that it must produce or log communications between FTC staff and the Commission and instead maintains its refusal to provide a privilege log of those communications. *See* Log at 1. It should be ordered to log such communications. 16 C.F.R. § 3.38A

CONCLUSION

For the reasons set forth herein and in Respondents' prior briefing, Respondents respectfully request that the Court grant Respondents' Motion to Compel Document Production.

Dated: March 16, 2011

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I caused to be filed via hand delivery an original with signature and one paper copy, and via FTC e-file a .PDF copy that is a true and correct copy of the paper original, of the foregoing document with:

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I also certify I delivered via electronic mail and hand delivery a copy of the foregoing to:

D. Michael Chappell
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I also certify I delivered via electronic mail a copy of the foregoing to:

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Exhibit A

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A DARK REPORT EXCLUSIVE!

California's Med-Cal Program Targets Discounted Lab Testing

From the Desk of

Labs Caught in the Crosshairs!

DARK REPORT

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

Restricted Information, see page 3

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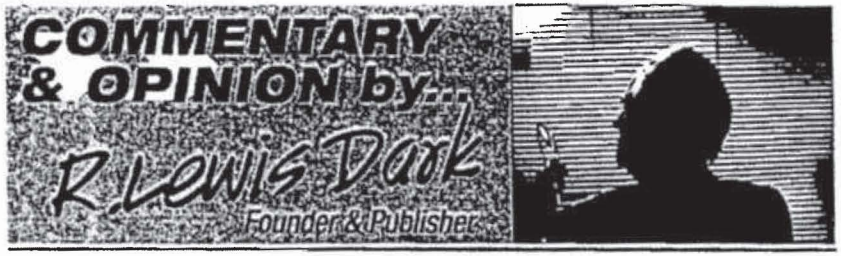

Any Future for Loss-Leader Lab Pricing?

OUTSIDE OF CALIFORNIA, few pathologists or laboratory administrators are aware of the unfolding enforcement campaign that was initiated by the state's Medi-Cal program. At issue is a decades-long practice of offering providers low laboratory test prices—in some cases well below the Medi-Cal fee schedule.

You may say, "what's the big deal?", since, for years, you've seen public laboratory companies in many other states give similar rock-bottom prices to providers and payers that are also much less than the Medicare Part B lab test fee schedule and/or local Medicaid fees.

Well, in California, the big deal is that the California **Department of Health Care Services** (DHCS) is now in the midst of enforcing its interpretation of a 40-year-old state law, section 51501(a), that deals with the issue of laboratories passing low prices to providers, but not passing those same lab prices to Medi-Cal, the state's Medicaid program. I will leave it to you to read this special issue of THE DARK REPORT and make up your own mind as to whether DHCS or the laboratory companies have the strongest legal position.

And this brings me back to my starting point. Once you read about the details of this unexpected enforcement campaign of California state law, I'd like you to ponder this question: If many state Medicaid programs are at the brink of insolvency, and if the federal Medicare program is outspending revenue, then how much longer will deep-discounting lab test price arrangements continue before catching the attention of government health program administrators? Can the lab industry defend a situation where a profitable big laboratory gives a below-cost test price of, say, $2 to a client, then turns around and bills the federal/state health program the full fee-for-service price of $10 or $20, on a patient seen in the same doctor's office, no less!

I would further observe that the financial times in 2011 are much different than in 2000 and 2005. Government health programs are desperate to find the money needed to fund their mission. With that in mind, allow me to ask you this question: If you were in Las Vegas at the oddsmaker's desk, would you bet your own money that, in five years, government health plans will still allow labs to give providers discounted prices that are less than Medicare and Medicaid fees, while not also passing those same low prices along to the Medicare and Medicaid programs? If you wouldn't make that bet, you may be acknowledging that loss-leader pricing for lab tests doesn't have much of a future. TDR

Discounted Lab Prices Become Issue in California

➤Low prices for lab tests come under scrutiny of regulators at both the state and federal level

➤➤CEO SUMMARY: For decades, California's lab testing market has been considered the Wild West because clinical lab companies have felt relatively free to offer deeply-discounted prices to expand market share and take business away from competitors. Now these discounted pricing practices are being scrutinized by no less than three government bodies. First came a whistleblower lawsuit still winding through a state court. Next were Medi-Cal officials and then it was the Federal Trade Commission.

IN CALIFORNIA, THREE UNRELATED ACTIONS by three different government regulatory bodies may soon unleash disruptive forces on the Golden State's intensely competitive market for lab testing services.

At the core of the three government agencies' concerns is the widespread practice of offering deeply-discounted lab test prices to selected physicians, private payers, and other providers as a way to win business from competing laboratory companies.

Three government agencies are now separately reviewing the marketing practices of medical laboratories in California—for different regulatory reasons. But one common theme in these government reviews is the practice of clinical laboratory companies using low lab test prices as a marketing tool to gain new clients and expand market share.

There is a high probability that the regulatory decisions that result from these government agencies will end up triggering major changes in how and when laboratory testing companies can offer private providers a price for lab tests which is lower than these labs charge government health programs like Medi-Cal.

For this reason, this entire issue of THE DARK REPORT is devoted to the events now unfolding in California. Pathologists and laboratory administrators working in other states are generally unaware of the details about these developments.

The significance of these regulatory events should not be underestimated. Clients and regular readers of THE DARK REPORT are encouraged to make their own informed analysis of each government body's interest in enforcing a laboratory industry activity that incorporates the use of

deeply-discounted lab test pricing for marketing purposes. Such an analysis points to a primary conclusion that, within California, there are likely to be important changes in how state healthcare officials interpret and enforce existing statutes that govern how a lab can offer lower test prices to a provider than it charges to the Medi-Cal program.

