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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 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Procter & Gamble Moves into the Neighborhood

LAST MONTH, A NEW RESIDENT BOUGHT INTO THE LABORATORY TESTING NEIGHBORHOOD. **Procter & Gamble Company** spent a third of a billion dollars to enter a joint venture with **Inverness Medical Products, Inc.**, with the specific goal of selling diagnostic test kits to consumers in pharmacies, grocery stores, and other retail outlets.

As you will read on pages 7-9, Inverness Medical Products—already a major player in consumer self testing—just outbid **Beckman Coulter Corporation** to acquire **Biosite, Inc.**, which has a significant presence in the point-of-care test (POCT) market. On the same day that Inverness announced its acquisition of Biosite, it also announced the formation of its joint venture with Procter & Gamble. The two companies formed **SPD Swiss Precision Diagnostics GmbH** (SPD), which will be based in Geneva, Switzerland. Inverness tossed its kits for home pregnancy tests and fertility/ovulation monitoring into the joint venture. Procter & Gamble made a $325 million investment for its contribution.

I consider this to be a notable development. It brings one of the world's most respected companies in consumer products a step closer to the laboratory testing marketplace. P&G's interest in consumer self testing is based on its belief that consumer demand for health services and healthcare products will soar in the coming decades. Thus, it wants to position itself to be a distribution, marketing, and sales channel for healthcare-related products.

Some of you keen observers probably already know that P&G markets a number of therapeutic drugs. For example, when Prilosec, the heartburn medicine, came off patent, P&G convinced the drug's owner, **AstraZeneca**, to allow it to market over-the-counter sales of Prilosec.

What does Procter & Gamble's move into the laboratory testing neighborhood mean for pathologists and lab directors? In the short term, there is likely to be no impact. However, in future years, P&G's vaunted expertise in product development and its ability to launch new products that quickly achieve market dominance could be harnessed to introduce specific diagnostic technologies that expand the types of consumer self-tests sold on retail shelves. That is not likely to affect the volume and menu of tests performed in clinical laboratories. But it certainly has the potential to transform consumers into more sophisticated users of diagnostic tests. TDR

Quest Wants It Both Ways With Payer Contracts

Disruption in managed care contract status quo could eventually harm entire laboratory industry

CEO SUMMARY: Once again, public laboratory companies are pursuing short-term strategies that promise competitive advantage to themselves. But these strategies also carry long term risks that could burden the entire laboratory industry. Contradictions in the current cycle of competition for exclusive managed care contracts are already visible. Ongoing consolidation of payers is another wild card in this scenario.

By Robert L. Michel

SINCE THE MID-1980s, publicly traded laboratory companies have generally set the market for managed care contract pricing and terms.

As regularly noted in THE DARK REPORT over the years, single-minded pursuit of competitive advantage and profits by these public laboratory companies has often caused turmoil and disruption across the entire laboratory industry.

Thus, the current battles for exclusive managed care contracts by **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** are nothing new to the laboratory industry. Recent contract awards of exclusive national provider status by **UnitedHealth Group, Inc.** in favor of LabCorp and **Aetna, Inc.'s** national deal with Quest Diagnostics are just the latest developments in a story that has been unfolding for more than 22 years.

The consistent theme over these two decades has been the willingness of many public laboratory companies to pursue market ploys that offer short-term competitive advantage, but also come with considerable long-term risks—risks that the entire laboratory industry has often been endured.

For example, following cuts in Medicare reimbursement for laboratory services in the late 1980s, public lab companies took the lead in creating and introducing "bundled" test panels to physicians. These laboratories used this scheme to unbundle tests within the panel and separately bill them to Medicare, thus generating more revenue to offset the reduced levels of reimbursement.

Within a few years, in 1992, federal healthcare prosecutors had successfully

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

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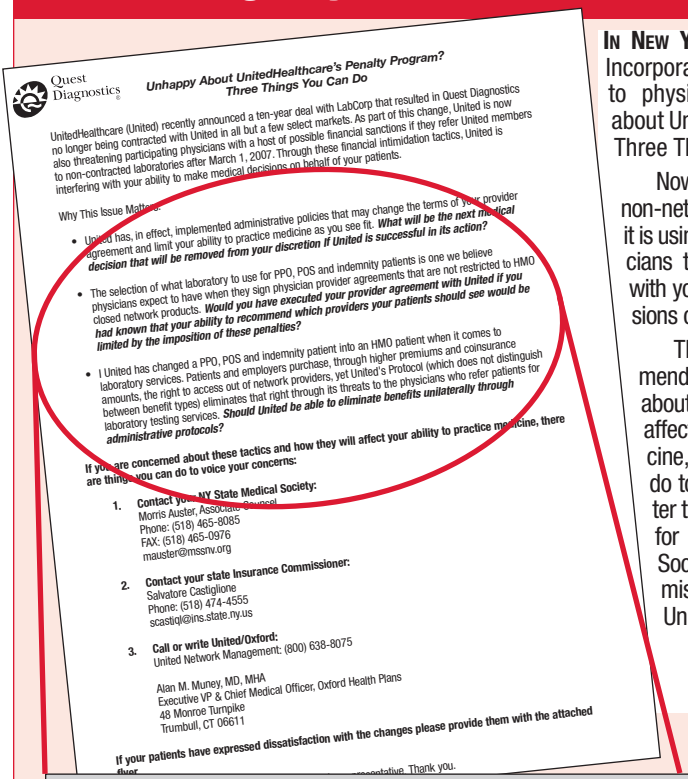
Advocating Physician Choice for Lab Provider...



Quest Diagnostics

Unhappy About UnitedHealthcare's Penalty Program? Three Things You Can Do

UnitedHealthcare (United) recently announced a ten-year deal with LabCorp that resulted in Quest Diagnostics no longer being contracted with United in all but a few select markets. As part of this change, United is now also threatening participating physicians with a host of possible financial sanctions if they refer United members to non-contracted laboratories after March 1, 2007. Through these financial intimidation tactics, United is interfering with your ability to make medical decisions on behalf of your patients.

