Volume IX, Number 7 Monday, May 13, 2002

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R Lewis Dark

Founder & Publisher

Survivor: Story of the Nation's Largest Lab Firm

TELEVISION'S "SURVIVOR" IS THE UNFOLDING STORY of how one person competes to outlast 16 fellow players in a remote outdoor setting. The winner of "Survivor" walks away with a $1 million prize. The show has proven to be popular and is now airing episodes of its fourth group of competitors, stuck on a tropical island in the South Pacific.

Since the early 1990s, competition among public lab companies has been intense. The number of competitors declined steadily. The process was much like the TV show "Survivor." One at a time, lab companies would falter and disappear from the marketplace. Their labs, their clients, and their employees would be absorbed by a surviving lab company, usually through acquisition.

Thus, it was 1995 when the public lab industry ended up with three billion-dollar lab companies. They were **Quest Diagnostics Incorporated**, **Laboratory Corporation of America**, and **SmithKline Beecham Clinical Laboratories** (SBCL). Here is where my story begins. In a national market overshadowed by three billion-dollar lab testing behemoths, one was to pursue a business strategy that would make it the true survivor in the public lab consolidation game.

Around the offices of THE DARK REPORT, we remember the comments made by Quest Diagnostics CEO Ken Freeman in the years following its 1997 spin-off from **Corning Corporation**. Freeman observed publicly that, in any industry where three companies were large and dominant, economic forces invariably worked to eliminate one of the three. In this business analysis of his company's situation, it became a strategic goal of Quest Diagnostics to survive this expected shake-out.

Thus, when Quest Diagnostics acquired SBCL in 1999, it did not surprise those in the lab industry who understood the business strategy underpinning this acquisition. Freeman was taking active steps to insure the survival of his company by pushing the commercial lab industry into the two-company oligopoly that it is today and making Quest Diagnostics one of its two survivors.

I think this story is relevant for hospital lab administrators and pathologists. At a regional level, these same management dynamics argue that metropolitan areas dominated by three major hospitals or health systems will eventually see that number reduced to just two. For that reason, hospital labs and pathology groups in such cities should develop a business strategy that insures they are one of the two survivors! TDR

More Lab Consolidation: LabCorp Buys Dynacare

LabCorp gains entry into new regional markets and expands into Canada

CEO SUMMARY: Recent weeks brought many rumors about an impending deal between Laboratory Corporation of America and Dynacare. That speculation was ended last week when it was disclosed that LabCorp would pay about $685 million in cash, stock and assumed debt to acquire Dynacare. The acquisition also spells the end to Dynacare's strategy developing lab testing joint ventures with hospitals.

NEWS THAT **Dynacare, Inc.** would be acquired by **Laboratory Corporation of America, Inc.** confirms that 2002 will be a milestone year in the ongoing consolidation of independent commercial laboratory companies.

LabCorp's purchase of Dynacare follows on the heels of two earlier acquisitions involving the purchase of **American Medical Laboratories, Inc.** and **Unilab Corp.** by **Quest Diagnostics Incorporated**, announced since January 1 of this year.

The acquisition agreement was announced last Thursday. LabCorp will pay approximately $480 million in cash and stock. It will also assume $205 million of Dynacare's debt. Dynacare reported annual revenues of $402.4 million for 2001 and operates 24 laboratories in the United States and Canada. It has 6,300 employees.

There are three interesting aspects to this transaction. First, it removes another independent laboratory company from the physicians' office marketplace and concentrates that testing volume into LabCorp.

Second, LabCorp now acquires laboratory operations in Canada. This makes it the first United States-based laboratory firm in many years to have a presence in that country.

Third, the end of Dynacare as an independent laboratory company represents a failure of the business strategy that originally brought Dynacare into the United States back in the mid-1990s. Dynacare had declared its

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 1731 Woodland Terrace Center, Lake Oswego, Oregon 97034, Voice 1.800.560.6363, Fax 503.699.0969. **(ISSN 1097-2919.)**

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.55 per week elsewhere (billed semi-annually).

intent to build a laboratory testing business based on developing lab testing alliances and joint ventures with hospitals and health systems.

The sale of Dynacare to LabCorp is due, in part, to its failure to develop a sufficient number of viable lab testing ventures with hospital partners. In fact, as part of the announcement that it would sell to LabCorp, Dynacare also confirmed that it is terminating two of its four existing joint ventures with hospitals in the United States. The JVs with **Ellis Hospital** in Schenectady, New York and **Allegheny General Hospital** in Pittsburgh, Pennsylvania will be ended.

Benefits To LabCorp

In acquiring Dynacare, LabCorp is projecting that it will boost cash flow significantly as it integrates Dynacare's operations into its own. By the end of 30 months, LabCorp predicts it will gain $45 million in cash flow, attributable to operational consolidation, internalizing esoteric testing, and its lower costs for reagents and supplies.

"The numbers provided by LabCorp indicate they believe they can double the current profitability of the Dynacare business they are acquiring," stated Bill Bonello, Senior Analyst at **U.S. Bancorp Piper Jaffray**, based in Minneapolis, Minnesota.

Economies of Scale

Bonello's assessment about LabCorp's ability to squeeze more profit from Dynacare's business supports either of two conclusions about the lab marketplace in the United States, mainly: 1) Dynacare was operating in a relatively inefficient manner and had unrealized potential for substantial cost savings; or 2) LabCorp's economies of scale give them significant cost advantages over regional independent laboratory companies.

