Volume X, Number 14 Monday, October 20, 2003

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

Chipping Away at Laboratory Reimbursement

PROPOSED NEW MEDICARE RULES by the **Office of the Investigator General** (OIG) dealing with "discriminatory billing practices" and "usual charges" should be seen as part of a larger trend. The government doesn't have the money to pay for Medicare and Medicaid. Thus, it is exploring indirect ways to reduce the amount of money it pays providers.

As you will read on pages 2-5, the OIG's publication of the proposed new rules in the *Federal Register* last month is just the newest in a series of attempts to align a law passed years ago with today's healthcare pricing practices. According to this law, no provider should bill Medicare for more than its "customary charge." Back in the days of fee-for-service medicine, this was a relatively easy thing to do.

But the 1990s brought a host of new contracting and pricing models to the American healthcare system. Not surprisingly, bureaucrats in the federal healthcare programs fell behind developments in the marketplace. So this latest attempt to offer more precise guidance on the subject of discriminatory billing practices is laudable. But I would like to suggest that the proposed new rules represent a new regulatory cycle. Medicare officials recognize that many providers are willing to provide healthcare services at prices that are significantly below Medicare's.

Focus, for the moment, on the laboratory industry. It is tough to justify a situation where a laboratory performs a test for a physician's patient, then client-bills the physician for, say, $5.00. (Of course, the physician will then turn around and bill the private insurance company for a greater amount and pocket the difference.) The lab, doing the same test for a Medicare patient, generally bills the Medicare program for its full reimbursement, which, in our hypothetical example, might be $15 or $20.

It seems to me that, sooner or later, senior policymakers within the government, whose mission is to see that Medicare does not pay more than private insurers for similar services, will recognize this situation as one which needs correction. Whether that is motive behind this round of proposed new rules is not for me to say. But I can read all the tea leaves. Client bill arrangements and heavily-discounted fee-for-service contracts between labs, insurers, and IPAs certainly expose this industry, collectively, to a reasonable claim that Medicare is not getting the lab industry's "usual charge." TDR

OIG Moves to Address "Usual Charge" Issue

"Discriminatory billing practices" is target of new rules published on September 15

CEO SUMMARY: Federal regulators are taking another crack at defining "usual charges." Language in the proposed rules published last month precisely defines which payers should be included in determining "usual charges" and what charge basis to use for specific payers. Once effective, the new rules will have financial impact on many laboratories, particularly those known to offer clients heavy discounts.

ONCE AGAIN the **Office of the Investigator General** (OIG) is tackling the subject of "discriminatory billing practices" in the Medicare and Medicaid programs.

On September 15, 2003, the OIG published rules in the *Federal Register* that would amend regulations related to the Medicare/Medicaid prohibition against discriminatory billing practices. The public can comment on the proposed language until November 15.

Clinical laboratories typically discount lab test prices to HMOs and certain other payers, physician clients, employers, and other customers. Because price discounting is widespread across the laboratory industry, the proposed new rules could have significant financial impact on many laboratories.

"This issue revolves around a long-standing federal law that basically says 'providers should not bill Medicare more than they customarily bill others'," stated Jane Pine Wood, Partner in the Cleveland, Ohio-based law firm of **McDonald Hopkins**.

"The law itself is unambiguous," she added. "It says that no provider shall bill Medicare for services at a price which is 'substantially in excess of such individual's or entity's usual charges or costs for such items or services to any of their customers, clients, or patients.' The ambiguity has always been in the definition of 'usual charge.'

"This is at least the third major attempt by federal rulemakers to address this issue," Wood said. "Their concern is that Medicare pays more for services

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.

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than the private sector, because it doesn't get discounts equal to what providers will offer private clients."

Within the laboratory industry, this is certainly true. Highly-discounted fee-for-service contracts between laboratories and payers are widespread. In states that permit physicians to mark up, it is common for laboratories to offer those physicians extremely low prices in client-bill arrangements while generally submitting claims to Medicare for the full amount allowed under Medicare reimbursement guidelines.

"The proposed new regulations are very precise in several ways," observed Thomas P. Joseph, a billing and compliance expert with **Sprick, Stegall and Associates**. "For the first time, there are detailed definitions of the key terms 'usual charges' and 'substantially in excess.' *(See Sidebar on next page.)*

"While not specifically mentioned, account bill clients appear to fall under the categories of payers that should be included in the usual charge calculation," explained Joseph. "The financial impact could be considerable for labs that maintain a high proportion of account-bill clients who get significant discounts in the price of their lab tests.

Detailed Analysis Required

"Also, the proposed language makes it clear that the rules apply to individual procedures, not charges for all combined procedures," he added. "That means labs will have to do a detailed analysis of each procedure to determine the 'usual charge.' These calculations will need to be updated periodically to ensure compliance to reflect changes in the laboratory's payer mix or as changes occur in different payers' fee schedules.

"Certainly in the long run, the proposed rules, if implemented as written, will limit a laboratory's ability to negotiate reduced fees to HMOs, managed care organizations, physicians, and other clients," Joseph said.

Significant Impact on Labs

"Further, the inclusion of Medicaid in the proposed rules may create a significant impact for laboratories operating in states where Medicaid program fees are substantially less than Medicare fees," said Joseph. "For example, if the Medicaid program is reimbursing at 70% of the Medicare rate for lab tests, to meet the excessive charges requirement in the new rules, a much higher proportion of that lab's charges would need to be reduced."