➤California State Court Case

The first threat to current lab pricing practices is a whistleblower case in a state court that could result in a decision or settlement that alters existing lab industry marketing practices in situations where labs offer providers lab test prices that are less than what the same labs charge Medi-Cal.

Then, at the beginning of the summer, the **California Department of Health Care Services** (DHCS) initiated an unexpected and aggressive new enforcement program to address its interpretation of the state statute that deals with the issue of low prices for laboratory tests (and other health services) that are less than the provider charges to the state Medicaid program. This enforcement program goes further than any previous lab price enforcement effort by DHCS.

Meanwhile, early this December, the **Federal Trade Commission** (FTC) formally challenged the acquisition of **Westcliff Medical Laboratories, Inc.**, in Santa Ana, California, by **Laboratory Corporation of America**. The FTC stated that its concerns were about market concentration.

➤Lab Test Prices Play A Role

But, a closer reading of the FTC's analysis of the downstream market consequences of the acquisition is a concern that the new owner would raise lab test prices from current levels. The FTC notes that this would be negative for the public health clinics, IPAs, and other providers that benefit from lower lab test pricing.

THE DARK REPORT is the first lab industry publication to identify the common theme of deeply-discounted lab test prices that is central to the issues now in front of these three different government bodies. If just one of these agencies successfully prevails in issuing a ruling against current marketing practices for pricing lab tests, that would alter the ability of labs to offer deeply-discounted lab prices to favored customers.

Such a ruling would likely trigger significant disruption to California's competitive market for lab testing services. There would be new winners and losers among the labs operating in the Golden State.

A word of warning before reading further. Government bodies with enforcement and regulatory powers are tackling a lab industry marketing practice that is controversial even within the laboratory profession. Lab executives, attorneys, providers, payers, and government health program regulators will line up on opposing sides of this issue.

➤Interpreting Existing Laws

Each party will put forth compelling arguments that favor their interpretation of laws that govern lab test marketing practices. However, it is judges, elected officials, and regulatory agencies with the raw power to effect their interpretation of the law. That is, at least until a state legislature or Congress steps in and passes a new law that overturns a regulatory practice or clarifies the law in response to an unpopular court ruling.

The point here is that an impassioned debate about the legitimate use of deeply-discounted laboratory test prices is about to take place in California. It will be an emotionally-charged debate because an interesting mix of healthcare stakeholders will all stand to win or lose.

In the intelligence briefings which follow, THE DARK REPORT provides information and perspectives about these unfolding events. Because of the billions of dollars at stake, high-powered legal teams on both sides of the low price issue will be earnestly working to see that their clients' interests prevail in whatever decisions are made by the courts and government regulators. **TDR**

Medi-Cal Gets Tough on Low Lab Test Prices

➤This summer, state Medi-Cal officials targeted up to 30 labs for immediate suspension & restitution

➤➤CEO SUMMARY: This may be the most significant lab industry story of 2010, which has gone unreported until now. Starting in June and July, California's Department of Health Care Services determined that between 10 and 30 labs had submitted what the agency considers to be false claims. It sent out letters to these labs to notify them that they were suspended from the Medi-Cal program. It has since softened that stance, but in September, the agency sent letters to as many as 300 laboratories requiring them to self-audit their Medi-Cal claims.

ENFORCEMENT ACTIONS by California's Medi-Cal program that were both unannounced and uneven have roiled the competitive marketplace for laboratory testing in the Golden State. Upset owners of lab testing companies singled out for enforcement action have even complained to elected officials.

At the core of this issue is the fact that California's **Department of Health Care Services** (DHCS), beginning this summer, singled out between 10 and 30 California laboratory companies for submitting what the state's Medicaid agency asserts are fraudulent claims because they were priced in violation of California state law.

➤Allegations Of False Claims

DHCS sent letters to these labs informing them of its decision on the alleged false claims, along with notice that it had immediately stopped Medi-Cal reimbursement payments to these laboratories and was suspending their Medi-Cal licenses.

Meanwhile, the majority of the state's laboratory companies continued business as usual, offering the same competitive lab test pricing as the handful of labs that had received the Medi-Cal enforcement and suspension letters from DHCS.

This inequity in enforcement action was quickly recognized by those lab companies whose Medi-Cal payments and licenses had been suspended by DHCS. It put these laboratories at a competitive disadvantage in the day-to-day conduct of their business and raised a host of legal issues.

Of interest for the entire laboratory industry: did DHCS follow due process of law when it singled out the first 10 to 30 laboratory companies and sent them a letter with the notice that it was immediately withholding all Medi-Cal payments to that laboratory, as well as suspending its Medi-Cal license? Were these laboratory companies getting equal treatment under the law, relative to all the laboratories operating in California that extend similar low lab test prices to clients?

Apparently, in response to the problems caused for the handful of labs unlucky enough to be singled out for

immediate suspension of Medi-Cal payments and licenses, DHCS has stayed the suspensions of those laboratories.

However, DHCS still had the problem of selective enforcement, since it targeted only between 10 and 30 laboratories in the state for audits and suspension. That may be why, in September, DHCS next mailed out letters to most other laboratories in California directing them to conduct a self-audit of Medi-Cal claims submitted between July 1, 2009 to December 31, 2009.

DHCS told the labs receiving the letter that failure to conduct the self-audit could lead to sanctions that could involve suspension from the Medi-Cal program. In its letters, DHCS describes this enforcement program as the "DHCS Laboratory Price Sweeps Special Project."