The right answer is important. If it is true that the nation's two billion dollar testing behemoths have intrinsic cost advantages due to their sheer size and purchasing volume, then more trouble lies ahead for the handful of larger independent commercial labs that still remain in business. It means the two blood brothers will continue to dominate the market segment for physicians' office-based lab specimens.

After all, as of January 1 this year, AML ($300 million), Unilab ($390.2 million), and Dynacare ($402.4 million) were the three largest independent lab companies still competing against Quest Diagnostics and LabCorp. It must be assumed that each of these three sizeable companies decided to sell, at least in part, because they believed selling their company was a better financial option than continuing to compete against the two blood brothers.

SIgn Of Market Change

The fact that all three "second tier" public lab companies decided to sell to either of the two blood brothers within a four-month period may be an important signal about the changing marketplace for specimens originating in physicians' offices. It may mean the clout and market power of Quest Diagnostics and LabCorp now make it extremely difficult for an independent commercial lab company to compete in this segment of lab testing.

This leaves hospital lab testing outreach programs and hospital-owned, for-profit commercial lab ventures as the only viable class of competitors for specimens from physicians' offices. It will be interesting to see what happens to these lab organizations now that Quest Diagnostics and LabCorp have removed the largest remaining commercial laboratory companies from the marketplace. TDR

Contact Bill Bonello at 612-303-5532.

Specialty Labs Coping With Unique Challenges

Regulatory sanctions and lab consolidation each require a detailed management response

CEO SUMMARY: Few laboratory executives have ever been tested as intensely as those of Specialty Laboratories, Inc. Since the first of the year, Quest Diagnostics Incorporated has purchased two of its biggest lab clients. In April, state and federal lab regulators issued sanctions. Both developments are roiling the market for hospital send-out testing.

IT'S THE PROVERBIAL "rock and hard spot" for **Specialty Laboratories, Inc.**, based in Santa Monica, California. Not only has it been hit by sanctions from state and federal lab regulators, but **Quest Diagnostic Incorporated** has acquired two its biggest lab clients.

As Quest Diagnostics integrates the operations of **American Medical Laboratories, Inc.** (AML) and **Unilab Corp.**, it is expected that much of the reference testing referred to Specialty Laboratories by these two companies will be redirected to labs belonging to Quest Diagnostics.

Plan of Correction (POC)

Even as this unfolds in coming months, Specialty Labs must also come to an understanding with its lab regulators and develop a plan of correction (POC). It will then need to implement that POC and correct the deficiencies which triggered sanctions announced in April.

Strategically, this means that Specialty Laboratories must develop a business plan which addresses declines in specimen volume caused by the acquisition of two big clients, along with reductions in its test menu as an internal response to its regulatory situation.

One impact of the federal sanctions issued to Specialty Laboratories is the uncertainty they raised about Medicare billing for referred testing. Since federal regulations lack clarity about the unique circumstances of Specialty Labs' case, the lab company has issued a letter of opinion from its law firm. This letter of opinion can be found on the company's Web site at *www.specialtylabs.com*.

Resolution of the federal and state sanctions is the most pressing priority at the Santa Monica-based lab company. The departure of Chairman and CEO James B. Peter, M.D., Ph.D. last month and the appointment of Douglas Harrington, M.D. as interim CEO is a major part of that effort. Dr. Harrington is a long-time board member for Specialty Labs. He is also Chairman of **Chromavision, Inc.**, based in San Juan Capistrano.

One reason for Dr. Harrington's appointment as interim CEO is his considerable experience at working with laboratory regulators from the **California Department of Health Services** (CDHS) to correct deficiencies in an esoteric laboratory setting.

One of the lab industry's best-kept secrets is that, in the late 1980s and early 1990s, Nichols Institute, then an independent, publicly-traded lab company, was inspected by CDHS and found to have serious deficiencies, some involving the same issues of "non-licensed personnel" performing and supervising tests. *(See pages 16-17.)* Dr. Harrington supervised development of a plan of correction (POC) which resolved those deficiencies and brought Nichols Institute back into compliance. This type of experience obviously now has high value within Specialty Laboratories.

Reduced Test Menu

Another part of Specialty's effort to address deficiencies involves its existing test menu, numbering some 3,000 assays. Clients should expect to see a reduction in the number of available tests. Infrequently-ordered assays will probably no longer be offered. By reducing the wide spectrum of seldom-ordered tests, Specialty Labs will find it easier to reorganize lab operations and cure the deficiencies that were cited by state and federal regulators.

For lab executives and pathologists, the sanctions issued to Specialty Laboratories raise questions about whether lab regulators are actively sending a message to the lab industry. In particular, are federal lab regulators preparing to become tougher in their enforcement of CLIA-88 standards?

On pages 16-17 of this issue, THE DARK REPORT reviews earlier cases of lab deficiencies in California. These earlier cases seem to indicate that some of Specialty Lab's current problems are similar to deficiencies identified by state regulators at other labs in past years. When the full story becomes public, there is also most likely lots of blame in how the executive team at Specialty Labs responded to the concerns of lab regulators.

Unrealistic Regulations

As well, another contributing factor will turn out to be the rather unrealistic regulations that define a CLS—clinical laboratory scientist—and how CLS-licensed personnel conduct and supervise laboratory tests in the state. This is particularly true for Ph.D.s whose line of study may not have included much of the "med tech" curriculum that California regulations require for a CLS license.

THE DARK REPORT will also go out on a limb and predict that the end to the Specialty Labs-regulator spat may come sooner than anyone expects. Certainly Specialty Labs has every incentive and motivation to negotiate a speedy and swift resolution to its problems with state and federal lab enforcers.