Why This Issue Matters:

- United has, in effect, implemented administrative policies that may change the terms of your provider agreement and limit your ability to practice medicine as you see fit. ***What will be the next medical decision that will be removed from your discretion if United is successful in its action?***
- The selection of what laboratory to use for PPO, POS and indemnity patients is one we believe physicians expect to have when they sign physician provider agreements that are not restricted to HMO closed network products. ***Would you have executed your provider agreement with United if you had known that your ability to recommend which providers your patients should see would be limited by the imposition of these penalties?***
- United has changed a PPO, POS and indemnity patient into an HMO patient when it comes to laboratory services. Patients and employers purchase, through higher premiums and coinsurance amounts, the right to access out of network providers, yet United's Protocol (which does not distinguish between benefit types) eliminates that right through its threats to the physicians who refer patients for laboratory testing services. ***Should United be able to eliminate benefits unilaterally through administrative protocols?***

If you are concerned about these tactics and how they will affect your ability to practice medicine, there are things you can do to voice your concerns:

1. **Contact your NY State Medical Society:**
   Morris Auster, Associate Counsel
   Phone: (518) 465-8085
   FAX: (518) 465-0976
   mauster@mssnv.org

2. **Contact your state Insurance Commissioner:**
   Salvatore Castiglione
   Phone: (518) 474-4555
   scastiql@ins.state.ny.us

3. **Call or write United/Oxford:**
   United Network Management: (800) 638-8075

   Alan M. Muney, MD, MHA
   Executive VP & Chief Medical Officer, Oxford Health Plans
   48 Monroe Turnpike
   Trumbull, CT 06611

If your patients have expressed dissatisfaction with the changes please provide them with the attached flyer. ...representative. Thank you.

IN NEW YORK STATE, Quest Diagnostics Incorporated has distributed this letter to physicians. It is titled "Unhappy about UnitedHealth's Penalty Program? Three Things You Can Do."

Now that Quest Diagnostics is a non-network provider with UnitedHealth, it is using this letter to point out to physicians that "UnitedHealth is interfering with your ability to make medical decisions on behalf of your patients."

The Quest letter then recommends that "if you are concerned about these tactics and how they will affect your ability to practice medicine, there are three things you can do to voice your concerns:" The letter then lists the contact information for the New York State Medical Society, the state insurance commissioner, and the main office for United/Oxford.

"Through these financial intimidation tactics, United is interfering with your ability to make medical decisions on behalf of your patients.

Why This Issue Matters:

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- The selection of what laboratory to use for PPO, POS and indemnity patients is one we believe physicians expect to have when they sign physician provider agreements that are not restricted to HMO closed network products. Would you have executed your provider agreement with United if you had known that your ability to recommend which providers your patients should see would be limited by the imposition of these penalties?
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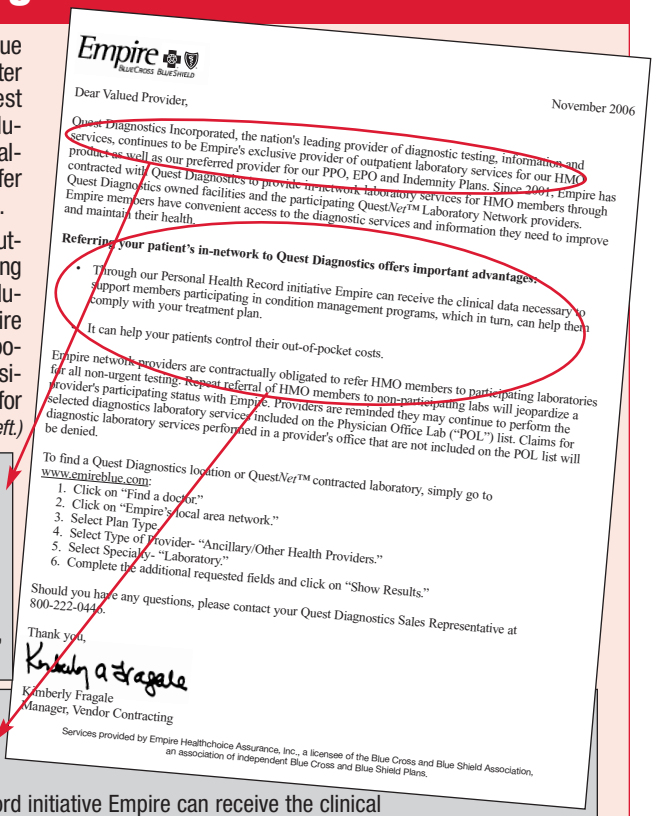
If you are concerned about these tactics and how they will affect your ability to practice medicine, there are things you can do to voice your concerns:"

...While Enforcing "Sole Source" Lab Contract

ALSO IN NEW YORK STATE, Empire Blue Cross Blue Shield is distributing a letter reminding physicians that Quest Diagnostics Incorporated is the exclusive laboratory provider and that penalties may result from continuing to refer patients to non-network laboratories.

Quest Diagnostics is also distributing its own letter to physicians calling attention to the fact that it is the exclusive contract laboratory for Empire patients. This policy is the direct opposite of its position on supporting physician choice of laboratory provider for UnitedHealth patients. *(See sidebar at left.)*



Empire BlueCross BlueShield

Dear Valued Provider,

November 2006

Quest Diagnostics Incorporated, the nation's leading provider of diagnostic testing, information and services, continues to be Empire's exclusive provider of outpatient laboratory services for our HMO product as well as our preferred provider for our PPO, EPO and Indemnity Plans. Since 2001, Empire has contracted with Quest Diagnostics to provide in-network laboratory services for HMO members through Quest Diagnostics owned facilities and the participating QuestNet™ Laboratory Network providers. Empire members have convenient access to the diagnostic services and information they need to improve and maintain their health.

Referring your patient's in-network to Quest Diagnostics offers important advantages:

- Through our Personal Health Record initiative Empire can receive the clinical data necessary to support members participating in condition management programs, which in turn, can help them comply with your treatment plan.
- It can help your patients control their out-of-pocket costs.

Empire network providers are contractually obligated to refer HMO members to participating laboratories for all non-urgent testing. Repeat referral of HMO members to non-participating labs will jeopardize a provider's participating status with Empire. Providers are reminded they may continue to perform the selected diagnostics laboratory services included on the Physician Office Lab ("POL") list. Claims for diagnostic laboratory services performed in a provider's office that are not included on the POL list will be denied.