DHCS said the mandatory self-audit was "to ensure compliance with California Code of Regulations (CCR), Title 22, section 51501(a), which states in part, 'Notwithstanding 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...'"

➤National Labs Were Audited

Both **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** have disclosed in their respective public filings that, in the third quarter of 2010, each laboratory company was audited by the Department of Health Care Services. *(See sidebar on page 11.)* It is not known whether DHCS initially suspended Medi-Cal payments and the Medi-Cal licenses of either national lab company after it completed its audits.

LabCorp and Quest Diagnostics are currently defendants in a *qui tam* lawsuit in California. The plaintiffs charge that, dating back to 1995, seven laboratories filed Medi-Cal false claims that violated California's 51501(a) statute. Trials in this lawsuit for LabCorp and Quest Diagnostics are scheduled to commence during 2011. *(See TDR, April 9, 2010.)*

Both the set of letters sent to the 10 to 30 laboratories earlier in the summer, and the subsequent set of letters sent out this fall, were signed by Jan Inglish, N.P., Chief, Medical Review Branch, Audits & Investigations at DHCS. People involved in negotiations say that Inglish had a primary role on behalf of DHCS during meetings this summer between DHCS and the laboratories facing immediate suspension from the Medi-Cal program.

When the first DHCS letters announcing the suspension of Medi-Cal payments and licenses were delivered to between 10 and 30 labs in June and July, no laboratory executives with knowledge of this situation were willing to talk publicly about this matter.

➤Follow-Up To DHCS Letters

Since each lab was in negotiations with DHCS on a possible settlement, no lab executive wanted to be first to criticize the manner in which DHCS was conducting audits to determine instances of fraudulent claims, and then suspending Medi-Cal payments and licenses of the audited laboratories.

The reluctance of clinical laboratory executives to make public statements was understandable. When the DHCS letter arrived at a targeted lab, that laboratory was faced with four major issues.

First, DHCS was "(1) temporarily withholding 100 percent of payment to you, effective the date of this letter." This denied payment to the laboratory for all Medi-Cal claims currently in the pipeline for reimbursement. The DHCS action was a serious blow to the lab company's cash flow, particularly if it served a high proportion of Medi-Cal patients. It would also further undermine the ongoing financial stability of the laboratory.

Second, DHCS was "(2) temporarily suspending and deactivating your Medi-Cal provider number and National Provider Identifier (NPI) number, effective [on a date 15 days from the date of the letter]." This enforcement action meant that the laboratory would be unable to handle Medi-Cal specimens from its clients, even as it continued performing work for private pay patients. That would create an immediate competitive disadvantage with the targeted lab's client physicians.

Third, the DHCS letters typically stated in direct language that the department had determined that the laboratory was guilty of submitting false claims.

➤False Claims Defined

Here is how DHCS explained its findings of false claims to one laboratory that had its Medi-Cal payments withheld:

[Name deleted] Lab routinely submitted false claims to the Medi-Cal program by misrepresenting that the amount that they charged to the Medi-Cal program was not more than what [name deleted] Lab charged to other payor types for the same service as per California Code of Regulation, Title 22, section (22 CCR §) 51501, which states in part, "(a) 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..." This was evidenced by a review of invoices for private pay patients that were obtained from [name deleted] Lab and/or its referring providers.

In another part of the letter, DHCS reinforces its decision about false claims by writing that "The evidence set out above, which includes evidence of fraud, leads the DHCS to conclude that you may have committed fraud or willful misrepresentation against the Medi-Cal Program."

Because it had sent a letter of finding that the target laboratory company had "routinely submitted false claims," DHCS was creating additional legal jeopardy for the laboratory. There are numerous federal and state statutes that criminalize the submission of false claims to a federal health program. To avoid the potential of criminal action against the laboratory company and its executives individually, it was important for the targeted laboratory to take immediate steps to challenge the evidence and the legal process used by DHCS to assert that false claims had been submitted to the Medi-Cal program.

LabCorp Acknowledges Medi-Cal Claims Audit

In its third quarter financial statement, Laboratory Corporation disclosed some details about the Department of Health Care Services audit of one of its laboratories in the Golden State. LabCorp wrote that:

During the third quarter, the Company responded to an audit from the California Department of Health Care Services ("DHCS") of one of the Company's California laboratories for the period of January 1, 2010 through June 30, 2010.

DHCS subsequently indicated that this laboratory charged the Medi-Cal program more than what was charged to other payers for some lab services and that this is inconsistent with DHCS's current interpretation of California regulations. DHCS provided the Company with a proposed agreement related to the Company's billing to the Medi-Cal program, including a requirement that the Company charge Medi-Cal the "lowest price" it charges others for a particular laboratory test.

The Company disagrees with DHCS' contentions and interpretation of its regulations and believes that it has properly charged the Medi-Cal program under all applicable laws and regulations. The Company is continuing to cooperate with DHCS with respect to the audit.

The fourth major issue linked to the DHCS's enforcement campaign is subjective and relates to the process of resolving the issues raised in the DHCS letter. Executives of the laboratory facing suspension describe the series of events as more like a "shake down" than due process of law. That's because, from the first contact with DHCS after receiving the letter announcing that DHCS was withholding Medi-Cal payments, DHCS officials made it clear to the lab executives that the matter could be speedily resolved.

➤ Follow-Up To DHCS Letters

However, the department's proffered resolution would require the laboratory to agree to terms that would place it at a competitive disadvantage because other laboratories in the state would continue to charge the lower prices common in California. That would not be true of the targeted laboratory company. It would need to agree to extend lab test prices that comply with 51501(a) and remit the substantial sum of money that DHCS had already determined to be the amount of "Medi-Cal overcharges" associated with its definition of the "false claims" submitted by the laboratory.