But what of the enforcers? The decision by federal regulators to issue sanctions that include the revocation of Specialty Labs' license, now stayed on legal appeal, has put them squarely in the spotlight. This first-ever revocation of a public lab company's CLIA-88 license, and its financial consequence to Specialty Labs, certainly attracts the scrutiny of elected officials from both the executive and legislative branches.

THE DARK REPORT's point is simple: both parties to this dispute have good reasons for a speedy resolution. If that happens within weeks, it will be a welcome break for the beleaguered executives at Specialty Laboratories. TDR

High Cost of New Assays Stretching Lab Budgets

Increased costs of new test technologies are busting hospital laboratory budgets

CEO SUMMARY: Growing numbers of hospital labs report that higher costs of new diagnostic tests have become a new management problem. That's because diagnostic manufacturers are developing tests around a new business model, one that calls for higher pricing based on a premise of higher clinical value. Marketing campaigns for these new assays will become increasingly sophisticated and pervasive.

TO INTRODUCE new diagnostic tests, manufacturers are adopting more sophisticated marketing models, some of which are designed to support higher prices for these new assays.

In a growing number of hospital laboratories, the higher cost of new reference and esoteric testing is causing concern. In response, many lab directors and pathologists have begun to develop formal procedures within the hospital to guide physician utilization and educate them about the actual costs incurred by these new tests.

Problem Expected To Grow

THE DARK REPORT predicts that the problem of higher costs for new lab assays will become a bigger management challenge for hospital laboratories in coming years. That's because companies introducing new diagnostic tests built upon genomic and proteomic technology design their business model upon the assumption they can sell their new lab tests for a relatively high price.

Such companies want to copy the success of **Cytyc Corporation's** ThinPrep® Pap Test, which, since its launch in 1995, has captured more than 50% of the Pap testing market in the United States, causing Cytyc's stock price to soar in value.

Besides copying Cytyc's new product launch strategy, diagnostic test developers will increasingly borrow marketing techniques from the pharmaceutical industry. This will include direct-to-consumer advertising and "detail reps" paid to visit clinicians in their offices and educate them about the test and how and when to order it.

One direct consequence of this trend is that clinical laboratories will be bypassed, in certain ways, because these types of marketing campaigns are aimed directly at clinicians and patients. When this occurs, clinical laboratories lose their primary role as the source of information and education about new diagnostic tests for the clinicians they serve.

For hospital labs seeking to control test utilization and the cost of send-out

testing, this is a troublesome trend. The desire of diagnostic manufacturers to introduce tests which generate higher profits is in direct conflict with the hospital lab's need to control the overall cost of testing done on its patient population.

The strategic marketing plan used by Cytyc to introduce its ThinPrep Pap test is now considered a textbook example for how to launch a new diagnostic test. That is why it is being studied and emulated by other diagnostic companies.

...this is a troublesome trend. The desire of diagnostic manufacturers to introduce tests which generate higher profits is in direct conflict with the hospital lab's need to control the overall cost of testing done on its patient population.

In the ThinPrep marketing plan, Cytyc attacked with four distinct initiatives. First, it worked diligently to see that clinical studies claiming benefits from the ThinPrep test were widely-publicized in the medical community. Two, it worked diligently to get health plans to agree to adequate reimbursement for ThinPrep tests—then publicized those agreements as a way to encourage other insurers to make the same decision.

Direct-To-Consumer Ads

Third, Cytyc marketed ThinPrep directly to female consumers. In magazine advertisements and other literature, the company subtly implied that ThinPrep was a "safer" test than conventional Pap smears. Cytyc also played a role in supporting advocates of improved women's health as they lobbied payers and Medicare to make favorable decisions to include the ThinPrep Test as a covered procedure.

Fourth, Cytyc carefully structured the pricing structure of ThinPrep testing to make it more profitable for commercial laboratory companies than conventional Pap smear testing, so long as local health plans offered adequate reimbursement for ThinPrep.

Cytyc's Next Test

The success of Cytyc's marketing promotion of ThinPrep testing is reflected in its revenues and profits. For 2002, the company expects revenues to top an estimated $272 million. To diversify its product line, last fall Cytyc paid $167.5 million to acquire rights to "ductal lavage," a procedure that can be used in breast cancer screening.

By understanding this four-pronged marketing strategy, lab executives and pathologists can track Cytyc's efforts to duplicate its ThinPrep marketing strategy for ductal lavage. The early efforts are already visible. Thus, a press release on April 3, 2002 trumpeting the decision by **CareFirst BlueCross BlueShield** (with 3.1 million beneficiaries in Maryland, Delaware, DC, and Virginia) to "adopt a positive coverage policy for ductal lavage." It is worth noting that the definition of a "positive coverage policy" is not provided.

This announcement was followed on April 24, 2002 by Cytyc's financial earnings report. In this report, Cytyc confirmed that two of the four elements of its marketing plan were already in play.

First, Cytyc has a team of sales people now calling on clinicians. "In January, Cytyc's specialty sales force began promoting to breast surgeons and radiologists the use of FirstCyte Ductal Lavage." Second, Cytyc notes that **Empire Blue Cross** (New York) announced coverage of ductal lavage test-

ing. Cytyc also declared that "currently, health plans representing nearly 20 million members cover ductal lavage."

In coming months, the laboratory profession will probably see news releases about clinical studies of ductal lavage. It is important for the company to demonstrate clinical efficacy if it wants clinical use of ductal lavage for breast cancer screening to become more common. Thus, the company will widely-publicize any positive findings from these studies.