To help clients and readers of THE DARK REPORT, Joseph prepared tables to show, based on assumptions of payer mix and proportion of discounted business, how much of a typical laboratory's book of business would be considered "excessive charges" and how that would change the Medicare billing rate. *(See sidebar on page 5.)*

Even if these rules take effect, this may not be the final word on the issue of Medicare "discriminatory billing practices" and "usual charges," according to attorney Wood. "The original letters which defined usual charges were issued by the **Healthcare Finance Administration** (HCFA, now **Centers for Medicare and Medicaid** [CMS]) and the OIG back in the 1980s. That predates HMOs and a variety of new healthcare contracting models which appeared in the 1990s," stated Wood.

Send written comments on the proposed rules by November 14, 2003 to: Office of Inspector General, Department of Health and Human Services, Attention: OIG-53-P, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201. The rules were published in the September 15, 2003 edition of the Federal Register (pp 53939-53945).

Feds Get Specific on "Usual Charges"

DEFINITION OF USUAL CHARGES: Proposed new rules would determine usual charges by evaluating a provider's charges to selected payers using a defined charge (depending on the payer). The key elements to be used in the calculation of usual charges are summarized below.

Usual charges calculations include:

Payer	Basis for calculation[1]
Cash-paying patients	Entire charge billed[2]
Patients covered by indemnity insurers with which the provider has no contract	Combined insurance + patient payments
Fee-for-service rates from any payer, including discounted fee-for-service rates with managed care plans[3]	Negotiated contract rate + any co-pay
Hybrid fee-for-service arrangements where <=10% of the payment is in form of a bonus or withhold	Contracted fees + 50% of the withheld amount
TriCare (Including TriCare Standard)[4]	Contracted rates

1 Would be based on either the weighted average (mean) or median of all charges for these payers during a 12-month period.
2 As long as a good faith effort is made to collect the entire charge.
3 Including Medicare+Choice plans, state managed care plans and other federal managed care plans
4 Unless based on capitated or hybrid fee-for-service arrangement with >10% of payment withheld.

Calculation of usual charges would not include:

- Uninsured patients who receive services free of charge or at a substantially reduced rate
- Capitated payments
- Hybrid fee-for-service arrangements where >10% of the payment could be paid in the form of a bonus and/or withhold payment
- Medicare and certain state and federal health care programs

DEFINITION OF "SUBSTANTIALLY IN EXCESS": The OIG is proposing that "only those charges or costs that are more than 120% of a provider's usual charges or costs will be deemed to be "substantially in excess."' It should be noted that this would apply to individual laboratory procedures, not aggregate payments to payers.

"Each revision to these rules is an attempt by regulators to clarify existing law," she continued. "The proposed rules are much more precise than earlier attempts. However, for laboratories that like a level playing field for compliance, there is still a loophole.

"The rules specify a formula for determining excess charges relative to Medicare and Medicaid fees. This formula determines an average of charges and creates the opportunity for manipulation by an aggressive laboratory."

Wood's observation strikes at the heart of the compliance conundrum within the laboratory industry. Laboratories which follow conservative compliance policies often find themselves at compet-

Gauging the Financial Impact on Labs

THE TWO TABLES ON THIS PAGE illustrate the net financial effects of the proposed rule on a hypothetical laboratory, based on specific assumptions about payer mix and fees. They offer insight into the economic implications of these proposed rules. The example is based on the top 100 procedures of a laboratory, and assumes a typical Payer mix using actual charges, Medicare, and third party fee schedules.

When the mean (weighted average) usual charge is calculated for the 100 procedures and compared to Medicare screens, 25% were outside of the guideline of excessive charges. Reductions in charges to Medicare lowers the resulting Medicare reimbursement by 5.6%; but by only 2.2% if the charge to Medicare was reduced to the usual charge x 120%.

Table 1: Payer Mix and Relative Level of Reimbursement from Various Payers

	% of Total Charges	Reimb. Relative to Medicare
Medicare	25%	1.00
Medicaid	8%	0.54
Managed Care	27%	0.52
Commercial	20%	1.22
Self Pay	5%	2.14
Client (@50% disc)	15%	1.07
Total	100%	

Table 2: Effect of Proposed Rules as Client Bill Mix and Discount Changes

PCT CLIENT BILL	% DISCOUNT FROM LIST								
	0%	10%	20%	30%	40%	50%	60%	70%	80%
40%	5%	5%	5%	11%	15%	19%	**33%**	**55%**	**83%**
35%	5%	5%	7%	12%	15%	19%	**31%**	**53%**	**78%**
30%	5%	5%	8%	10%	15%	**22%**	**31%**	**51%**	**69%**
25%	5%	5%	9%	10%	17%	**24%**	**31%**	**47%**	**61%**
20%	5%	8%	9%	13%	19%	**25%**	**32%**	**46%**	**55%**
15%	8%	9%	12%	15%	**20%**	**25%**	**33%**	**40%**	**50%**
10%	11%	14%	16%	**20%**	**22%**	**25%**	**31%**	**39%**	**43%**
5%	19%	**20%**	**22%**	**24%**	**24%**	**27%**	**30%**	**34%**	**38%**
0%	**34%**	**34%**	**34%**	**34%**	**34%**	**34%**	**34%**	**34%**	**34%**

IF THIS HYPOTHETICAL LABORATORY increased client bill accounts to 35%, with a 70% discount from list, 53% of the procedures would be classified as excessive. This would reduce Medicare payments by 15.7% if charges to Medicare were reduced to the usual charge level and by 7.4% if reduced to usual charges x 120%. (Note: If a lab's clients had a higher proportion of fee-for-service or agreements that are more heavily discounted than shown above in the payer mix table, then that lab might face more significant reductions in its Medicare payments.)