This aspect of the Medi-Cal enforcement action has not been disclosed to the public until now by THE DARK REPORT. Off the record, more than one laboratory executive over the course of the summer has told THE DARK REPORT that the amount of settlement demanded by DHCS was equal to or greater than one year's total reimbursement paid to that laboratory by the Medi-Cal program.

➤ Restitution Amount

In conversations about these meetings with their colleagues, laboratory executives who traveled to Sacramento to negotiate a resolution with DHCS officials said that the strategy and approach of DCHS was communicated to them in a blunt and direct manner. The message was along the lines of "We've determined that your lab broke the law on pricing. Here is the amount your laboratory must pay in order to restore its standing as a Medi-Cal provider."

Information gathered by THE DARK REPORT indicates that it would be reasonable to describe many of these hearings, meetings, or negotiations as hostile and the outcome not in doubt, from the perspective of DHCS officials. Their view is that labs broke the law. They have data generated from the audits to support their position that they have appropriately identified the number and amount of false claims involved in the case. Until the laboratory pays the designated amount back to Medi-Cal, state officals assert that it should not expect to be restored to good standing as a Medi-Cal provider.

This highly intimidating position taken by state officials is probably a major reason why, over the past six months, no laboratory executives nor their attorneys spoke out in a candid fashion about the DHCS demand letters. Nor did they issue a public statement of their confidence that their labs have complied with the law and that they have specific legal defenses with which to respond to the DHCS payment withhold and suspension letter.

➤ Labs Must Conduct Self-Audit

Since the latest enforcement campaign launched by DHCS this fall involves requiring clinical laboratories across the state to conduct a self-audit, it remains to be seen how the department may treat those laboratories which identify Medi-Cal claims that would violate 51501(a).

Moreover, since it is asking nearly every laboratory in the state to conduct a self-audit, DHCS may find itself overwhelmed by the need to negotiate a resolution should it rule that a large number of laboratories are in violation of its interpretation of 51501(a). Plus, DHCS has already learned that withholding payments to just a handful of laboratories can prove disruptive to labs, physicians, and patients alike. TDR

Who Wins and Who Loses With 51501 Enforcement

➤ Over many years, California's health system has benefited from the nation's lowest lab prices

➤➤ CEO SUMMARY: Assume that California's Department of Health Care Services (DHCS) wins all challenges to enforcement of its interpretation of 51501(a). DHCS will get a one-time cash infusion as it collects money from labs which violated the state statute. But going forward, federally qualified health centers, independent practice associations, private payers, and patients will pay more—and the bill will likely exceed an additional $100 million per year in higher lab test fees.

IT HAS YET TO OCCUR to many pathologists and laboratory executives in California that their state's free-wheeling, competitive market for laboratory testing services is about to be transformed in fundamental ways.

By all appearances, officials at California's Department of Health Care Services (DHCS) are prepared to strictly enforce their interpretation of California Code of Regulations (CCR), Title 22, section 51501(a). That's the part of the state code which says that the best price a provider gives to another provider must also be given to Medi-Cal.

Assume, for the moment, that DHCS prevails in all legal challenges to its interpretation of 51501. Lab executives believe that, moving forward, strict adherence to 51501(a) will result in the Medi-Cal lab test fee schedule turning into the de facto "lowest price" that clinical laboratories will offer to providers.

This will generate interesting consequences. For most of the past two decades, lab test prices in California have been consistently lowest in the nation. The direct beneficiaries of this have been patients, physicians, and private payers, as well as the Medi-Cal program itself. Because of the intense competition for market share among the state's laboratory companies, many lab clients pay much less for lab testing than the existing Medi-Cal fee schedule.

Thus, if DHCS does enforce 51501(a) in a strict, consistent manner, laboratories will probably decide to raise all their lab test prices up to the "floor level" of the Medi-Cal fee schedule. This means a significant lab test price increase is in the immediate future for providers in California.

This will create new winners and losers within the California healthcare system. It is instructive to speculate on who will be a winner and who will be a loser in this new competitive market environment. Here are some informed guesses at how things may play out in California.

California Medi-Cal Program:

If 51501(a) is enforced, many laboratory executives tell THE DARK REPORT that their laboratory will raise any discounted prices to be equal to the Medi-Cal fee schedule.

That would indicate, at least in the near term, that Medi-Cal will see little ongoing benefit from its enforcement of 51501(a), since it would continue to pay most lab test claims at its current fee schedule.

Because of its audit program, Medi-Cal will definitely be a winner because of all the restitution money and penalties it may collect from laboratories for past violations of 51501(a). But that is a one-time cash infusion into the financially-strapped program.

Will California labs have an incentive to discount below the Medi-Care fee schedule, then charge Medi-Cal the same lower fees to stay in compliance with 51501(a)? Few lab executives predict this will happen on any significant scale. But they don't rule out that possibility.

Federally Qualified Health Centers (FQHC):

Currently these medical clinics and care centers—organized to serve uninsured patients—benefit from the nation's lowest lab test prices. This group is predicted to be losers, since California laboratories must raise their deeply-discounted lab test prices up to the level of the Medi-Cal fee schedule.

FQHCs already recognize this threat and are feeling the financial pinch of higher laboratory test prices. This summer, some of those labs audited by DHCS did raise test prices to all clients, including a few FQHCs, to comply with DHCS' interpretation of 51501(a).