Labs "Out of the Loop"

THE DARK REPORT believes it is important for lab directors and pathologists to understand the marketing strategies used to introduce new diagnostic assays. Because these marketing strategies call for the manufacturers to advertise directly to consumers and educate clinicians with their own sales reps, laboratories will be "outside the loop," at least until test requests for the new assays are received in the lab.

As many pathologists know from first-hand experience, being outside the loop means a surprise when a clinician requests a multi-test esoteric panel, costing several thousand dollars, following a visit by that manufacturer's sales rep to the clinician. These surprises are hitting hospital labs more frequently, demonstrating that more esoteric testing sources are using this marketing strategy.

New Set Of Challenges

As growing numbers of new assays based on genomic and proteomic science hit the clinical marketplace, hospital laboratories will find themselves dealing with an entirely new set of problems involving physician utilization and the cost of send-out testing. Many of these will be a direct result of the different business models and marketing strategies used by diagnostic manufacturers.

Not All Labs Will Get Access to New Assays

EVEN AS DIAGNOSTIC MANUFACTURERS change the way they market new laboratory tests, they are also changing the way they distribute these new assays to clinical laboratories.

To build a "brand" (think **Coca-Cola**, **MacDonald's**, and **Mercedes-Benz**) from a new diagnostic assay, companies need to develop a distribution channel to the clinical marketplace. To accomplish this, they will sign exclusive agreements with specific laboratories they think can help them build market demand. These agreements will prevent other labs from having access to the test.

Becoming the distribution partner with diagnostics companies is a key strategy of **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**. They believe it will be a source of competitive advantage. *(See Ken Freeman's comments on this subject in TDR, April 22, 2002.)*

Visible Genetics, Inc. is using this strategy with its FDA-approved TRUGENE HIV-1 genotyping test kit. It has agreements with **Esoterix**, **Bio-Reference Laboratories**, and a handful of other selected labs to offer this test in competition against the "branded" home brew assays offered by some of the national lab companies.

While this may be a good business strategy for the diagnostic manufacturer, it restricts access to the test by early-adopter labs which want to set up and run the test for their clinicians.

In summary, the experience of many laboratories demonstrates that fundamental changes are already occurring in the way new diagnostic tests are brought to market. These changes may be adding extra costs without providing better clinical outcomes. **TDR**

Contact Robert Michel at 503-699-0616.

Commercial Lab Consolidation is The Culprit

Is Physicians' Office Testing Evolving Toward an Oligopoly?

***CEO SUMMARY:** One of the most unpopular industries with consumers is the airline industry. At the national level, it is an oligopoly—dominated by seven carriers. But in many cities, it is a monopoly, with one airline flying 80% of the seats in and out of town. Ongoing consolidation of regional commercial labs by the Two Blood Brothers is creating a parallel situation in the lab industry segment serving physicians' offices. Nationally, that market segment is now an oligopoly. But in many cities, it is already a monopoly, dominated by one national lab company. Consequences of this trend will soon be obvious.*

BY ROBERT L. MICHEL

IS THE LABORATORY TESTING INDUSTRY in the United States becoming an oligopoly, a market typically dominated by two or three companies?

Economists familiar with the details of the lab testing industry would increasingly answer "yes"—specifically for the physicians' office testing segment of the market. This has been the primary source of specimens and revenues for independent commercial laboratories during the last two decades.

But more provocatively, I would posit that, on a city-by-city analysis, it can be argued that the physicians' office testing segment of the laboratory industry is already a monopoly. Consequences of this duality—oligopoly at the national level, monopoly at the regional level—have yet to play out in the marketplace. Thus, most lab executives and pathologists are not yet alarmed at the negative dynamics that often result from markets characterized by monopolistic and oligopolistic characteristics.

By way of illustration, I believe the American airline industry provides a good example of the duality of a national oligopoly supported by regional monopolies. Most laboratorians have first-hand experience with the consumer-unfriendly service and prices offered by airlines. Over time, similar service and pricing practices can be expected to emerge in the commercial laboratory segment of our industry as this oligopolistic and monopolistic duality becomes more entrenched.

Two-Lab Oligopoly In U.S.

Ongoing consolidation of the commercial laboratory segment of the industry is creating a two-company oligopoly, comprised of **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**. During 2002, the two companies will do an estimated $4.3 billion and $2.6 billion, respectively.

But their dominance of the national market becomes evident when looking at the third biggest public lab company that remains. That is **Bio-Reference Laboratories, Inc.** (BRLI), with projected revenues of $90 million in 2002. **Lab*One*, Inc.**, at $234 million, shouldn't be overlooked. However, the lion's share of its testing volume does not come from physician's offices, but from life insurance testing.

This year, acquisitions of **Unilab, Inc.** ($390 million in 2001) and **American Medical Laboratories, Inc.** (AML –$300 million in 2001) not only made Quest Diagnostics bigger, but removed two of its three largest laboratory competitors from the marketplace. *(See TDR, April 22, 2001.)* Last week LabCorp announced that it would acquire **Dynacare, Inc.**, with estimated 2002 revenues of $410 million from its lab operations in the United States and Canada. It has been the ongoing acquisitions of independent commercial labs such as these that concentrated testing from physicians' offices into the hands of just two national laboratory companies.

Customers Pay More

Most laboratorians are familiar with the concept of a business monopoly—dominance of a market by one company. Such dominance allows a company to manipulate supply in order to artificially raise prices. Because customers pay more than they would otherwise, monopolies have long been considered "bad," thus making them valid targets for government antitrust action. Innovation and service generally suffer because the monopoly company doesn't have to improve its products and services, since its customers have no alternative choice. (Think "airlines.")