Tables and analysis prepared by Thomas P. Joseph

itive disadvantage when other labs in their region take a more aggressive position on compliance. Because federal regulators seldom act on "minor" compliance infractions, laboratories with the laxer policies gain economic advantage, often for years. These new regulations promise to rectify some of the inconsistencies in the marketplace, but still leave room for interpretive mischief. TDR

Contact Thomas Joseph at 734-741-0356 and Jane Pine Wood at 508-385-5227.

No Disruptive Technology In Lab Industry's Future

Experts discuss trends and technologies which give labs new testing capabilities

CEO SUMMARY: As new diagnostic technologies move through the development pipeline and into widespread clinical use, the scientific knowledge and skill sets needed by laboratory staff and management will change. The emphasis in laboratory medicine will evolve to include more molecular technology, but this evolution will proceed incrementally, giving all laboratories time to adapt.

RAPID ADVANCES in genomics and proteomics promise to revolutionize healthcare and the laboratory testing industry. But it will be a few more years before truly disruptive technology becomes a reality.

That was the consensus of three experts who participated in a strategic planning session with the Board of Directors of the **American Society of Clinical Pathology** (ASCP). The session took place last month in New Orleans at the ASCP's annual meeting.

The three experts included Myla Lai-Goldman, M.D., Executive Vice President and Chief Medical Officer of **Laboratory Corporation of America**, Tim Orr, Vice President, United States Marketing for **Johnson & Johnson's Ortho-Clinical Diagnostics** (OCD) and Robert L. Michel, Editor-In-Chief of THE DARK REPORT.

There was surprising consensus among the expert panel on at least three key points. First, there is no "disruptive technology" in the pipeline which would create rapid and far-reaching changes in the clinical laboratory industry. Most technologies currently in development will take about five to eight years to enter the marketplace and gain widespread acceptance and use.

Second, the knowledge base for laboratory medicine is going to steadily shift toward the fields of genetics and proteomics. This will happen gradually, not suddenly.

More Complexity Ahead

Third, more complexity is coming to the management of clinical laboratories, in several ways. As new assays are approved for clinical use, these assays will require more sophisticated skills and equipment in the laboratory. The organization of the laboratory itself will undergo change, with testing migrating out from the core lab into point-of-care, near-patient, and patient self-test settings. As well, management philosophies and techniques used in the laboratory will become more sophisticated.

Each expert panelist has a unique perspective on the laboratory market-

place and emerging technology. For that reason, the convergence of views on these three points is noteworthy.

Lai-Goldman, as LabCorp's Chief Medical Officer, is uniquely positioned to see the wide range of diagnostic technology that is under development. A large number of biotech and pharmaceutical companies regularly approach LabCorp to demonstrate emerging technologies. They want LabCorp's perspective on whether the healthcare marketplace would accept these technologies. In addition, LabCorp has its own research and development effort under way. It is continually looking for promising technology which it could commercialize.

Early Look At Technology

In a similar way, Ortho-Clinical Diagnostics also gets to see promising new diagnostic technology as it undergoes development and evaluation. As one of the world's largest diagnostic manufacturers, OCD is motivated to actively seek out and acquire promising technologies. For this reason, Orr is privy to a wide range of emerging diagnostic technologies.

For laboratory directors and pathologists interested in the strategic direction of the laboratory industry in the near future, this panel of experts had reassuring news.

The perspective of Michel complements that of the large commercial laboratory and the large diagnostic manufacturer. As Editor-In-Chief of THE DARK REPORT, he constantly visits laboratories and industry vendors. He closely watches the point of intersection where new diagnostic technology first enters the clinical marketplace.

For laboratory directors and pathologists interested in the strategic direction of the laboratory industry in the near future, this panel of experts had reassuring news. During the next few years, it is expected that diagnostic technologies currently under development will take between five and eight years to enter the marketplace and gain widespread acceptance.

The example of liquid preparation Pap smear tests illustrates this dynamic. In 1998, this technology was just entering the marketplace. It took five years for liquid prep Pap tests to capture a market share which is now considered to be more than 65% of the 55 million Pap tests done annually in the United States. It was the opinion of all three panelists that this example would be representative of the clinical acceptance curve for most new diagnostic technologies currently in the development pipeline.

Consensus around the second key point, the shift toward greater use of genetic and proteomic science in laboratory medicine, reinforces the experience of individual laboratories. At LabCorp's Center for Molecular Biology and Pathology in Research Triangle Park, North Carolina, that future has already arrived. This laboratory is home to the most advanced and complex testing done inside LabCorp.