There are 478 FQHC clinic sites in California. These clinics serve 2.9 million patients, so this is a significant segment of the California healthcare system.

This first round of lab test price increases was painful for the affected FQHCs. In a letter circulated to some California laboratories, the **California Primary Care Association** (CPCA), which represents FQHCs, writes that "if discounting of laboratory services below Medi-Cal rates is eliminated, CPCA estimates that the financial impact on FQHCs will be between $40-$55 million annually."

Independent Physician Associations (IPA):

California's IPAs play a major role in care delivery. IPAs often contract globally for laboratory testing services. As a competitive sales strategy, lab companies have freely discounted the IPA contract work as a way to access the more lucrative fee-for-service specimens.

There are 142 IPAs in the state and they serve 4.6 million patients. Assume that half of these patients are covered by a global lab testing contract at a deep discount. Assume the same cost increase factor as used by CPCA. That projects that IPAs would pay between $55 million and $64 million more annually should their lab test fees be raised to the level of the Medi-Cal fee schedule. This negative financial consequence puts IPAs in the category of loser.

Clinical Laboratory Companies:

California's laboratory companies go into the winner's column. Once the state's labs have made restitution to DHCS for past discount pricing sins and paid any penalties, they will see increased cash flow as they raise all discounted lab test prices up to the same level as Medi-Cal fees.

As the higher lab test fee estimates for FQHCs and IPAs indicate, California laboratory companies will see an estimated revenue increase of between $95 million and $119 million annually just from these two sources! And those higher fees will flow into the state's laboratories for years into the future.

Private Practice Physicians, Patients, and Private Payers:

California laboratories regularly extend low lab test prices to these entities, who are likely to be in the loser category because laboratory companies will raise fees to the level of the Medi-Cal lab test fee schedule to comply with 51501(a). TDR

How Could So Many Labs Violate California Law?

➤51501(a) has been on the books for 40 years, as has the practice of labs offering low prices

➤➤CEO SUMMARY: If a 40-year-old state law on Medi-Cal pricing was known to regulators and clinical laboratories alike, how did the legal and compliance departments of so many laboratories—staffed by some of the smartest legal minds in California and nationally—interpret the law in such a different way as the state's primary laboratory regulator? After all, the civil and criminal penalties for submitting false claims to government health programs can be crushing and career-ending.

FEARING THE POWER that regulators have over the companies they regulate, it is no surprise that the usual lab industry spokespeople have not stepped into the public eye to speak out about how the California **Department of Health Care Services** (DHCS) suddenly launched an aggressive enforcement action based on its interpretation of state code 51501(a). They are wary of the wrath of bureaucrats who prefer that the regulatory matter stay out of the media spotlight.

But this is quiet acquiescence to a bureaucracy that is suddenly challenging a business practice that it has observed for decades, yet never took the types of actions that normally get the full attention—and strict compliance—of the companies under its regulation. So why now?

And why did DHCS design an enforcement campaign that suddenly drops a letter on the target laboratory company, declaring it to be a lawbreaker and notifying it that its Medi-Cal payments are immediately withheld and its Medi-Cal license is being suspended? The United States of America is a republic where the rule of law provides order to society, there is justice for all, and those charged with a crime are considered innocent until proven guilty.

It should not be overlooked that submitting false claims to a government health program can trigger criminal charges and criminal convictions. Laboratory executives received letters from DHCS where it was written that the department "...conclude(s) that you may have committed fraud or willful misrepresentation against the Medi-Cal Program." This sobering statement represents serious jeopardy because the civil matter in dispute could lead to criminal charges.

➤Payments Were Withheld

As reported on these pages, DHCS's decision to withhold Medi-Cal payments without advance notice caused some labs to lay off employees. It disrupted the service relationships these labs had with physicians and patients in California. While singling out these labs for enforcement, DHCS allowed other laboratories to continue using the same lab test pricing

practices, with no apparent regulatory restriction or contemporary warning on their marketing and business activities.

Further, as described on pages 5-6, should DHCS prevail in enforcing its interpretation of 51501(a), there is a high probability that the state's poorest citizens—and the medical clinics that serve them—will end up paying higher prices for lab tests. The **California Primary Care Association** (CPCA) estimates that, just for FQHCs in the state, the lab test cost increase would top out at $55 million per year. It would seem these outcomes are at cross purposes with the government's goal of improving care for California's neediest residents.

➤Asking The Larger Question

However, there is a larger question which must be asked. If medical labs in California are guilty of breaking the law by offering low prices, then the state's patients, physicians, and medical laboratories in California are owed an explanation. How could so many laboratories engage in a business practice—offering providers lower prices than the Medi-Cal fee schedule—for as long as 40 years if, as now insisted by DHCS officials, these low laboratory prices were in clear violation of 51501(a)?

Regulated companies have responsibilities and legal obligations. The same is true of the regulatory agencies that oversee their activities. Thus, over the past 40 years, did the government agencies of the State of California provide an accurate interpretation of the law governing situations where provider prices were less than the Medi-Cal fee schedule?

During this same time period, was the government's interpretation of 51501(a) reinforced by high-profile enforcement actions against laboratory companies or other types of healthcare providers that it judged in violation of 51501(a) by their continuing use of low prices, while not giving Medi-Cal those same lower prices?

Did California's regulators issue and/or update guidance on low pricing practices that became common as the healthcare marketplace evolved? The use of capitated, full-risk managed care contracts in the early 1990s is one example of such a new development.

➤Public Record About 51501(a)

The public record of such statements, such enforcement actions, and such advisory opinions is what guides the compliance programs that are required of every provider participating in a government health program. Some of the smartest lawyers in California and across the United States have studied the body of law and the regulatory actions associated with 51501(a).

