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DIAGNOSTIC TESTING & Emerging Technologies

New Trends, Applications, and IVD Industry Analysis

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Screening Blood Donations for Zika, Costly With Low Yields

Screening the entire U.S. blood supply for Zika virus may not be worth the $42 million price tag. Fifteen months of screening all donations to the American Red Cross yielded only nine Zika-positive donors, according to a study published May 10 in the *New England Journal of Medicine*, and of these only four had an acute infection.

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Genetic Testing Emerges As New Trendy Workplace Benefit

West Coast technology companies competing for talent in a tight job market have begun offering novel health-related benefits, like overnight breast-milk shipping and elective egg freezing. Increasingly, genetic testing is being offered as an in-demand benefit in the current consumer-oriented health care environment.

Despite concerns from experts over the lack of clinical benefit of screening healthy populations for rare mutations, companies and employees are interested. Companies promote the benefit as a means to personalize health care through development of a custom prevention strategy and early detection. Additionally, employers believe that over time such screening may lower health care costs for employees.

Employees largely like the idea. According to the results of a survey conducted on behalf of Wamberg Genomic Advisors, two-thirds of respondents would be interested in genetic testing if their employer offered "easy and affordable" testing and the results were only shared between the employee and their doctor. The survey, of 536 U.S. consumers from 26 to 64 years old with employer-sponsored health insurance, was conducted in the fall of 2017. Wamberg Genomic Advisors reported that one-quarter of employees want genetic testing only if it was free, and nine percent have no interest in employer-offered genetic testing.

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Screening Blood Donations for Zika, Costly With Low Yields, *from page 1*

The American Red Cross processes more than 40 percent of the nation's blood donations. In June 2016 the organization began screening for Zika RNA using the Procleix Zika Virus Assay on the Panther System (Grifols Diagnostic Solutions) under a Food and Drug- (FDA-) approved investigational-new-drug protocol in 16-member minipools. Testing began with donations from five southeastern U.S. states thought to be at high risk. In August 2016, in light of revised FDA guidance, the American Red Cross began testing all blood donations nationally and began the migration from minipool testing to individual donation testing using the same transcription-mediated amplification (TMA) technology.

Donations that initially were reactive were retested in triplicate with the same testing platform. Additional confirmatory testing of reactive donations involved real-time reverse-transcriptase polymerase chain reaction, IgM serologic testing, and red-cell TMA. To assess the sensitivity of minipool TMA, positive individual donations were tested in triplicate in exploratory 16-sample minipools that mixed the reactive donation with 15 nonreactive donations. Costs were calculated for testing conducted between June 2016 and September 2017. The American Red Cross and Grifols Diagnostic Solutions funded this analysis.

Overall, testing yielded a positive predictive value, 5.6%; specificity, 99.997 percent.

The researchers found that of the 4,325,889 donations that were screened over the 15-month period, 9 percent were initially tested in 24,611 minipools, with no reactive donations detected. Of the 3.9 million donations that were subsequently tested individually, 160 were initially reactive with nine confirmed as positive—a rate of confirmed Zika-positive donations of 1 per 480,654. The remaining 151 initially reactive donations were ultimately deemed nonreactive based on alternate nucleic acid testing, serologic testing, or additional TMA testing. Overall, testing yielded a positive predictive value, 5.6%; specificity, 99.997 percent.

Four of the nine confirmed-positive donations were IgM-negative, meaning the blood was collected before seroconversion had occurred. Three of these four donations had enough sample left over to be tested using minipool TMA and all three were reactive. The five confirmed, IgM–positive donations were nonreactive in TMA minipool testing and detection of Zika RNA at index using alternate nucleic acid testing was unsuccessful.

Each confirmed-positive donor consented to participate in the Zika Virus Follow-up Study and provided follow-up samples. Zika RNA levels in red cells ranged from 40 to 800,000 copies per milliliter and were detected up to 154 days after donation, versus 80 days in plasma at levels of 12 to 20,000 copies per milliliter.

Costs for minipool nucleic acid testing were $6, which is similar to that for other transfusion-transmitted viruses for which minipool nucleic acid testing is currently used, the authors say. Costs were $10 for individual-donation nucleic acid testing. Overall, the cost of Zika testing was approximately $41.7

DTET

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> — Evan Block, M.B.Ch.B.

million over the 15-month study period, or approximately $5.3 million per Zika RNA–positive donation.

