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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

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Early Warning on LDTs and Pre-Authorization

Any pathologist or laboratory manager who considers this to be a quiet time in the laboratory testing industry is setting themselves up for a rude awakening in the not too distant future. Several stories in this issue are written specifically to call attention to major developments in the profession of laboratory testing.

First is the subject of proposed FDA regulation of laboratory-developed tests—frequently called "home brew" tests by some of your colleagues. Plenty of media attention is given to the oft-voiced concerns of government officials that proprietary genetic tests (as exempted LDTs) offered directly to consumers via the Internet is a "Wild West" marketplace that screams for regulation. This is our lead story and is covered on pages 3-8.

However, by proposing to regulate *all* tests currently exempt under the LDT requirements, the FDA is poised to bring nearly every clinical laboratory and pathology group under its regulatory umbrella. That would be considered a most unwelcome outcome by the majority of the nation's pathologists, Ph.D.s, and laboratory scientists, once they realized that such long-accepted assays as Pap smears and microbiology cultures—currently exempt as LDTs—would come under some form of FDA regulation. Thus, any proposal the FDA puts forth to change the way LDTs are currently regulated has the potential to effect major changes in how all the nation's laboratories operate each day.

The second major development brewing in the lab testing industry is the clear intention of health insurers to actively pre-authorize expensive genetic and molecular tests. What makes this an important battleground for local laboratories is the singular fact that molecular and genetic testing represents the high-value future of laboratory medicine. These are the assays which provide physicians, payers, and patients with diagnostic and prognostic information which can initiate tens of thousands of dollars of treatments and prescription drugs—or prevent the unnecessary utilization of those same expensive clinical services.

For these reasons, every local laboratory and pathology group should be developing—in a proactive manner—a strategy to provide added value to physicians and patients about when to order genetic and molecular tests, as well as the right clinical actions to take, based on the results of these lab tests. Hockey Hall-of-Famer Wayne Gretzky attributed his success to the fact that he always skated to where the puck was going to be. Labs should plan now to position themselves to be at the place where they can deliver value at pre-authorization. TDR

Lab Industry Unprepared For FDA Action on LDTs

Laboratory-developed tests (LDTs) performed daily in almost every clinical laboratory in the U.S.

CEO SUMMARY: News stories about the FDA's stated intention to regulate laboratory-developed tests (LDTs) generally play up the agency's comments about the need to assert regulatory oversight of genetic tests and direct consumer access testing. But what has gone unremarked by the lab industry press is the simple fact that, if the FDA were to regulate all LDTs, many of the established lab tests run daily by the nation's clinical labs might immediately fall under those new FDA regulations.

JUST AS RIP VAN WINKLE SNOOZED while Sleepy Hollow grew, so are many laboratory professionals across America unaware of how the FDA's declared intent to regulate laboratory-developed tests (LDTs) has the potential to disrupt the daily clinical routine of almost every laboratory in the nation.

That is a powerful statement and is likely to catch most pathologists and laboratory administrators by surprise. That's because, if the **Food and Drug Administration** (FDA) were to enact strict regulation of all laboratory-developed tests—commonly called "homebrew tests"—performed daily in this country, it would be immediately disruptive to long-established clinical lab testing activities.

After all, the conventional Pap smear is an LDT. That is equally true of FISH testing, flow cytometry, and many infectious disease assays. These are examples of LDTs that have been around for decades and have wide clinical acceptance. Yet, if the FDA ends up regulating all tests currently classified as an LDT and in common clinical use, assays like those listed above would immediately come under regulation.

Probably not since the passage in 1988 of CLIA (the Clinical Laboratory Improvement Amendment), has a single government agency embarked on a regulatory path that could be directly disruptive to nearly every laboratory now serving patients in the United States. For this reason, it is essential that pathologists and laboratory administrators understand the probable consequences of FDA regulation of laboratory-developed tests.

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This summer, on July 19-20 in Hyattsville, Maryland, the FDA convened a two-day public meeting on oversight of laboratory-developed tests. More than 700 people—an overflow crowd—showed up to participate in the meeting and many more watched the events via a webcast.

FDA Regulation Of LDTs

Much of the attention during this public meeting dealt with the rapidly-expanding field of molecular diagnostics and genetic testing. Many companies developing and offering proprietary molecular and genetic tests use the laboratory-developed test exemption. The FDA is on record as stating that it has the statutory authority to regulate these tests.

However, even as the public discussion centers on how the FDA would plan to regulate molecular and genetic tests, there are wider consequences to such regulatory actions that have the potential to be disruptive to every academic center lab, clinical lab, and pathology group in the United States currently performing high-complexity testing. Comments made during the FDA's two-day public meeting, along with interviews with knowledgeable experts, reveal at least three key issues of concern associated with the FDA's proposed regulation of LDTs.

Burdensome Regulation

First, as defined under current law, LDTs cover a wide spectrum of lab tests. The emerging class of molecular and genetic assays is frequently the subject of comments made by FDA officials as they discuss the need for regulatory oversight. The lab industry generally recognizes how FDA regulation of this sector of laboratory testing could prove burdensome and impede progress in this field of medicine.

The second key area involves academic centers. What is seldom publicly acknowledged by the FDA is that LDTs as defined today also cover the entire range of laboratory tests that are developed in academic centers and used regularly in clinical settings.

FDA regulation of these types of assays would create new regulatory hurdles. At a minimum, this would raise the cost of conducting the immense amount of research and development (R&D) that regularly produce new and powerful diagnostic assays. At a maximum, such regulation could create serious roadblocks that might discourage academic center labs from maintaining R&D efforts at or above current levels.