Over the past 40 years, as legal advisors to California's laboratory companies, their interpretation of the law, based on relevant court cases and the published commentary by regulatory bodies on this section of state law, have formed the basis of the compliance policies that guide each laboratory licensed by the Medi-Cal program.

➤Lab Test Pricing Policies

Thus, why did such a sizeable number of well-established, respected laboratory companies fail to extend to Medi-Cal the same lower prices they were offering to IPAs, physicians, patients, FQHCs, and payers for periods extending back decades? The answer to this question represents a strong legal position for those laboratories currently in the cross hairs of DHCS, now that the agency has determined that the low pricing policies of the laboratory violated its interpretation of 51501(a).

It is quite unusual for a regulatory "mass non-compliance" event to occur in a highly regulated industry. Moreover, with hundreds of millions of dollars at stake, it is not difficult to predict that the stakeholders on both sides of this issue will not hesitate to go toe-to-toe. However, because the government typically holds most of the high cards in the deck, labs contesting DHCS' interpretation and enforcement of 51501(a) will face daunting odds. TDR

Calif. Officials Back Off From Suspending Labs

➤Settlement talks started last summer, but Medi-Cal officials have left the issue unresolved

➤➤CEO SUMMARY: Early in the summer, California's Department of Health Care Services (DHCS) delivered letters to between 10 and 30 laboratory companies notifying them that, effective immediately, it was withholding their Medi-Cal payments and was suspending each lab's Medi-Cal license. However, the intense reaction triggered by this unexpected and unequal enforcement campaign apparently caused DHCS to defer the ongoing withhold of Medi-Cal payments. DHCS also has yet to suspend the licenses of these labs.

IT WAS GRIM NEWS BACK IN JUNE AND JULY for a handful of laboratories that received compliance enforcement letters from the California **Department of Health Care Services** (DHCS). Upon opening the letters, each lab learned that DHCS was immediately withholding Medi-Cal payments to the lab and that the lab's Medi-Care license would be suspended within 15 days.

Because DHCS officials decline to comment on this matter, no one knows the precise number of laboratory companies which received these letters. It is known that more than 10 labs, and possibly as many as 30 labs, were sent these letters by DHCS during the summer months.

Recently THE DARK REPORT was able to speak with Byron J. Gross, who is an attorney with **Hooper Lundy & Bookman** in Los Angeles. His firm represents several of the laboratories that received DHCS letters this summer and faced the immediate withhold of their Medi-Cal payments and a suspension of their lab's Medi-Cal license. Gross was willing to discuss certain aspects of these cases.

"We represent five or six labs that got these withhold and suspension letters" stated Gross. "I know of other labs that also were sent these letters by DHCS, so there are at least 12 or 13 labs, maybe more, that were targeted in this way by DHCS.

"To my knowledge, none of the cases have been settled," added Gross. "Moreover, I don't think DHCS followed through and actually suspended the Medi-Cal licenses of the laboratory companies that received such a letter.

➤Licenses Not Suspended

"The laboratories we represent got the notices from DHCS, but the suspensions were never put into effect," he said. "Payments to these labs were withheld for a few weeks and the state is still holding that money.

"We hear that the amounts withheld range from $100,000 up to $1 million depending on how much Medi-Cal business the lab does," stated Gross. "One laboratory company we represent does 50% of its business with Medi-Cal. They really suffered and had to lay off staff.

"Although the department threatened to suspend the labs from the Medi-Cal program, when we met with the department, they decided not to suspend any of our lab clients," he noted. "The department did withhold money for a few weeks, and the department is still holding some money for a number of labs."

➤Medi-Cal Audits of Labs

Gross said that the letters sent by DHCS last summer were in response to on-site audits the department had conducted at these laboratories in earlier months. "Last year, the department did audits for the six months of July 1, 2009, through December 31, 2009," he stated. "From these audits, DHCS developed a number it says is owed by each laboratory.

"DHCS asserts this number is an overpayment, meaning the difference between what Medi-Cal paid and the lowest price that the lab charged other payers for the same tests," Gross explained.

"The department has released some of the Medi-Cal money that it withheld from these laboratories because of the alleged overpayment," he continued. "But DHCS has not released all the funds pending settlement agreements with the laboratories.

"Work on a draft settlement agreement between these labs and DHCS is proceeding, but has not been finalized," commented Gross. "I am not aware that any laboratory has settled this matter with DHCS."

➤One Lab May Have Settled

THE DARK REPORT believes at least one laboratory did settle with DHCS this summer. This lab is said to have agreed to repay the alleged overpayment amount to DHCS, along with a penalty.

"Frankly, it's crazy to call this fraud and suspend labs when every laboratory in the state has offered clients the same range of competitive prices for years," declared Gross. "In our first meetings with the department, we explained that they can't just pick these 12 labs and withhold funds and suspend them when all other labs—especially the biggest lab companies in the state—are doing this. If you suspend these 12 labs, other labs will simply offer lower prices, and take over the business."

"For DHCS to take this action is unexpected," Gross said. "This has never been something that they enforced, except in a couple of isolated incidents. We do not think it's legal for them to do so.

"In the past, the department has taken the position that state law requires laboratories to give Medi-Cal the lowest rate," he added. "However, over the years, several different lawsuits were filed on this issue and the results were mixed.

➤*Qui Tam* Case Clouds Issue

"As we all know, in California, there is a *qui tam* [whistleblower] false claims action pending against a number of labs for this specific pricing principle," Gross explained. "While the *qui tam* case is being litigated, no laboratory in California has changed its pricing practices.