The authors say this projects to $137 in annual screening costs nationally, which would pose "an additional strain" on the blood industry.

"The argument we're trying to make is that Zika should be treated just like West Nile or HIV … and not have to test each donation individually. Because it's certainly a waste of resources and a waste of our capacity," senior author Susan Stramer, from the American Red Cross, told *STAT News*.

Back in December 2017 the expert Blood Products Advisory Committee advised the FDA that the blood supply operators be allowed to revert to pooled testing for Zika. But as of mid-May, the FDA hasn't instituted the change.

"There is no doubt that Zika poses a major public health threat. However, the actual and perceived risks to the blood supply seem to be conflated," writes Evan Block, M.B.Ch.B., from Johns Hopkins University in Baltimore, Md., in an accompanying editorial. Yet, Block and colleagues say, "Cessation of blood-donation screening may actually prove to be far more challenging than the decision to start. Indeed, there is no historical precedent for the termination of a blood-donation testing program for a given pathogen."

Takeaway: Individual testing of all U.S. blood donations is costly with very low yield. The blood industry is awaiting a possible recommendation by the FDA to return to pooled testing.

Current Testing Criteria Miss Breast Cancer Mutations

Women who do not meet breast cancer genetic testing criteria have a similar number of cancer-associated mutations as women who do meet the criteria, according to two separate studies presented at the American Society of Breast Surgeons meeting (Orlando, Fla.; May 2-6). In both studies, which evaluated differing criteria, the authors question the efficacy of existing clinical testing criteria, saying that actionable mutations likely remain undetected in women not meeting the current guidelines for testing..

In the first study Peter Beitsch, M.D., from TME Breast Cancer Network in Dallas, Texas, and colleagues showed that women are missed when the National Comprehensive Cancer Network (NCCN) guidelines are used.

The researchers created a community-based registry based on patients from 18 breast physicians experienced in cancer genetic testing and counseling. Participants underwent testing with an 80-gene panel test (InVitae Multi-Cancer Panel) to determine differences in the incidence of pathogenic and likely-pathogenic (P/LP) mutations based on meeting or not meeting NCCN testing criteria.

While the study has an accrual goal of 1,000 patients, these early results are for 235 patients with available genetic testing results. To date, 12.4 percent

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> — Peter Beitsch, M.D.

of patients who met NCCN criteria had test results with a P/LP mutation versus 11.5 percent of patients who did not meet criteria, but had a P/LP mutation. While the percentage of mutations was similar whether or not women met testing criteria, the detected variants varied by testing eligibility. BRCA1/2 and other common variants were more likely to be detected among women who met NCCN testing criteria, while women not meeting the criteria had a larger proportion of less common variants, but that still have guidelines for clinical management.

Beitsch reported that had the nonguideline-compliant patients been tested only for the 11 mutations recommended by NCCN, more than 40 percent of the detected variants would have been missed.

"Economically based guidelines for genetic testing of breast cancer patients are anachronistic, miss a significant number of pathogenic variants, and we believe they should be abolished immediately," Beitsch said during a press briefing at the conference.

A second study similarly found that the rate of LP/P variants was similar among patients who did and did not meet criteria for BRCA1/2 genetic testing, but this group used Medicare criteria for genetic testing, which focuses on high-risk genes and requires the patient to have a cancer diagnosis.

Three-quarters of the 1,990 patients in the cohort met Medicare testing criteria. Positive results were similar between the groups regardless of whether just BRCA1/2 results were considered or whether all positive genetic mutations were considered. The researchers estimate that almost half of Medicare patients with actionable variants will be missed if testing is restricted to those meeting current Medicare testing criteria.

"These criteria do not adequately reflect evolving genetic knowledge, and they miss patients who should have increased cancer screening or should receive different systemic therapy," said Jennifer Axilbund, from the genetic testing company Invitae. "Testing criteria should be broadened to include unaffected individuals with a positive family history and affected individuals with less severe presentation."

Takeaway: Analysis reveals that women who do not meet two different breast cancer genetic testing criteria still have a similar number of cancer-associated mutations to women who do meet the criteria.