To find a Quest Diagnostics location or QuestNet™ contracted laboratory, simply go to www.empireblue.com:

1. Click on "Find a doctor"
2. Click on "Empire's local area network."
3. Select Plan Type.
4. Select Type of Provider- "Ancillary/Other Health Providers."
5. Select Specialty- "Laboratory."
6. Complete the additional requested fields and click on "Show Results."

Should you have any questions, please contact your Quest Diagnostics Sales Representative at 800-222-0446.

Thank you,

Kimberly Fragale

Kimberly Fragale
Manager, Vendor Contracting

Services provided by Empire Healthchoice Assurance, Inc., a licensee of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans.

"Quest Diagnostics Incorporated, the nation's leading provider of diagnostic testing, information and services, continues to be Empire's exclusive provider of outpatient laboratory services for our HMO product as well as our preferred provider for our PPO, EPO and Indemnity Plans."

"Referring your patient's in-network to Quest Diagnostics offers important advantages:

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prosecuted **National Health Laboratories** (NHL) for this business practice. NHL's CEO, Robert Draper, pled guilty to criminal charges and went to jail. NHL paid $112 million in restitution and fines. This case triggered a wave of federal action against laboratory companies, both public and private.

By 1997, when the dust cleared on what federal prosecutors had dubbed "Lab Scam," laboratories had collectively paid more than $1 billion in restitution and fines. Further, the laboratory industry was saddled with federal rules requiring each laboratory to develop and maintain a compliance program.

Of course, most lab managers and pathologists with long memories remember how eager public lab companies were to sign HMO contracts in the 1990s that promised exclusive provider status. These lab companies accepted rock bottom capitated reimbursement, often accompanied by unlimited utilization risk, in order to

gain exclusive provider status and lock out their competitors.

That business strategy proved to be such a financial disaster that, by 1996 and 1997, the public sector of the lab industry was at a financial crossroads and underwent major financial restructuring. The decline in closed panel HMO enrollment, which began in these years, was one factor in easing the pressure on the nation's largest lab companies.

Apprehension At Local Labs

So there is an element of déjà vu in the recent actions of LabCorp and Quest Diagnostics to use exclusive managed care contracts as a tool to gain competitive advantage over their competition—both national and regional. It would not be an understatement to say that many lab managers and pathologists across the country are apprehensive about the future consequences that will result from the current infighting among the industry's two billion-dollar behemoths. Their fear is that the intensified willingness to fight for exclusive national contract status will somehow turn out badly for their own laboratories.

At a minimum, the 10-year exclusive national pact between UnitedHealth and LabCorp has ushered in a new cycle of managed care contracting. Because of payer consolidation, it may have been inevitable that the status quo that Quest Diagnostics and LabCorp maintained over the past eight or more years was going to change. But, given the past history of many public lab companies shooting themselves in the foot because of their desire to cede pricing and other terms to gain exclusive provider status—and competitive advantage—there is justification in speculating how current managed care contracting practices might adversely affect the entire lab industry.

The question about future consequences also highlights the dilemma now confronting Quest Diagnostics. The largest managed care contracts are now so big that losing contract access with a single large payer directly translates into a major loss of specimen volume, revenue, and market share.

The current situation with UnitedHealth's national contract shows how payer consolidation has changed the managed care contracting game. UnitedHealth has 26 million beneficiaries and pays $2 billion annually for laboratory testing services. Both of the blood brothers need access to these patients to sustain their market share and support ongoing growth in specimens and revenue.

Now that Quest Diagnostics is excluded as a contract provider, of course it is willing to argue to individual physicians that "choice of laboratory provider" is their right and they should forcefully make this view known. As the letter reproduced in the sidebar on page 4 demonstrates, when it comes to the UnitedHealth contract, Quest Diagnostics is an advocate of open provider panels and allowing physicians to choose their lab provider.

But Quest Diagnostics is not willing to support that position with other managed care plans where it is the sole contract laboratory provider. The letter from **Empire Blue Cross Blue Shield of New York**, reproduced in the sidebar on page 5, reminds physicians that they must use Quest Diagnostics exclusively or face penalties.

Negative Consequences?

The willingness of a national lab company such as Quest Diagnostics to argue, in a market like New York, for "open provider access" on one payer contract and to take active steps to enforce "exclusive provider status" on another payer contract is the contradiction that catches the attention of managers and pathologists in regional laboratories. It is the type of situation that causes them concern about how this corporate behavior might trigger negative consequences for the entire lab industry in coming years. TDR

Contact Robert Michel at labletter@aol.com.

Inverness Buys Biosite, Has New Venture with P&G

New partnership with P&G signals its pursuit of consumer diagnostics market

CEO SUMMARY: On the same day that Inverness Medical Innovations announced that it would acquire Biosite, thus beating out Beckman Coulter in the bidding war for Biosite, Inverness also announced that it had entered into a joint venture with Procter & Gamble. Together, the two companies will develop, make, and market consumer diagnostics products to be sold in retail outlets. Inverness expects to mine the Biosite development pipeline for other assays that can be marketed as point-of-care tests.

IT WAS A BIDDING WAR for **Biosite, Inc.**, and **Beckman Coulter Corporation** came up short as **Inverness Medical Innovations, Inc.,** walked away with the prize. But there is bigger news connected to Inverness' acquisition of Biosite.

On May 17, after announcing that it would pay $1.68 billion to acquire Biosite, Inverness Medical made a second announcement, one that has significant implications for the laboratory industry. Inverness Medical and consumer products giant **Procter & Gamble Company** have formed a joint venture company specifically to develop and market diagnostic tests for the consumer self-test market.

Consumer Diagnostics

The joint venture company will be called **SPD Swiss Precision Diagnostics GmbH** (SPD). The goal of this 50-50 partnership is to develop, manufacture, market, and sell consumer diagnostic products. Excluded from the product mix of the joint venture will be tests related to cardiology, diabetes, and oral care.

Inverness Medical has existing assets in the consumer self test market. It is contributing these assets to the joint venture. Procter & Gamble's contribution is an investment of $325 million. The new company will be based in Geneva, Switzerland, and develop, make, and market rapid at-home diagnostic products. The two companies said SPD will be the world's leading provider of home pregnancy tests and fertility/ovulation monitoring products.