Lai-Goldman told the ASCP board that MTs hired to work in this laboratory generally must undergo several weeks of additional classroom training before they are ready to work at the bench. This training emphasizes the molecular science that supports the sophisticated esoteric assays performed at that site. She recommended that MT training programs should evolve to provide more training in these new areas of diagnostic testing. This is the knowledge that will be required to support most of new diag-

(Story continues on page 15)

Hollywood Glamour Comes to the ASCP: CSI Star William Peterson Gets Award

At far left, William Peterson, star and Co-Producer of* CSI:Crime Scene Investigation*, receives the ASCP Special Recognition Award from ASCP President Eugene Baille, M.D.

FORENSIC PATHOLOGY IS THE THEME of the nation's top-rated television show. *CSI: Crime Scene Investigation* is a ratings blockbuster and has brought pathology to the attention of many television viewers.

CSI's star and Co-Executive Producer is William Peterson. He has developed a reputation as someone who wants to get both the science and the details of the program as accurate as possible. At least three pathologists (two who are members of the ASCP) are regularly consulted during script development and filming to insure the authenticity of the show, in every detail.

To recognize these accomplishments, the American Society of Clinical Pathology (ASCP), at its annual meeting in New Orleans last month, awarded Peterson its "ASCP Special Recognition Award" for his contributions to the pathology profession.

Not only has Peterson increased public awareness of pathology and laboratory medicine through his television program, but he has also testified before the Senate Judiciary Committee in 2001 to support increased funding for crime labs.

This is only the third time that the Special Recognition Award has been given out. The first was in 1979, when Jack Klugman of the television show *Quincy* received the award from the **California Association for Medical Technology**. The second award was in 1989, when C. Everett Coop, M.D. received the award following his term of service as the U.S. Surgeon General.

Peterson spent considerable time at the ASCP convention, participating in discussions and making several presentations. One evening presentation covered the laboratory technology incorporated into CSI and the specific special effects used to make each scene look authentic. This session was heavily attended.

Useful Strategic Planning Insights For Laboratories

Looking at Fast-Growth And Slow-Growth Areas In Diagnostic Testing

CEO SUMMARY: This exclusive intelligence briefing predicts how specific new technologies may drive changes in the laboratory-testing marketplace during the next five years. The key message is that change is expected to be incremental, not disruptive–given the technology known to be in development at this time. But the more provocative insight relates to how even incremental change will create a labor challenge within the nation's laboratories. The basis of laboratory medicine is shifting to new areas of science, requiring existing lab staff to acquire new training and experience.

CORRECTLY ANTICIPATING CHANGES in the test menu mix during the coming years is a key element of strategic planning for clinical labs.

To help laboratory directors and pathologists in this area of strategic planning, THE DARK REPORT was given permission to share the contents of an exclusive briefing on how new laboratory test technologies are expected to enter clinical use over the next few years.

At a strategic planning session conducted by the Board of Directors for the **American Society of Clinical Pathology** (ASCP) during its annual meeting in New Orleans last month, Tim Orr provided a concise overview of the existing and projected market trends for different areas of diagnostic testing. Orr is the Vice President, U.S. Marketing for **Ortho-Clinical Diagnostics** (OCD), a **Johnson & Johnson** company.

"In looking at how diagnostic technology will affect clinical laboratories during the next decade, I have six fundamental points," stated Orr to the ASCP board. "First, in mature areas of diagnostics, automation will be the primary driver of change. Second, clinical chemistry and immunoassay testing will be increasingly integrated onto single instrument systems.

"Third, expect molecular diagnostics to go mainstream, as technology becomes easier to use and test methods become more automated," he continued. "Fourth, everything we see at OCD points to a slow (verus rapid or exponential) emergence of new, high-value tests during the next five years. Fifth, new diagnostic technologies will emerge at an equally steady pace during that same period.

"Sixth, in coming years, clinical laboratories will place greater emphasis on improving operational processes," offered Orr. "As it relates to higher test quality, improved productivity, labor optimization, and improved service levels, operational excellence will become a distinguishing characteristic of the nation's best-run labs."

In reviewing different areas of diagnostic testing, Orr noted that, to date, home testing in the lab market has had little impact. Outside of glucose and pregnancy testing, the sales volume of home diagnostic test kits remains small. In a similar way, direct access testing (DAT) by consumers has yet to become a significant part of the overall market for laboratory testing. Laboratories offering DAT consider it a small part of today's business, although it is expected that future consumer demand will increase.

Growth in POCT

Point of care testing (POCT) will continue to grow in importance relative to core lab testing. "In 1998, core lab testing and POCT testing was about $15 billion and $4 billion, respectively, as measured by manufacturers' sales," stated Orr. "Core lab testing is expected to grow about 2% per year, while POCT testing is growing at 12% to 16% per year. It is projected that, by 2008, core lab testing will increase modestly, to about $18 billion, while POCT will total $14 billion.

"These projections demonstrate that laboratories should plan to see more POC testing within the clinical communities they serve," he said. "The numbers above demonstrate that the core lab will neither shrink in volume nor importance. Rather, the added value of doing testing at the point of patient care will encourage more testing outside the core laboratory."

