Volume XII, Number 10 Monday, July 11, 2005

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

Using OIG Advisory Opinions to Level Playing Field

TWICE DURING THE PAST 12 MONTHS, the **Office of the Inspector General (OIG)** has issued a negative opinion on a marketplace arrangement between a laboratory company and a physician group. The most recent was OIG Advisory Opinion 05-08, released on June 13, 2005 and responding to a request to evaluate how a lab might reimburse a physician for phlebotomy services performed by his office. *(See pages 5-6.)*

The earlier opinion was OIG Advisory Opinion 04-17. It was released on December 17, 2004 and addressed a request to evaluate a model of "anatomic pathology laboratory condominium" services between a laboratory company and a physician group. *(See TDR, January 3, 2005.)*

Having carefully read both opinions, I believe they share something in common. I believe both opinions were requested by laboratory companies that actually wanted the OIG to issue a negative opinion in response to the business scenario described in their original request letters. In both cases, if the requesting lab company got a negative advisory opinion from the OIG, that opinion, now on public record, would inhibit laboratory competitors from engaging overtly and aggressively in that type of behavior.

I consider this to be an interesting strategy for labs that want to "level the field" against competitors. It gives them a way to respond, legally, when they observe a competing laboratory offering physicians inducements, benefits, or business arrangements that can be argued to be in violation of Medicare statutes. A negative OIG opinion on that particular marketing practice certainly gives the requesting laboratory a credible document to show physicians and educate them about the compliance risks they assume should they participate in an arrangement that the OIG has deemed to be in violation of Medicare laws.

Since we've seen two of these types of advisory opinions issued in the past 12 months by the OIG, it may be that an increasing number of laboratory executives and pathologists are willing to use this approach to counter what they consider egregious marketing practices by laboratory competitors. In this sense, labs requesting these opinions are taking a proactive approach to Medicare compliance. They are initiating regulatory rulings on abusive marketing practices in the lab industry. TDR

Nichols Diagnostics Stops Product Sales

Are "Black Belts" getting a "black eye" from significant manufacturing problems?

CEO SUMMARY: It's an odd story. One of the nation's most respected names in diagnostics quietly ceases delivering products–and no one in the laboratory industry pays much attention. Last month, Nichols Institute Diagnostics, acknowledging production problems it has not yet resolved, announced to its laboratory customers throughout the United States that deliveries of its diagnostic kits would cease.

QUIETLY AND WITH LIMITED PUBLIC DISCLOSURE, a prominent diagnostic kit manufacturer ceased selling products to laboratories in the United States.

Nichols Institute Diagnostics, Inc., based in San Clemente, California, issued "Customer Bulletin CR-05-20" on June 16, 2005 to client laboratories. Titled "Product Inventory Hold," the first paragraph made a succinct statement, declaring "This is to advise you of a new quality initiative at Nichols Institute Diagnostics (NID) and an *accompanying hold on all products at NID*." *(Our italics.)*

With this sentence, Nichols Institute Diagnostics told its laboratory customers in the United States not to expect further deliveries of test kits and other products. It was an unexpected withdrawal from the market.

Nichols Institute Diagnostics is a division of **Quest Diagnostics Incorporated**. It manufactures an instrument called the "Nichols Advantage® Specialty System" and sells a menu of assays that can be run on that instrument.

Although Quest Diagnostics does not specifically disclose the financials of NID, the company has told analysts that annual revenues for this division represent no more than 1% of the company's revenues. That would place NID's yearly revenues at a maximum of about $50 million.

Because the company is no longer shipping product, laboratory customers throughout the United States are scram-

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. **(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, $13.65 per week elsewhere (billed semi-annually).

bling to to set up and validate comparable assays from alternative vendors. The situation is exacerbated by NID's lack of candor about its problems. Some laboratory customers of NID are troubled that NID is silent on the subject of whether or not, and when, it will resume shipment of new products.

Will NID Continue?

Some laboratory customers speculate that Nichols Institute Diagnostics may be preparing to exit the business. There has been speculation in recent years that Quest Diagnostics has considered selling Nichols Institute Diagnostics, primarily because the diagnostic assay manufacturing business is a distraction from the company's core business strategies.

There is evidence that significant and deep problems plague NID. On March 2, 2005, the **Food & Drug Administration** (FDA) published a recall for the NID 25-Hydroxy Vitamin D Assay. NID had previously recalled this test by a customer bulletin on June 30, 2004. The FDA next published two recalls on May 18, 2005. They were for NID's IRMA Intact PTH Assay and the Bio-Intact PTH (1-84) Assay. NID had previously issued recall letters for these assays in March 2005.

Additional Product Recalls

On June 15, 2005, the FDA published two additional recalls for the Nichols Sample hGH Diluent Set and the TSH–Third Generation Assay. Both assays had been recalled by NID on May 2 and April 28, 2005, respectively.

NID issued Customer Bulletin CR-05-20 one day following the last published FDA recall notices. That is strong evidence that Nichols Institute Diagnostics is responding to FDA concerns about its failure to manufacture products which meet specifications. By voluntarily pulling its products from the market, it is likely that NID was forestalling more forceful action by the FDA on these quality deficiencies.

All of this occurred under the radar screen of most lab industry watchers. And this story has a rather peculiar aspect. The fact that a business unit of one of the lab industry's most respected brands—Nichols Institute—has pulled test kits from the marketplace because of quality problems has yet to catch the attention of the laboratory industry.