"Among the defendants in the *qui tam* lawsuit are the nation's two largest laboratory companies," added Gross. "Both **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** are fighting this issue and continuing to offer lower rates than they offer to Medi-Cal.

"No one understands why the DHCS suddenly decided that labs haven't changed their billing practices, and so it was necessary for them to do these audits, then withhold funds and threaten to suspend these labs as providers to the Medi-Cal program."

For a state agency that was in a hurry last summer to immediately "shut down" or exclude a handful of laboratories from the Medi-Cal program—apparently to send a message to the rest of the laboratory industry—progress on the settlement agreements has been slow.

"Since we worked on a draft settlement agreement during the summer months, we haven't heard anything official from the state and the state has not pressured us to settle," Gross explained. "We thought that if we pushed back on certain issues and tried to work out a settlement, state officials would respond with guideline language about what is okay and what isn't okay.

➤Awaiting DHCS Guidelines

"However, because legal action in the *qui tam* lawsuit is ongoing and there are billions of dollars at stake, it may be that DHCS has been stymied by the California Attorney General (AG) who is prosecuting the case," postulated Gross. "It could be the AG does not want DHCS to set any specific guidelines until this *qui tam* suit is finished.

"Clarification and guidelines on interpretation of California statues is much needed," noted Gross. "For example, one issue we want clarified for medical laboratories in California involves pricing for the federal qualified health centers (FQHC) that provide care to the poor.

"The goal of these centers is to cover as many people as possible," he continued. "Many labs have agreements with these centers to charge them less for lab tests than they charge other payers.

➤FQHCs Are Concerned

"We have pushed back on this point and so has the **California Primary Care Association** (CPCA), which fears that its members will see the cost of laboratory testing increase," said Gross. "This example shows that there are situations where the lower prices offered by clinical laboratories are consistent with government health policy and legislative intent."

In fact, the CPCA believes its member FHQCs do meet certain safe harbors and the lab test price provided to these clinics are protected arrangements. It is actively lobbying all stakeholders with the goal of maintaining legal access to lower laboratory test prices.

Because the Department of Health Care Services did decide to forestall withholding Medi-Cal payments and suspended the licenses of those laboratories it had audited, that is an indication that a number of important legal issues involving low prices for laboratory tests are being contested. TDR

Contact Byron J. Gross at bgross@health-law.com or 310-551-8125.

—By Joe Burns

Attorney for Targeted Labs Lays Out the Issue of FQHCs

ONE GROUP OF LABORATORY CLIENTS in California that is widely recognized to get low-priced laboratory test prices are medical groups that operate as Federally Qualified Health Centers (FQHC). These health centers are eligible for Federal Section 330 grants and provide care to individuals without health benefits, or who lack access to quality healthcare.

"Low lab test pricing that is extended by California labs to FQHCs is an important element in this case," stated attorney Byron J. Gross of Hooper Lundy & Bookman. "It is our opinion that the California state Business and Profession's Code Section 667 specifically allows for discounts to uninsured patients.

"This means labs could charge low rates to Federally Qualified Health Centers," he said. "Similarly, these lab test discounts would be allowed under most agreements with physicians because, in many cases, the lab offers these discounts to benefit the uninsured treated by that client physician.

"While the regulations say that Medi-Cal can't pay more for comparable care under comparable circumstances, we would argue that an agreement with a FQHC is not a comparable circumstance," emphasized Gross. "In most cases, low rates are for uninsured patients and we believe that it is the legislature's intent that these patients be given a discount. But state officials have been stubborn and claim that low price agreements with other payers do not override the way they interpret the regulations."

Did Qui Tam Suit Trigger Medi-Cal Price Concerns?

➤Unsealing of whistleblower lawsuit in 2009 gave Medi-Cal officials a roadmap for lab audits

➤➤CEO SUMMARY: It is easy to track backwards to understand why the California Department of Healthcare Services (DHCS) began aggressive enforcement of its interpretation of statute 51501(a) against a number of labs this summer. DHCS officials were given a full education and a roadmap for action when, in April, 2009, the whistleblower lawsuit that accused seven lab companies of violating 51501(a) was unsealed and joined by Attorney General Jerry Brown. It appears that, informed by facts in this lawsuit, DHCS then decided to vigorously pursue the low price issue.

IT'S BEEN 21 MONTHS since California Attorney General Edmund G. Brown Jr., joined a whistleblower lawsuit filed against seven private laboratories to recover hundreds of millions of dollars in what Brown charged were illegal overcharges to the state Medi-Cal program for the poor.

At the time, Brown was joining a *qui tam* lawsuit filed under seal in 2005 by **Hunter Laboratories, LLC**, and Chris Riedel. The legal action alleges violations of the state's False Claims Act and was filed in San Mateo Superior Court. The suit charged that seven labs (including **Laboratory Corporation of America, Quest Diagnostics Incorporated, Westcliff Laboratories**, and four other labs based in California) had overcharged the Medi-Cal program since 1995. *(See TDR, April 9, 2009.)*

The basis of the whistleblower lawsuit is California Code of Regulations (CCR), Title 22, section 51501(a). Plaintiffs charged that the named defendants violated 51501(a) and said, "False claims result when providers submit claims to Medi-Cal at prices higher than what other providers were charged. The Medi-Cal program is entitled to restitution of the false claim payments."

THE DARK REPORT believes that it is the public unsealing of this lawsuit last April that directly led to the unprecedented enforcement campaign against low lab prices that was instituted this summer by the California **Department of Health Care Services** (DHCS). The state Medi-Cal agency's enforcement campaign is based on its interpretation of 51501(a).