More specifically, Orr notes that ongoing miniaturization of diagnostic test devices will play a significant role in expanding the ability of POCT. Specific areas of ongoing technology development to watch are: micro-array, micro-fluidics (which support "lab on a chip" efforts), MEMS (micro-electrical mechanical systems), and wireless connectivity.

New diagnostic markers and molecular testing was addressed. "Without ques-

tion, knowledge from the human genome is already generating new diagnostic tests," noted Orr. "The expectation is that labs will see new markers emerge for diagnosis of cancer, diabetes, heart disease, Alzheimer's, and CNS disorders. Alliances between lab test developers and pharma companies will lead to specific diagnostic tests married to specific therapeutic drugs.

Greater Role For Informatics

"What will surprise most laboratory directors and pathologists, however, is the importance of informatics in diagnostics," predicted Orr. "This is happening on two levels. First, there are active and highly-visible efforts to eliminate paper records in healthcare. The goal is to capture clinical information digitally and make it feasible to move clinical data seamlessly among all types of providers and payers. Because laboratory data is the heart of the patient record, the informatics capabilities of individual clinical laboratories will become very important. Laboratories will find themselves handling more information and handling it in a different way than in the past.

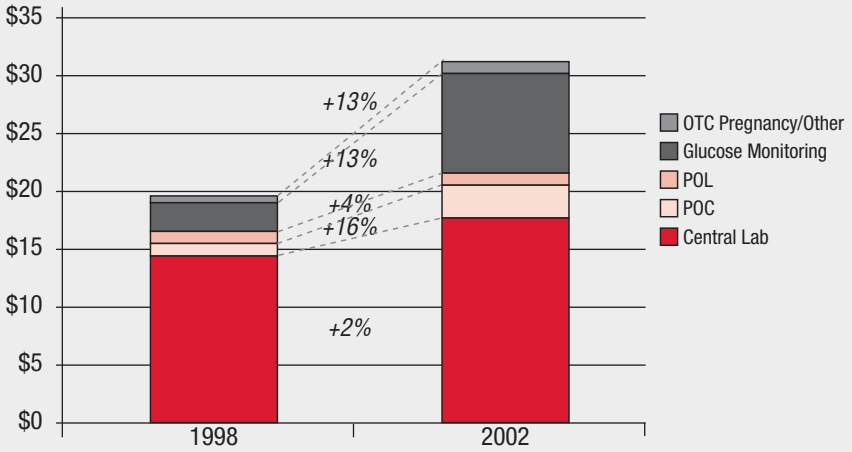
"Equally important will be the lab's ability to capture the high volumes of data coming from those new assays which are based on genetic and proteomic science," he explained. "For example, new instrument systems will need to simultaneously measure tens, even hundreds of proteins for a single laboratory diagnosis. The **Luminex** system and **Ciphergen's** protein chip are early steps in this direction."

Mass Spectrometry

Orr then made a particularly interesting observation. "Mass spectrometry is an emerging area for clinical diagnostics. It is catching on for selected diagnostic applications. The fascinating aspect of mass spectrometry is that

Changes in Relative Size of Core Lab Testing Versus POCT

This graph illustrates how, by 2008, the volume of point-of-care testing (POCT) will almost equal the volume of core lab testing. Core lab testing is predicted to grow about 2% per year between 1998 and 2008, while POCT will grow at rates approaching 16% per year.



Source: EAC research and projections

Predictions About Technology Pipeline For Different Diagnostic Capabilities

Technology	Potential Impact on Laboratory
Capillary Electrophoresis (CE)	• Over 100 laboratories now estimated to be using CE instruments • CE will eventually replace slab gels for DNA and serum protein analysis • CE has many potential clinical applications: drug assays, DNA analysis, immunoassays • CE also used in large DNA sequencers and micro-fluidic lab chip technologies
Micro-Electrical Mechanical Systems (MEMS)	• MEMS is similarly closely aligned with micro-fluidic lab chip technologies. MEMS refers to miniaturization of pumps, valves, etc. that can be incorporated into "lab chip" technologies • Currently at an early stage of development
DNA Microarrays	• Currently in use in specialty reference labs for selected applications (e.g. HIV resistance) • Utilization of micro-arrays in the clinical laboratory will grow with advent of new applications and systems
Protein Chips, Arrays	• Proteomics is still largely limited to life science research • Selected clinical applications will emerge over next 5 years leading to Protein Chip or other array technologies in the clinical lab
Mass Spectrometry	• Mass Spec is currently widely used in life science research • Clinical applications now emerging • Expect more clinical applications in future
Micro-fluidic "Lab-on-a-Chip" Platforms	• Micro-fluidic technology has made transition from development to marketed products • Likely future clinical applications include DNA sequencing, SNP and mutation detection, biochemical assays, hematology

IN LABORATORY STRATEGIC PLANNING, it can be challenging to both identify and track specific technologies which are moving from use in primary research and finding applications in clinical diagnostics. The management challenge is to know when the time is right to acquire and offer these emerging technologies to clinicians. The table above was prepared by Tim Orr, Vice President, U.S. Marketing, Ortho-Clinical Diagnostics for presentation to the Board of Directors of the ASCP at a recent strategic planning session.

Impact of MT Shortage On Lab Operations

WITH FEWER MEDICAL TECHNOLOGISTS (MT) available, laboratories face serious strategic challenges, which new diagnostic technologies may intensify.