In the short term, the obvious impact of NID's withdrawal from the market is that its laboratory customers are now under time pressure to locate alternate sources of comparable assays and avoid disruptions in lab testing services to their client-physicians. Historically, disruption by a vendor like NID in the supply of its products usually alienates a large number of its laboratory customers.

Released From Contracts

That alienation of the customer base makes it difficult for an IVD vendor to re-enter the marketplace at a future date and re-establish relationships with its former customers. One sign that Nichols Institute Diagnostics recognizes it faces an uncertain future is the fact that it has released lab clients from contracts covering instruments and assay kits.

There is an additional dimension to the story of product quality problems at Nichols Institute Diagnostics which raises several interesting questions. Nichols Institute Diagnostics is owned by Quest Diagnostics Incorporated. Quality failings and management inadequacies at NID are directly at odds with the quality message that executives at Quest Diagnostics deliver to the public and Wall Street alike.

First, if quality management systems and philosophy are firmly rooted within Quest Diagnostics and its constituent business units, how could production failures within Nichols

Institute Diagnostics compound to the point where it was forced to cease selling its products? After all, the major goal of Six Sigma and similar quality management systems is to give a company the tools and knowledge it needs to continuously improve the quality of its products and services. This does not seem to have happened within Nichols Institute Diagnostics.

Second, after production and quality problems were uncovered at Nichols Institute Diagnostics, at least as recorded by the recalls issued by NID and FDA, why has this company offered so little communication to the laboratory marketplace about the situation? This contradicts the spirit of quality management, which emphasizes that meeting customer expectations is what defines quality.

Lost Corporate Asset

Three, does this episode reflect negatively on the management culture within Quest Diagnostics, which has, to this point, allowed its NID business unit—and its estimated $30 to $50 million in revenues—to literally drop out of the market? In absolute terms, that's a sizeable corporate asset to "vanish," notwithstanding Quest Diagnostics' $5 billion in annual revenues.

Four, isn't this a major tarnish on the long-respected reputation of Quest Nichols Institute? This is not likely to be mentioned publicly. However, many lab directors and pathologists know how NID was spawned from Nichols Institute in 1984 and how NI founder Albert Nichols, M.D. infused a remarkable emphasis for quality into his company from its earliest days. (In fact, even today many ex-Nichols employees still remember the acronym Dr. Nichols constantly stressed: Q R I S P, where the Q came first and stood for Quality.)

Despite the fact that this story has remained under the lab industry's radar screen to date, THE DARK REPORT believes it is significant in at least two ways. First, it is another example of how in vitro diagnostic manufacturers are struggling to maintain consistency in the quality of their reagents and test kits. Nichols Institute Diagnostics is not the only company that has grappled to deliver products to lab customers which fully meet their own published specifications.

Second, it has been almost six years since Quest Diagnostics Incorporated announced to the world that it would use Six Sigma and other effective tools to raise the quality of its services and products. The experience at Nichols Institute Diagnostics—and its withdrawal from the market due to product quality problems—is a reminder that any company's journey into quality management systems requires intense effort and unrelenting attention. TDR

NID's Problems Seemed To Start With Vitamin D

IT MAY BE THAT THE UNRAVELING of Nichols Institute Diagnostics (NID) was its 25-Hydroxy Vitamin D assay. The story began in early 2004.

Several technical laboratory directors have told The Dark Report that NID acknowledged that the assay was undermeasuring the D-2 fraction of vitamin D. Nichols Institute Diagnostics issued a Customer Bulletin on June 30, 2004 notifying customers of this fact. These lab directors note that, in September 2004, NID staff informed them that NID would establish a time line on a fix for this assay. However, in the months since that statement, NID has issued no additional statements on a fix.

The first FDA recall notice involving an NID product was published on March 2, 2005 and involved the 25-Hydroxy Vitamin D assay. This was followed by a cascade of recall notices in subsequent months involving many of NID's remaining assays.

New OIG Opinion 05-08 On Phlebotomy Fees

This advisory opinion tackles lab payments to compensate physicians who draw blood

CEO SUMMARY: At the request of a yet-unidentified laboratory, the Office of the Inspector General issued Advisory Opinion 05-08 last month. It is a negative opinion on a proposed arrangement where a laboratory would reimburse client physicians as much as $6 for each blood draw performed by the physician and/or his staff. It is unlikely that many laboratories will be affected by this negative opinion.

PHLEBOTOMY SERVICES PROVIDED by physicians and reimbursed by labs is the subject of OIG advisory opinion 05-08, issued on June 6, 2005.

Labs which are involved with phlebotomy services in doctors' offices will want to study this opinion. Labs not contemplating such an arrangement will not be affected.

The **Office of the Inspector General** (OIG) of the U.S. **Department of Health and Human Services** issued the opinion in response to the request of an unnamed lab. The requesting lab described a specific arrangement where the lab would reimburse physicians for performing phlebotomy services and furnish drawing supplies free of charge to the physicians.

In its response, OIG declared that such an arrangement would be a substantial risk that the lab would be generating remuneration in violation of the anti-kickback statute, which could subject violaters—on both sides—to both criminal and civil penalties. The OIG also points out that this fact scenario would not fit into the safe harbor provisions for personal services and management contracts because the physicians here would be paid on a per-patient basis. Also, safe harbor regulations require that aggregate compensation paid for such services be set in advance and be consistent with fair market value in an arm's-length transaction.

