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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Big Payers Want to Bring Order to Genetic Testing

IMPORTANT CHANGES ARE POISED TO TRANSFORM genetic testing. As this happens, there will be a new crop of winners and losers among genetic testing labs.

Recent events can be interpreted as favoring two trends that most genetic testing companies consider as unfavorable to their interests. One trend is adoption of genetic test prior-authorization programs by health insurers both large and small. The second trend is increased federal oversight of genetic testing. This entire issue of THE DARK REPORT is devoted to the unfolding events in recent weeks that involve both trends.

Our lead story is about the systemic error in genetic tests performed by **Invitae Corporation** and it was THE DARK REPORT which first reported this development. Clinical pathologists who are medical directors will recognize the significance of this episode. When Invitae revised its genetic tests, it omitted the material for a rare mutation associated with inherited cancers. It then performed genetic tests from September 2016 through 2017 and, during this time, its quality control program never detected this error.

Only in July, after a clinician notified Invitae about discordant results reported by two labs, did Invitae investigate and uncover this error. In response, the company is quick to point out that it estimates only 2 to 15 patients had false negative test results for the omitted mutation. But, as part of its root cause analysis, Invitae will contact physicians and retest 50,000 patients. Clinical pathologists understand all the implications in these events and federal and state regulators are sure to react to these developments, possibly using this episode to argue in favor of FDA regulation of laboratory-developed tests.

The other news story is that **Anthem** and **UnitedHealthcare**—the nation's two largest health insurers—are initiating genetic test prior-authorization programs within months of each other. But that's not all the bad news. THE DARK REPORT has interviewed two major genetic testing labs about the difficulties they are having obtaining prior-authorization for their physicians ordering genetic tests. The second interview is presented in this issue, on pages 16-18.

Might there be irony in the fact that the two big developments in recent months involve making it tougher for labs to get paid for genetic tests and giving lab regulators a systemic lab failure that can be used to justify tougher oversight of genetic testing labs? TDR

50,000 Patients to Retest After Invitae Finds Errors

Company acknowledges that, for 11 months, it failed to test for the MSH2 Boland Inversion

CEO SUMMARY: In recent weeks, a client notified Invitae of discordant results on a patient. The notification caused the genetic testing company to discover it had a systemic error that failed to test for a specific rare mutation associated with inherited cancer. Company officials believe only 2 to 15 patients received a false negative test result due to this error, yet because the error went undetected for 11 months, the company will retest 50,000 patients.

ONE OF THE NATION'S LARGER GENETIC TESTING COMPANIES is dealing with a significant problem that may have long-term consequences for how genetic testing labs are regulated at the federal and state level.

Last week, THE DARK REPORT was first to break the news that **Invitae Corporation** reported inaccurate genetic test results for what it said could be is as many as 50,000 patients over 11 months, starting in September 2016 and ending in July 2017.

The company admitted it failed to test for a specific rare mutation associated with hereditary cancer. In recent weeks, Invitae became aware of the problem and began contacting clinicians to notify them of the error in the genetic test results it reported for certain patients and to arrange to retest those patients. Invitae would not say exactly when it discovered the problem beyond saying, "in recent weeks."

In a statement to THE DARK REPORT, Invitae said, "For the past several weeks, Invitae has been working with clinicians to address an issue related to our analysis of a rare genetic variant in the MSH2 gene associated with Lynch syndrome (0.007% of inherited cancer tests), also known as the Boland inversion, which we believe could have led to a false negative report for a small number of patients (estimated 2-15 patients impacted).

"Because of the unique characteristics of how we were testing for the MSH2 Boland inversion, our quality control checks did not catch omission of the components of the assay," the statement continued. "As soon as the omission was

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recognized and relevant components returned to the assay, it once again performed properly. We have added two separate quality controls to ensure this issue will not reoccur."

For two reasons, this failure may have significant repercussions—not just for genetic testing companies, but also for the entire clinical laboratory industry. First, Invitae determined that the genetic tests for 50,000 patients were subject to this systemic testing error, a number that is likely a record high for such an error. Second, these assays are laboratory-developed tests (LDTs), which the FDA said in 2014 should be subject to regulation.

Similar Vulnerabilities

Additional factors that make this a significant event for the clinical laboratory profession include the following. Pathologists who are medical directors of genetic laboratories will recognize how these events demonstrate vulnerabilities that exist in their own labs. This episode also highlights the limitations of the current state of technologies and systems used in genetic testing.

In its statements to THE DARK REPORT and in interviews with reporter Turna Ray at *Genomeweb.com*, Invitae acknowledged the following:

- When it developed a new assay version in 2016, Invitae did not recognize that the probes for the Boland inversion mutation were not included.
- This error occurred in September 2016 and from that time, in normal daily testing operations, Invitae's internal quality controls did not detect this problem.
- In July 2017, 11 months after it launched the new assay, a clinician notified Invitae of discordant results on a patient who had been tested twice, once by Invitae and once by another genetic testing lab company.
- After being alerted to the discordant results, Invitae confirmed the systemic error and began notifying clinicians of the error and arranging retesting for those patients.
- Invitae said it will retest 50,000 patients and it has notified the **College of American Pathologists**, its CLIA accreditor, of the genetic testing error.

Story Has Two Dimensions

This story will unfold in two dimensions: among investors and among clinicians. Clinicians include physicians and genetic counselors who use genetic tests, and pathologists and laboratory scientists who perform genetic tests.

News reports and financial analyst commentary will die down quickly after investors decide this episode won't affect Invitae's ability to pursue its growth plans. In this dimension, the problem at Invitae will be deemed as not material to the company's future profitability. Wall Street and the news media may dismiss Invitae's characterization that the errors should affect only 2 to 15 patients (out of 50,000 genetic tests) as not material and continue to cover the company as usual.