In our nation's history, examples of "bad" monopolies were John D. Rockfeller's **Standard Oil** Trust and Andrew Carnegie's **United States Steel** Trust. At the turn of the century, federal "trustbusters" took decisive action to break up such monopolies.

1970s OPEC Oligopoly Yielded to Competiton

DURING THE 1970S, OPEC's oil cartel represented an oligopoly in the crude oil markets. Through overt collusion, member-countries were able to restrict supplies of oil, causing prices to artifically double and triple between 1973 and 1981.

Early in the 1980s, OPEC lost its oligopolistic-derived power to keep oil prices artificially high as non-OPEC countries brought increased supplies of crude oil into the world market. The arrival of new suppliers eroded the oligopoly's effectiveness and restored a degree of competitive balance.

For the lab industry, the OPEC example demonstrates that having multiple competitors offering lab testing in the same market is one effective way to break an oligopoly. But because healthcare is local, the key is to have multiple lab competitors in a region, each capable of providing comparable lab testing services to physicians' offices in that region.

In so doing, government regulators developed the basic principles of antitrust law which are still in use. One prominent recent example is the government's antitrust case against **Microsoft Corporation**. Federal regulators charged that Microsoft Windows has a monopoly share of the market for PC operating systems and that Microsoft has engaged in anticompetitive behavior to protect this monopoly.

But an oligopoly has important differences from a monopoly. Because there are at least two competitors, efforts to truly control supply and artifically raise prices requires, at worst, outright collusion and, at best, careful synchronization between the oligopolists to implement "uncoordinated and unplanned" moves that constrict supply and increase prices.

In the United States today, probably the best example of an oligopoly market is air travel. At the national level, seven airline companies control inter-city air travel in the United States. At this level, their control of the supply of seats between cities, and the prices of those seats, is a "competitive" process that is carefully manipulated.

However, at a regional level, these same airlines become monopolies. This is a result of the hub-and-spoke business model that developed during the 1980s. For example, **Northwest Airlines** controls more than 80% of the flights going in and out of Detroit's McCarran Airport, giving it monopoly pricing power in that regional market. In North Carolina, **USAir** has a similar market share at Charlotte/Douglas International Airport, which was recently judged to have the highest airfares of any airport in the United States.

From this perspective, the oligopolistic business practices of the nation's seven airlines can offer instructive insights into the business practices of the two blood brothers, Quest Diagnostics and LabCorp.

Monopolies At Local Level

My contention is that laboratory testing offered to physicians' offices by commercial laboratories is becoming an oligopolistic market at the national level—and is already monopolistic in specific regional markets.

Thus, if the national market for physicians' office testing segment is becoming a true oligopoly, does this portend a better or worse future for career laboratorians. And how will this dichotomy of oligopolistic/monopolistic characteristics at the national and local level affect the customers served by labs, including physicians, patients and payers?

I pose this question for a good reason. I believe, in particular, that the

back-to-back acquisition of Unilab and AML by Quest Diagnostics, assuming that antitrust enforcers approve the Unilab deal, is a sentinel event in the American laboratory services marketplace. That is to say, in calculating market share to determine whether proposed lab mergers and acquisitions would be anti-competitive, regulators are willing to lump *all* classes of testing into one pot and then calculate the post-merger impact against that pot.

Market Share Threshold

Generally, one element that triggers antitrust concerns is whether, post-merger, the combined enterprise will hold more than 30% market share of the area served. As many laboratorians recognize, the combination of Unilab and Quest Diagnostics in California would certainly exceed that threshold by a sizeable factor—if the testing segment served is measured as the share of physicians' office send-out testing within the Golden State. If it includes all lab testing, including hospital inpatient/outpatient and POL (physician's office laboratory), then it probably doesn't.

That is why, if antitrust concerns are not triggered by the Unilab/Quest Diagnostics merger in the California regional market, it will be a sign that antitrust concerns will apparently not be triggered by the continued acquisition of local independent commercial lab companies by the Two Blood Brothers. That implies further consolidation of the dwindling number of viable independent lab companies in the United States that are organized to primarily serve the send-out testing needs of physicians' offices.

Are hospital laboratory testing outreach programs a viable and competitive factor in this analysis? That depends. In certain cities, one can find flourishing and viable hospital lab testing outreach programs. However, across the nation, there is a depressingly low number of successful hospital outreach testing programs operated by the nation's 4,800 hospitals and the 600+ integrated delivery networks.

In fact, in the nation's biggest cities, such as New York, Los Angeles, and San Francisco, there are less than a handful of hospital outreach programs. Most of these serve "captive" business—physicians's offices owned or managed by the hospital or health system itself. In those cities, lab outreach programs which are viable competitors against the Two Blood Brothers are difficult to find.

In contrast, Detroit, Seattle, and several large Florida cities have highly-competitive lab testing markets. Hospital lab outreach programs are every bit as competitive as the national labs in fighting for lab testing business that originates from physicians' offices. They have professional managed care contracting capability and their contracts are usually serviced by a regional laboratory network.

Regional Lab Networks

THE DARK REPORT has written about Detroit's **Joint Venture Hospital Laboratories** (JVHL), the **Florida Reference Laboratory Network** (FRLN), and Washington State's **PacLab Network**. Since healthcare is a regional business, it is not surprising that there are some regional successes. However, in many communities across the United States, no hospital lab outreach program exists, leaving those regional markets wide open for the Two Blood Brothers.