"There is widespread recognition that the supply of trained technical labor is already inadequate," stated Tim Orr, Vice President, U.S. Marketing, Ortho-Clinical Diagnostics. "That is why automation is increasingly viewed as a way to substitute for scarce labor. But molecular diagnostics and the need to generate and manage greater quantities of information will add to the problem.

"Today, the technical staff in most laboratories have neither experience nor training in molecular diagnostics. Moreover, most educational programs have yet to incorporate much molecular science into the curriculum," said Orr. "Similarly, there will be a growing need for new skill sets to interpret genomic and proteomic diagnostics."

LAB STAFF VACANCY RATES,
(From a recent ASCP survey)

HOSPITAL LABORATORIES:
- 10.9% in histo-technologist staff
- 9.1% in histo-technician staff
- 9.0% in phlebotomist staff

REFERENCE LABS & PRIVATE CLINICS:
- 10.7% in cyto-technologist staff
- 10.6% in phlebotomist staff

PHYSICIAN PRACTICES:
- 10.0% in medical laboratory technician staff

OUTPATIENT CLINICS:
- 13.8% in medical laboratory technician staff
- 11.4% in medical technologist supervisors

it is reagentless technology. It promises new capabilities in sensitivity and specificity.

"Having looked at the wide range of technology influences on the laboratory testing menu of the future, it is appropriate to step back and comment on the big picture," commented Orr. "The evidence today indicates the diagnostic marketplace is moving forward in small steps. It is appropriate to view lab testing as moving forward by incremental improvements to existing technologies and methodologies.

Disruptive Technology

"Obviously the potential exists for some type of disruptive technology to emerge—a technology that would rapidly change both lab operations and clinical practices. However, no clear candidate is visible now that could cause such disruption," said Orr.

"In fact, the past ten years provide us excellent insight into the current lab testing marketplace," he explained. "During this time period, only about five to ten 'new' diagnostic tests have achieved wide-ranging success, as judged in both clinical terms and significant new volumes of specimens. Examples would include BNP, Triponin, PSA, HCV, and HIV.

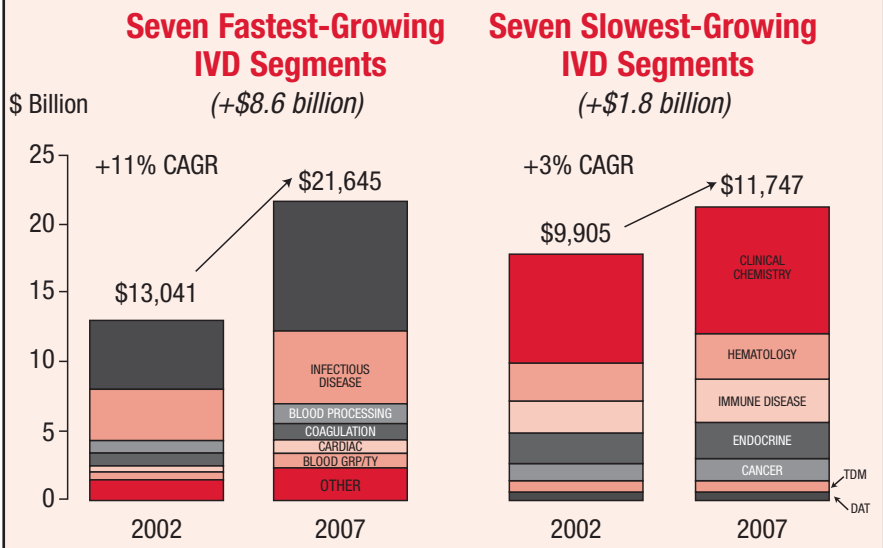
Primary Challenge Ahead

"From my perspective, new diagnostic test technology will not be the primary challenge facing laboratory directors and pathologists during the next few years. It will be staffing issues," declared Orr.

"First, does each laboratory have adequate numbers of technical staff to do the work?" he asked. "Second, and more importantly, does this staff have the specific scientific training and practical laboratory experience required to properly set up and perform diagnostic tests which utilize technologies that did not exist when

Which Areas Will Drive Growth in Lab Testing Volume

IT'S NO SURPRISE that the low-growth segments of laboratory testing involve mostly clinical chemistry and hematology. (*See graph below right.*) The fast-growth drivers in laboratory medicine will be primarily diabetes testing and infectious disease testing. (*See graph below left.*)



Source: Boston Biomedical Consultants, Inc.

most medical technologists were in school?

"If most improvements in diagnostic technology will be incremental, then laboratories have the time to prepare for new assays and new technologies," he continued. "At the same time, these incremental improvements will add complexity into all facets of laboratory operations. That is one reason why I believe that the training needs for technical staff should be a strategic priority for every laboratory."

Overlooked Point

THE DARK REPORT observes that Orr's insights drive home a point that is often overlooked when laboratories undertake strategic planning exercises. The challenge is not new test technology which is expensive and complex. Rather, the challenge is whether the laboratory has incrementally advanced the technical skills of its staff, allowing it to capably deploy new test technologies as they are ready for "prime time."