The third key area of concern is equally significant to all pathologists, Ph.D.s, and other types of laboratory scientists. As mentioned earlier, many lab tests used daily in clinical labs are LDTs, such as the conventional Pap smear. This class of assays has a long history of physician acceptance and clinical use.

Disruptive Potential

On the Web site *www.labtestsonline.org*, laboratory-developed tests are described. The web site tells consumers that examples of LDTs include "microscopic examinations (such as Pap smears and manual cell counts), erythrocyte sedimentation rates (ESR or sed rates), microbiology cultures and susceptibility tests, examination of tissue sections (including staining protocols), and blood cross-matching procedures."

Were FDA officials to successfully assert regulatory authority over this menu of LDT tests, it would immediately become an important new regulator of almost every laboratory in the United States that provides testing to patients. In this way, FDA regulation of LDTs has the potential to be disruptive to almost every clinical laboratory and pathology group—large and small—across the country doing high-complexity testing.

It is this far-reaching aspect of FDA regulation of LDTs that has yet to catch the attention of the working pathologist and laboratory scientist. During the

FDA's Intent to Regulate Homebrew Lab Tests Has Potential to Touch Every Clinical Lab in U.S.

By proposing to regulate the entire class of tests that fall under the laboratory-developed test (LDT) exemption, the Food and Drug Administration is embarked on what seems to be the largest expansion of federal oversight of laboratory testing activities since passage of the Clinical Laboratory Improvement Amendment back in 1988.

LDTs, also called "homebrew" tests, are performed daily in almost every clinical laboratory and pathology group in the United States. Thus, regulation of this class of laboratory tests has the potential to disrupt patient care in a number of serious ways if the final regulations are not crafted carefully.

Facing FDA regulation of LDTs, different sectors of the laboratory testing industry are lining up to lobby in favor of their interests. For example, *in vitro* diagnostic (IVD) manufacturers are required to clear their instrument systems and lab test kits through the FDA. They argue that a biotech company which launches a proprietary lab test under the LDT exemption has an unfair advantage and should be required to meet similar FDA requirements as are required of laboratory test kits.

For their part, biotech companies like the status quo. They are expected to lobby in favor of minimal regulation of their laboratory-developed tests. To date, this exemption has allowed this class of companies to introduce new assays into clinical use without having to undergo the expensive and time-consuming process of obtaining FDA clearance.

Three-Tiered Approach

On behalf of the pathology profession, the **College of American Pathologists** (CAP) is advocating a tiered approach in its meetings with the FDA. It proposes three tiers based on risk: low, moderate, and high. It recommends that the FDA only regulate tests in the high-risk category. CAP suggests that moderate-risk tests could be reviewed by the laboratory's accreditor (which can often be the CAP's own laboratory accreditation program).

The **Association of Molecular Pathology** (AMP) concurs that tests with the highest risk to the patient most likely should meet some type of FDA oversight. However, AMP points out that assessing the risk of assays in the middle- and low-risk categories often varies with the particular clinical condition of the patient. Thus, AMP has concerns about the final regulatory requirements that the FDA might issue.

However, when it comes to Internet-based firms selling genetic tests marketed directly to consumers, most observers believe that FDA regulation of this class of laboratory-developed tests is a certainty.

course of their careers lasting decades, these pathologists, Ph.D.s, and other types of laboratory scientists have performed these tests daily in support of long-accepted patient-care protocols.

In the coming months, it is expected that the FDA will issue proposed regulations on the subject of laboratory-developed tests. This will open up a period for public comment.

As that happens, laboratory administrators and pathologists may want to educate their entire laboratory staff to this issue by circulating the FDA's proposed regulations around the lab. It would also be productive to encourage individual laboratory staff members to send comments about the proposed regulations to the FDA.

Finally, once the FDA issues a concrete proposal on how it plans to regulate LDTs, this is likely to immediately become a high-profile issue across the laboratory testing and biotech industries. TDR

Many Questions About FDA Regulation of LDTs

➤Federal agency intends to look at patient risk as a primary factor in how it will regulate LDTs

➤➤CEO SUMMARY: Ask most pathologists and laboratory administrators about the FDA's intent to regulate laboratory-developed tests (LDTs), and they will likely answer that it is to control web-based direct-to-consumer lab testing companies and the rapidly-growing number of proprietary tests. Although that is true, any move to regulate LDTs also has the potential to cover a huge number of long-established and clinically-accepted homebrew tests that are performed daily in almost every lab in the country.

Few pathologists and laboratory professionals recognize the wide-reaching impact that FDA regulation of laboratory-developed tests (LDTs) could have on the entire laboratory testing industry.

That's probably because, when the FDA does comment on why it needs to regulate LDTs, it most commonly identifies the rapidly expanding number of molecular and genetic tests that companies introduce into clinical practice using the LDT exemption. The FDA also expresses concern about the lack of regulation in the direct-to-consumer lab testing market, which is awash in LDTs that have little or no clinical research data in support of their accuracy and efficacy.

It is for these reasons that many pathologists and laboratory professionals have not paid closer attention to the FDA's plans to regulate laboratory-developed tests, also known as "homebrew" tests. However, any effort by the FDA to regulate LDTs is likely to require every academic center lab, clinical lab, and pathology group in the nation to comply. That is because nearly every lab in the United States currently offers some number of laboratory-developed tests.

On pages 3-5 of this issue, The Dark Report explained why FDA regulation of LDTs would have profound consequences for virtually every laboratory in the United States doing high-complexity testing. Regulation of LDTs has the potential to turn into a serious threat to the clinical integrity and financial stability of the nation's laboratories. That fact has not yet been fully recognized and acknowledged by the majority of lab administrators and pathologists in this country.