A Negative Answer

"I think the factual scenario laid out in the request for an opinion was worded in such a way as to draw out a negative answer," stated Jane Pine Wood, Partner at **McDonald Hopkins**, based in Cleveland, Ohio. "The facts here are really laid out to emphasize the improper intent of at least one of the parties.

"That's consistent with the reason why the unnamed lab was requesting an advisory opinion from the OIG," she continued. "It sought the opinion because competing laboratories were engaged in the practice. That's why I think the lab here was looking for a specific answer to address a specific situation in its market.

"In its request for an opinion, the unnamed lab stated that it wished to enter into the proposed arrangement with

physicians because competing laboratories in that market were paying referring physicians to perform blood draws," she explained. "It is likely that this lab recognized that the activity was probably in violation of the anti-kickback statute and sought to eliminate the practice among competitors in its market."

"Intent" Plays A Role

Wood wanted to emphasize that "intent" is something that the OIG normally takes into consideration when evaluating these types of arrangements, because the Medicare and Medicaid Anti-kickback law is an intent-based statute. "Look at this type of arrangement from another perspective," offered Wood. "Use the scenario of a rural setting. Patients must drive a long distance to reach a lab that can draw blood. This could be a real inconvenience for some patients.

"In a case like this, an arrangement to have the physicians draw the blood specimens and for the lab to pay the physician for that service might be seen by the OIG as a benefit to the patient and might get a more favorable response. The OIG is going to factor in the intent on both sides," she stated.

"Further, in any such situation, the laboratory would reduce its compliance risk if those physicians wanting to provide in-office phlebotomy services were to also directly bill the patients," she noted. "Of course, physicians don't want to do this because they recognize the difficulty of collecting fees for phlebotomy services. It would be a losing proposition.

"Not only are physicians committing staff time to do the blood draws, but there would be the added expense of billing and collection. Under the proposed arrangement in OIG 05-08, however, such physicians wouldn't have that overhead and might realize a profit on the service."

Under the proposed arrangement discussed by OIG 05-08, the laboratory would pay physicians between $3 and $6 for each blood draw. The OIG commented on this fact. It pointed out that the Medicare program provides for payment of $3 per patient encounter for the services envisioned.

"It's interesting to note the OIG's concern that, under the proposed arrangement, physicians might be paid 'twice the $3 amount Medicare pays for blood specimen collection'," observed Wood. "In its opinion the OIG goes on to say, 'Where a laboratory pays a referring physician to perform blood draws, particularly where the amount paid is *more than the laboratory receives in Medicare reimbursement*, (italics added) an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory.' Does this mean that Medicare is suddenly setting fair market value?"

Use Caution

Wood recommended caution in such situations. "If a lab is considering an arrangement to pay physicians for in-office phlebotomy services, it should examine the proposed arrangement very carefully," she said. "Consider every party that might benefit from such an arrangement. If the facts fall outside the anti-kickback prohibitions, be sure the justifications are well-documented. Keep the dollar amount reasonable and document why it's reasonable. If the lab can convince the physicians to bill patients directly, all the better."

The compliance issues raised in OIG 05-08 are likely to evolve further in the coming months. Pathologists and laboratory administrators facing competitive pressure in their markets to enter into similar arrangements with physicians for in-office phlebotomy services, should tread carefully.

Contact Jane Pine Wood at 508-385-5227.

—By Pamela Scherer McLeod

Michel Wins Investigative Reporting Award from Peers

2004's coverage of anatomic pathology lab condos earns recognition in national journalism contest

IN A PRESTIGIOUS JOURNALISM CONTEST conducted by NEPA (**Newsletter and Electronic Publishers Association**), THE DARK REPORT'S Editor-In-Chief, Robert L. Michel, was recognized last month in the category of "best investigative reporting" for his story series on anatomic pathology laboratory condominiums. *(See TDRs, July 19, 2004 and August 9, 2004.)*

This journalism award is confirmation for clients and regular readers of THE DARK REPORT that they are getting high-quality business intelligence, well-written, and presented with organization and clarity.

Here's a list of NEPA's "Best Investigative Reporting" winners and a description of each winning story topic.

FIRST PLACE: *TELECOM MANAGER'S VOICE REPORT, UCG. Publisher Jonathan Stern* won the David Swit Award for his story in February 2004 concerning a massive fraud telecom giant **Nortel** used to prop up its stock price and hold on to customers lured by a rival's new technology. The story, in conjunction with actions by the U.S. Securities and Exchange Commission, resulted in Nortel's firing its CEO, CFO, and controller; launching an audit-committee probe of its management practices, restating several years of financial results; and coming under investigation by Canada's Ontario Securities Commission.

SECOND PLACE: *JANE'S DEFENCE WEEKLY, Jane's Information Group. Reporter Joseph Bermudez* won the David Swit Award for his exclusive report in August 2004 on North Korea's ability to launch two previously undisclosed ballistic missiles. The article, based on years of tracking the country's missile developments, outlined how Russian personnel aided the systems' development.