How Will Clinicians React?

Among clinicians, Invitae's current woes may have consequences over many years. Some physicians, genetic counselors, and other clinicians will consider Invitae's omission of the MSH2 Boland inversion mutation to be minor—a hiccup in a field that advances through trial and error. But there will be some clinicians who distrust Invitae enough to refer their tests to other lab companies.

The next question is how lab regulators will react. Lab regulators have a history of being tough when such errors come to light. When they learn of these failures, government regulators conduct rigorous inspections in an effort to uncover any problems that might otherwise go undetected.

Federal and state inspectors recognize that it is extraordinary for any laboratory to have performed inaccurate tests on

Finding the 1 patient in 1,000,000 with Rare Mutation Is the Main Goal of Every Genetic Testing Lab

IN THEIR PUBLIC COMMENTS about the systemic error in the genetic tests performed for 50,000 patients, executives at Invitae Corporation emphasize that they estimate that only 2 to 15 patients received a false negative report.

If their message to the media and investors is that this is not a systemic error that should cause concern about the integrity of the company's genetic testing activities and, if the small number of patients who got false negative results for a rare mutation associated with inherited cancers supports that conclusion, there are others in the genetic testing industry who disagree with that view.

Several medical directors at genetic testing laboratories expressed their personal opinion to THE DARK REPORT that the problem represents an important failure of the genetic testing company and should be taken seriously.

One lab industry executive says that the primary service every genetic testing laboratory provides to physicians and patients is its ability to accurately and consistently identify rare mutations that would be clinically-relevant for the individual patient.

"Think of it in this way," stated Richard Faherty, formerly Executive VP, Administration, for **BioReference Laboratories, Inc.** and its **GeneDx** subsidiary. "The essential product of a genetic testing laboratory that says it detects rare mutations for inherited genetic disease is the ability to *always* find that one mutation in a million for the patient. After all, isn't that why the referring physician and the patient ask a genetic testing lab to identify whether any such mutations are present?

"Thus, for any lab like Invitae to tell its physicians that the genetic test performed for 'only a few patients' may have reported a false negative result betrays the quality and accuracy that all physicians, patients, and their families expect of our labs," explained Faherty. "Remember that what physicians and patients do with these results is very drastic because it determines how therapies such as surgery, radiation, and cancer drugs will be used.

"This is why I consider it a massive failure anytime a genetic lab—whether large or small—misses rare mutations in even a small number of patients because of a failure at the bench," added Faherty.

50,000 patients over 11 months and never detect the systemic error through its quality control program.

Also, government lab regulators understand the significance of a systemic error involving such a large number of patients and the extent of the potential harm such an error can cause, even if only a few patients are affected.

Pathologists and lab administrators will watch closely to see if officials inspect the Invitae lab in San Francisco, what deficiencies they identify, and what enforcement actions they take. Any regulatory action may set new precedents in how genetic testing laboratories are inspected.

For lab directors, the lessons to gain from this episode will include what they can learn to improve their own lab's quality control programs, what deficiencies federal and state regulators identify, and how to eliminate those deficiencies in their own labs through improved quality control procedures.

In important ways, this problem at Invitae has the potential to cause the entire genetic testing industry to undergo more regulatory scrutiny and tougher inspections of their laboratories. New and tougher regulations may result and the FDA will have this episode to support its efforts to gain congressional approval to regulate laboratory-developed tests. TDR

Regulatory Update

Estimating Total Costs When Genetic Tests Must Be Retested

INVITAE, A GENETIC TESTING COMPANY IN San Francisco, has begun a retest program involving 50,000 patients. Such a large retest effort is without precedent in the still-nascent genetic testing marketplace.

Clinical laboratories and genetic testing companies commonly find that, in daily operations, a batch of samples produced unreliable or inaccurate results. These discoveries are made as part of every lab's quality control procedures and typically these discoveries involve tens or hundreds of specimens. Physicians understand this aspect of lab testing.

But when the numbers reach into the tens of thousands, medical directors at other genetic testing labs take notice to learn how to respond effectively if their lab has a similar problem.

Invitae's retesting effort comes after it learned in July that the materials for a rare mutation associated with inherited cancer were omitted from a new assay version of its genetic tests that it developed last year. From September 2016, until the systemic error was identified in July 2017, Invitae reported erroneous genetic test results.

One Mutation Omitted

These genetic assays did not test for the Boland inversion mutation on the MSH2 gene. This gene is associated with Lynch syndrome, which is also known as hereditary nonpolyposis colorectal cancer. Late on Friday, Turna Ray reported for *GenomeWeb* that Invitae's CEO Sean George estimated that 2 to 15 patients had gotten a false-negative result. To be certain that it identifies all possible patients who may have received a false-negative result, Invitae said it would retest 50,000 patients, Ray reported.

The number 50,000 may be about right, according to Richard Faherty, a consultant with **RLF Consulting LLC** and formerly with **BioReference Laboratories** and its **GeneDx** division. "There is another way to look at Invitae's accession volume and test menu," he said. "First, consider the number of tests on the Invitae test menu that includes testing for MSH2 and therefore the Boland inversion coverage. There are at least 18 such tests. *(See sidebar next page.)*

Extrapolating Test Volume

"We don't know Invitae's test-ordering mix," Faherty explained. "But during the company's fourth quarter earnings conference call, there was a discussion about the number of tests that Invitae ran last year and that number was 60,000.