Expanded Carrier Screening IDs Rare Variants in Diverse Populations

Expanded next-generation sequencing-based carrier screening improves detection of rare and novel pathogenic variants even in a pan-ethnic population, according to a study published May 10 in the *American Journal of Human Genetics*. Despite patient interest, given the remaining challenges of classifying the significance of novel variants, the authors say that making expanded carrier screening available to everyone will require further enhancement in interpretation.

Traditionally, carrier screening focused on targeted disorders for certain ethnic populations, but there has been rapid expansion in the breadth of genes that can be screened for with NGS technology. Experts caution, though, that the utility of using this technology in routine care among healthy populations remains unclear, as does the downstream impact of clinical application.

As part of the NextGen study, researchers used NGS to analyze a pre-selected list of 728 genes known to be associated with disorders (autosomal-recessive and X-linked conditions), plus 148 genes for medically actionable conditions, among 131 women and their partners (n = 71) who were planning a pregnancy. Only pathogenic and likely pathogenic variants were confirmed and reported.

The researchers found that an average of 1.5 variants per individual, for a total of 304 variants. More than three-quarters of participants (78 percent) were carriers for at least one of the 700 tested-for conditions. Twelve carrier couples were identified as carrier for common conditions, including eight for hereditary hemochromatosis. Among the novel variants identified, one was reported in F8, known to be associated with hemophilia A. Prenatal testing showed that the male fetus harbored this variant and the neonate suffered a life-threatening hemorrhage, which was anticipated and appropriately managed. Just under half of all variants (48 percent) were missense. Additionally, 3 percent of participants had variants that were medically actionable.

The vast majority of the participants (93 percent) wanted to receive information for all categories of carrier results, whether the disorder was mild, severe, adult-onset, or unpredictable. Seven percent did not want to know their carrier status for unpredictable or adult-onset onset conditions, but nearly every participant (99 percent) requested the return of medically actionable findings.

"The 2015 American College of Medical Genetics and Genomics variant interpretation guideline is a powerful tool for systematic and organized classification for rare and novel variants that are detected by genomic sequencing," write the authors led by Sumit Punj, from Oregon Health & Science University in Portland. "In our experience, the ability to accurately classify variants and predict outcomes is more challenging in a healthy population than in an affected individual and is less robust than in individuals presenting with an adverse phenotype."

Takeaway: While NGS-enabled expanded carrier screening detects more rare variants than traditional screening, the ongoing challenges of classifying the significance of novel variants remains a barrier to routine clinical use of expanded carrier screening.

INSIDE THE DIAGNOSTICS INDUSTRY

New Study Provides Most Comprehensive Overview of Genetic Test Development, Usage and Spending

As might be expected, there has been rapid growth in genetic test availability and spending on these tests since 2014. But, comprehensive new collaborative analysis conducted by Concert Genetics (Franklin, Tenn.) and researchers from University of California San Francisco shows that 10 new tests enter the market daily.

The most rapid growth in spending occurred on genetic tests for prenatal health, hereditary cancer, and multigene panels. The study, published in the May special issue of *Health Affair*s on precision medicine, holds substantial health policy implications, including for current debates over the most appropriate means for regulatory oversight and payer coverage of these emerging tests.

"The rapid growth in test availability and spending is a result of the convergence of multiple forces that have implications for relevant health policies," explains lead author Kathryn Phillips, Ph.D., from University of California San Francisco. "These forces include the clinical need for better tools to predict, diagnose, treat, and monitor disease; increased understanding of the molecular basis of disease; patient demand; industry investment; and regulations that allow the marketing of tests without [Food and Drug Administration] approval."

Unique Data

The researchers undertook this comprehensive analysis to fill a gap in empirical evidence on test availability and spending reflective of the overall genetic testing landscape and not just specific genes or a single payer. This was enabled through use of proprietary data from Concert Genetics' test catalog and its genetic testing claims database on commercial payer spending for privately insured populations.

The test catalog database contains information from public websites that has been curated, standardized and organized using tools developed by Concert Genetics. The dataset tracks existing and new tests marketed by CLIA-certified laboratories, as long as the laboratories market the tests externally. This data was used to evaluate trends in genetic test products available from 257 laboratories between March 2014 and August 2017.