THIRD PLACE: *THE ENERGY DAILY, King Publishing Group, Reporters Jeff Beattie and George Lobsenz* won for a series of stories that forced the Energy Department to reveal a $500 million bailout of one of its contractors—British-owned **BNFL Inc.**—at the behest of a foreign government. The reporters' investigation revealed that the DOE agreed to buy out two BNFL cleanup contracts (under which the company had been hit by huge cost overruns) as payback to British Prime Minister Tony Blair for his support of the Bush administration's decision to invade Iraq. DOE remained mum on the story throughout the year, finally announcing the deal early this year.

HONORABLE MENTION: *THE DARK REPORT, The Dark Group, Inc. Editor-in-Chief Robert L. Michel* won for a pair of stories in July and August 2004 on the development and problems with anatomic pathology laboratory condominiums. The stories gave a clear, concise description of what the labs are and how they work; why they are a fast-growing threat to the pathology profession; and why they have the potential to trigger federal health-care agencies' civil and criminal sanctions. **TDR**

Payer Consolidation: United Buys Pacificare

Consolidation may be a result of larger trends soon to pressure health insurance companies

CEO SUMMARY: For the second time in nine months, a health insurer company has spent around $9 billion to grow by acquisition. This time, it is UnitedHealth Group purchasing PacifiCare Health Systems. These types of deals impact local labs and pathology groups as existing contracts expire. However, the most interesting wild card is consumer-driven healthcare and how payers intend to respond.

BIG CHANGES ARE AHEAD for the nation's largest health insurers. The trigger is **United HealthGroup's** acquisition of **PacfiCare Health Systems**.

The deal was announced on July 6, 2005. United HealthGroup will pay approximately $8.5 billion in cash and stock to purchase PacifiCare, which is based in Cypress, California. UnitedHealth will add PacifiCare's three million beneficiaries to its current total of 23 million beneficiaries.

Analysts praised the deal and noted that PacifiCare's assets complement existing holes in United's national infrastructure. In particular, the deal beefs up UnitedHealth's limited presence in California and expands its capabilities in private Medicare plans.

For the laboratory industry, there will be short-term and long-term consequences from this acquisition, once it is completed. In the short-term, as PacifiCare contracts for lab testing services expire, it is likely that UnitedHealth's contracting preferences will take precedence. This will probably have the greatest impact on regional laboratories and hospital lab outreach programs which want to retain access to PacifiCare's beneficiaries.

Over the longer term, this deal creates pressure for additional mergers among the nation's largest heath insurers. Each of these acquisitions will affect lab testing contracts held by smaller laboratories.

More Consolidation?

Consolidation in the health insurance industry is a fact. Just last fall, **Anthem Inc.** acquired **WellPoint Inc.** for $14.1 billion dollars. That created a company with 26 million beneficiaries in 13 states. Now, just nine months later, UnitedHealth Group is paying $8.5 billion to purchase PacifiCare, creating a company that also insures about 26 million people.

Some analysts believe each deal described above creates pressure for additional consolidation. Both **Aetna, Inc.** (14.4 million beneficiaries) and **Cigna Corp.** (nine million beneficia-

ries) would be expected to have the motivation to increase their geographical coverage as a response to UnitedHealth's acquisitions. Health insurance companies likely to be involved in coming rounds of consolidation are considered to be **Health Net, Inc.**, **WellChoice, Inc.**, and **Humana, Inc.**

Tracking New Trends

Two insights will help lab directors and pathologists track evolution in the health insurance industry. First, UnitedHealth is now considered to be the best bellwether of general industry trends. Its strategic business moves in recent years have generally earned praise. In the mid-1990s, Aetna served as an industry bellwether. But its widely-publicized financial problems several years ago have knocked it off that perch.

Second, some of this consolidation must be viewed as a response to major changes about to take place in the Medicare program. Expect to read and hear more about Medicare Part C (which covers the newly-renamed Medicare Advantage Program—the private insurance plans for Medicare beneficiaries) and Medicare Part D (the new prescription drug program).

More Part C & Part D

The nation's largest health insurers understand how Part C and Part D activities will infuse more funding into the healthcare areas they cover. Acquisitions are one way to position themselves to gain maximum benefit from these new programs.

THE DARK REPORT predicts that enlargement of the new Medicare Advantage programs is going to put Medicare beneficiaries formerly in the Part B fee-for-service program into a private Medicare health insurance plan. It is likely that laboratory services for these plans will be bid on exclusive or limited-panel contracts.

That means local laboratories and pathology groups should carefully build relationships with local health insurers. As these payers enroll more people in Medicare Advantage Plans, local laboratories should fight hard to retain access to these patients. The natural tendency of payer network managers is to do sole-source or limited panel testing contracts with national labs and the largest regional labs.

If there is a wild card in this market evolution, it is consumer-directed healthcare. On the following pages, you can read how this growing phenomenon is likely to force a restructuring of the health insurance industry as we have known it for the last few decades. In recent years, THE DARK REPORT has regularly observed how the consumer movement in healthcare changes everything.

Consumer as King

With the consumer as king, he/she chooses his/her physician, hospital, and laboratory without restriction by an employer or health plan. For labs and pathology groups excluded by payer contract from providing services, isn't this the desired outcome? It enables local laboratories and pathology groups to compete on service, quality, and personal relationship.

Price is less of an issue with a consumer than it is with a payer's network director. Consumers will pay extra for the services they deem to have value. On the following pages, you will learn how the health insurance industry must undergo reform and evolution if it is to effectively serve a "customer-first" healthcare system.