This statute, which essentially tells a provider that it cannot bill Medi-Cal at a higher price than it charges another provider, is familiar to most laboratory executives. Further, over the past 20 years, DHCS officials have regularly stated their interpretation of this statute. But what the agency has failed to do during these same two decades is to take significant enforcement action against one or more clinical laboratories or other providers it views as having violated the pricing requirements of 51501(a).

Similarly, over the past two decades, as new pricing dynamics emerged in the healthcare marketplace, state officials have not regularly issued specific guidance on how to comply with 51501(a). For example, is 51501(a) violated if a capitated, full risk managed care or IPA contract was priced by a lab, a hospital, or a physician's office at a price that is less, on a fee-for-service basis, than what is billed to Medi-Cal?

Lacking ongoing regulatory enforcement action and updated guidance on situations like this, laboratory companies in California have continued the practice of low prices and deeply-discounted pricing into the present day. In legal challenges to its current enforcement actions against laboratories, DHCS will have to defend its current enforcement policy in the face of years of its perceived quiet acceptance of this market status quo.

THE DARK REPORT believes it was the public unsealing of the whistleblower lawsuit in April 2009 that motivated the Department of Health Care Services to mount its major enforcement campaign of 51501(a) this summer. That lawsuit lays out the massive scale of price discounting for laboratory tests that has been common for the past 20 years.

➤Whistleblower Lawsuit

As alleged in the *qui tam* lawsuit, the seven California laboratories regularly offered other providers laboratory test pricing that was significantly below the price these same labs charged the Medi-Cal program. In the unsealed and redacted lawsuit against LabCorp, the plaintiffs claim that Labcorp owes Medi-Cal a total of $72 million in overcharges, based on violations of 51501(a) that accrued over the past 14 years. During this time, the lawsuit says Medi-Cal paid Labcorp over $104 million.

In the case of Quest Diagnostics, plaintiffs say that the 14-year total of Medi-Cal payments was $726 million and overcharges associated with 51501(a) violations by Quest total $509 million.

These numbers reveal the extent to which the two national laboratories were willing to deeply discount lab test prices to favored providers, relative to the prices paid by Medi-Cal. Lab executives often complain that Med-Cal reimbursement for certain lab tests is below the cost of performing the test. The numbers provided in the whistleblower lawsuit give a different perspective on the pricing practices of the nation's largest lab companies.

➤Eyes Are Opened At DHCS

Further, one can now understand the reaction of DHCS officials to the details contained in this lawsuit. For bureaucrats at the cash-strapped Medi-Cal program, disclosure of overcharge amounts such as these must have been a true revelation.

Can it be a coincidence then, that Medi-Cal auditors began to show up at clinical laboratories in California in the months following the unsealing of the *qui tam* lawsuit? Next, having completed audits that revealed how, in the normal course of business, these laboratories were charging some providers less than they charged Medi-Cal, it would be expected that DHCS was now confronted with the dilemma of how to enforce their interpretation of 51501(a).

This is where DHCS found itself in a paradox of its own making. DHCS may be on the public record about its interpretation of 51501(a). But it had no history of ongoing enforcement of 51501(a), particularly as it applied to low-priced laboratory tests. Nor did DHCS have the benefit of having publicly provided detailed guidance, in prior years, on certain low price arrangements it may have determined violated its interpretation of 51501(a). *(See sidebar on page 18.)*

Therefore, both DHCS and California's clinical laboratories have reasons to be unhappy over the current situation involving low prices for laboratory tests as it relates to 51501(a). Each side comes to the table with a legal position that squarely opposes the other. How these events turn out is anyone's guess. However, it is likely that, going forward, DHCS intends to be diligent in enforcing its interpretation of 51501(a). TDR

Exhibit B

Trout, Philip B.

From: Wilkinson, Stephanie A. [SWILKINSON@ftc.gov]
Sent: Wednesday, March 02, 2011 9:31 PM
To: Habeeb, Christine N.
Cc: Bernick, Justin W.; Demarchi Sleigh, Lisa
Subject: RE: Foundation document production

Hi Christine,

In answer to your question, I can confirm that the FTC produced all documents that were in our custody and control at the time of the discovery request or subsequently, including non-privileged third party communications. If the emails you referenced were not produced, it is because they were not in our custody and control at that time. We have produced a copy of our document retention policy, and have complied with it. If you have any further questions about our document production, please contact Lisa DeMarchi Sleigh at 202-326-2535 or demarchisleigh@ftc.gov.

Best regards,
Stephanie

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Fax: (202) 326-2655
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From: Habeeb, Christine N. [mailto:christine.habeeb@hoganlovells.com]
Sent: Tuesday, March 01, 2011 9:03 PM
To: Wilkinson, Stephanie A.
Cc: Bernick, Justin W.
Subject: Foundation document production

Stephanie,

I'm sorry to bother you as you are preparing for additional depositions this week, however, I have a question regarding this morning's Boyamyan deposition.

Justin and I were more carefully reviewing the documents Mr. Boyamyan produced to us this morning, and we noticed an inconsistency. He gave us two e-mails from June 17, 2010, that we had not previously seen and that we are unable to locate in the FTC production database. The first is an e-mail containing the draft declaration from Stephanie Bovee to Mr. Boyamyan, and the second is also from Stephanie Bovee to Mr. Boyamyan, discussing the need for an urgent response to the declaration. I have attached scanned copies of them both.

Can you either confirm that these documents were produced or please let us know why they were not?

Thanks,
Christine Habeeb

Christine Habeeb *

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