Both deals announced on May 17 by Inverness Medical are examples of the land rush by investors and companies to position themselves in promising areas of clinical diagnostics, particularly by acquiring companies that have a development pipeline that can feed new molecular tests into the marketplace.

Biosite and its portfolio of diagnostic tests was a prize desired by both Beckman Coulter and Inverness Medical. On March 25, Beckman announced an agreement to acquire Biosite for approximately $1.55 billion. Within days, Inverness Medical had upped that bid, forcing Beckman Coulter to respond with a richer offer for Biosite. *(See TDR, May 5, 2007.)*

By going after Biosite, Beckman and Inverness were seeking increased presence

Biosite's Fast Growth Follows Slow Start

FOR BIOSITE, INC., OF SAN DIEGO, CALIFORNIA, growth came slowly at first. The company was incorporated as Biosite Diagnostics, Inc., in 1988. But it did not commercialize its first product, the Triage Drugs of Abuse Panel, until February 1992.

Five years later, it completed an initial public offering (IPO) and Biosite stock began trading at $12 per share under the stock symbol: BSTE.

In March 1998, Biosite got FDA clearance to market the Triage C. difficile Panel, a test designed to support the rapid diagnosis of C.difficile-associated disease. Later that same year, Biosite won FDA approval to market the Triage Parasite Panel, a test used to aid in the diagnosis of intestinal parasitic disease.

Biosite entered the cardiovascular disease market in February 1999 when it launched the Triage Cardiac System, a rapid blood test to aid in the diagnosis of heart attack.

In November 2000, Biosite got FDA clearance to market the Triage BNP (B-type natriuretic peptide) Test, an aid in the rapid diagnosis of congestive heart failure.

Three years later, in 2003, Biosite got FDA clearance to market the Triage Cardio ProfilER. This test panel includes assays for Troponin I, CK-MB, myoglobin, and BNP. It can by used by clinicians in assessing such conditions as heart attack, congestive heart failure, and for the risk stratification of patients with acute coronary syndromes.

In January 2004, Biosite won FDA clearance to market the Triage BNP Test for use with capillary whole blood, as obtained by a finger prick. Last year, Biosite was given a CLIA waiver for the Triage BNP Test.

For 2006, Biosite had revenue of $309 million. This was up from 2005 revenue of $288 million.

in the immunoassay testing market. Inverness, which specializes in pregnancy and fertility tests, has been considering expanding into other areas, according to *Med Tech Sentinel*. In its reporting, the publication described a new point-of-care business that Inverness Medical was developing in rapid HIV testing.

In February, Inverness Medical Innovations acquired the exclusive marketing rights from **Chembio Diagnostics, Inc.,** of Medford, New York, to sell Chembio's FDA-approved rapid HIV tests. As a result of that agreement, Inverness will market any future tests developed using Chembio's proprietary Dual Path Platform (DPP) technology, for which Chembio was recently awarded a U.S. patent. Experts believe the DPP technology will offer considerable advantages over today's single path tests.

➤ HIV Screening

In February, Inverness started marketing Chembio's Rapid HIV tests in the United States under an exclusive marketing agreement between Chembio and Inverness. The joint venture is using the brand name "Inverness Clearview." Its first products are the Clearview HIV 1/2 Stat-Pak and Clearview Complete HIV 1/2. Both are rapid qualitative screening tests for the detection of antibodies to HIV-1 and HIV-2 in human whole blood, serum, and plasma. The tests use a single lateral flow test strip which displays results through visual observation of a control line (non-reactive result) and a test line (reactive result) within 15 minutes.

In announcing the marketing agreement, Chembio's President and CEO, Lawrence Siebert, said, "I believe Inverness is well positioned as it has an extensive U.S. point-of-care marketing organization which supports a large distributor network."

In addition to offering tests for pregnancy, ovulation/fertility, and HIV, Inverness also offers cardiac tests. This fact led observers to believe Inverness

Inverness' Willingness to Fight For Biosite Deal Demonstrates High Value of IVD Acquisitions

ONCE AGAIN, AN *IN VITRO* DIAGNOSTIC (IVD) MANUFACTURER agreed to purchase another IVD firm, only to find an unwanted bidder enter the picture with a substantially higher offer for the target company. This time, it is Beckman Coulter Corporation being outbid for Biosite, Inc. by Inverness Medical Innovations, Inc.

Last fall, it was **Ventana Medical Systems** that announced a friendly acquisition agreement with **Vision Systems Limited** of Melbourne, Australia, for a price of $346 million. Within weeks, **Cytyc Corporation** jumped in with an offer of $375 million for Vision Medical. But even that offer was topped when a third bidder, **Danaher Corporation** (a division of **Leica Microsystems**) tendered a price of approximately $520 million. *(See TDR, November 6, 2006.)*

These stratospheric prices for IVD companies were verified by another recent deal. On May 20, 2007, **Hologic, Inc.,** disclosed an agreement to purchase **Cytyc Corporation**. It is paying $6.2 billion for Cytyc, which had 2006 revenue of $608.2 million. Hologic paid a 33% premium above Cytyc's closing share price on the day before the deal was announced. *(See Dark Daily, March 22, 2007.)*

These examples show how Wall Street recognizes the potential of *in vitro* diagnostics to generate substantial profits in coming years, as new technologies create diagnostic assays which have greater sensitivity to identify disease and to guide clinicians in selecting those therapies that may work best for the patient.

This same heightened investor interest in diagnostic testing is a factor that drives the higher prices paid for laboratory companies. The most recent example is **Quest Diagnostics Incorporated's** purchase, for $2 billion, of **AmeriPath, Inc.**, which posted revenue of $752.3 million for the fiscal year ending on December 31, 2006. *(See TDR, April 23, 2007.)*

wanted Biosite because the combined companies would have a significant presence in the fast growing field of cardiac diagnostics.

Cardiac Diagnostics

In fact, Biosite was coveted for its diagnostic heart tests. Recognizing that cardiovascular disease will become the leading cause of death worldwide by 2020, surpassing infectious diseases, biotechnology companies are racing to develop tests and forge alliances to take advantage of this trend. These companies believe the goal is to stop the spread of cardiovascular disease by identifying those patients who are at the highest risk of a cardiac event, such as a heart attack or stroke, according to published reports.