It is easy to dismiss this as being years away. However, in less than twelve months, over 1 million people have chosen HSA (Health Savings Account) plans. That's a consumer movement now moving at great speed. TDR

Consumer-Directed Healthcare by Mango

Former lab industry executive generates national attention with his strategic analysis

CEO SUMMARY: This former laboratory executive declares that Consumer-Driven Healthcare Plans (CDHPs) are "the most significant development in health insurance since the widespread introduction of HMOs in the 1980s." Paul Mango, now at McKinsey & Co., has plenty of good news for lab managers and pathologists. He predicts that CDHPs will drive deep reforms across the American healthcare system.

By Robert L. Michel

RECENTLY A FORMER LAB INDUSTRY EXECUTIVE received national attention for his strategic thinking on a key issue in healthcare: consumer-directed healthcare.

Not only is Paul Mango causing healthcare experts to pay attention to his views on this subject, but his thoughts should be studied by lab executives and pathologists. Mango is predicting significant changes to the American healthcare system, driven by the growing acceptance of consumer-driven healthcare by the American public.

Today, Paul Mango is a consultant for **McKinsey & Co.**, the respected international consulting firm. Paul Mango's name is still familiar to many in the laboratory industry because of his leadership in creating the **Reference Laboratory Alliance** (RLA), a regional laboratory network that included 40 hospitals in and around Pittsburgh, Pennsylvania.

While working at Pittsburgh's **Institute For Transfusion Medicine** in the mid-1990's, Mango was the business mind behind the design and execution of RLA. When the competing **Allegheny** and **UPMC** health systems acquired most of the community hospital members of RLA, Mango resigned to return to work at McKinsey & Co. He still lives and works in Pittsburgh.

Health Strategy Issues

I've stayed in contact with Mango over the years. At McKinsey, he is continually involved in consulting for healthcare organizations. This work has lead him to study the impact of consumer choice on healthcare. The fruits of this strategic thinking are now reaching the public. In January, *The Wall Street Journal* published an opinion piece by Mango and his McKinsey colleague, Vivian Riefberg, on consumer-directed healthcare.

In recent months, McKinsey published the nation's first study of consumer responses to Health Savings Accounts (HSAs). Since this new form of health benefit plan became available

last year, more than 1 million people have enrolled in such plans.

Four McKinsey consultants, including Paul Mango, produced the new study. The opening sentence will grab the attention of lab managers and pathologists. The authors of this study declare Consumer-Directed Health Plans (CDHPs) to be "arguably, the most important development in health insurance since the widespread introduction of HMOs in the 1980s."

THE DARK REPORT concurs with this assessment. Over the past ten years, we have regularly emphasized the growing role consumers play in the American healthcare system. This has allowed our clients and regular readers to factor this trend into the strategic planning done within their laboratory or pathology group.

A good introduction to Mango's predictions about how consumer-driven health plans will change the healthcare landscape is contained in the story reproduced below. This was published in the *Wall Street Journal* last January.

For clinical laboratories and anatomic pathology groups, Mango's predictions promise much good news for laboratories. He expects that consumers will increasingly take responsibility for choosing their providers. They will base these choices on how they perceive the balance of quality versus cost offered by a physician, a hospital, and a laboratory.

What follows is Mango's predictions about how the health insurance industry must respond to the consumer-driven healthcare trend. It makes for interesting reading, since Mango expects a radical restructuring of the traditional health insurance industry. I'll bet that these positive changes to payers can't come too soon for most pathologists and laboratory managers! TDR

MANGO & RIEFBERG ON THE REASON HEALTHCARE'S "THIRD PARTY IS OVER"

UNITEDHEALTH GROUP'S acquisition of Definity, a tiny insurer with one of the first consumer-driven health plans on the market, is only the latest in a series of moves by the nation's big insurers to position themselves in the emerging market for health savings accounts (HSAs). How many employees ultimately end up in these plans remains to be seen. What is clear, however, is that even modest adoption of these plans will revolutionize the $1.8 trillion healthcare industry.

Previous efforts to reform the U.S. healthcare system have yielded disappointing results. This time may be different because the new "consumer-driven health plans" address some of the fundamental problems of the current system. For instance, the new HSAs largely end the third-party payer system that has separated consumers from the costs of their healthcare choices. With the ability to accumulate unspent funds and invest them, tax-free, rather than the "use it or lose it" feature of previous health savings accounts, they give consumers a strong incentive to avoid unnecessary care and become more cost-conscious.

The new HSAs also put pressure on medical providers to improve the quality of care and service they deliver to consumers, while maintaining a competitive

price. By creating a new consumer culture in healthcare, just 15% of insured Americans choosing these plans will usher in significant change for the industry.

Although it is too early to predict exactly how the industry will evolve, today's integrated health-insurance model could well split into four distinct businesses. This will create new competitive threats and opportunities for industry incumbents and entrants alike. These four businesses are:

UNDERWRITERS

Group health insurers today look at perhaps a half-dozen variables, such as gender, average age, and the type of work in which an employee base engages. Individual insurance products, like automotive, consider hundreds of variables and use very sophisticated models to assess risk. These players may be better positioned than traditional group-oriented health insurers to confront the risks of individual medical insurance and underwriting. Health insurers will need to either develop or acquire these skills if they are to sustain their leadership position in this part of the value chain.

PAYMENT TRANSACTION SPECIALISTS

The Third Party's Over...