The business intelligence offered by Orr represents an analysis of the diagnostic marketplace made by one of the world's leading diagnostic manufacturers. It is the type of intelligence not often shared with the general laboratory public. THE DARK REPORT would like to acknowledge the willingness of both the American Society for Clinical Pathology and Ortho-Clinical Diagnostics to share these insights with our clients. TDR

Contact Tim Orr at 908-218-8500.

"No Disruptive Technology"

(Continued from page 7)

nostic assays expected to enter the clinical marketplace during the next five years.

For the ASCP, one message was unmistakeable. Training programs for medical technologists (MT) and medical laboratory technicians (MLT) must be revised to accommodate this gradual shift in the laboratory testing menu. Molecular science will play a greater role as routine chemistry and hematology testing receives less emphasis and molecular assays gain greater clinical importance.

More Complexity Ahead

The trend toward more complexity in laboratories reflects fundamental changes within healthcare and the economy in general. Consumers increasingly want healthcare customized to their specific needs and particular medical conditions.

At the same time, medical science is gaining the ability to discern the differences between individuals. These differences explain why some people get disease and others do not; why a specific disease is more virulent in some people and not in others; and why some people benefit from therapeutic drugs and others do not.

Three Dimensions

For laboratories, the complexity trend will play out in three dimensions. First, treatment algorithms for disease will become more complex. As science enables clinicians to understand more about disease processes, diagnosis and therapy will become more detailed and specific. Laboratories will need to respond to the more sophisticated demands of clinicians in this area. Advances in diagnosing and treating different types of breast cancer illustrate this principle.

Second, advances in molecular diagnostics will add to the complexity of performing laboratory tests. In simple terms, a routine chemistry test panel is much less complicated to perform than a test to identify genetic mutations present in an HIV patient. The technical knowledge required by the laboratory staff to support such testing will be more detailed and intricate.

Third, the organization and operation of clinical laboratories will become more complex, in at least three dimensions. In the first dimension, laboratory testing will be migrating out from the core laboratory. New standards for patient safety and higher quality care are already pulling testing into settings like the hospital emergency department. Consequently, laboratories will end up managing diagnostic testing being performed in a variety of locations within the healthcare system.

In the second dimension, increased medical specialization will generate specialized diagnostics to support it. Laboratories now organized around traditional departments will need to develop subspecialty expertise and support the diagnostic needs of these subspecialties. The organization chart for the laboratory will become more complicated.

In the third dimension, management of laboratories will evolve toward more sophisticated management systems and methods. The earliest successes of laboratories adopting ISO-9000, Six Sigma, and Lean management systems provide evidence of this trend. Management of laboratory operations will require more complex and subtle skills.

In conclusion, the three key insights suggest that change within the laboratory profession will be incremental, not disruptive. This gives lab directors and pathologists needed time to respond appropriately to the steadily-evolving healthcare marketplace. TDR

Dark Index

Two Blood Brothers Ramp Up Marketing of New Lab Assays

National lab firms launch campaigns to promote their versions of colorectal cancer screening tests

GROWTH IN SPECIMEN VOLUME and revenues is the major challenge at the nation's two largest laboratory corporations.

How **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** solve this problem will affect and influence every remaining clinical laboratory and pathology group practice in the United States. That's because the marketing and pricing strategies of the two blood brothers tend to establish new competitive norms in the healthcare marketplace.

Until this year, public laboratory companies relied on acquisitions of smaller independent laboratories as the most reliable way to generate growth in revenues and earnings. However, as clients and regular readers of THE DARK REPORT know, in 2002, LabCorp and Quest Diagnostics purchased four of the largest remaining public laboratory companies (**American Medical Laboratories**, **Dynacare**, **Unilab**, and **DIANON Systems**). Only a handful of potential lab acquisition candidates remain.

Lab Test Distribution

Because this situation makes the "growth by acquisition" strategy less viable, the two multi-billion-dollar lab testing behemoths are transitioning to a different strategy. Each hopes to increase both specimen volume and revenues by using their unique position as a lab test distribution channel. It is a way to gain advantage from their relationship with hundreds of thousands of the nation's doctors.

Laboratory directors and pathologists can watch this strategy unfold in real time. The first big play involves colorectal cancer. Both national labs want to transform the market for colorectal cancer screening. To accomplish this, each is ramping up a marketing campaign for their particular assay. At LabCorp, its Pregen-Plus™ test has been available since August. LabCorp licensed technology from **Exact Sciences**. Quest Diagnostics is offering a test it calls InSure™ which uses technology it licensed from **Enterix**.

Substantial Market Potential

Colorectal screening was identified as a potentially lucrative market because it currently lacks a viable screening methodology that is patient-friendly, reasonably priced, and offers acceptable levels of diagnostic sensitivity and specificity. The need for a better test is obvious. Each year, approximately 147,000 new cases of colorectal cancer are diagnosed and 53,000 deaths occur. It is ranked as the number three cause of death for men and women in the United States.

The marketing formula is simple. Both national labs want an assay with patent-protected technology. They want to brand the name with physicians and

consumers. This excludes other laboratory competitors from offering that test. The test must be reimbursable by major payers at levels sufficient to make the test profitable and must have clinical research that demonstrates its effectiveness over existing methodologies.