➤FDA Soliciting Comment

In recent months, the FDA has accelerated its efforts to design a regulatory scheme involving LDTs. The FDA is actively gathering public comment about its stated goal of regulating LDTs. Several lab industry associations and organizations are in discussions with FDA officials.

At the **American Clinical Laboratory Association** (ACLA), President Alan Mertz has taken part in meetings with FDA officials and other health policymakers on the subject of FDA regulation of

LDTs. "This is truly a sleeper issue for much of the laboratory testing community," said Mertz, "The FDA has threatened to regulate LDTs for a long time. However, since this spring, FDA officials have begun spending more time on this issue and wide-ranging new regulations could soon emerge.

Regulating All LDTs

"Amidst all the recent publicity about the FDA's intentions, what escapes the notice of many laboratory professionals is that the FDA is looking at regulating *all* LDTs!" he emphasized. "This goes beyond the LDTs run by the largest laboratories and the various genetic tests offered by specialty lab companies. The FDA would regulate the laboratory-developed tests run daily by hospitals, physician group practices, small genetic testing laboratories, reference laboratories, regional laboratories, and national laboratories.

"It doesn't matter whether it's a small laboratory or a big laboratory; whether its an independent lab company or a community hospital lab that offers an LDT—the FDA is looking at the risk to the patient," said Mertz. "It was clear in those public meetings that the FDA doesn't intend to regulate based on the type of lab test. Rather, it intends to regulate based on how high the risk is to the patient."

"Although the popular perception is that the FDA is targeting primarily genetic tests, that is not the full story," explained Mertz. "LDT's cover a wide range of lab tests performed daily in hospital-based labs and other sites. We're talking about flow cytometry, FISH testing, and infectious disease testing, as well as all the tests for cancer—even cultures and microbiology.

"A high number of these assays are LDTs," he continued. "Many of them are adapted lab-by-lab, hospital-by-hospital, and academic center-by-academic center. Each laboratory makes adjustments to their LDTs to deal with specific populations, local needs, or diseases that have changed or mutated. HIV genotyping is a good example of the latter.

"Another factor is that published literature and the science changes continuously," he added. "It is why these laboratory tests are continually improved and updated—often in a site-specific manner to meet the needs of the local patient population. Some of these updated tests are LDTs. Some are test kits that need to be modified to keep up with the disease.

"There is another aspect to LDTs," observed Mertz. "Many laboratory-developed tests are for rare diseases that affect a very small population. It would be prohibitively expensive to run each type of such lab tests through the FDA review process.

"Amidst all the recent publicity about the FDA's intentions, what escapes the notice of many laboratory professionals is that the FDA is looking at regulating *all* LDTs!" emphasized Mertz.

"This is important testing which is typically performed on a small scale," he noted. "The lab may perform tens of tests or several hundreds of tests—even as it adjusts that testing for very small populations. How could such a lab go through the 510(k) FDA process that costs potentially millions of dollars, and could take months or years to adjust the lab test for 12 patients? This illustrates why the FDA faces a challenge in regulating LDTs."

The FDA's Approach

Mertz says that, based on public and private meetings about LDT regulation, it appears FDA officials do not fully understand the role that these types of laboratory-developed tests play in personalized medicine.

"On the plus side, however, indications are that the FDA does at least recognize the burden that requiring pre-market approval would impose on laboratory tests that must be modified: 1) on an individual basis; or,

2) for very small groups; or, 3) for rare diseases," he commented. "The FDA is also saying that it does not intend to disrupt the majority of tests that are well established, clinically validated, and in use.

"The intention of the ACLA and our representative healthcare organizations is to help the FDA to concentrate its regulatory focus on a small subset of laboratory tests that it truly considers to entail patient risk and that would warrant independent government validation, such as tests that are the sole determinant of whether a patient receives a particular treatment," Mertz said.

Traditionally, FDA involvement in laboratory medicine has been restricted to the *in vitro* diagnostic (IVD) and commercial vendor sector of the industry. These companies understand the FDA's pre-market approval process. Laboratory analyzers and lab test kits cleared by the FDA through this process can then be sold to laboratories throughout the United States.

Impact Of FDA Regulation

Were the FDA to regulate the full range of laboratory-developed tests currently in use, there would be significant changes to laboratory medicine as it is practiced today. "What the laboratory medicine profession needs to understand is that FDA regulation of all LDTs currently in use today would—for the first time—directly affect the daily activities of pathologists and working clinicians as they go about their normal medical practice," stated Mertz.

"Over recent decades, working pathologists and laboratory scientists in independent laboratories and community hospital-based laboratories have had little interaction with the FDA's various authorities and processes," he explained. "Were the FDA to regulate the broad range of laboratory-developed tests, it would require working laboratory scientists to interact with the FDA. That would create a serious problem and has the potential to disrupt long-established clinical testing practices in ways that could set back patient care.

"We did bring this problem to the attention of the FDA," stated Mertz. "It is a fact that the working side of the laboratory medicine community doesn't interface or interact with the FDA in the same manner as the IVD or commercial side.

Interaction With The FDA

"Unlike the staff of the large IVD manufacturers, most pathologists and clinical chemists don't likely speak the FDA language. To a large extent, the FDA doesn't (and they admit this) completely understand the world of clinical lab testing and laboratory medicine.

"This is why a number of laboratory industry associations and groups are having conversations with the FDA about its goal of regulating LDTs," said Mertz. "We believe this input is essential before the FDA publishes proposed rules, or new requirements involving LDTs are made into law."

However, Mertz wants to encourage wider discourse between the laboratory testing profession and the FDA. "The entire lab community needs to be engaged in this dialogue with the FDA," stressed Mertz. "LDTs are not limited to just testing labs or big national labs that do research. LDTs are not just performed in academic medical centers.