The ability to draw the right amount from multiple payment sources (primary and secondary insurance, the HSA, the employee's pocket and, perhaps, an employee line of credit) will become an essential skill. Companies offering consumer-driven plans will need to report HSA balances to employees on demand, preferably in real time, much like ATMs allow bank customers to see their balances. Today's health insurers lack these capabilities. Third party payments specialists, such as those now serving credit-card issuers, are already evaluating opportunities in the industry.

INFOMEDIARIES

Making informed healthcare choices is complicated. In other industries, such as personal computers, automobiles, and financial services, objective agents exist to better inform consumer choices. Similar infomediaries, such as WebMD, have emerged in health care. Given the legacy of consumer mistrust stemming from the days of strictly-managed HMOs, independent advisers and patient health advocates have a strong competitive opening.

ASSET MANAGERS

Consumer-driven health plans now need to specify funding and asset management options for employees. As many as 20 financial institutions have announced plans to market HSAs, in much the same way as they do Individual Retirement Accounts, 401(k)s, and 529 plans for educational expenses.

In each of these four businesses, incumbent health insurers' positions are open to attack from new entrants. They will need to decide whether to try to build the new skills themselves, acquire them, or partner with others. The growth and popularity of the new HSAs is exceeding expectations, so resolving these questions quickly will be vital. Insurers, asset managers and banks have already announced several key acquisitions and alliances that will exclude others from locking up the best partnerships.

The smart money is already moving fast to stake out its place in the new marketplace. Hold on for what promises to be an interesting ride.

Paul Mango and Vivian Riefberg are partners of McKinsey & Company.

Techniques to Defend Against Patient ID Theft

Legal experts recommend laboratories take proactive steps to close the door on this crime

CEO SUMMARY: It's a crime that can strike anyone anywhere–and usually without warning. In fact, identity theft is the July 4 cover story in* Newsweek Magazine*. However, clients of THE DARK REPORT got the lab industry's first warnings on this fast-growing crime months ago. To help labs prepare to deal with this threat, Attorneys John R. Christiansen and Thomas Bartrum offer nine specific recommendations.

FOR HEALTHCARE PROVIDERS, including laboratories, identity theft is already a reality. That was one of the unexpected dimensions of the audio conference conducted on June 24, 2005 by THE DARK REPORT.

Another new development is a just-issued directive by the **Department of Justice** (DOJ) which sets new policy on enforcement of HIPAA (Health Insurance Portability and Accountability Act). During the audio conference, both expert presenters stressed the point that patient identity theft is already an established and major threat to providers.

"Is patient identity theft a real problem that warrants use of limited resources at this time?" queried Thomas E. Bartrum, attorney with **Waller Lansden Dortch & Davis** in Nashville, Tennessee. "Institutions like **Yale Medical School**, **University of Chicago Hospitals**, and **Seattle Cancer Care Alliance** have already been in the headlines for such incidents. Smaller, rural hospitals are particularly vulnerable to this crime. In fact, it is the growing number of such episodes over the past 12 months that's teaching us how vulnerable personal information has become."

Also stressing the "here and now" of patient identity theft was lawyer John R. Christiansen, J.D., of **Christiansen IT Law** in Seattle, Washington. He is a national expert on privacy laws and is personally familiar with the case of phlebotomist Richard Gibson, who was criminally convicted of patient identity theft under the HIPAA statute last year.

New DOJ Memorandum

Christianson explained that, on June 1, 2005, the **U.S. Department of Justice (DOJ)** issued a memorandum limiting the scope of liability under the statute to "covered entities." This reverses the basis for Gibson's conviction under the HIPAA statute.

"My concern about this new DOJ policy," stated Bartrum, "is that, if prosecutors will not go after the individuals, will they instead prosecute the 'covered entities'—the providers?

THE DARK REPORT has disclosed how, in the Gibson case, the patient insisted that the hospital *not* be targeted for investigation.

"That patient's benign attitude toward the hospital and the hospital's existing policies and procedures were important factors," added Bartrum. "Those were reasons federal prosecutors exercised their discretion not to take action against the provider, in this case, a major hospital in Seattle."

Substantial Penalties

Penalties for breaches of patient privacy involving identity theft can mount up fast. What may appear a trivial amount for a single incident can be catastrophic where multiple records are compromised. The two lawyers had nine key recommendations for laboratories and other providers.

"The first point is that HIPAA penalties only apply to 'covered entities'," said Christiansen. "Corporate entities can only act through their authorized officers, employees, and agents. For this reason, I recommend that laboratories and all providers have clear policies which define scope of authority.

"This is important because corporate authority is ultimately defined by how your organization does business, along with its compliance policy documentation and oversight, training and monitoring, and consistent policy enforcement," he continued. "If an employee was acting within his scope of authority when he committed a crime, the provider is liable. If outside the scope of authority, it's not. If the provider does a good job on policy infrastructure and enforcement, it has taken important steps to reduce its exposure to liability.

"The second point is to use care whenever the provider is part of a business association, group or affiliation," Christiansen warned. "Management should review how these relationships are governed. Know whether liability would extend to all members of the group or affiliated organization.

"Third party business associates would only be liable for their violations if they are 'covered entities'," stated Christiansen. "But your organization may become liable if it failed to take action to deal with a business pattern or practice of which it was aware. Look closely at how third party business associates are managing information from your organization."