It should not be overlooked that the ranks of independent commercial lab companies have been dramatically reduced through mergers and acquisitions. On page 14, a table of the largest, non-hospital-owned independent laboratory companies is present-

ed. Estimates of the annual revenues of these private lab companies show that only a couple exceed $50 million per year in annual revenues.

Defacto, and independent of subsequent federal antitrust policy, there now exists a duality of national oligopoly and regional monopolies in the market segment of send-out lab testing for physicians' offices.

Impact On Small Labs

Assuming that to be true, it becomes important for those regional lab competitors which are still in business to think strategically about how this oligopolistic/monopolistic duality impacts their business.

After all, oligopolies create interesting and complex challenges, both for the tiny competitors trying to survive on the fringes of the market, and for government regulators. Again, the airline industry is instructive. Any time a start-up airline emerges, the oligopoly of the seven major airlines works in concert to squeeze it before it gets financial traction. They do this by adding flights and seats on the same routes and discounting ticket prices.

A great example of this was in Dallas, hub for **American Airlines**. In the last 18 months, an upstart airline began flying regional jets from Dallas Love field, non-stop, to major markets. American immediately put comparable jets into Love Field (although it had *never* scheduled service there since the opening of Dallas-Fort Worth Airport in the 1970s). American matched the upstart's flights and discount fares. When the discount airline failed, American ceased flying from Dallas Love Field.

No AntiTrust Enforcement

Antitrust behavior by a regional monopolist and a national oligopolist? Certainly most individuals with common sense would think so, but federal antitrust regulators decided not to bring a case. This scenario happens regularly to start-up airline companies and preserves the basic oligopoly for existing airline companies.

Could the collective number of hospital lab outreach programs and small independent commercial labs that still operate in the United States somehow act as a counterweight to many business practices of the Two Blood Brothers?

Probably not. Take managed care contracting, for example. Size gives the Two Blood Brothers clout, both at the national level and the local level. Not surprisingly, in most urban markets, the Two Blood Brothers hold almost all the major managed care contracts.

Clout In MC Contracting

That's because, on one hand, the national insurance companies like the simplicity of "cutting one contract" with one lab company to serve all their local plans. On the other hand, the two national labs are willing to provide testing at prices which are uneconomically-low for local lab providers serving local markets. Yet, these same managed care companies will complain about the poor service levels of the Two Blood Brothers, while denying local labs, with recognizably better infrastructure and service, the opportunity to serve those beneficiaries.

It is important for the laboratory industry to recognize the reality of this national oligopoly and regional monopoly in the physicians' office testing segment. It has changed the competitive dynamics of the lab industry.

Furthermore, ongoing consolidation of anatomic pathology groups could bring about a similar situation in future years. This would be particularly true if the Two Blood Brothers decided to also begin acquiring local pathology group practices. TDR

Contact Robert Michel at 503-699-0616.

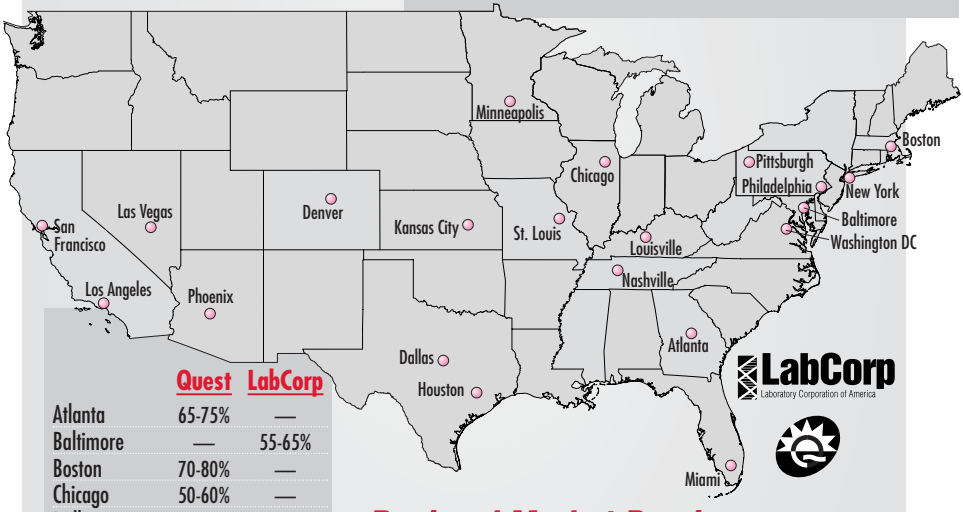
Lab Market Duality of National Oligopoly And Regional Monopolies Exists In U.S.

National Lab Oligopoly

How thin are the ranks of privately-owned independent lab companies serving the physicians' office market? The list at right shows almost all the non-hospital labs (i.e.: not owned in whole or part by a hospital entity) remaining in the United States which do at least $25 million per year in revenues. Revenue estimates were based on information from several sources, including Dun & Bradstreet.

