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HIGHLIGHTS

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Labs Increase Pressure On FDA Regarding LDT Regulation

The laboratory sector's movers and shakers are ratcheting up the pressure on the U.S. Food and Drug Administration (FDA) to back off of its plan to regulate laboratory-developed tests (LDTs).

The FDA announced last July that it intended to regulate LTDs, with a particular focus on companion diagnostics. The agency noted that at a time when personalized medicine is gaining more of a foothold in the day-to-day medical decisions of Americans, LDTs should be more closely scrutinized to ensure that the assays do not lead to inaccurate diagnoses—which in turn could spur unnecessary procedures and care.

The FDA said it would classify tests by risk, and only the assays with the greatest potential impact on patient care would be subject to pre-market review and a requirement that labs report any adverse events associated with the tests. It also said it would take nearly a decade to phase in the changes.

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AdvanDx Gets FDA Clearance for Blood-Based Staph Test

AdvanDx, the Massachusetts-based molecular testing lab, has received approval from the U.S. Food and Drug Administration (FDA) for a test that would detect the presence of Staphylococcus aureus directly from blood samples.

The FDA granted 510(k) clearance for the test, known as mecA XpressFISH. It can detect both methicillin-resistant and methicillin-susceptible strains of the bacteria (MRSA and MSSA). The test has a one-hour turnaround time. That's dramatically quicker than conventional means of determining the presence of the bacteria, which requires culturing and can take up to 48 hours to obtain a result.

"mecA XpressFISH detects and identifies expression of the gene, which will help clinicians determine if the infection is resistant to commonly used, well tolerated drugs," said Geoffrey A. McKinley, AdvanDx's senior vice president of research and development and business development. "The test will guide caregivers to the best

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■ **AdvanDx Gets FDA Clearance for Blood-Based Staph Test**, *from page 1*

course of antibiotic treatment, discontinuing the use of broad-spectrum antibiotics for patients with routine Staphylococcus aureus infections."

MRSA, which is also referred to as the "super bug," has become a growing concern among health policy officials in the United States. Individuals commonly acquire such infections at health care facilities such as hospitals and dialysis centers, and the indiscriminate use of antibiotics over the decades has made it more difficult to treat, making swift identification of the particular strain in each patient increasingly crucial.

About 100,000 cases of Staphylococcus aureus are diagnosed in the United States every year, killing about 11,000. Of those fatalities, about half are linked to the MRSA strain of the infection.

"Rapid results allow for the most appropriate anti-microbial therapy, which will improve patient outcomes and empower antibiotic stewardship programs," said Thomas Davis, M.D., director of clinical microbiology at the Indiana University School of Medicine.

Takeaway: AdvanDx has brought to market a rapid MRSA test that could cut down on the outbreak of infections in the United States. G2

Once Quick-Growing HDL Cuts Jobs

After years of booming growth, Health Diagnostic Laboratory (HDL) has hit a wall, making deep job cuts as the company's role in potentially illegal activity continues to be scrutinized.

The Virginia-based HDL laid off 132 employees last month, about 15 percent of its entire staff. All but 20 of the jobs were based at its Richmond headquarters, a $68 million facility it had opened last year. The Richmond cuts constituted nearly 20 percent of its workforce. Since August, HDL has cut a total of 162 positions, or about 18 percent of its total employees.

HDL said in a brief statement from Chief Executive Officer Joe McConnell that it was refocusing on its core capabilities: cardiovascular and diabetes testing. "We deeply regret the business necessity that made this reduction in force necessary and we are all mindful that this will pose difficulties and challenges for our former colleagues and their families," he said. "At the same time, these necessary changes provide us with the opportunity to re-energize our company."

However, HDL is being investigated as to whether a $20 shipping and handling fee it routinely paid physicians for blood draws was actually a kickback intended to draw in their business. The company grew from virtually no sales to more than $400 million a year between 2009 and 2012, although revenue stalled last year.

Sources had told *Laboratory Industry Report* in late 2013 that HDL was drawing scrutiny for paying the fee, but it was not confirmed until last July. In June, it discontinued paying the fee to physicians after the U.S. Department of Health and Human Services issued an advisory that such practices likely violated the Stark

anti-kickback laws. HDL said it was cooperating with an ongoing U.S. Justice Department investigation.

In September, HDL co-founder and chief executive officer Tonya Mallory resigned, not long after the *Wall Street Journal* published a front-page article on the laboratory's business practices. McConnell, who was the chief laboratory officer, was named as her replacement.