Tests were characterized by the clinical domain they are used in (e.g., prenatal tests, hereditary cancer tests, oncology diagnostics and treatment, biochemical tests, pharmacogenetic tests, noncancer hematology tests, human leucocyte antigen typing, neurological tests, gastroenterological tests, tests for identity and forensics, tests of disease risk, cardiological tests, and tests for pediatric and rare diseases). Tests were also classified by type (e.g., single-gene tests, multiple-gene tests, multi-analyte assays with algorithmic analyses, noninvasive prenatal tests (NIPTs), whole-exome sequencing, whole-genome analysis [conducted using

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> — Kathryn Phillips, Ph.D. & Colleagues

sequencing, microarrays, and karyotype], and miscellaneous Current Procedural Terminology [CPT] codes).

Concert Genetics' genetic testing claims database was used to examine commercial payers' spending on genetic tests from January 2014 through December 2016. More than 1.7 million commercial payer claims for genetic tests were submitted over the three-year, which contains information for approximately 40 million covered lives from all 50 states and 28 health plans, excluding Medicare Advantage. Relevant claims were identified using the Healthcare Common Procedure Coding System (HCPCS) codes, based on CPT codes. Spending was defined as the allowed amount on the claim, including the amount the health plan paid plus the amount paid by the patient as copayment or coinsurance.

Findings and Implications

The researchers found that over the study period there were approximately 75,000 genetic tests on the market, representing approximately 10,000 unique test types. The majority of genetic tests (86 percent) were single-gene tests. The remaining tests were multigene panesl, including 9,311 multi-analyte assays with algorithmic analyses, 85 NIPTs, 122 whole-exome sequencing tests, and 873 whole-genome analysis tests, which included whole-genome sequencing tests.

Remarkably, 10 new tests enter the commercial market daily—of which two or three per day are panel tests—with nearly 14,000 tests becoming commercially available since March 2014. For both NIPTs and exome tests, two new tests enter the market each month.

For spending, prenatal tests (including both carrier screening and noninvasive prenatal tests) accounted for the highest percentage of spending on genetic tests highest percentage of spending in 2014–16, ranging from 33 percent to 43 percent per year. The second highest spend came from hereditary cancer tests, which accounted for approximately 30 percent. Interestingly, spending on oncology diagnostics and treatment was only about 10 percent of total spending, while pharmacogenetic testing accounted for less than 5 percent of all spending.

Phillips and colleagues write that, "Factors contributing to the growth of NIPTs include that these tests meet a clinical need by being an alternative to prenatal screening methods that incur a risk of miscarriage (such as amniocentesis) and that private payers have moved quickly to cover NIPTs for high-risk women."

But not all genetic tests have had these favorable conditions, potentially stymying clinical adoption among tests in other clinical domains.

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"Regulatory and coverage mechanisms need to evolve to keep pace with the growth and expansion of genetic tests," write the authors. "Traditional means of regulating tests one kit or process at a time may be a poor fit for the current landscape. The rapid influx of tests and the fact that many genetic tests are lab-developed tests that do not require FDA approval create regulatory and coverage policy challenges."

The authors say that there is continued need to develop better evidence on the number, types, and quality of tests to inform future policy.

"Such evidence can be useful to multiple stakeholders," the authors explain. "Patients and providers benefit from knowing what tests are available, payers benefit from the ability to focus on rapidly growing test categories with high current spending and significant predicted future growth, research funders benefit from understanding future trends to support research, test developers benefit from a deeper understanding of market trends for product development, and the government benefits from being able to target key policy development efforts precisely."

Takeaway: This comprehensive analysis of the genetic testing landscape verifies growth in commercially available tests and private spending on such tests. It further highlights the strong adoption of NIPTs, but suggests the need for greater clarity around reimbursement policy for other genetic tests.

Blood Cultures for Cellulitis Commonly Needlessly Ordered

Despite existing recommendations, blood culture is overused in patients with suspected, uncomplicated cellulitis, according to a research letter published April 2 in *JAMA Internal Medicine*.