Comments From Labs

"The FDA's regulatory scheme for LDTs will affect all of us," continued Mertz. "This is why we all need to get involved during the next open comment period. If this regulation isn't done correctly, it could be very disruptive. That's why we're so intent on working with the FDA to get it right. That's also why informed comment by laboratory professionals from any and all labs and pathology groups is needed during the coming months." TDR

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Lab Market Update

Hospital-Owned Medical Groups Serving More Patients Per Doc

It's widely known by pathologists and laboratory administrators that hospitals and health systems are buying up private medical practices at an accelerating rate. This is a trend that favors hospital laboratory outreach programs, but may not be auspicious for the national laboratories.

For this reason, certain findings in the **Medical Group Management Association's** (MGMA) latest survey of office-based physicians are revealing. The MGMA survey is given great credibility because it has been conducted for more than 50 years. It also includes data from 45,000 providers, making it "the largest provider population of any cost survey report in the United States."

The report, titled "Productivity, Costs, and Revenue Linked to Practice Ownership" shows an interesting difference in productivity between physicians in private practice groups and physicians in medical groups owned by hospitals or integrated delivery systems (IDS).

Not-Hospital/IDS-Owned

First, the MGMA study authors looked at trends in relative value units (RVUs). For medical groups not owned by hospitals/IDS, over the past five years there was a .09% increase in total RVUs per patient and a 13% increase in work RVUs per patient.

By contrast, the survey determined that hospital/IDS-owned multispeciality groups reported a decrease of .55% in total RVUs per patient and a decrease of 17.85% in work RVUs per patient during the same five-year period.

The next finding is of more direct interest to clinical laboratories and pathology groups. The survey determined that, for non-hospital/IDS-owned medical groups, "the number of patients per provider has decreased nearly 9% in the past five years." It was the opposite for hospital/IDS-owned medical groups, where the number of patients seen per provider increased by 9% over the same five years.

Capturing More Patients

This would imply that medical groups owned and operated by hospitals and health systems are capturing a larger share of patients compared to privately-owned medical groups. It is unclear what is causing physicians in hospital/IDS-owned medical groups to see almost 10% more patients per physician.

Still, it is important to recognize that, over a five-year period, the trend in the number of patients seen per physician is moving in opposite directions for privately-owned medical groups and hospital/IDN-owned medical groups. At a minimum, this must be considered a positive trend for hospital laboratory outreach programs. That's because, whenever a hospital or health system buys a medical practice, that medical group is asked to switch its laboratory test referrals to the hospital/health system laboratory.

Further, the MGMA study also suggests that competition for patients is intense among medical groups in a community. Because hospitals and health systems are ongoing buyers of physician groups, it would appear that these community institutions will continue to buy up market share. Development of accountable care organizations (ACOs) will also fuel this trend. TDR

Boosting the Value Labs Deliver to Doctors and Payers

Systems Approach For Pre-Authorization Of Genetic Tests

CEO Summary: Pre-authorization of expensive genetic and molecular tests is a threat to local clinical laboratories and pathology groups if payers exclude them from provider networks in favor of labs which bid the lowest prices. But one major healthcare corporation believes there is now an opportunity for clinical labs and pathology groups to deliver added value to payers—and be paid appropriately for that value. It has built an integrated, system-based service that allows laboratories to provide real-time information to both payers and physicians.

Part Two of Three Parts

ACROSS THE NATION, health insurers are taking steps to control utilization of expensive genetic and molecular tests for pre-authorization. This is a clear threat to any clinical laboratory or pathology practice that fails to respond appropriately to the pre-authorization trend.

Pre-authorization is a natural response to the ever-increasing pressure on payers to rein in the year-over-year cost of healthcare. Better management of diagnostic utilization is becoming a high priority goal for payers.

In part one of this special three-part series, THE DARK REPORT discussed why and how managed-care companies were taking steps to implement pre-authorization requirements for a growing number of genetic and molecular assays. It is a trend which is still in its earliest stage.

Part two of this series looks at solutions that different companies are developing to help health insurers and clinical laboratories better manage the utilization of genetic and molecular tests. In some cases, these emerging pre-authorization products and services actually boost the ability of local clinical laboratories and pathology groups to help payers and physicians appropriately utilize genetic and molecular tests.

Part three will provide a case study of a laboratory already involved in pre-authorization requirements with the major health insurers in its regions. Collectively, these three installments provide lab administrators with the essential intelligence they need to develop an appropriate strategy to respond to the pre-authorization trend.

The increased demand for genetic testing has health insurers scrambling to manage this new source of increased costs. "Payers have a traditional response to help control appropriate use," stated Matthew B. Zubiller, Vice President, Advanced Diagnostics Management, at San Francisco, California-based **McKesson Corporation**. "Payers will either deny coverage requests for these new procedures or require pre-authorization. This is how payers have reacted for decades, each time they were faced with a new, complex healthcare technology or a prescription drug that quickly became a major cost."

In part one, Zubiller helped lab administrators and pathologists understand why payers are adopting pre-authorization requirements. More importantly, Zubiller identified opportunities for clinical labs and pathology groups to add value to payers.

Zubiller asserts that "those clinical labs and pathology groups who work more closely with health plans on this issue, can help shift the model for lab test reimbursement from one in which payment is based on fee-for-service or capitation—typically based on a commodity mind-set of cheapest price—to a model based on performance, on value, and on appropriate utilization."

Payers Have Three Needs

As Zubiller explained in part one, payers have three needs that laboratories can step up and meet in an added-value manner. "The primary three issues facing health insurers are: 1) the need to control the growing annual cost-per-beneficiary of advanced testing; 2) the need to manage an already huge number of molecular and genetic assays—to which new assays are being added weekly; and 3) the desire to significantly reduce the cost required to pre-authorize genetic and molecular tests, as well as the cost to process the resulting claims."