Mallory has since begun working for ITS Manufacturing, a precision parts company that supplies the aerospace industry and was founded by her brother. Mallory indicated in a recent interview with the *Richmond Times-Dispatch* that she continues to hold a stake in HDL and serves as an adviser to the company, keeping in regular contact with the company's executives and board.

Takeaway: Health Diagnostic Laboratory is dialing back its operations as the company tries to get through a federal investigation. G2

Pathway Genomics Latest Lab to Join PROMPT Registry

San Diego-based Pathway Genomics is the latest lab to participate in creating a registry of cancer patients who have undergone complex genetic testing.

The agreement between Pathway and the Prospective Registry of Multiplex Testing, or PROMPT, was announced late last month. PROMPT is being managed by physicians and scientists from the University of Pennsylvania, the Dana Farber Cancer Institute, the Mayo Clinic, and Memorial Sloan-Kettering Cancer Center. It collects data from patients who have undergone multigene panels—including those who have been determined to have an elevated risk for cancer—and uses it to determine what the risks and outcomes are for patients based on how they test for cancer-related genes. The data may be identified or deidentified at the discretion of each patient and their family.

The initial undertaking of the PROMPT initiative is to create a cohort of individuals and families who have consented to participate in studies examining cancer-causing genetic mutations. It launched its patient portal in July and began collecting patient data in late summer.

"We are honored to collaborate with the country's leading cancer experts to help advance the understanding of cancer risk, the genes associated with it, and take steps to end preventable hereditary cancers," said David Becker, Pathway Genomics' chief scientific officer.

Pathway provides testing for breast cancer mutations beyond BRCA (which is excluded from the PROMPT agreement) and also conducts analyses of genetic changes and variants among family members to determine if there is a specific link between them and medical conditions.

Pathway Genomics is among several laboratories in the United States that is participating in the PROMPT registry. Ambry Genetics and Myriad Genetics are among the other participants. They joined PROMPT last June.

Takeaway: A patient registry of those who have undergone multigene panel testing is beginning to pick up momentum by obtaining participation from the larger laboratories. G2

Esoteric Labs Report Higher Test Volumes, Revenues

The earnings reports of the major esoteric laboratories have trended toward higher test volumes and revenues—with one significant exception for now.

That would be Myriad Genetics. The Salt Lake City-based laboratory had been flying high through its patent on testing for patients to determine if they had the gene associated with a high likelihood of developing breast cancer. Business was boosted further in spring 2013 when actress Angelina Jolie disclosed she had undergone a preventive mastectomy due to her BRCA test results.

But a little more than month after Jolie disclosed her condition and course of treatment, the U.S. Supreme Court ruled that companies cannot hold a patent on a single gene. That opened the market to other labs to offer testing for BRCA1 and BRCA2, and despite ongoing litigation by Myriad, it was quickly plunged into a market where a variety of other labs started offering the same assay, many at far lower price points.

"Revenue contribution from our pharmaceutical industry partnerships was particularly strong, which highlights one aspect of our diversified revenue streams."
—Michael Pellini, M.D., Chief Executive Officer, Foundation Medicine

For the first quarter of fiscal 2015, which ended on Sept. 30, Myriad reported revenue of $73.7 million for its BRACAnalysis Test, which focuses on the risk of both breast and ovarian cancer. The revenue derived from the test during the first quarter of fiscal 2014 was just under $150 million, or nearly three-quarters of Myriad's total. Overall, its revenue for cancer testing dropped 20.5 percent, and molecular diagnostic testing revenue declined 15 percent.

Although Myriad had shifted its focus to multigene testing, it encountered capacity issues for filling orders for a new test, a hereditary cancer panel call myRisk, whose volume increased 95 percent from the fourth quarter of fiscal 2014 and now accounts for nearly a third of Myriad's revenues.

As a result of these issues, the company reported a 17 percent drop in revenue for the quarter, which declined to $168.8 million from $202.5 million a year ago. Net income was $16 million, down more than 72 percent from $55.5 million.

However, company officials remain bullish on Myriad's growth: Chief Executive Officer Peter Meldrum indicated in a conference call with analysts that the company projects it will report full fiscal year revenues of $800 million to $820 million. That would represent growth of 3 percent to more than 5 percent over the 2014 fiscal year.

Foundation Medicine

The Cambridge, Mass.-based Foundation Medicine, which focuses on oncology testing, doubled up on its revenue during its third quarter, ending Sept. 30. The company reported revenue of $16.4 million, compared to $8.2 million for the year-ago quarter, with a 122 percent increase in clinical testing revenue and 75 percent growth in revenue from pharmaceutical firms. Overall test volume was up 149 percent.