"Cellulitis is a common bacterial skin infection affecting an estimated 14.5 million American annually. In 2014, the Infectious Disease Society of America released evidence-based guidelines against the use of blood cultures except in patients who were highly immunocompromised, exhibiting systemic toxic effects, or who had sustained animal bites. (The guidelines also advised against imaging in most cases.)

The researchers retrospectively reviewed the cases of 183 patients seen in Massachusetts General Hospital's emergency department (October 2014 to February 2017) for suspected uncomplicated cellulitis and who were subsequently admitted to inpatient medicine or an observation unit. The clinical usefulness and cost of blood cultures (and imaging) was evaluated.

Despite the existing recommendations, nearly one-third of patients (32.8 percent) received blood cultures, but only 18 of the 60 blood cultures were appropriately ordered. Growth was detected in just one of these 60 cultures.

> *"Radiologic imaging and blood cultures have low clinical usefulness for evaluation and treatment of cellulitis."*
>
> — Lauren Ko

The authors said that results from blood cultures "seldom" altered diagnosis or treatment.

Based on estimates of blood culture costs and imaging (which was ordered inappropriately in two-thirds of all patients), the yearly cellulitis hospitalization rate, and the rate at which imaging and blood cultures were ordered within this cohort, the authors estimated that approximately $226.9 million dollars is spent annually on these "largely clinically useless diagnostic studies."

"Radiologic imaging and blood cultures have low clinical usefulness for evaluation and treatment of cellulitis," write the authors led by Lauren Ko, from Harvard University in Boston. "In addition, they portend significant cost to the health care system."

Takeaway: Blood cultures are commonly inappropriately ordered in the diagnostic workup of patients with suspected cellulitis.

HCV Screening Rates Very Low Among Exposed Infants

The number of pregnant women infected with hepatitis C virus (HCV) is growing rapidly due to the opioid epidemic, yet most prenatally infected children are not being screened, despite the risk that approximately 6 percent will become infected, according to a study published May 2 in *Pediatrics*. Less than one-third of HCV-exposed infants receiving well-child care are being tested for HCV.

"Without appropriate screening, children who are at risk for perinatal transmission may remain undiagnosed until they become symptomatic or have abnormal liver enzyme levels found incidentally," write the authors led by Catherine Chappell, M.D., from University of Pittsburgh in Pennsylvania. "Delays in diagnosis could lead to delays in appropriate referrals and curative treatment or irreversible liver disease, such as cirrhosis or hepatocellular carcinoma."

According to recommendations from the Infectious Diseases Society of America, all infants born to HCV-infected women should be screened for HCV with an HCV antibody test at or after 18 months of age. (Before age 18 months, HCV RNA can be detected by a polymerase chain reaction (PCR), but this is not the screening test of choice for perinatal HCV transmission and chronic pediatric HCV infection.)

Researchers retrospectively identified a cohort of pregnant, HCV-infected women who delivered at the University of Pittsburgh Medical Center health system between 2006 and 2014 through billing codes. Infant records linked to the HCV-infected pregnant women were assessed for the receipt of well-child services in the same health care system, defined as the presence of hemoglobin and/or lead testing at or after nine months of age. The status of HCV screening was assessed in this cohort.

The researchers found that 1,043 HCV-infected pregnant women delivered over the study period (1.2 percent of all deliveries). The prevalence of HCV increased by 60 percent over the nine years. Roughly one-third of infants

> *"Given the difficulties involved with risk-based screening and the increasing prevalence of HCV among pregnant women, consideration should be given to the evaluation and implementation of universal HCV screening during pregnancy, especially in high-prevalence areas."*
>
> — Catherine Chappell, M.D. & Colleagues

(n=323) received well-child services in the health care system, but less than one-third of these exposed infants (30 percent) were screened for HCV. Infants whose mothers had a diagnosis of opioid use disorder were more likely to receive HCV screening.

Of the 96 screened infants, three-quarters were screened with HCV antibody tests, while one-quarter were screened with HCV PCR tests, and 3 percent were screened with both tests simultaneously. Suboptimal HCV screening was performed in 23 children either because HCV antibody tests were sent before 18 months of age (48 percent) or because HCV PCR tests were sent after 18 months of age (52 percent).

The authors say that one reason for low screening of infants is that maternal HCV status may not transfer to pediatric records. Furthermore, the authors suspect that the prevalence of HCV-infected pregnant women and exposed infants could be underreported, since HCV is not universally tested for during pregnancy.