This second installment of the THE DARK REPORT'S three-part series will explain how different companies are targeting pre-authorization of genetic and molecular testing. Among other developments, it appears that laboratory test formularies—similar to prescription drug formularies—may become common.

"Formularies for prescription drugs have long been used by pharmacy benefit man-

agers (PBMs) to manage the cost of these drugs," stated Zubiller. "Prescription drug formularies are a vehicle to identify and encourage use of less-expensive drugs which are considered clinically equivalent.

"However, there are challenges to adopting the formulary model to diagnostic testing," he continued. "That's because diagnostic testing is a more complex and nuanced clinical activity."

Lab Test Formulary

Zubiller says early efforts to move toward a diagnostic or lab test formulary can be seen in the healthcare marketplace. "Health insurers, for example, use contracting to manage their networks of par and non-par labs," he explained. "Health insurers are in the earliest stages of employing medical necessity guidelines to control utilization of genetic tests.

"These efforts may incorporate products such as **InterQual's** Molecular and Genetic Testing module or the services of **Hayes, Inc.**, in their policy development and utilization management," added Zubiller. "Further, the industry is beginning to see efforts to clarify the coding and identification of genetic tests through McKesson's work, plus ongoing progress at the **National Institute of Health's** (NIH) genetic testing registry (GTR) and with the **American Medical Association's** (AMA) CPT panel.

As a market force, a new class of companies is emerging with a goal of interposing themselves between the provider ordering the test, the patient, the payer, and the laboratory which will perform the test. For example, in 2009, **Humana, Inc.**, announced a pre-authorization and patient counseling program for genetic and molecular tests. It contracted with **DNA Direct, Inc.**, of San Francisco to provide both the pre-authorization and genetic counseling services.

Then, earlier this year, DNA Direct was acquired by **Medco Health Solutions, Inc.**, one of the nation's largest pharmacy benefit managers (PBM). Officials at both companies stated that the merger of the two companies would strengthen Medco's capabilities in pharmacogenomics and personalized medicine.

When **Generation Health, Inc.**, of Upper Saddle River, New Jersey, announced its formation in November, 2008, it described itself as "a newly formed company focused on genetic testing benefit management." Ex-Medco executives created the company.

Another participant in the field of pre-authorization and patient counseling for genetic and molecular testing is McKesson Corporation. Its strategy is to involve laboratory test providers in an integrated system that supports appropriate utilization of laboratory tests.

Starting in 2007, McKesson began building the infrastructure to support a new business model designed to enable labs, payers, providers, and patients to make better, more informed decisions regarding advanced testing. This work led to the formation, in early 2009, of a new business unit called "Advanced Diagnostics Management" (ADM).

Existing Relationships

What makes ADM of particular interest for pathologists and laboratory administrators is the fact that ADM was created based on McKesson's assets and existing business relationships with pharmacies, health insurers, hospitals, clinical laboratories, and pathology group practices.

"Advanced Diagnostics Management was developed in direct response to McKesson's existing everyday interaction with laboratories, payers, patients, pharmacies, hospitals, and other healthcare organizations," noted Zubiller. "We spotted an opportunity to create a service that would advance clinical care and patient outcomes, while helping physicians and health insurers deliver the right laboratory test for the right patient at the right time.

Monthly Cost of New Cancer Drugs Is Expensive

CERTAINLY THE HIGH COST OF GENETIC TESTS AND MOLECULAR ASSAYS is one reason why health insurers are instituting pre-authorization requirements. Equally important is the need for payers to manage utilization of the growing number of new prescription drugs for various types of cancers. A $3,000 genetic lab test may lead to a $50,000 cancer drug prescription.

The table below shows several of the most commonly prescribed cancer drugs, along with the monthly cost of each. These drugs are extending the life of cancer patients. Leonard Saltz, M.D., a colon cancer specialist at **Memorial Sloan-Kettering Medical Center**, has published data that indicate, for patients with advanced colorectal cancer, drugs available in 1996 had a total cost of about $500 and expected survival was 11 months. By 2006, drugs to treat advanced colorectal cancer cost $250,000 per patient and expected survival was 24 months.

Monthly Treatment Cost for Drugs to Treat Cancer

Drug	*Manufacturer*	*Monthly Cost*
• Avastin	Genentech	$ 4,400
• Erbitux	ImClone/Bristol-Myers	$10,000
• Gleevec	Novartis	$ 2,600
• Herceptin	Genentech	$ 3,000
• Nexavar	Bayer Pharmaceuticals	$ 4,300
• Revlimid	Celgene	$ 4,500
• Rituxan	Genentech	$ 4,200 to $13,000[1]
• Sutent	Pfizer	$ 4,000
• Tarceva	Genentech/OSI Pharmaceuticals	$ 2,400 to $2,700[1]

[1] Cost varies with type of cancer treated.

Sources: Manufacturer's data. Originally published in USA Today *on July 11, 2006.*

"This is a system that gives a front-line role to local clinical labs and pathology groups, specifically to help them become even more of an added-value resource," explained Zubiller. "ADM does this by providing laboratories with the capabilities they need to proactively manage utilization. It helps them partner with a health insurer's genetic testing pre-authorization program in ways that deliver added value to that payer."

Zubiller's work with ADM gives him an insider's view of how and why the nation's health insurers want to require pre-authorization of expensive genetic and molecular tests—along with interesting perspectives on why laboratories should offer an automated, systems-based solution to health insurers.