Dwindling Number of Privately-Owned Independent Commercial Lab Companies

	Lab	City	($000s) Est. Rev
1.	Clinical Pathology Labs	Austin, TX	$80
2.	Doctors Laboratory	Valdosta, GA	$35
3.	Sunrise Medical Labs	Hauppauge, NY	$30
4.	Boyce & Bynum Med Labs	Columbia, MO	$30
5.	Universal Diagnostic Labs	Brooklyn, NY	$25
6.	Westcliff Medical Labs	Newport Bch, CA	$25
7.	Metropolitan Medical Labs	Davenport, IA	$25
8.	Healthline Clinical Labs	Burbank, CA	$25



	Quest	LabCorp
Atlanta	65-75%	—
Baltimore	—	55-65%
Boston	70-80%	—
Chicago	50-60%	—
Dallas	30-40%	55-65%
Denver	65-75%	—
Houston	55-65%	30-40%
Kansas City	—	50-60%
Las Vegas	85-95%	—
Los Angeles	60-70%	—
Louisville	—	70-80%
Miami	45-55%	30-40%
Minneapolis	70-80%	—
Nashville	—	75-85%
New York	70-80%	—
Philadelphia	60-70%	—
Phoenix	65%	30%
Pittsburgh	65-75%	—
San Francisco	65-75%	—
St. Louis	65-75%	—
Washington DC	65-75%	—

Regional Market Dominance

Shown above are a number of major American Cities where one of the Two Blood Brothers is believed to hold 50% or more of the physicians' office testing segment in that region. It demonstrates how, city by city, the two national labs have expanded their dominance of selected urban markets in recent years. Estimates of market share come from lab professionals familiar with these areas and represent their "best guess" at current market share of physicians' office testing for these cities.

Public Laboratory Rankings

2001 Another Year of Fast Growth!

Boom times continued during 2001 for both the clinical laboratory industry and anatomic pathology profession.

Throughout 2001, almost every public lab company was able to post double-digit revenue growth. For a number of companies, this growth was accomplished by acquiring smaller laboratory companies.

But most lab companies also report strong increases in specimen volume attributable to sales efforts. This is compelling evidence that investments in professional sales and marketing programs are worthwhile in today's healthcare environment. Hospital outreach programs and local pathology groups should take note and develop their own effective sales program.

General Reference Laboratories

Ranking By 2001 Annual Revenue ($s in millions)

Rank	Laboratory	2001 Revenue	% Change	2000 Revenue
1.	Quest Diagnostics Incorporated[1]	$3,627.7	+6.1%	$3,421.2
2.	Laboratory Corporation of America	$2,199.8	+14.6%	$1,919.3
3.	Dynacare, Inc.[2]	$402.4	+14.0%	$352.9
4.	Unilab Corp.	$390.2	+15.6%	$337.5
5.	American Medical Laboratories[3]	$297.0	+13.9%	$260.8
6.	LabOne, Inc.[4]	$233.9	+38.0%	$169.2
7.	Bio-Reference Laboratories, Inc.[5]	$81.6	+22.7%	$66.3
	Total: General Reference Laboratories	***$7,232.6***	***+10.8%***	***$6,527.2***

[1] *Quest Diagnostics has an agreement to acquire Unilab in 2002.*
[2] *LabCorp has an agreement to acquire Dynacare in 2002.*
[3] *Quest Diagnostics acquired American Medical Labs in 2002.*
[4] *BRLI's fiscal year ends 10/31/01.*
[5] *Majority of LabOne's revenues come from life insurance testing.*

Niche & Pathology Lab Companies

Ranking By 2001 Annual Revenue ($s in millions)

Rank	Laboratory	2001 Revenue	% Change	2000 Revenue
1.	AmeriPath, Inc. (*pathology management*)	$418.7	+26.8%	$330.1
2.	IMPATH Inc. (*oncology*)	$189.6	+37.2%	$138.2
3.	Specialty Labs (*reference*)	$175.2	+14.3%	$153.2
4.	DIANON Systems, Inc.[1] (*anatomic pathology*)	$125.7	+31.3%	$95.7
5.	PharmChem, Inc.[2] (*substance abuse*)	$43.9	-6.2%	$46.8
6.	MedTox (*substance abuse*)	$49.1	+14.5%	$42.8
	Total: Niche & Path Lab Companies	***$1,002.2***	***+24.1%***	***$806.8***

[1] *DIANON acquired UroCor during 2001.*
[2] *PharmChem was delisted from NASDAQ in 2002.*

Calif. Lab Regulators Are A Tough Bunch

Other public lab companies in Golden State have run afoul of state laboratory regulations

CEO SUMMARY: By law, government regulators cannot comment publicly about the actions they take against the companies they regulate. That's why the lab industry never learned that other public lab companies operating in California, following inspections by state authorities, were judged to have some deficiencies similar to those found at Specialty Laboratories.

BY NOW, JUST ABOUT EVERYONE in the lab industry knows that **Specialty Laboratories, Inc.** was hit by sanctions that included revocation of its CLIA-88 license, subject to an appeal which was filed by the troubled laboratory company last month. *(See TDR, April 22, 2002.)*

What most laboratorians don't know is that California laboratory regulators have been tough on several other well-known laboratory companies in past years. What was different in most of these earlier cases is that the public lab companies were able to keep news of regulatory deficiencies from becoming public knowledge.

Undisclosed Facts

THE DARK REPORT has tracked these fascinating stories over the years, since they provide insights into the enforcement philosophies of laboratory regulators. For example, back around 1989, **Nichols Institute**, then an independent public company, was inspected by the **California Department of Health Services** (CDHS). Deficiencies were deemed serious enough that Nichols Institute was required to develop an acceptable plan of correction (POC) and was subject to state inspections for a two-year period, ending around 1991. News of this situation was kept confidential and never became public knowledge.

Another situation occurred in the 1998-99 time period. CDHS lab regulators cited the Van Nuys laboratory owned by **SmithKline Beecham Clinical Laboratories** (SBCL) for deficiencies. This was prior to SBCL's acquisition by **Quest Diagnostics Incorporated**. SBCL ceased certain lines of testing at that facility and was forced to send those specimens to its lab in Dublin, California until the deficiencies in Van Nuys were corrected.