THE DARK REPORT observes that the laboratory industry should expect more consolidation in the *in vitro* diagnostics marketplace. Established IVD companies will be hunting smaller firms that have established assays, along with a development pipeline that includes promising diagnostic testing.

Further, pathologists and laboratory directors should not be surprised when consumer products companies, such as Procter & Gamble, and retailers, such as **Wal Mart**, **Walgreens**, and **CVS**, make investments that position them to offer diagnostic tests directly to consumers. These companies recognize the profit potential of providing useful clinical information to consumers in a retail environment. Collectively, these developments point to even more rapid changes in the lab testing marketplace. TDR

CEO SUMMARY: When 330-bed Botsford Hospital of Farmington Hills, Michigan, got interested in laboratory outreach 10 years ago, it brought in a new laboratory leader, invested in new analyzers and informatics, and then let the quality of the operation attract new business from the community. Today, Botsford's outreach program performs 2.4 million tests per year and generates annual revenues in excess of $14 million. Here's a look at the key business strategies that fueled this lab's growth.

NEW LEADERSHIP BUILDS LAB CAPABILITIES, THEN GROWS REVENUE

Community Hospital Builds Thriving Lab Outreach Program

WHY WOULD A COMMUNITY HOSPITAL enter the laboratory testing outreach business with a regional laboratory of one of the two blood brothers located nearby?

Just a few years ago, that was the question facing **Botsford Hospital** of Farmington Hills, Michigan. It was almost in the backyard of the **Quest Diagnostics Incorporated** regional laboratory, located in Auburn Hills, just nine miles away. Botsford Hospital was preparing to compete against a national laboratory on its home turf.

Then again, how many community hospital outreach programs have the clinical lab director go out personally to meet with referring physicians to attract new business? When the chairman of Botsford Hospital's pathology department visits an office-based physician to discuss clinical lab outreach, the positive effects on the physician are significant.

Profitable Outreach Program

Today, Botsford's laboratory outreach program generates in excess of $14 million in annual revenue and boasts an automated, state-of-the-art laboratory. Its ability to overcome the challenges in its market and profitably capture market share demonstrates that community hospitals can build successful and thriving laboratory outreach programs. In addition, Botsford's experience provides several useful management lessons for any community hospital preparing to enter the laboratory outreach business.

The story starts in 1997, when administrators at 336-bed Botsford Hospital decided they wanted a robust laboratory outreach program. Their first business priority was to give the laboratory new leadership. "I was hired in 1997 to do several things," stated Gilbert E. Herman, M.D., Ph.D., Chairman of the Department of Laboratory Medicine and Medical Director of the laboratory. "One of the most important tasks was to build an outreach laboratory.

"To succeed with a lab outreach program requires appropriate infrastructure," he noted. "Our laboratory was equipped to serve the inpatient needs of the hospital, but, in most respects, we were starting from scratch with what was necessary to create a profitable, high-service lab outreach program. Fortunately our administration was prepared to support the significant investment that we would need to develop our outreach program."

When he embarked on the project, Herman had an inpatient and small outpatient hospital lab. His laboratory now performs 2.4 million tests annually, of which 50% are outreach or outpatient. It also offers an expanded test menu that benefits both hospital inpatients and outreach clients.

The key to such strong growth is using automation judiciously and integrating robotics and automated analyzers with sophisticated informatics, including billing systems, Herman explained. In addition, the laboratory uses innovative reagent rental strategies for equipment financing and strives to always have more processing capacity than it can use.

Improving Lab Infrastructure

"None of this happened overnight," observed Herman. "When I arrived, a significant number of tests were referred to outside labs, which was a drain on the lab budget. So a first priority was to bring those tests in-house. Also, it required about four to five years of operational development to give our laboratory the technical capabilities it needed to handle outreach testing effectively and efficiently. That was why our first steps were to improve the infrastructure. We needed the right instruments, assays, and software.

"Our goal was to acquire instruments and analyzers that were tech friendly and could do mass production," he added. "Back in 1997, our lab had only the most basic modules of the **SCC Soft Computer** LIS (laboratory information system) and other standard corporate-issued software.

"To boost our technical capabilities, we did several projects in sequence," continued Herman. "We upgraded the servers to sup-

JVHL Network Fosters Outreach Success

ONE REASON THE LABORATORY AT BOTSFORD HOSPITAL has developed a successful outreach program is its association with **Joint Venture Hospital Laboratories** (JVHL), which is based in Allen Park, Michigan. JVHL represents more than 100 hospital-affiliated laboratories in a variety of managed care contracts. This helps its member labs compete against large national chain laboratories.

"As a member of JVHL, our lab outreach program serves a number of important managed care contracts in this region," stated Gilbert Herman, M.D., Ph.D., Medical Director and Chairman of the hospital's Department of Laboratory Medicine. "In this community, there are no inpatient deals [as part of hospital contracts with payers] that directly assist our outreach lab activity.

"All managed care work is handled via JVHL. Doctors tend to send everything to the Botsford Hospital laboratory rather than split," he continued. "If necessary, we cull out specimens that we cannot test due to insurance restrictions and send to the appropriate lab. The **United Auto Workers** (UAW), for example, has some restricted **Blue Cross Blue Shield** groups. The only issue is that these patients may have a higher co-payment if Botsford General Hospital does the analysis.

"We still report and bill this insurance and our doctors have not requested that their work go elsewhere," Herman explained. "In addition, the **UnitedHealth** national contract with LabCorp has not had a significant effect on us because, again, JVHL fully participates in the UnitedHealth contract. So, there are no issues. In fact, it would have been more difficult to compete with commercial labs without having managed care contract access through JVHL. It has allowed us to test restricted insurance contract work and open up the market for our hospital to compete."

port a strong flow of information throughout the lab. Doing so allowed us to connect more instruments to the LIS. We instituted a fully computerized anatomic pathology (AP) system, which allowed us to eliminate the antiquated word processor in use at the time. Also, we added billing programs that would be robust enough to handle outpatient billing.