"When it comes to the ever-growing menu of genetic tests and molecular assays, it is no longer enough for health plans to simply accept, deny, or pre-authorize," said Zubiller. "In today's modern medicine, a genetic test that costs, say $3,000, may be used to qualify a patient for a cancer drug or therapy regimen that often costs $50,000 to $100,000 per patient.

Patient Outcomes

"Because physicians, labs, and health insurers want to improve patient outcomes and efficiencies, this becomes a place where all the stakeholders' interests are aligned," he continued. "It creates the need for a systems-based approach to pre-authorization and patient counseling.

"From the payers' perspective, the first step to improving patient outcomes in this way is to measure and understand utilization," stated Zubiller. "Today, that is nearly impossible because of the limited number of reimbursement codes available for genetic and molecular tests. There are just a few dozen codes compared to the 2,000+ genetic and molecular laboratory tests now available.

Step-By-Step Program

"Requiring time-intensive pre-authorizations for all genetic and molecular tests is not the right approach for payers," said Zubiller. "Rather, a step-by-step program should start by instituting a targeted, less invasive 'notification program.' Initially, no medical review is required as payers measure actual lab test utilization and they decide how to manage that utilization.

"To achieve this and move toward full pre-authorization, health insurers can utilize new, more sophisticated tools that incorporate decision-support information within the clinical workflow," continued Zubiller. "With this solution in place, a broad, real-time notification requirement remains. The more intrusive pre-authorizations are only required in selected situations.

"Once a health insurer has such a real-time notification process in place, it can better understand utilization," he explained. "As the payer measures utilization, use of an automated decision-support tool can reduce hassle and administrative cost while guiding test selection.

"Now, not only can the payer identify unwarranted variation in care in collaboration with the laboratory and the provider, the payer can use the automated system to issue authorization requirements where truly necessary," stated Zubiller. "The payer can also provide real-time authorization responses to the data that was submitted. Where connected to an EMR or provider workflow, this becomes a seamless process.

"At McKesson, our vision is to use a systems-based approach that enables health insurers to collaborate in ways that support a more effective and targeted interaction with labs and their providers who are ordering genetic or molecular tests," commented Zubiller. "This systems-based approach requires automated tools and smart software that enable real-time, added-value decision support at the point of care, smart utilization management of genetic and molecular tests, and performance-based network management tools.

Lab Tests As A Commodity

"Such integrated, automated tools can allow a positive shift to occur in the working relationships between managed-care companies, clinical laboratories, and the referring clinicians," he said. "As it works today, managed-care networks typically include those laboratories which agree to the most deeply-discounted lab testing fees. These payers tend to treat laboratory tests as a commodity.

"We believe that what is required is a systems-based approach to evaluating utilization, managing pre-authorization, and providing state-of-the-art decision support to the ordering physician," declared Zubiller. "This must happen if clinical labs and pathology groups are to deliver increased value—and then be reimbursed appropriately for that value.

"Our goal is to provide laboratories with an integrated informatics solution that puts them in a position to: 1) educate and engage physicians about the appropriate use of genetic and molecular tests; and then, 2) based on their payers' rules and coverage, help them make appropriate decisions regarding 'when, where, and which' lab tests to order for a patient," he said.

"We see this arrangement as consistent with the ultimate goal of the healthcare system," added Zubiller. "All parties want a payment model built on performance, value, and appropriate utilization.

McKesson Uses Similar Systems Approach As Was Developed for Pharmacy Utilization

"Existing processes used by health insurers and providers to manage pre-authorization and requests for reimbursement for molecular and genetic tests are flawed," asserted Matthew Zubiller, who is Vice President, Advanced Diagnostics Management, at McKesson Corporation.

"That's because the utilization management systems used by health insurers are antiquated and insufficient to the task," he explained. "To manage utilization of genetic and molecular tests, payers need a systems approach that allows labs, providers, and health plans to collaborate to devise a solution.

"This is the opportunity that opens the door for us," continued Zubiller. "We've been solving these kinds of problems for a very long time. To improve utilization of prescription drugs, we created a system that brought pharmacies, providers, and health plans together by providing each with the data needed to identify the most appropriate medications for each patient."

"For medication reimbursement, health insurers have pharmacy and therapeutics (P&T) committees that make coverage decisions for each specific drug," he noted. "P&T committees work reasonably well. However, few health insurers have corresponding committees to handle the long-tail requests (where many labs perform few tests) for molecular and genetic tests.

"Certainly there are differences in how physicians use laboratory tests and prescription drugs," he said. "But for payers, the utilization problems are nearly identical. It is the same for doctors, who commonly don't have adequate decision support at the point of care.

"Over recent years, the pharmacy has gained sophisticated tools that do several things: 1) analyze which prescription drugs are appropriate; 2) check for drug-drug interactions; and, 3) access formulary information," noted Zubiller. "A pharmacist will not dispense a drug if the pharmacy won't get paid for that prescription.

"We need to make similar information available for laboratory testing," Zubiller commented. "That would be the foundation for helping payers understand utilization of genetic and molecular tests. It would provide the detailed and accurate information that enables a determination of the true value that genetic tests and molecular assays can bring to patients when physicians appropriately utilize such tests."

But in today's healthcare system, there is a fundamental disconnect between what laboratories currently do versus the coverage guidelines and reimbursement policies of most payers.

"This disconnect is a systemic problem common throughout all of healthcare," commented Zubiller. "It exists between payers and all types of providers, so it is not unique to clinical laboratories and pathology groups.

"The problem exists because neither health plans nor laboratories have the systems in place to address the issue of how to mutually understand, cover, and pay for something as complex as a molecular or genetic test," he observed. "Lacking these systems, payers find their only options are to deny, approve, or pre-authorize.