"From that discussion, we know that about 80% of those tests were cancer tests and that the vast majority of those cancer tests were for hereditary breast and ovarian cancer," he added. "We can apply that proportion to test volume to give us some idea about the numbers," he added.

"This approach generates an estimate of 45,000 patients that Invitae will probably need to retest, and that number is close to the 50,000 Invitae reported," he noted. "Now, can we estimate how much all the retesting might cost?

"Invitae told *GenomeWeb* that the cost to retest is about $10 per test—a cost most lab directors would consider to be a low

estimate," commented Faherty. "That may be possible, depending on what technology the company will use. But that cost of $500,000 would be the materials only and probably does not include staff time to run the test and analyze the results or to contact doctors and patients to discuss the need to retest and the results of each test."

Faherty added an important point about patients' anxiety. "We have to assume that many of these 50,000 patients or their clinicians will ask about the reliability of the retest and what that level of reliability means for them," Faherty added. "All that anxiety might mean additional time on the phone for Invitae's genetic counselors and other staff, and that also costs money."

Estimating Retesting Costs

One lab expert familiar with a large retesting program estimated that it might cost as much as $60 per sample. "There are several methods—such as multiplex ligation-dependent probe amplification and breakpoint PCR—both of which are high-throughput assays that a lab could run for about $35 a sample in reagents," the expert said. "When you add the expense of labor and reporting, costs start to approach $50 per sample.

"I would assume you would need to dedicate a team to do this work because 45,000 to 50,000 samples is no small undertaking," she added. "All of these calculations do not include the cost of recontacting patients and having to re-isolate DNA on a percentage of them. That would easily add $5 to the per-sample cost.

"Considering all of these factors, I estimate that a lab would be hard pressed to do this retesting for less than $60 a sample," she stated. At $60 per sample for 50,000 samples, the cost climbs to $3 million.

"While $10 to $60 per retest seems reasonable, other experts have suggested that the cost to retest could climb as high as $250 per test," Faherty added. "If that's true, then Invitae would have a much higher total of as much as $12.5 million just for retesting and not including the costs for contacting doctors and patients." TDR

—Joseph Burns

Contact Richard Faherty at rfaherty@mindspring.com.

Which Invitae Genetic Assays Address MSH2 Mutation?

FROM THE INVITAE TEST MENU, it is possible to estimate the number of assays that would test for the presence of MSH2. There are 18 such genetic tests as follows:

1) Invitae Constitutional Mismatch Repair-Deficiency Panel
2) Invitae Lynch Syndrome Panel
3) Invitae Prostate Cancer Panel
4) Invitae Myelodysplastic Syndrome/Leukemia Panel
5) Invitae Pediatric Hematologic Malignancies Panel
6) Invitae Gastric Cancer Panel
7) Invitae Pancreatic Cancer Panel
8) Invitae Colorectal Cancer Guidelines-Based Panel
9) Invitae Pediatric Nervous System/Brain Tumors Panel
10) Invitae Colorectal Cancer Panel
11) Invitae Renal/Urinary Tract Cancers Panel
12) Invitae Breast and Gyn Cancers Guidelines-Based Panel
13) Invitae Common Hereditary Cancers Panel (Breast, Gyn, GI)
14) Invitae Sarcoma Panel
15) Invitae Breast and Gyn Cancers Panel
16) Invitae Nervous System/Brain Cancer Panel
17) Invitae Pediatric Solid Tumors Panel
18) Invitae Multi-Cancer Panel

Invitae Investing Heavily To Expand Market Share

To become dominant, genetic testing company pushes aggressively to capture the market share

CEO SUMMARY: In its first five years of offering clinical tests, Invitae has outspent revenue by $330.7 million. Yet its executives are confident that their company is on a path to becoming one of the dominant players in the genetic testing sector. This profile of Invitae will help pathologists and lab administrators understand more about the company when its sales reps show up to ask for genetic test referrals. Its strategy is to spend to grow fast now and make money later.

IN THE CURRENT MARKETPLACE for genetic testing services, there is much optimism among investors and the executives running the handful of genetic testing companies that are considered frontrunners in the race to gain market dominance as physician utilization of genetic tests expands.

That optimism was reinforced recently when it was announced that **Konica Minolta** would pay up to $1 billion to acquire **Ambry Genetics**, the genetic testing company based in Aliso Viejo. It confirmed for many in the genetic testing industry that investors would continue to provide the funds needed by other genetic testing companies to continue their expansion. *(See TDR, July 17, 2017.)*

One genetic testing company that is determined to carve out a major slice of the genetic testing marketplace is San Francisco-based **Invitae Corporation**. Most clinical lab administrators and pathologists know the company by name, but are unfamiliar with its business model. In just the past 12 months, the company has more than doubled both the number of accessions and the number of lives covered by its managed care contracts.

Invitae began operating in 2010 and launched its first assay in November 2013. Its current Chairman is Randal W. Scott, PhD, who previously was CEO at **Geneomic Health, Inc.** Invitae's CEO is Sean E. George, PhD, who is also a co-founder of the company.

Invitae conducted a successful initial public offering in February, 2015. It raised $116.8 million in gross proceeds. Its shares trade on the New York Stock Exchange under the symbol: NVTA.

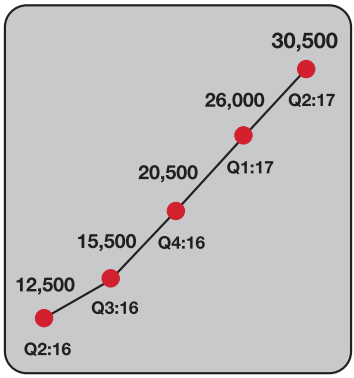
Growth in Accessions

It may be true that specimen volumes are flat or declining at most of the hospital and health system labs throughout the country. That is not the case at Invitae. In the 12 months ending in June, 2017, it saw accessions skyrocket from 12,500 in Q2-16 to 30,500 in Q2-17. That's an increase of 244% in just 12 months.