An even more interesting case involved **PharmChem, Inc.**, the drugs-of-abuse testing company. In recent years, while it was still based in Menlo Park, California, PharmChem was caught in the regulatory crosshairs of CDHS lab officials. Of the

deficiencies cited, some mirrored those at Nichols in 1989 and Specialty Labs in 2002, most notably the use of "unlicensed personnel" to perform and supervise testing.

Since a number of public lab companies have experienced similar episodes with California lab regulators, Specialty Lab's case is exceptional specifically because sanctions reached the point of license revocation.

As with other labs cited by CDHS inspectors, PharmChem had Ph.D.s, some with board certifications in diagnostic specialties, working in the lab, but not holding a license as a clinical laboratory scientist (CLS) under California regulations. Since these Ph.D.s lacked the CLS license, CDHS regulators found the lab to be in violation of state regs requiring CLS-licensed individuals "to perform and supervise" testing.

One unique feature of PharmChem's dispute with its regulators involved the interpretation of state lab regulations covering "patients." Unlike earlier years, CDHS regulators began defining the individual who provided a drugs-of-abuse test specimen as a patient. Based on this new interpretation, CDHS then cited PharmChem for deficiencies under regulations intended to address clinical laboratory testing, despite the company's activities in drugs-of-abuse testing.

Legislative Branch Appeal

Executives at the laboratory tell THE DARK REPORT that the situation escalated to the point where regulators actually drafted a "cease and desist." To resolve the issue, this laboratory company went to the state legislature, pled its case, and gained relief through passage of legislation clearly defining the differences for regulating clinical laboratory testing as distinct from drugs-of-abuse testing. In recent years, this lab company relocated its testing activities outside the state of California.

THE DARK REPORT has been told that the same regulators involved in this case are also involved in the Specialty Laboratories case. As noted above, THE DARK REPORT has documented serious regulatory actions between the California Department of Health Services and Nichols Institute, SBCL, PharmChem, and, most recently, Specialty Laboratories.

Each was a public lab company at the time that regulators identified deficiencies during inspections. Taken collectively, this is factual evidence that, at some level, the fundamental relationship between certain lab companies in the state and CDHS lab enforcers is probably not amicable.

LIttle Information Available

Since a number of public lab companies have experienced similar episodes with California lab regulators, Specialty Lab's case is exceptional specifically because sanctions reached the point of license revocation. The differences are difficult to judge, since few details about the deficiencies have been disclosed by either lab regulators or Specialty Laboratories.

But each of these earlier cases does support a conclusion that aspects of California's lab regulatory environment have become unwieldy. Changes in laboratory technology, such as molecular and genetic diagnostics, and the growing shortage of technically-trained laboratorians, may have outmoded existing regulations which were created years ago to address a different set of problems. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Guess whose DNA was used by **Celera Genomics** during its project to map the human genome back in 1999? It was primarily the DNA of J. Craig Ventor, Ph.D., who was Chairman of Celera at that time. The disclosure, made last week, has stirred some controversy. Defenders say it is in the tradition of self-experimentation by researchers. But critics say it was motivated by Dr. Ventor's desire to immortalize himself. At any rate, the disclosure now lets laboratorians involved in genomic research know the source of the human DNA with which they work.

DIANON POSTS STRONG GROWTH

DIANON System, Inc.'s acquisition of **UroCor, Inc.** last year is paying off. The anatomic pathology company reported an increase of 66% in revenues for the quarter, from $26.8 million in Q1 2001 to $44.6 million for Q1 2002. Net income increased by 128% for the quarter.

FIRST "ID CHIPS" IMPLANTED IN HUMANS

Last week, doctors in Florida implanted "ID chips" into several humans. When a handheld scanner is waved over the chip, it emits a signal with an ID number. This number, when entered into the Web site of the manufacturer, **Applied Digital Solutions, Inc.**, allows the user to obtain medical or other information about the individual carrying the chip. The goal is to eventually provide medical histories and information about the individuals carrying the chips. The technology is similar to that used by pet ID chips. One barrier to use is that hospitals and physicians do not have the scanners, which cost at least $1,000. Since lab data is a major part of most medical records, laboratorians should keep an eye on this developing technology.

ADD TO: *ID Chips*

Here's another example of how implanted instruments in humans can generate diagnostic data. **Biotronik** has developed a pacemaker that includes a computer chip which tracks heart rhythm and the number of jolts delivered. Ordinarily the physician must see the patient to evaluate the effectiveness of the pacemaker. But Biotronik's model links to a transmitter the patient keeps nearby. This connects to Biotronik and downloads the performance details of the pacemaker. Biotronik then sends a fax with this information to the physician. This type of technology may demonstrate the feasibility of in vitro diagnostic monitoring.

Beckman Coulter Reports Earnings

For the first quarter, **Beckman Coulter Corp.** posted revenue growth of 3.9% and earnings growth of 20%. Its clinical diagnostics business increased by 3.9.% for the first quarter, totaling $313.9 million versus $302.1 million for first quarter 2001. Fastest-growing products were in robotic automation and genetic analysis, which grew 20%, and immunodiagnostics, which increased by 8%.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 3, 2002.

UPCOMING...

- *First Reports From the* **Executive War College***: New Directions for Hospital Labs.*
- *Pathology Billing and Coding: Fixing the Ten Most Common Errors.*
- *What's Up with the Web? How Mergers Are Changing Browser-based Lab Services.*

For more information, visit:
www.darkreport.com