"Three, don't forget that many states already have laws which cover identity theft," advised Bartrum. "States are enacting a raft of new security breach notification laws. California is at the forefront, having enacted legislation requiring encryption of sensitive data and notification of customers in the event of a breach."

"Some states passed legislation requiring police to take a statement in a claim of identity theft. Some identity theft victims are seeking to create 'fear factor' class action cases, alleging that they have fear that their information will be used and therefore are entitled to damages. Every provider should prepare policies and educate staff on how to respond appropriately to these types of issues," added Christiansen.

Proactive Measures

"Protecting your organization against patient identity theft and shielding yourself from liability in the event it does occur really boils down to your policies and procedures," observed Christiansen. "It's about making sure your IT and business processes are in compliance with the various privacy and security laws. The goal is to implement security measures sufficient to reduce risks and vulnerabilities to a 'reasonable and appropriate' level.

"Four, don't publish policies that say 'It is contrary to our policy to do these

things in violation of HIPAA and then fail to communicate those policies, train people, and monitor compliance," warned Christiansen. "Not only does the staff need to be educated about these policies, but the provider must actively monitor how its employees are following these policies.

"Fifth is to prepare for a crisis in advance. If lightning does strike your organization and a privacy violation occurs," advises Christiansen, "you want your staff to respond responsibly and confidently to the situation. That is why they must be trained before such incidents happen. It is important to have an effective identity theft response program already developed and ready—before it is needed.

Security Against ID Theft

"Start by re-evaluating your existing security measures against the threats of identity theft," he explained. "Does everyone understand the organization's vulnerability? Can you identify the weakest link and strengthen it? Are Social Security numbers still used as identifiers? Which employee positions are highest risk? The time to fix these things is before anything happens.

"Sixth, determine in advance who will investigate should a claim of identity theft become known. Train them on what points they should investigate and how they should respond to the patient. Know which agencies should be alerted to this incident and which should get the results of your investigation. Do any security breach notification laws apply in your state?"

Seven, when an event occurs, do a root cause analysis," Christiansen recommended. "How did it happen? What information was taken? What steps can your organization take to remedy the situation? What actions can you take to prevent this from happening again?

"Seven, establish procedures for handling any employees suspected of involvement in the complaint." noted Christiansen. "Should they be fired immediately? Will they be suspended or re-assigned? If they are left in their current duties, are they monitored as part of an effort to build a better case? These are reasons why such policies should be developed now and disciplinary procedures put into place. The rights of employees should be factored into these policies."

"Eight, don't overlook the potential of whistleblower suits," cautioned Christiansen. "Providers should be ready for such a development. When such lawsuits become public knowledge, the provider is judged as much in the court of public opinion as in a court of law. Carefully document your investigation with an eye toward litigation. Frame your responses and actions from the perspective of moving toward judicial review.

"Respond in a serious way to all complaints," noted Bartrum. "A proactive response plan might include helping the victim file reports with police and credit bureaus. Be sure your response team cooperates fully with investigators. Be a good citizen. Anticipate what will happen if and when the news hits the media."

Always A "People Problem"

"Nine, we both want to emphasize that the real problem is always people," stated Bartrum. "A provider must balance the burdens of its response strategy against the risk. Doing background checks at hire, particularly in the positions that carry the greatest risk, is becoming an important policy. Don't forget to include confidentiality agreements with employees." TDR

Contact John Christiansen at 206-301-9412, and Thomas Bartrum at thomas.bartrum@wallerlaw.com.

—By Pamela Scherer McLeod

Info Technology Update

Amazing New IT Products Arriving in Healthcare Market

How about cell phones as "pulse oximeters"? Advances in info technology drive this trend

TECHNOLOGY INNOVATIONS are triggering a flow of remarkable new information technology (IT) products into the healthcare marketplace.

Not all of these products will gain a foothold, but some have the potential to trigger radical changes in how information flows between patient, provider, and payer. Here's a round-up of IT products that THE DARK REPORT finds novel and which may have application in some clinical laboratories and pathology group practices.

PORTABLE PATIENT RECORD

One company is using mini-USB drives to let patients carry their health information with them on a key chain. **CapMed, Inc.**, of Newton, Pennsylvania, is marketing their "Personal Healthkey™." In combination with specially-written software, a patient can record visits to his/her physician, update prescriptions, record immunizations, and even store medical images. CapMed says it has already sold 10,000 of its healthkeys. It has also distributed 400,000 CD-ROMs that contain copies of its "personal health record" software program.

"MOBILE PULSE OXIMETER"

For cell phones capable of using Java language programs, a patient can create their own "mobile pulse oximeter." **MedicTouch, Inc.** of Paradise Valley, Arizona sells a software program that, once installed on a cell phone, allows that cell phone to capture information from a MedicTouch sensor device which fits on a finger. The cell phone can then transmit this information to the patient's physician or other provider by either a wired connection or use of Bluetooth wireless technology.

DIGITAL PEN

Hewlitt Packard, Inc. of Palo Alto, California now offers a unique digital pen that works with special paper forms. Paper forms are created with a pattern of invisible dots. The Digital Pen 200 has both a ball-point ink cartridge and a small camera. As the pen is used, the camera captures the pen strokes and converts them into digital form. The pen is then placed in a docking cradle and the data is automatically uploaded into the enterprise data base.