During this same 12-month period, Invitae reported that the number of lives under managed care contracts increased from 95 million to 203 million. That's an

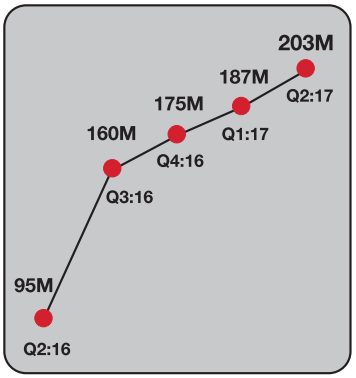
Four Charts Tell the Story of Rapid Growth In Volume of Genetic Tests Performed at Invitae

Accessioned Volume



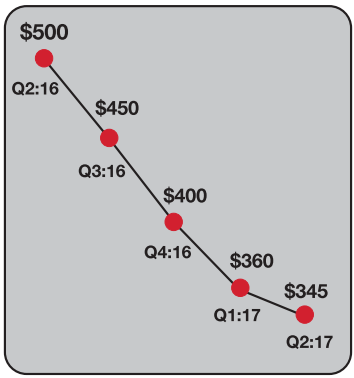
In just 12 months, Invitae's accessions increased by 244% from 12,500 accessions in Q2-16 to 30,500 accessions in Q2-17. This is rapid growth in the workload that the lab team must handle.

Lives Contracted



During the same 12-month period, from Q2-16 to Q2-17, Invitae expanded its managed care contract coverage from 95 million lives to 203 million lives. Competitors say that Invitae is offering very low prices and health insurers are adding them to their networks, then telling other genetic testing labs that they must match Invitae's low prices.

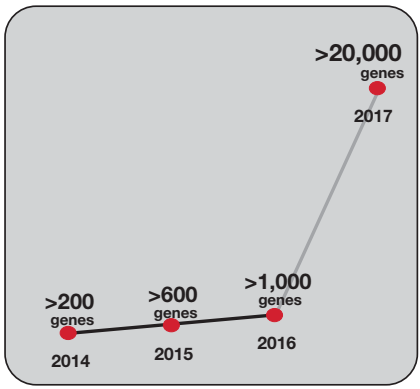
COGS per Sample



In the 12 months shown, Invitae lowers its cost of gene sequencing per sample by 31%, from $500 to $345. It accomplishes this even as it adds more sequencing data by increasing the number of genes covered by its tests.

Charts from Invitae Corporation, second quarter 2017 earnings report.

Content Available



This chart shows how Invitae has increased the number of genes covered by its menu of tests from 200 genes in 2014 to 20,000 genes in 2017.

increase of 214% and includes Medicare lives.

Low Price Strategy

Competitors gripe that Invitae is using very low prices for its genetic tests to generate new business and win additional managed care contracts that make it a network provider. That pricing strategy is familiar to clinical lab managers, as it is virtually identical to what **Laboratory Corporation of America** and **Quest Diagnostics** have done over the past two decades by offering payers deeply-discounted prices for clinical lab tests in exchange for network status.

But that low-price strategy has come with a cost for this genetic testing company. Invitae has outspent revenue every year since it entered the market. For the years 2012 through 2016, it generated total revenue of $35.2 million. During these same four years, the company lost a collective $271 million.

The story is similar during 2017. For the first six months, Invitae's revenue totaled $24.7 million and its net loss was $55.5 million. As of June 30, 2017, Invitae reported that its accumulated deficit was $330.7 million.

More Capital From Investors

Invitae has covered this revenue gap by raising funds from investors. For example, at the end of July, Invitae announced that it would sell $73.5 million of stock in a private placement. Much of the money will come from existing shareholders.

The company is also willing to spend heavily on sales in order to increase test referrals. During the first six months of 2017, it spent $24 million on sales and marketing. That was almost the exact amount of the company's total revenue of $24.7 million for the same six months.

Another cornerstone of Invitae's growth strategy is to continually expand its menu of genetic tests and genetic test panels. During its second quarter earnings call, Invitae executives reported that, whereas the company's test menu in 2014 included about 200 genes, by 2017, its test menu expanded to include 20,000 genes.

In many respects, Invitae is following the popular growth strategy that has emerged from the Silicon Valley during the past two decades. In simplest terms, the "growth first, revenue later" strategy says it is necessary to spend heavily in the early years to become the dominant company in that space, despite incurring substantial losses.

Market For Genetic Tests

Recognizing that the clinical market for genetic testing is still in its infancy, Invitae wants to become the major provider of such tests. That way, as the market grows and matures, it holds an unassailable market position. **Amazon** is an example of this. Founded in 1995, it lost money for almost two decades. But it became dominant in multiple industries and its share price continues to go up.

Most pathologists and lab administrators tend be conservative in how they manage their clinical laboratories and pathology groups. Incurring costs that create substantial losses quarter after quarter is an uncomfortable business concept for them.

In fact, some lab professionals will look at the company's rapid growth and ongoing losses as a factor that may have contributed to the systemic error in its genetic tests that happened during the past year. They know how chaotic a lab can be while it is rapidly adding staff and instruments to accommodate increased volumes of specimens.