Intense Use Of Informatics

"When I arrived at Botsford, the lab used programs from **SCC Soft Computer**, a laboratory information system vendor in Clearwater, Florida," recalled Herman. "We have regularly added software modules to support our increased work volume and growing outreach program. Software modules have been added to support lab automation, rules engines, SoftWeb (to enter orders and view results), ODBC, AP, accounts receivables, GUI blood bank, and quality management monitoring. We are increasingly sophisticated in our use of information technology and that technology helps set us apart in the outreach marketplace.

"Having good information systems puts us on a level playing field with the commercial labs," Herman explained. "The commercial labs have had at least three decades to develop their own software to expedite ordering, tracking of specimens, billing and reporting. Our present SCC computer software is every bit as good as the proprietary commercial laboratory software. That means we can compete with them.

"It took four to five years of dealing almost exclusively with these infrastructure issues before we felt we were ready to introduce the laboratory outreach program," recalled Herman. "It was 2000 when we started the outreach business.

"The first sales objective was to market our laboratory to physician groups that the hospital owned. At this time, all these physicians used other laboratories, predominantly Quest Diagnostics," stated Herman.

"Our job was to entice these practices into referring specimens to our lab. There was no edict by hospital administration for these physicians to use our lab.

"That meant our laboratory had to be as good as or better than their existing lab providers," he explained. "Ultimately, we won over our doctors. By 2003, the next target was the private doctors on our medical staff. It didn't take long before we started adding them as clients of our outreach program. After that, we began marketing to all the physicians in our community, whether or not they were on the medical staff of Botsford Hospital.

Volume Growth

"This sales strategy produced successive increases in our outreach volume," Herman said. "We went from zero in 1999 to about 445,000 tests by 2003. In the past four years, the outpatient program added 300,000 tests. Today, our outreach and outpatient program performs over 1.0 million tests annually and generates over $14 million per year in revenue."

Herman's care in building the lab's infrastructure before entering the outreach business paid big dividends in another way. "Because of our infrastructure of instruments and informatics, the laboratory has absorbed these additional specimens without an increase in employees who perform tests," observed Herman. "In fact, our medical technologist FTE count today is actually less than what it was in 1998!"

Laboratory Staffing

The Botsford Hospital laboratory department employs about 100 staff members, including four pathologists and 27 medical technologists (MTs).

Herman is particularly proud of the productivity of his full-time billing staff. "For all this outreach work, we have only four full-time billers," he stated. "They do everything, including initial billing, posting, secondary billing, and professional and technical billing. Many laboratories doing our outreach volume would have about 20 people in billing. Even as our hospital-based lab provides services to meet the inpatient mission, our outreach laboratory has managed to be fully competitive with any commercial laboratory in the country."

In building up the lab's capabilities, Herman used several management strategies to add functionality while minimizing capital investment in the laboratory. "We understood this basic fact about the outreach business," declared Herman. "Commercial labs run on volume, and this gives them several competitive advantages. To service volume, a laboratory must have the instruments and analyzers that can handle the work flow and deliver economies of scale.

"In building our capabilities to handle expanded volume, we wanted to pursue economies of scale," he continued. "Because of judicious purchasing strategies, the new lab equipment did not require a significant financial investment from the hospital. One source of savings was improving on the contracts that the hospital had negotiated during the 1990s. In many cases, the hospital was paying more than it should have paid. As we added equipment—and capacity—we negotiated tremendous deals that actually saved money on almost every instrument acquisition.

> ***"It took four to five years of dealing almost exclusively with these infrastructure issues before we felt we were ready to introduce the laboratory outreach program."***

"For example, prior to my arrival, the hospital would purchase its lab instruments. Our business strategy now is to negotiate reagent rental agreements. This

allows us to pay for the instruments with every test performed. Doing so greatly reduces our capital spending on laboratory equipment."

Using Volume To Advantage

Volume plays a role in the reagent rental strategy, and Herman understands why outreach specimen volumes are important in helping the laboratory manage its costs. "Our reagent rental contracts are done in a staircase fashion," he commented. "For example, the first 30,000 tests are the most expensive because you're paying off your instrument and your service charges. The next 30,000 are cheaper, and the next 30,000 are even cheaper because, as you do more volume, the costs go down for the instrument, as do the contracted service fees for each test.

"Obviously, it's expensive to have a reagent rental with low volume, because the cost of the instrument must be defrayed against the low volume," Herman continued. "But when you get to higher volume, you actually pay less per test for the instrument surcharge.

"Increased specimen volume also contributes to lowering—on a 'per test' basis—your labor, equipment, electricity, and square footage costs," he explained. "Having instruments and automation that can handle this volume without additional labor is essential to be competitive in the outreach market. If your laboratory hires another med tech every time you bring in 30,000 more tests, you won't be competitive, and you won't deliver good financial results to your parent hospital."

Philosophy On Lab Capacity

"Keeping fixed costs low is an important management secret because that allows you to add the instrumentation your lab needs," Herman observed. "That's why we always aim to have more processing capacity than we need. We definitely overbought in instrumentation. Right now, we could double or triple the volume of testing we do and still not require more instruments because we purchased this additional capacity on purpose.

"Having excess capacity allows us to do two things: First, it means we can handle substantial increases in specimen volume as needed. And, second, it means we don't max out an instrument," he said. "If you max out the equipment, you can burn up the instrument, shortening or ending its service life prematurely. Alternatively, you may have to get more instruments and our laboratory doesn't have space for that. Our plan is to have the instruments run at 20% to 25% of capacity, which means they don't break down. In this way, instruments last longer and our lab can bring on a huge new account and handle the increased workload without strain or stress."

Challenges of Manual Testing

Herman also offered insight into how laboratories should respond to the increase in manual testing that an outreach program generates. "Whenever you take on a new doctor's account, the vast majority of the work is automated," he explained. "But there are always manual tests too, including microbiology, biopsies, and cytology," Herman noted. "You must take care not to overwhelm your manual systems. Laboratory staff members with the skills to do manual testing are hard to find and hard to keep.

"Another factor in managing manual testing is the loss of staff due to retirement or a change of jobs," offered Herman. "Our strategy to deal with this is to have computerized systems behind everything we do. This includes electronic test ordering and electronic reporting of results.