Revenue and Earnings for Major Esoteric Laboratories

Company Name	3Q14 Net Income	3Q13 Net Income	3Q14 Revenue	3Q13 Revenue
Myriad Genetics	$16 Million	$55.5 Million	$168.8 Million	$202.5 Million
Foundation Medicine	-$13 Million	-$12.5 Million	$16.4 Million	$8.2 Million
NeoGenomics	-$291,000	$900,000	$23.2 Million	$16.9 Million
Sequenom	-$6.1 Million	-$28.1 Million	$37.9 Million	$33.3 Million
Trovagene	-$5.4 Million	-$4.4 Million	$57,000	$44,000

Source: Company Reports

"Revenue contribution from our pharmaceutical industry partnerships was particularly strong, which highlights one aspect of our diversified revenue streams," said Foundation Chief Executive Officer Michael Pellini, M.D. "As our clinical business expands further into the community setting, we are learning more about our clients' needs and are developing programs to expand access to our testing."

The company lost $13 million for the quarter, compared to a $12.5 million loss for the third quarter of 2013.

For the first nine months of the year, Foundation reported a loss of $38.9 million on revenue of $42.4 million. That compares to a loss of $29.9 million on revenue of $19.3 million.

NeoGenomics

Florida-based NeoGenomics, which specializes in oncology-related genomics testing, reported revenue of $23.2 million for the quarter ending Sept. 30, up 38 percent from a year ago, when revenue was $16.9 million. Test volumes rose by one-third, although much of that growth was in its lower-priced assays.

The company reported a $291,000 loss for the quarter, compared to net income of $900,000 for the third quarter of 2013. One-time expenses of about $571,000 dragged the company into the red.

Douglas Van Oort, NeoGenomics' chief executive officer, noted that the company raised $34.5 million in a public equity offering and was able to terminate its credit facility. Cash collections also added $3.2 million in cash flow. The growth came despite the fact that more than $1.2 million

remained uncollected from FISH billings due to the ongoing dispute with Medicare over its National Correct Coding Initiative.

Sequenom

San Diego-based Sequenom, which focuses on prenatal genetic tests, narrowed its loss for the third quarter to $6.1 million, compared to $28.1 million during the third quarter of 2013. Revenue rose 14 percent to $37.9 million for the quarter, compared to $33.3 million a year ago.

The improved numbers came despite the fact that accessioned patient samples dropped 3.5 percent for the quarter, as operating expenses were cut by $14.2 million, a drop of nearly 40 percent.

"We are particularly pleased with the significant improvement in our cash burn compared to the third quarter of the prior year, as we are working toward our goal of positive cash flow," said Carolyn Beaver, Sequenom's chief financial officer. The company burned through $6.7 million during the quarter, compared to $26.1 million during the third quarter of 2013.

For the first nine months of the year, Sequenom reported a loss of $17.3 million on revenue of $114.8 million, compared to a loss of $88.5 million on revenue of $86.9 million during the first nine months of 2013.

Trovagene

Trovagene, a San Diego-based lab that is developing cell-free oncology assays, reported a 30 percent increase in revenue for the third quarter, ending Sept. 30, to $57,000 from $44,000. Virtually all of the company's revenue is from royalty income rather than from testing, although Chief Executive Officer Tony Schuh said in a conference call with analysts that its urine-based BRAF V600E assay and KRAS mutation assay using next-generation sequencing had become market ready. The former is for monitoring the status of melanoma patients, while the latter may be used for colon, lung, pancreatic, and other solid tumor cancers. Trovagene is also working with the MD Anderson Cancer Center and U.S. Oncology to develop other tests.

> ***"We are particularly pleased with the significant improvement in our cash burn compared to the third quarter of the prior year, as we are working toward our goal of positive cash flow."***
>
> ***—Carolyn Beaver, Chief Financial Officer, Sequenom***

The company's net loss rose to $5.4 million from $4.4 million in the third quarter of 2013.

For the first nine months of 2014, Trovagene reported a loss of $10.4 million on revenue of $224,000. That compares to a loss of $7.8 million on revenue of $212,000 during the first nine months of 2013.

Takeaway: The continuing growth of personalized medicine is reflected in the earnings being reported by the major esoteric laboratories.

■ **Labs Increase Pressure on FDA Regarding LDT Regulation,** *from page 1*

So far, the sector—which has complained about regulatory overreach—mostly appears unmoved. And while a public comment period on the draft proposal released in October runs until February, laboratory lobbying groups appear more willing to air their grievances directly with the public first before submitting them to the agency.