On the other hand, Invitae does have momentum in the genetic testing market. Assuming it can continue to raise the needed capital to offset its current operating losses, it does hold a strong position from which to expand its market share. TDR

Two Largest Payers Start Lab Test Pre-Authorization

Actions by UnitedHealthcare, Anthem bring genetic test prior-authorization to 80 million people

CEO SUMMARY: Once Anthem and UnitedHealthcare establish their respective genetic test prior-authorization programs, a new era for genetic testing will commence. The 80 million beneficiaries served by these two payers make up half of the individuals who have private health insurance. It is reasonable to expect that other health insurers will follow the lead of Anthem and UHC and institute their own programs to manage how physicians utilize genetic tests.

GROWTH IN THE UTILIZATION OF GENETIC AND MOLECULAR TESTS reached a tipping point during 2017. Faced with a swift increase in both the number of genetic tests available for clinical use and the volume of such testing being ordered by physicians, the nation's two largest health insurers have taken tough action.

First to act was **Anthem, Inc.**, which announced in April that it would institute its genetic test prior-authorization program on July 1. Just two months later, **UnitedHealthcare** made a similar announcement, saying Nov. 1 would be the start of its genetic test prior-authorization program. *(See TDR, June 26, 2017.)*

Major Development For Labs

These actions are a major development for the nation's genetic testing laboratories. UnitedHealthcare and Anthem each cover about 40 million beneficiaries. That means some 80 million individuals—about half of all Americans with private health coverage—will be in a plan with a genetic test pre-authorization requirement by year end.

The new policies at both companies could be problematic for labs offering molecular diagnostic and genetic tests. Typically, an insurer's prior-authorization policy means that the insurer won't pay the lab performing the test if the ordering physician did not get prior authorization first.

One aspect of UnitedHealth's plan to require prior-authorization of genetic tests is that—when considered with its earlier decision to implement a pre-authorization and pre-notification policy in Florida—it makes it easier for health insurers across the country to institute their own prior-authorization programs.

These announcements could be positive developments for genetic testing labs that offer payers two things. One is they have good data on their genetic test's accuracy that shows how physicians can use the genetic test results to improve patient outcomes. The second is prices that are reasonable for the clinical value that the genetic tests provide to physicians. These labs will have an easier time negotiating coverage and becoming in-network providers.

For lab companies that lack sufficient data on accuracy and clinical utility, genetic test pre-authorization requirements will make it tougher to win network status and get paid.

Two stories about these genetic test utilization programs follow. On pages 13-14, THE DARK REPORT provides the first details about UnitedHealthcare's national genetic test prior-authorization program. One feature of interest is that UHC will have **BeaconLBS** handle some aspects of this program, which will be different than UHC's laboratory benefit management program in Florida. *(See sidebar at right.)*

The story that follows on pages 16-18 presents an interview with a vice president of managed care at a major laboratory that provides genetic and molecular testing services. This lab executive discusses the issues his lab is having with Anthem's prior-authorization program.

Problems With The Program

This is the second lab to provide THE DARK REPORT with inside information about the difficulties and problems that labs are encountering as they attempt to work with their client physicians and Anthem (along with Anthem's **AIM Specialty Health** division which manages the program) to obtain prior-authorization for their genetic tests. *(See Aug. 7, 2017.)*

There is significance in the fact that, at nearly the same time, the nation's two largest health insurers acted to implement genetic test prior-authorization programs. It shows that the utilization of these tests has increased to such an extent that payers recognize the need to better control how physicians use genetic tests.

What health insurers are about to discover, however, is the complexity associated with using any lab test to diagnose disease and guide decisions to treat. Early experience with the Anthem program indicates there are many issues to be resolved before acceptable normalcy is achieved. TDR

—Joseph Burns

United Healthcare Comments on Pre-Authorization Plan

IN RESPONSE TO QUESTIONS about the national genetic test prior-authorization program from THE DARK REPORT, a spokesperson for UnitedHealthcare said the following:

"Regarding UHC's Molecular and Genetic Testing Notification/Prior-Authorization program, the UnitedHealthcare Lab Benefit Management pilot in Florida and the UnitedHealthcare Molecular and Genetic Prior-Authorization/Notification program are two different programs with different requirements.

"The Lab Benefit Management (LBM) program pilot is for commercial, fully-insured members in Florida, and includes 79 specific tests on the current LBM Decision Support Test list; among those, there are currently a few tests related to genetic testing, including cystic fibrosis and BRCA tests. This list will not change with the deployment of the Molecular and Genetic Prior-Authorization/Notification.

"Separately, the Molecular and Genetic Testing Notification/Prior-Authorization program is an online prior-authorization/notification program. It will begin on Nov. 1, 2017 for UHC's fully insured membership nationally outside of Florida.

"Regarding the laboratory benefit management program in Texas, UHC announced in January that it would delay the implementation of claims impact for the LBM program pilot in Texas. We have been closely monitoring progress of the pilot, giving us time to make refinements based on feedback from Texas care providers.

"Network physicians continue to have access to the physician decision support tool and are encouraged to use it when ordering decision support tests to continue building their familiarity with the lab ordering system. Care providers will be notified at least 90 days before the claims impact associated with the LBM program goes into effect," concluded the UHC spokesperson.

UnitedHealth to Start Gene Test Pre-Approval

BeaconLBS, a LabCorp subsidiary, will manage national prior-authorization effort starting Nov. 1

CEO SUMMARY: With programs now at the nation's two largest insurers, is it possible to argue that prior-authorization is going mainstream? Some observers say, yes, as THE DARK REPORT predicted. What is certain is that starting Nov. 1, UnitedHealthcare is requiring prior authorization for genetic and molecular tests for its fully-insured commercial members nationwide. That comes just 12 weeks after Anthem started its genetic test management effort on July 1 in all 14 states where it operates.