"Like other successful hospital lab outreach programs, we offer our physician clients a number of options for lab test reporting. We support both autoprinting and autofaxing of reports to physician accounts. We offer Web browser-based lab test ordering and results reporting. We use auto-verification to complete the result

Efficiency, Quality Service Combine to Deliver Regular Growth in Botsford's Outreach Program

IN A COMPETITIVE MARKET, physician loyalty can help a hospital outreach program succeed. But loyalty is just one factor that contributes to success, observed Gilbert E. Herman, Ph.D., M.D., Chairman of the Department of Laboratory Medicine and Medical Director at Botsford Hospital in Farmington Hills, Michigan.

To succeed over time, a hospital outreach program needs to deliver efficient results and high quality service. "There is loyalty, of course," Herman commented. "But that only goes so far. Office-based physicians expect a high level of customer service. That is a given. In addition, we make sure that our referring doctors know about the benefits of using the Botsford Hospital laboratory outreach program by getting out and visiting them in their offices. It also helps that our hospital's administrators are highly supportive of our efforts and they encourage physicians to use our lab."

One fascinating aspect to the launch of Botsford Hospital's laboratory outreach program is that its lab is located almost in the backyard of Quest Diagnostic Incorporated's regional laboratory in Auburn Hills, less than 9 miles away. "Of course, Quest tried to keep the accounts to the best of their ability," explained Herman. "They had numerous sales representatives storm the offices of the physicians in this community, but we prevailed in the end.

"And we have no sales people!" Herman said. "We built a $14 million laboratory outreach program by talking to our medical staff in departmental meetings, in the doctors' lunch room, and by visits to the physicians' offices. Medical administration also has several physician liaison members who help sell our laboratory to physicians in the community.

"In addition, our medical administrators routinely take new staff members on tours of the laboratory so these new physicians can see our operation," continued Herman. "Our Outpatient Services Manager, Tim Morris, C(ASCP), has spent countless hours working the bench and traveling to doctors' offices to drum up business.

"In addition, I have regularly visited physicians' offices over the years," noted Herman. "We find it's a big deal for a hospital chairman to visit a private doctor's office. To my knowledge, the medical directors of the big national lab companies do not regularly visit physicians' offices.

"Having pathologists and hospital administrators helping to sell the program is one reason the income from the outreach lab now accounts for 25% of the entire hospital corporation's bottom line profit," concluded Herman.

entry process and issue our data nearly instantaneously without human intervention, if the specimen meets criterion.

"Billing for our laboratory outreach program is totally electronic," he added. "All our SCC software programs are totally integrated across the laboratory's entire work flow. To make this operation work, we integrated the instruments and the computers behind them. By having all major instruments interfaced, we minimize the need for manual data entry. That further reduces keypunch errors and increases staff productivity.

"At the end of the day, all completed tests pass electronically to our billing mod-

ules," he added. "On the first pass through our editing software, the yield is consistently 80% to 85% for clean claims. These clean claims pass directly to our third party payers. Most payers remit to us electronically and we use the electronic statement to post the payments to each line item.

"If any patient has an account balance remaining, we electronically roll that over to secondary insurers or directly to the patients," explained Herman. "Ultimately, we send a file electronically for bad debt and bad debt placement, which saves time and increases cash flow.

Forward Thinking

"In the coming months and years, the best opportunities for hospital lab outreach programs may come from specialty tests," Herman predicted. "These tests will require a lot of investment in personnel and equipment and will require a large volume to be profitable. We are a meat and potatoes lab that needs only more volume of what we currently do in order to accomplish our goal, which is to be financially viable and contribute profits back to our parent hospital.

"We want a strong afternoon shift so all instrument stations are open for business," he continued. "That means we can help the hospital reduce length of stay and increase turn around times in the emergency room, all leading to more efficiency throughout the hospital."

For pathologists and lab directors, the success of the Botsford Hospital outreach program offers three lessons. First, this mid-sized community hospital is an example of a professionally managed laboratory outreach program that has lowered inpatient lab test costs while offering an expanded menu of lab tests. At the same time, it has built strong relationships with physicians in the community and generated a net profit that puts money back into the parent hospital.

Second, Botsford Hospital challenged a national laboratory (in this case Quest Diagnostics Incorporated) even though Quest operated a regional laboratory facility almost in the same neighborhood as Botsford Hospital. The lab outreach success at Botsford argues well that community hospital outreach programs can compete head-to-head with national labs, as long as they offer physicians comparable or better lab testing services.

Contribution Of Leadership

Third, lab directors and pathologists should not overlook the leadership contribution of the laboratory department's chairman, Dr. Herman. Not only did he provide a strategic vision of how the laboratory could be organized to serve inpatient, outpatient, and outreach testing needs, but he also demonstrated the value of face-to-face contact between the chairman and referring physicians. Herman regularly visits prospective physician clients in their offices to win their business. The fact that Botsford Hospital has built its outreach program to over $14 million in just seven years, without a full time sales representative, confirms the value of pathologists interacting directly with referring physicians.

Growth In Lab Outreach

THE DARK REPORT observes that the success of Botsford Hospital's laboratory outreach program demonstrates why the number of community hospitals with active lab outreach programs is increasing each year. The additional specimen volume from the outreach market allows the laboratory to enjoy economies of scale, expand the in-house test menu, and deliver net profits to the parent hospital.

Botsford's lab outreach program also is a reminder that physicians will support their local hospital laboratory—but only if the outreach program will deliver services equal to or better than competing laboratories also in the community. TDR

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Labs Are Finding Ways To Link Variety of EMRs

Physicians using EMRs often demand electronic delivery of laboratory test data

CEO SUMMARY: Three speakers at the Executive War College last month in Miami, Florida, offered case studies on how labs are developing electronic interface gateways between their LIS's and EMRs in the offices of client physicians. Physician clients frequently want lab data to be among the first links they develop. In many situations, it is critical for labs to dictate the specifications of the links between labs and physician offices.

ONCE PHYSICIANS INSTALL AND BEGIN TO USE electronic medical record (EMR) systems, they are quick to ask their laboratories to electronically enable reporting of results and lab test ordering. This fast-growing trend was the subject of a full-day program at the *Executive War College on Lab and Pathology Management* in Miami, Florida last month.