Payer Acceptance

Quest Diagnostics is pricing its InSure test at $95. LabCorp's Pre-Gen Plus is priced at $795. Quest Diagnostics reports that 50 payers, including **Aetna**, have agreed to reimburse for InSure.

Acceptance by insurers is an essential part of this growth strategy. Quest Diagnostics introduced ten new assays during the past year and claims that all ten tests were accepted by at least 35% of the health insurance industry. Internally, it considers 50% acceptance to be an attainable goal.

To drive acceptance of these colorectal screening tests, both national laboratory companies are gearing up their sales and marketing teams. Collectively, several thousand sales reps from the two companies are even now calling on physicians and providing information and encouragement to add these assays into their regular ordering mix. Local laboratory competitors tell THE DARK REPORT that they are seeing evidence of this effort.

Watching Sales Success

It's not just laboratory competitors that are watching this emerging new marketing model for new diagnostic tests. Wall Street is keenly interested to see whether or not the two blood brothers can generate substantial increases in sales volume from this strategy.

It takes regular increases in revenues and earnings to support the share prices of these companies. If the two national labs cannot demonstrate the ability to push revenues up by introducing proprietary new tests which clinicians find useful, then their stock prices will lag behind the general market.

Moreover, some of the savvier investors know one of the ongoing weaknesses in the commercial laboratory business model is field sales. Historically, few of the public lab companies have been able to generate sustained revenue increases because of the new accounts opened by their sales representatives. New accounts were generally offset by the number of accounts lost to competitors.

For this reason, both lab companies have an extra challenge in demonstrating that this market strategy can work. They must demonstrate that they can organize and manage a force of sales reps that can predictably and profitably sell these new assays to physicians. Physician education about the series of new assays they want to introduce is the linchpin to the success of the "proprietary test" marketing model.

Competitive Strategy

In the short term, neither LabCorp nor Quest Diagnostics have enough proprietary assays to gain competitive advantage in winning physicians' office accounts from local competitors. The question that local lab administrators and pathologist must ask is "will either or both of these companies eventually lock up enough clinically-useful assays so that clinicians find the national lab option to be compelling over that of a local laboratory competitor?"

Expect the noise level to increase in the marketplace as the publicity machines of both blood brothers kick into gear. There will be news stories, TV reports, and media mentions of "the new tests that promise to improve existing medical practices." Early evidence of this is already visible in the news releases trumpeting clinical studies that validate the ability of Pregen-Plus or InSure to detect colorectal cancer at improved rates over other methodologies. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Here's a reminder that corporate fraud didn't bypass healthcare. Last week Albert Bergonzi, former Executive Vice President of **McKesson/HBOC**, pled guilty to violations of securities laws. He admitted that he had "cooked the books" around the time of HBOC's acquisition by McKesson. In a court filing, Borgzoni declared "we falsely inflated quarterly software sales revenues by... recording revenue on contracts that were conditioned on 'side letters' that permitted customers to cancel the contract or return software...and backdating contracts to record revenue in prior quarterly quarterly periods."

MORE ON: McKesson

The crimes were committed in 1998. When McKesson discovered the fraud and disclosed the news to the public in April 1999, its share price dropped from $65 to $34, costing investors $9 billion in lost market value! Bergzoni was indicted, along with two other HBOC officers whose trials have not yet been resolved.

"TALKING TUBES" MAY SOON BE IN NATION'S LABS

All too often, laboratories must cope with lost or misplaced tubes and specimens. However, a new technology promises to end that problem. Watch the technology curve for RFIDs, which stands for radio frequency identification tags. These are small plastic strips that contain a computer chip and a radio antenna. Current versions can hold 96 characters of information. The antenna broadcasts to a local receiver, which feeds the data into a computer for tracking and analysis. Stick an RFID on an object, like specimen tubes and slides used in labs, and the radio receiver can tell the operator both where it is and what it is. The military used versions of these to inventory and track containers of ammunition and supplies during the war in Iraq. Retailers are preparing to use them in grocery stores, department stores and other settings.

ADD TO: "Talking Tubes"

Prices for RFIDs are falling rapidly even as the device's capabilities increase **Wal-Mart** may be the first big retailer to deploy this technology. For clinical laboratories, RFIDs would allow an individual, holding the receiver, to find misplaced or missing specimens quickly. One pass near a rack of RFID-tagged tubes would identify all the tubes in that rack. Hospitals may be an early adopter of RFID products because of the difficulty in managing and tracking the huge inventories of items used in healthcare.

TRANSITIONS

• In Toronto Canada, Ene Underwood has left **Toronto Medical Laboratories** (TML), where she was President and CEO. TML is a large, joint venture laboratory in Ontario. Underwood will become the Executive Vice President and Chief Operating Officer of **Bridgepoint Health**, also located in Toronto.

• **Oregon Medical Laboratories** in Eugene, Oregon has a new acting CEO. Ran Whitehead was recently appointed to the position. He had been the lab company's COO since 2001.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 10, 2003

THE DARK REPORT

UPCOMING...

- *How One Hospital Lab Used Molecular Diagnostics to Give Added Value to Docs.*
- *Aetna Launches First Health Plan That Includes Only Better-Performing Physicians and Hospitals: How Pathology and Lab Testing Services Are Affected.*
- *Lab Acquisition Fever: Why Deals Are Still Done, But Without Public Disclosure.*

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