ONE MONTH AFTER **ANTHEM, INC.**, announced it would require physicians to use its genetic test management program, **UnitedHealthcare** said that, effective Nov. 1, it would require physicians to get prior authorization when ordering genetic and molecular tests for UHC members in fully-insured commercial plans.

With this decision, the nation's two largest health insurers have taken an important step to manage utilization of genetic tests. These actions may encourage other private payers to initiate their own programs aimed at managing how physicians order genetic tests.

Labs Asked To Register

In a letter, UHC asked labs to register by Sept. 15 to be included in "our new genetic and molecular lab testing notification/prior-authorization program." Thirty days before the program begins on Nov. 1, UHC will make training and more information available at UHCprovider.com, the letter said.

The letter described how labs and physicians would participate, stating: "Starting Nov. 1, 2017, a new online notification and prior-authorization process will be implemented for genetic and molecular lab tests for UnitedHealthcare commercial benefit plan members."

Beacon Laboratory Benefit Solutions, Inc., a lab services management company that is a subsidiary of **Laboratory Corporation of America,** is working with UnitedHealthcare and will register participating labs for the program and manage the online notification/prior-authorization request system, the letter said.

BeaconLBS manages a prior-notification program for UHC's HMO members in fully insured plans in Florida since 2015. Physicians and clinical labs have criticized that program for being difficult and time consuming and for failing to integrate with many common EMR systems, forcing ordering physicians to enter test orders and results twice.

UHC's letter continued: "We encourage all labs participating in UnitedHealthcare's network to register. BeaconLBS has created a streamlined prior-authorization process for care providers that will leverage

UnitedHealthcare's clinical policy requirements for all coverage determinations."

About BeaconLBS, a spokesperson for UHC said, "Beacon will collect the information for prior authorization, but UHC will do all of the reviews and decision making."

The test list is comprehensive. UHC said that, "Physicians ordering tests will initiate prior authorization through BeaconLBS when ordering tests such as BRCA1/2, hereditary cancer panels, pharmacogenetic panels, tier 1 and 2 molecular pathology procedures, genomic sequencing procedures, multianalyte assays with algorithmic analyses that include molecular pathology testing, and tests with the following CPT codes: 0001U; 0004M to 0008M; 81161 to 81421; 81423 to 81479; 81507 and 81519; and, 81545 to 81599."

A source at a large clinical lab who asked not to be named said these tests are among those for which UHC currently requires labs or physicians to get pre-approved. Therefore, the listed tests should not be much different from current practice, he added. The big difference will be how well UHC works with BeaconLBS on the data collection effort.

UnitedHealthcare's letter continued: "The ordering care provider will specify the test name and select the testing laboratory. To give ordering care providers the ability to select your laboratory for genetic and molecular tests when the requirement starts on Nov. 1, you need to register with BeaconLBS by Sept. 15 by going to BeaconLBS.com, login, and lab login."

Labs Asked To Register

Lab managers should note that, after Nov. 1, payments will be authorized only for those genetic and molecular tests performed by labs registered with BeaconLBS as part of the genetic and molecular lab testing notification/prior-authorization program.

"BeaconLBS will need the following information to complete your registration for all applicable testing to support accurate and timely prior authorization and claims payment: the test name, unique test identifier, all associated CPT codes and units billed," the letter said. Also, labs will need to supply their National Provider Identifier and CLIA numbers and a valid email address for the lab.

Florida Program Different

The lab director emphasized that this new nationwide genetic and molecular test pre-approval system will be different from the current prior-notification program BeaconLBS uses in Florida.

"It's clear that UHC wants to make the prior-authorization decision more efficient because they're saying Beacon can make that decision quickly," the lab director said. "If I called UnitedHealthcare today and requested prior authorization for BRCA testing, they would ask for medical records and this and that. But, with the design of this nationwide program, they say the BeaconLBS system can do this faster.

"Both UHC and BeaconLBS have electronic portals and I'm familiar with UHC's, which is quite basic," he added. "I'm not at all familiar with the planned Beacon prior-authorization portal. But I do know that it will be different from the portal BeaconLBS uses in Florida.

"In fact, it has to be different because the program in Florida is a prior-notification program and the nationwide program is a prior-authorization program," he explained. "And, it's different because UnitedHealthcare said it will make the decision on genetic and molecular tests and Beacon's role involves registering labs and collecting the prior-authorization data from labs and physicians."

Other lab executives point out that UnitedHealthcare is not leaving much time for physicians to sign up by the Sept. 15 date. They also want to know what recourse a lab would have if it performs a genetic test, but later learns the physician did not obtain the required pre-authorization. TDR

—Joseph Burns

Managed Care Update

Anthem/AIM Responds to Queries about Its Pre-Approval Program

AFTER SEVERAL LABS SPOKE about the difficulties in working with the new **Anthem/AIM Specialty Health** prior-authorization program for genetic tests, THE DARK REPORT sent questions to Anthem. Responses from Anthem/AIM were lengthy and have been edited to fit the available space:

Q: Is it true that labs cannot assist physicians in ordering tests through the Anthem/AIM program?
A: By having direct communication with the ordering physicians and their clinical team, we are able to determine not only the specific test they need for their patient but also the corresponding CPT codes in advance of the testing which makes the reimbursement process more efficient and cost effective.

Q: If it's true that labs cannot assist their client physicians, doesn't that make it difficult for doctors to get the tests they need for their patients and for doctors to understand the tests they're ordering for their patients?
A: The Anthem Genetic Testing Solution promotes appropriate use and provides education that addresses the clinical and financial complexities of genetic testing. Physician reviewers and board-certified analysts are available for consultation with providers Monday through Fridays during business hours to discuss cases. We feel that utilizing genetic analysts who are independent of laboratories helps to eliminate any conflict of interest in the test selection process.