The American Association for Clinical Chemistry (AACC) recently joined the American Medical Association—perhaps the most powerful health care lobby in the United States—and some four-dozen other groups in asking the FDA to withdraw its draft guidelines and submit them under a different set of federal rules that would require it to respond to the comments submitted and require its intended policy to be subject to an economic impact report—a process that would likely delay implementation by a number of years. The letter to FDA Commissioner Margaret Hamburg, M.D., was also signed by national laboratories Quest Diagnostics and LabCorp.

"Using the current guidance process, FDA does not have to publicly respond to comments nor conduct an economic impact analysis of the proposal—both of which inform policymakers and stakeholders as to the basis and consequences of FDA's actions," the AACC said in a statement. The organization said it would soon issue a formal position on the proposed regulations.

Meanwhile, the American Clinical Laboratory Association (ACLA) is taking a more combative stance. Its leadership has reiterated that the Clinical Laboratory Improvement Amendments would suffice for oversight of LDTs. ACLA recently retained two of Washington's most powerful attorneys—scholar and federal appellate veteran Laurence Tribe and former Solicitor General Paul Clement—to represent its interests regarding the FDA and LDTs.

"The FDA's proposal represents a sea-change in the regulation of LDTs that will have significant negative ramifications for diagnostic innovation, and in turn, for patients, physicians, and the entire laboratory community," said ACLA President Alan Mertz. "ACLA's decision to hire Clement and Tribe, and their decision to take this case, should be seen as an indication of the strength of our conviction that the merits favor protecting patients, labs, and physicians from this unjustified regulatory action."

Not every organization is against the FDA regulating LDTs. John L. Bishop, chairman of AdvaMedDX, which represents manufacturers of diagnostic tests, noted that the FDA's proposal "begins to strike a good balance between patient safety and continued innovation. Maintaining the current status quo on LDT oversight, on the other hand, would continue to permit the use of high-risk tests without sufficient clinical data and stifle investment in high-quality products that are assured to be safe and effective for patients."

Takeaway: The laboratory sector is demonstrating willingness to stall, if not outright battle, the introduction of regulatory oversight of LDTs. G2

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INDUSTRY BUZZ

Foundation Medicine Enters Into Clinical Translation Pact With Two Northwestern Medicine Entities

Cambridge, Mass.-based Foundation Medicine has entered into an agreement with two major academic medical providers in Chicago to launch a clinical translation program.

Foundation will be working with the Robert H. Lurie Comprehensive Cancer Center and the Northwestern Medicine Developmental Therapeutics Institute (NMDTI). Both are affiliated with the Northwestern Medicine provider network in Chicago.

Foundation, Lurie, and the NMDTI will work to develop new oncology therapeutics, as well as expand Foundation's genomic profiling capabilities.

"We are pleased to be partnering with the Lurie Cancer Center and NMDTI to continue to advance this transformation in cancer care by bringing together our collective expertise, experience, and resources," said Vincent Miller, M.D., Foundation Medicine's chief medical officer. "We believe this collaboration will serve to build upon the clinical applications of our products and further expand access to targeted treatment options for patients living with cancer."

Foundation has two assays on the market, FoundationOne and FoundationOne Heme. The FoundationOne test, which is used on patients with solid tumor cancers, seeks out 315 cancer-related genes and introns from 28 other genes that are often rearranged as the result of cancer. The test data can then be used to determine the best course of treatment for the patient. FoundationOne Heme focuses on hematologic and pediatric cancers, as well as sarcomas.

"Foundation Medicine is a pioneer in the use of molecular information to translate cancer biology into improved anti-cancer therapies, better treatment selection, and enhanced care of patients with cancer. Our alliance with them reinforces our leadership in the application of personalized medicine at both the individual patient and research levels," said Leonidas C. Platanias, M.D., director of the Lurie Cancer Center. "Foundation Medicine has already been instrumental to our rapidly expanding programs that offer patients cancer treatment tailored to the specific genomic alterations that drive their malignancies. This new program reflects our ongoing commitment to being a national leader in the battle to overcome cancer."

Takeaway: Foundation Medicine is collaborating with an academic medical center with the possibility of improving cancer treatments and potentially expanding its testing portfolio in the future. G2

References

American Clinical Laboratory Association 202-637-9466
Foundation Medicine 617-418-2200
Health Diagnostic Laboratory 804-343-2718
Myriad Genetics 801-584-3600
NeoGenomics 866-776-5907
Pathway Genomics 877-505-7374
Robert H. Lurie Comprehensive Cancer Center 312-695-0990
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