"Recognize, too, that healthcare reform is about to shift the types of organizations we define as payers," said Zubiller. "We shall soon recognize that a payer is really any risk-bearing entity. That can be a health plan, a PBM [pharmacy benefit manager], a capitated laboratory, a hospital system responsible for a DRG [diagnostic-related group], an inde-

pendent practice association (IPA), or an accountable-care organization (ACO).

"Even as the definition of a payer expands to include these other types of organizations, another market trend is unfolding," he continued. "That trend is adoption and use of EMRs due to healthcare reform incentives in support of the goal of integrated access to an electronic health record (EHR).

Labs Perfectly Positioned

"This ongoing integration of healthcare informatics will make it possible for all these patient-care stakeholders to interact in real time," predicted Zubiller. "We believe that clinical labs and pathology groups are perfectly positioned to add value in such an interconnected healthcare market.

"That is why—for genetic and molecular testing—we have developed a systems approach that will work with thousands of laboratories, hundreds of thousands of clinicians, and with all of the nation's health plans," he stated. "We've drawn upon our experience in helping physicians, pharmacies, and payers improve utilization of prescription drugs to develop this system to manage lab testing. *(See sidebar on page 15.)*

"Our challenge was to expand the traditional notion of who is a 'payer' for laboratory tests, since it is no longer just the health insurer," Zubiller explained. "Any entity managing lab test utilization—and responsible for risk—needs to make sure that the right test is done. That is true whether the entity is a health plan, an IPA, a hospital, an accountable-care organization, or the lab itself.

"Our model is specifically designed to give clinical laboratories the capability to collaborate with health plans and other types of payers," he noted. "Labs use this integrated system to give providers the information they need to make the right lab test selection.

"Further, our system can be connected to an EMR [electronic medical record system], an LIS [laboratory information system], an order-entry system, and to a case management or claims system," he added. "To our knowledge, this is the first automated and integrated system that makes it possible for *both* the laboratory and the payer to measure utilization of laboratory testing in real time.

"In sites where our system is operational, we know the full details about which lab tests are ordered by which providers," said Zubiller. "We also know the reason for each test request and which laboratories are performing those tests.

"Such real-time information gives us a systems' view of utilization of the genetic tests and molecular assays as they are ordered by physicians," Zubiller added. "In turn, access to that real-time information enables labs to more effectively negotiate reimbursement with health plans or other payers based on the value provided by the laboratory. That's because, for the first time, health insurers and labs together can review and manage utilization proactively and collaboratively."

Pre-Authorization Trend

Laboratory administrators and pathologists should recognize that payer preauthorization of expensive genetic and molecular tests is already under way. Every clinical laboratory and pathology group should pro-actively develop a strategy in response to this trend.

One interesting dimension to this trend is how integrated health informatics —including real-time data from physicians' EMR systems—creates an opportunity for innovative laboratories to leverage their knowledge and clinical expertise in diagnostic medicine in ways that make a clear contribution to improved patient outcomes. This is a service for which health insurers will reimburse labs more generously. **TDR**

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Quality Strategy Earns Honor for SD Laboratory

Avera McKennan Laboratory in Sioux Falls selected to be nation's first to offer HIV combo test

CEO SUMMARY: Here's a new lab product launch with a surprise twist. Upon earning FDA clearance for its new HIV Ag/Ab Combo Assay this spring, Abbott Diagnostics selected a hospital laboratory in Sioux Falls, South Dakota, to be the nation's first clinical lab to offer the assay. The honor was recognition of the Avera McKennan lab's accomplishments in achieving an industry-leading rate of lab test quality. Television news coverage of the test launch generated a five-fold increase in HIV tests.

WHY WOULD A HOSPITAL LAB in South Dakota be selected by a major IVD company to be first in the United States to offer its state-of-the-art fourth generation HIV assay? The answer is quality, in the form of Lean, Six Sigma, and ISO 15189 accreditation.

Beating out some of the nation's most prominent hospital and health system laboratories for this distinctive honor was the **Avera McKennan Hospital & University Health Center Laboratory** of Sioux Falls, South Dakota. **Abbott Diagnostics** selected it to be the first clinical lab in the United States to offer patients the ARCHITECT HIV Ag/Ab Combo Assay. This assay was cleared for market by the FDA earlier this year.

What put Avera McKennan at the top of Abbott's list were two things. First was the Avera McKennan lab's dedication to quality and to continuous process improvement. The second was the fact that the wider public, both in the lab industry and among consumers, recognizes the higher level of quality represented by use of Lean methods and the Avera lab's accreditation to ISO 15189.

"Avera McKennan had established a quality standard that few labs have achieved," stated David Wells, Health Systems Manager at Abbott Diagnostics. "The Avera McKennan laboratory is highly regarded in the lab industry and we pushed hard for their selection."

Although Avera McKennan's selection as the nation's first laboratory to offer this latest-generation combo HIV assay came as a surprise to the lab's management team, the reasons for Abbott's decision were actually confirmation of this laboratory's strategy to be a national leader in use of quality management methods and the ISO QMS (quality management system).

Committed To Quality

"I asked them why they picked us," recalled Leo Serrano, Laboratory Director at Avera McKennan. "And they said, 'Let's face it, you're committed to quality. You were the first hospital lab in the country to get CAP ISO 15189 accreditation, and you've maintained it.'

"Abbott recognized that our laboratory organization has a laser-sharp focus on continuous quality improvement," contin-

ued Serrano. "It is why they picked us. To be the first laboratory to offer this new HIV combo assay to patients is quite an honor."

"Our laboratory staff and the administration of our hospital consider this honor to be a major distinction," added Serrano. "It is a sign that *in vitro* diagnostics (IVD) companies recognize the quality and the commitment we give to our patients here at Avera McKennan, and that's very rewarding."