One beta user was **Cherokee Indian Hospital** in Cherokee, North Carolina. Over a two-year period, it reduced data entry costs from about $3.25 to under $1.00 per record. The system also increased productivity, reduced errors, and improved verification of data. As used in this hospital, staff members interview the patient, check boxes and enter comments on the form. Once the pen is cradled, the data automatically transmits into the patient record. Physicians and nurses can always review the record and make changes.

PERSONNEL SMART CARDS

One solution to the multiple password dilemma in hospitals and other provider settings is a new smart card introduced by **GemPlus International**, a firm based in Luxemburg.

Essentially, once someone logs into the system with the smart card and a personal identification number, they can call up their "customized dashboard" interface anywhere within the system. This eliminates a major problem in many health systems, where the user is required to enter the alphanumeric password six or seven times to finally access the data wanted. For IT departments, the benefit is that the smart card arrangement eliminates the need to issue temporary passwords when someone forgets his/her password.

In Puerto Rico, three million Medicaid beneficiaries are using a smart card sold by **Axalto, Inc.** of Amsterdam, The Netherlands. Axalto's smart card contains fingerprints as an added security measure. Three counties in Texas are in a pilot project to use this technology.

WI-FI BADGE

Ongoing advances in wireless technology and reduced costs have encouraged many hospitals to install wireless systems. **Vocera Communications, Inc.** of Cupertino, California now offers a single solution communication product that it calls a "voice-activated" badge.

Sold under the name "The Vocera Communications System," the unique part of the system is a two-ounce, clip-on communication badge small enough to be worn on a lapel. It is a hands-free device that is voice activated and uses voice recognition technology.

The individual simply says "call Dr. Smith" and the device will direct the call to that individual. In a laboratory, this type of system is designed to eliminate the loudspeaker, paging, and phone-tag communication systems and replace it with a single, simple system.

The Vocera wireless network can be interfaced with most PBX phone systems. It is already in use in about 150 healthcare settings, including hospitals. One hospital reported that, in one year, it saved 3,400 hours in its nursing division, which is about the same number of hours worked by two full-time employees.

SECURITY BADGE

Even the lowly and ubiquitous security badge is getting a high-tech makeover. **Entrust, Inc.** of Addison, Texas offers a product called "The Identity Card."

Like many security badges, it requests a user name and password at sign-on. Once that is provided, the system requests users to fill in three boxes with numbers or characters located on a grid on the back of the identity card. These grid coordinates are changed each time an individual logs on.

It offers three benefits. One, the capture of pass codes by identity thieves using "phishing" tools is thwarted. Two, it controls the practice of sharing passwords and log-in information. Three, each card costs about $1 to produce, compared to as much as $30 to $50 per security badge charged by other types of systems.

Fast-Changing IT Market

These items are just a sample of new technology products entering the market daily. The wireless phone as "mobile pulse oximeter" is a good example of how new technologies can shatter existing paradigms. Another technology with that potential is RFID (radio frequency identification) tags, technology THE DARK REPORT has covered in recent months. Collectively, all these examples demonstrate how the pace of change in information technology is accelerating and triggering a flood of new products. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There's been strong growth at two companies featured in *Fortune Magazine's* 2005 list of "America's Fastest-Growing Small Public Companies." **Ventana Medical Systems, Inc.** earned a ranking as number 28 on the list. **Bio-Reference Laboratories, Inc.** was ranked at number 64. Another company of interest which made the list was **Meridian Bioscience, Inc.**, listed at number 80. Meridian produces materials used in laboratory proficiency testing kits.

ADD TO: Top 100 Ranking

To compile this "fastest-growing" list, *Fortune* identifies public companies with annual revenues below $200 million and a share price that is at least $1. It then produced the rankings by using the criteria of earnings growth and revenue growth over the past three years, along with the performance of the company's stock.

VA GIVES I.T. SYSTEM AWAY FOR FREE AND HAS PLENTY OF TAKERS

If a health system with 1,300 hospitals and clinical sites nationally had a working I.T. system and was willing to give it away for free, would there be any takers? The answer is yes, if the system is the **Veterans Administration's** Vista, which stands for "Veteran Health Information Systems and Technology Architecture." Many foreign healthcare organizations are using the Vista system. In Mexico, the **Instituto Mexicano del Seguro Social** (IMSS) is preparing to install Vista in 112 of its 223 general hospitals. Premier hospitals in Egypt and Germany have extensive experience with Vista.

ADD TO: Free Software

Within the United States, 201-bed **Midland Memorial Hospital** in Midland, Texas is about to become the first acute care hospital in the private sector to activate and use the Vista system. Vista has been in the public domain for 20 years. It can be downloaded for free from any number of public Web sites. A copy of Vista on a CD-ROM can be purchased from the VA for $47. There is a group of developers, called WorldVista, who are developing Vista as an open-source system. Efforts are underway to adapt Vista to run on a Linux operating system and a GT.M version of MUMPS data base and programming language. Health officials in many countries consider Vista to be an extraordinary free resource that stretches their meager budgets for healthcare.

Here's another national healthcare story where THE DARK REPORT has scooped the national media! Three weeks ago, the *Washington Post* ran an extensive story about how **Virginia Mason Medical Center** (VMMC) in Seattle, Washington has gone "Lean" and is using the management quality methods developed at **Toyota** throughout its hospital and affiliated clinics. Of course, alert readers recall that *The Dark Report* presented the Virginia Mason story in detail last November 22, 2005, with a special emphasis on laboratory and pathology projects.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 1, 2005.