"Only about 20% of physicians have EMRs today, but that number should rise steadily," said Pat Wolfram, Global Product Manager for EMR Interoperability for **GE Medical Systems Information** in Beaverton, Oregon. "About 200,000 physicians will have them by 2011," he said.

"Lab results are required in 90% of the EMR systems that go live today and the other 10% want lab results in their EMRs shortly thereafter," Wolfram said. "But physicians do not use EMRs to send lab orders until they are very well adopted with the EMR."

Saying labs have an opportunity to work closely with physicians who have installed EMRs, Mark Johnston, Chief Information Officer for **Pathology Associates Medical Laboratories** (PAML), in Spokane, Washington, explained how labs can position themselves for effective integration. PAML provides lab services in five states in the Pacific Northwest and has developed EMR interfaces to seven different laboratory information systems (LISs).

Information Integration

"In addition, PAML has developed interface gateways to the EMR products of 15 different vendors," noted Johnston. "PAML has also created an enterprise master patient index (EMPI) that includes 42% of all the patients in our service area.

"We developed the EMPI to help on the billing end but it also has application on the clinical side," Johnston explained. "We have 22,000 doctor customers, and our goal is have one patient with one bill, one record, and one address.

"The electronic links that exist between PAML and our physician clients mean that 55% of our lab requisitions are generated through the physicians' EMRs," observed Johnston. "Even offices with just one and two physicians are asking for EMR links.

"When physicians install EMRs, they will come to the lab first for an interface," continued Johnson. "Lab test results are a fundamental requirement for an EMR system to deliver maximum benefit to physicians.

"As they recognize the value of getting patient information electronically, health plans are encouraging the development of extensive electronic systems to link physicians, labs, and other providers," he added. "For example, **Group Health Cooperative of Puget Sound**, a large health plan in Seattle, transmits lab orders and patient information to PAML in real-time."

The key to collecting data from health plans and physicians is a sophisticated interface engine that PAML developed. The system translates requisition data from a variety of physician offices so that PAML can interpret the requests and process the tests. "Then the interface engine translates the test results and sends them back to the physicians' EMRs in its native format," Johnston added.

Dictating Connection Terms

David Moore, CIO of **Spectrum Laboratory Network**, in Greensboro, North Carolina, agreed that connecting to physician offices can be challenging. "When physicians want to establish electronic links with Spectrum," noted Moore, "Spectrum dictates the technical requirements. Doing so ensures that the lab can deliver the data physicians use in the form they need without compromising the lab test data.

"Spectrum is growing by 20% annually since 2001 and this growth is due, in part, to its efforts to capture and report lab data electronically," added Moore. "We have interface gateways between our lab and 87 clients—who use EMRs from 14 different vendors. These clients represent 10% of our accession volume. One thing we have learned is that developers of EMR systems generally don't have a good understanding about how to handle lab information.

"For that reason, we tell each client we will not electronically connect them to our system until they have all the requisite hardware and software in place," Moore added. "They may need to upgrade the systems they have. We won't connect until we're convinced they can handle the information they will get from us."

There is a primary benefit to this policy. By interfacing lab test orders along with electronic delivery of lab test results, Spectrum gets complete data at order entry. This allows Spectrum to successfully file a higher ratio of clean claims.

Still Relying on Paper

"In our market, while labs have electronic links with many physicians, less than 10% of physicians are both ordering and accepting results electronically," said Eric Crugnale, CIO of **Sunrise Medical Laboratories** in Hauppauge, New York. "Further, in Metropolitan New York, only 17% to 24% of physicians have adopted EMRs.

"Sunrise has electronic links with 470 physicians' offices and gets 60% of its orders electronically," added Crugnale. "Demand increases for EMR interfaces, but predominantly, they ask only for electronic delivery of lab test results.

Problems are common. "Most EMR systems don't have the ability to get the lab data back into the EMR," Crugnale said. "There's a lack of consistent implementation, meaning each physician installation is unique. And, typically, there is a lack of a physician champion in the doctor's office."

THE DARK REPORT notes that labs have an opportunity to lead the implementation of electronic links to EMRs. PAML, Spectrum, and Sunrise are examples of first mover laboratories that are at the leading edge of this trend—and enjoying solid growth and profitability in their respective markets. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

When the *Lab Quality Confab* convenes in Atlanta on September 19-20, 2007, it will feature 40 speakers and sessions on how labs and pathology groups are using quality management methods to improve the performance of their lab organizations. If your laboratory would like to showcase its success or participate in poster sessions on Lean Six Sigma projects, go to *www.labqualityconfab.com* and use the form to notify us of your interest.

BATTLE BETWEEN DERMATOLOGY AND PATHOLOGY?

As the pathology profession fights to retain its professional relationship as a medical specialty, specialist physicians continue to look for ways to convert their anatomic pathology referrals into a profit-generating in-house service. Recently, *Skin & Aging*, a dermatology magazine, published a story on the ongoing struggle for who gets to bill for the patient service. "Pathology vs. Dermatology: The Battle Heats Up" (*http://www.skinandaging.com/article/7194*) characterizes the conflict in this way: "Many pathologists accuse dermatologists of conducting ethical breaches when they mark up any patient's bill. For their part, dermatologists say that pathologists want to squeeze as much money as possible out of patients by directly billing them or their insurers with no discount, and that the pathologists don't care about the patients paying more because they have no contact with the patients." Pathologists and practice administrators interested in the different perspectives on the client billing issue may want to visit the *Skin & Aging* Web site to read this story.

TRANSITIONS

- **Ciphergen Biosystems, Inc.**, of Fremont, California appointed Steve Lundy as its new Senior Vice President of Sales and Marketing, effective May 16, 2007. Lundy was most recently Vice President of Sales and Marketing at **GeneOhm**, before and after its acquisition by **BD Diagnostics.** Lundy was also a marketing executive at **Esoterix, Inc.**, prior to, and after its purchase by **Laboratory Corporation of America.**
- To implement plans to expand its laboratory outreach program, **UCLA Health Systems** of Los Angeles, California, has hired Susie Lu to be Associate Director, Operations for Outpatient and Ancillary Services. Lu comes to UCLA from **Stanford University Medical Center**, where she was Vice President, Department of Pathology and Laboratory Medicine.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, June 25, 2007.