Q: Is it true that the Anthem/AIM process requires ordering physicians to request the prior approval and then send the patient away while waiting to get the approval?
A: The Genetic Testing Program has moved a traditionally manual, labor-intensive, and post-service process to a real-time automated system that delivers prior authorizations. It can also reduce the likelihood of errors in filling out paperwork, which adds to labor and time. For many tests, using the solution can cut down the average time for submitting and processing an insurance claim from days to minutes because the prior authorization review provides specific CPT code information to the insurer to facilitate the claim processing. The vast majority of genetic tests are currently ordered outside of the EHR process, either via a separate portal for the servicing laboratory or by completion of a paper requisition form. Integration into EHR systems is currently being explored by AIM for genetic testing and we hope to offer this option in the near future.

Q: Is it true that some AIM reviewers are unfamiliar with Anthem's policies and so, while one reviewer will approve a test request, another reviewer will deny a request for that same test?
A: No. Case requests that meet clinical criteria are immediately approved. For a request that fails to meet evidence-based criteria at intake, our genetic analysts reach out to the ordering provider when alternate testing is available or additional clinical information may lead to approval. Through this exchange, the provider has an opportunity to provide additional clinical information necessary to adjudicate the request. TDR

Labs Report Problems with Anthem's Pre-Approval

➤One in-network lab says prior-authorization for genetic tests is frustrating at every level

➤➤CEO SUMMARY: Since the July 1 launch of its prior-authorization program for genetic tests, Anthem and its subsidiary, AIM Specialty Health, have authorized few genetic tests, said a national lab. Lab directors say they have been unable to communicate with Anthem/AIM when client physicians order tests. Also, labs are unaware if Anthem has trained ordering physicians in how to use the new system. Given that Anthem insures 40 million Americans, these problems may be a challenge for many genetic testing labs.

FOLLOWING THE JULY 1 START of **Anthem's** program to require pre-authorization of genetic tests, more genetic testing labs report trouble getting pre-approvals and payment for tests.

In response, some genetic testing labs have taken their concerns to the **American Clinical Laboratory Association**, although ACLA would not comment to THE DARK REPORT as to whether it is preparing a response to send to Anthem and its subsidiary, **AIM Specialty Health**. AIM runs the prior-authorization program that began July 1 in the 14 states where Anthem operates. *(See TDR, June 26, 2017.)*

Anthem is the nation's largest health insurance company, insuring almost 40 million Americans. Thus, any problems in obtaining pre-authorization and payment for genetic tests will affect many clinical lab companies.

To date, complaints about the program have come from sources who asked to remain anonymous. A vice president for one large genetic testing lab said Anthem has authorized few specimens from requests from ordering physicians. Also, in some genetic test orders that Anthem has approved, Anthem or AIM issued a prior authorization but used the wrong CPT code because the ordering physician didn't know which code the lab would use.

➤Labs Have No Role

"This lack of communication between the physician, the lab and the insurer is required under the protocols Anthem and its subsidiary, AIM Specialty Health, have adopted," stated the lab VP. Also, the staff in his laboratory was unaware if Anthem/AIM had trained any ordering physicians in how to use the new system, he added. Anthem/AIM responded to this and other complaints. *(See Anthem comments on page 15.)*

The problem this vice president described is similar to that of another laboratory director at a different genetic testing laboratory who also was frustrated when working with Anthem/AIM's genetic test prior-authorization program. *(See TDR, Aug. 7, 2017.)*

"We are accustomed to dealing with prior-authorization requirements, especially for genetic tests," commented that VP in an interview with THE DARK REPORT. "What makes the Anthem/Aim program different is that they have so far prevented us—as the ordering laboratory—from filing the prior-authorization request on behalf of the referring provider. That is one aspect of the program that we would like to see changed.

Too Little Time for Approval

"Another problem we're having is that the ordering provider has a 48-hour period to get the prior authorization," he said. "Essentially, it means the system Anthem/AIM has established is different from the way most payers require approval.

"Let me clarify that a bit. In the lab world, the date of service is usually equal to the date of collection," the VP said. "So, if the collection is on Monday, the laboratory typically does not have the specimen until Tuesday. At that point, the laboratory can call the ordering provider to explain that the physician submitted a specimen without the necessary prior authorization. The lab also will ask the provider to get the prior authorization and send the documentation to us.

"By the time the physician gets around to requesting the prior authorization, the 48-hour window usually has expired," he explained. "In a perfect world, the physician would obtain prior authorization before collecting the specimen, but that doesn't work well within the workflow of physicians' practices.

Lab Bears Financial Liability

"If a physician does not obtain the prior authorization, then our lab bears the financial liability of an unpaid claim after performing the genetic test that the physician requested," he added.

"Other health plans and lab benefit management companies allow labs to file for the prior authorization on behalf of the ordering provider and to use what we call the retro prior-auth period," he said. "Typically, the retro period is between eight and sometimes 30 days, depending on the payer. Sometimes, a lab needs all that time to get the necessary information. That is why the 48 hours under the Anthem-AIM program is much more frustrating—especially when compared with our experience with other health plans.

"When the 48 hours ends, we are in a quandary," he added. "That's when our lab faces the question of whether we should destroy the patient's specimen or run the test.

"Destroying the specimen could interfere with patient care, depending on the purpose for which the genetic test is being ordered," observed the lab VP. "But if our lab runs the test, there's a strong likelihood that we won't get paid.

"We could fight it on appeal, which is unduly expensive because we have to pay staff to file the appeal," the VP said. "And usually, the first appeal is denied and so we have to go to a second level of appeal.