There have been several direct benefits to the laboratory as a result of Abbott's decision. "Being selected raised the awareness of our quality and our prestige with the medical staff and the patients in the community," he noted. "This happened in some unpredictable ways.

"For example, the news that our laboratory was selected to be first in the nation to launch this new HIV combo assay was picked up and covered by local TV news teams and newspapers in the area," he recalled. "This news coverage emphasized that our laboratory at Avera McKennan was a national leader in quality and continuous improvement. Every laboratory wants this type of public recognition of its ability to deliver quality lab testing services.

Test Volume Skyrocketed

"In the first five days after that news coverage, our HIV testing volume skyrocketed!" he continued. "It increased fivefold. People want to have the best lab testing that's available. Once the public knew our laboratory had this test, it became a very big deal. That generated an enormous increase in the number of tests we've run."

The Dark Report observes that it is a relevant sign of the times when a hospital laboratory in South Dakota is selected by a major IVD company to be the first site in the country to introduce an important new assay into clinical practice. It shows how a laboratory's adoption of quality management methods contributes to improved analytical quality.

Equally interesting, however, is the fact that television news coverage generated a five-fold increase in HIV testing at Avera McKennan. It demonstrates that "people are listening" and ready to visit a laboratory provider they perceive offers them a superior quality of lab testing services. TDR

Contact Leo Serrano at 605-322-7109 or leo.serrano@Avera.org.

Improving Analytical Step With Quality Management

Use of quality management methods at the laboratory of Avera McKennan Hospital has contributed to significant improvements in the quality of laboratory testing performed there.

"We've been proponents of Lean and Six Sigma for a long time," stated Leo Serrano, Laboratory Director at Avera McKennan. "This lab was an early adopter of Lean Six Sigma back in 2004 and we are very proud of what we've accomplished. Because we measure everything, we have data that documents our progress.

"For example, we've used these quality management methods to make steady progress in reducing lab errors," he continued. "Our definition of a laboratory testing error is any time that a verified laboratory result has to be changed significantly, for whatever reason, whether it's operator or instrument.

"If, upon re-testing or upon request for re-evaluation, the lab result is significantly different, then we consider that a testing error," noted Serrano. "Currently, we've cut laboratory errors as defined above to 5.4 to 5.5 Sigma.

"This represents an average rate of 50 to 80 defects [lab errors] per million opportunities, which we consider to be a significant result of our quality efforts," he explained. "In the United States, particularly in labs which have yet to adopt Lean and Six Sigma methods, the lab test error rate falls somewhere between 3 and 4 Sigma. That indicates a rate of between 66,807 and 6,210 defects [lab errors] per million opportunities."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In Hawaii, two competing clinical laboratory companies have joined forces to save a medical technologist (MT) training program from closure. Together, **Clinical Laboratories of Hawaii, LLP** (CLH–owned by **Sonic Healthcare**), and **Diagnostic Laboratory Services, Inc.** (DLS), contributed more than $100,000 to the John A. Burns School of Medicine (JABSOM) at the **University of Hawaii at Manoa**. The money will be used to hire a full-time faculty member for two years. This will allow the university's four-year medical technology program to continue admitting and educating students.

OLYMPUS RELEASES NEW SOFTWARE FOR MICROSCOPES

Amidst all the excitement about digital pathology systems, some pathology companies continue to add functions to the standard clinical microscope. **Olympus America Inc.**, announced release of its labSens software suite. It notes that labSens works with its BX3 clinical microscope to create an "interactive environment for acquiring, displaying, commenting on, measuring, and handling images."

MORE ON: Microscope

The labSens software now offered by Olympus shows how microscope vendors are working to extend the functionality of the standard clinical microscope. It also is recognition that, moving forward, pathologists are likely to spend less time working directly with glass slides and more time viewing digital images captured from the glass slide.

TRANSITIONS

- **Gregory D. Clark, Ph.D.**, has assumed responsibilities as the System Director, Laboratory Services, at **Baylor Health Care System** in Dallas, Texas. Clark has served in executive positions at such laboratory companies as **Westcliff Medical Laboratories**, **Oregon Medical Laboratories**, and **UniLab**.
- **Susan Hertzberg** is the new CEO at **Boston Heartlab**, in Framingham, Massachusetts. Hertzberg was formerly President and CEO of **Ipsogen, Inc.**, the U.S. subsidiary of **Ipsogen, SA**. She earlier worked for a number of lab industry firms, including **Abbott Laboratories** and **Quest Diagnostics Incorporated**, as well as with **Oxford Health Plans**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 25, 2010.

Make plans Now!

Lab Quality Confab

Nov. 2-3, 2010 • Westin Riverwalk Hotel • San Antonio

Preview–Pamela Melcher, St. John Health: How Hospital Departments Collaborated to Create Patient-Friendly "One Stop" Registration

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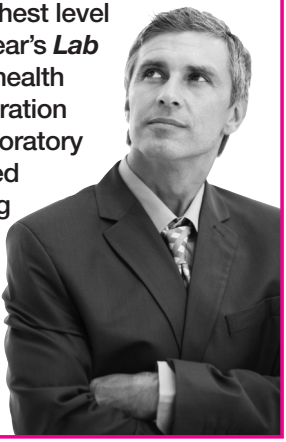

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visit www.labqualityconfab.com

UPCOMING...

- ***Laboratory Company Offers Patients a "Discount Coupon" for their Laboratory Tests.***
- ***Is Your Lab Ready for Its First Visit from a Medicare Recovery Audit Contractor (RAC)? Why It Pays to Be Prepared.***
- ***How Innovative Hospital Laboratory Contributes Improved Outcomes for a Multi-Hospital "Electronic ICU."***

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