Lengthy Process For Appeals

"The appeals period can vary but typically it will take 30 to 60 days to get through the initial denial," he added. "Then, our lab may need another 30 to 60 days for the second level of appeal. So our lab is looking at easily six to nine months to work through the process of getting a claim paid. And sometimes it doesn't even get paid on appeal."

Another problem is that, as of this time, physicians serving Anthem patients have yet to be trained on how to use the prior-authorization system. Early in July, the VP's lab asked Anthem/AIM to provide the training materials that it sends to its physicians to explain how to use the new prior-authorization program.

"What they sent were two provider newsletters of about 12 pages each. In the middle of the newsletter there is a small

three-paragraph section about AIM's prior-authorization program for genetic tests.

"That would suggest there wasn't much focus on provider education and I am unaware of any other effort by Anthem to educate the provider community," the VP said. "When I asked if Anthem would do any further education of providers, I was told that they recognized the need for additional training."

At that point, the VP was surprised to learn that Anthem/AIM wanted his lab to give it the names of all the physicians submitting tests without first getting the required prior authorization. "That request is particularly problematic because it puts a burden on us as a laboratory to report physicians to health plans," he commented.

Lab Asked to Name Names

"We would rather see Anthem look at claims that ultimately get denied because of no prior authorization and use that as their roster for physician education," he noted. "That would keep our lab out of an uncomfortable position and we would not need to pay staff to develop the report.

"All of this trouble is surprising because we have a national agreement with Anthem, so we are in-network in all of the 14 Anthem states, except for two where we're excluded due to a prior contractual arrangement," he said.

"After speaking with people at smaller labs (and even some of the larger labs), no one tells us they are having any success with the Anthem/AIM prior authorization program," the VP reported.

Asked how many tests his lab has submitted to Anthem/AIM under the new-prior authorization program, the VP could not say because the lab has been unable to use the Anthem/AIM portal.

"As an in-network lab provider, we are not able to log into the Anthem/AIM portal to initiate the prior authorization," he explained. "Nor will they speak with us by phone. When we call them, they'll answer. But once they find out who we are, they inform us that they will not speak with us about issuing a prior authorization. The whole system is extremely frustrating.

Rely On Ordering Physicians

"The end result is that our lab must rely on its ordering physicians to submit the prior-authorization request and ensure that the request gets approved in time," added the VP. "If not, our lab risks performing genetic tests for which it will not get paid.

"Our laboratory is in a difficult position," he commented. "For certain genetic test requests, we can wait because these tests are not critical to medical care. But, of course, other genetic tests are critical to medical care and that puts our lab in a difficult position because—at the very least—we are faced with the financial liability of an unpaid claim.

"But if we choose not to run the genetic test, then our lab faces the potential of some sort of lawsuit for malpractice," he added. "Stated another way, if our lab does not run the genetic test because the physician did not send us the prior authorization with the lab test order and the patient is denied necessary care or treatment, then who's to blame? Naturally, we feel compelled to do the right thing for the patient and rendering the genetic test results is the right thing," he concluded.

Will System Be Improved?

The issues encountered by this lab when working with physicians and Anthem are consistent with the issues described in an earlier interview published in the previous issue of THE DARK REPORT. Both labs are devoting considerable resources to understand the new Anthem/Aim genetic test prior-authorization program. If other lab managers have experiences to share, they can contact our editor. TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Genetic testing for dogs is the goal of **Embark Veterinary**, of Boston, Mass. Founded in 2015, the company just raised $4.5 million from investors, including Anne Wojcicki, founder of **23andMe**. Company executives say the genetic testing will help vets, pet owners, and breeders identify the disease risk of the dogs, as well as the animals' ancestry. The test can help breeders identify which dogs are carriers for specific health conditions to help the breeder avoid breeding two carriers. The test costs $199 (compared to 23andMe's price of $149 for a human genetic test).

MORE ON: *Embark*

Embark Veterinary says that it has a library of 200,000 genetic markers for canines. It can also identify 175 breeds. Consistent with the well-known fact that pet owners regularly pay their vet bills in cash, Embark believes there is demand for such a genetic test, pointing out that owners spent $66.8 billion on their pets last year.

SONORA QUEST TO ARRANGE LOANS FOR PATIENTS

Earlier this month, **Sonora Quest Laboratories** of Tempe, Ariz., agreed to work with **CarePayment**, a company that helps patients with medical bills. The press release stated: "CarePayment's easy-to-understand 0.00% APR financing solutions [will be offered] to any patient who uses Sonora Quest Laboratories for their medical testing exceeding $100 through a simple process that requires no application and has no impact on credit scores."

TRANSITIONS

• Sherrie Perkins, MD, PhD, is the new CEO of **ARUP Laboratories** of Salt Lake City. Perkins has been with ARUP for 20 years and has served as a member of its executive management team for eight years.

• Andrew Theurer is the new President at ARUP Laboratories. He was previously Senior Vice President and Chief Financial Officer at ARUP.

• **Laboratory Corporation of America** announced that Brian Caveney, MD, JD, MPH, was selected for the newly-created position of enterprise-wide Chief Medical Officer. Caveney was previously at **Blue Cross Blue Shield of North Carolina**.

• David Grenache, PhD, was appointed to be the first Chief Medical Officer for **TriCore Reference Laboratories** of Albuquerque, N.M. He comes to TriCore from the **University of Utah** and **ARUP Laboratories**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...a study by **Fidelity** that concludes Baby Boomer medical laboratory personnel and pathologists may defer their retirements due to the steady increases in the cost of healthcare and medical services.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 18, 2017.