"Given the difficulties involved with risk-based screening and the increasing prevalence of HCV among pregnant women, consideration should be given to the evaluation and implementation of universal HCV screening during pregnancy, especially in high-prevalence areas," write Chappell and colleagues.

Takeaway: HCV screening of prenatally exposed infants during well-child care is extremely low. Given the increasing prevalence of HCV in reproductive-aged women as a result of the opioid epidemic, strategies are needed to increase screening during pregnancy in exposed infants.

Home-Based Hospital Care Model Cuts Lab Utilization

Hospital care is notoriously expensive and potentially risky for older adults. There is interest in the home-hospital concept where acute services are provided in a patient's home, with the hope of improving the patient experience and reducing costs, while maintaining quality care.

A small study published in the May issue of the Journal of General Internal Medicine shows early evidence that use of home-hospital care does in fact cut costs, benefits the patient experience, and maintains quality of care. While optimal patient selection is important, the model cuts costs due to decreased utilization of services, including a significant decline in laboratory testing, compared to similar patients cared for in the hospital.

Nine patients were randomized to home hospitalization and 11 to usual hospital care for the treatment of infection or exacerbation of heart failure, chronic obstructive pulmonary disease, or asthma, following an emergency room visit.

The home hospital care intervention included two daily nurse visits, one daily physician home visit, intravenous medications, continuous monitoring for

> *"Reimagining the best place to care for select acutely ill adults holds enormous potential."*
>
> — David Levine, M.D. & Colleagues

heart rate, respiratory rate, telemetry, movement, falls, and sleep via a small skin patch, video communication, and point-of-care blood testing.

The researchers found that there were no adverse safety events and no transfers back to hospital among home-care patients. For home patients median direct costs were 52 percent lower than for usual care inpatients. Furthermore, for home patients the median direct costs for the acute care plus 30-day post-discharge period was 67 percent lower than for inpatients. Home patients had fewer readmissions, but they also had significantly fewer laboratory tests ordered during the care episode—a median of six versus 19 for inpatients.

David Levine, M.D., the study's lead author, tells DTET that the point-of-care test conducted most frequently in at-home patients was the basic metabolic panel, whereas complete blood counts and metabolic panels were most frequently not ordered, compared to inpatients. He says that lab testing in the home setting was only conducted when it would change clinical management. Levine also credits "a wonderful collaboration" with the laboratory for making home-based care feasible. He said that the hospital laboratory was able to process home hospital lab tests (drawn at nurse and doctor visits) in a timely manner and in multiple locations.

"Reimagining the best place to care for select acutely ill adults holds enormous potential," writes Levine and colleagues from Brigham and Women's Hospital in Boston, Mass. "This differs from most home-based models in its ability to handle high patient acuity and enmesh physician medical decision-making with a patient-tailored care team. Careful patient selection also minimized risk."

Takeaway: Laboratory test utilization is significantly reduced in the home-hospital model. This care model is one the laboratory industry should watch.

Genetic Testing Emerges As New Trendy Workplace Benefit, *from page 1*

Color (San Francisco), which built its initial business through offering low-cost physician-ordered genetic testing for hereditary cancer risk, has now become a notable player in the employee genetic screening market. The company's platform enables employees of companies like Snapchat, Visa, and Salesforce to confidentially gain information about their genetic risk for common hereditary cancers and inherited heart conditions in consultation with Color's genetic counselors. Ongoing follow-up includes reanalysis in light of changes to guidelines, risk information, or variant classification. Additionally, Color provides the employer a monthly aggregated, de-identified analysis of employee participation.

Yet, both legal and genetic experts have concerns about privacy protections and the downstream health care utilization as a result of the genetic tests. There is concern on both ends of the spectrum that this information could lead healthy people with average disease risk to forgo recommended screening tests, like colonoscopies, as a result of false assurance from genetic tests. There is also concern that broadening the use of these tests for rare genetic conditions to the broader population could also lead people to undergo unnecessary medical procedures, as a result of concerns about test results.

Takeaway: Employees and employers are eagerly jumping into the use of genetic testing as a wellness benefit, despite ongoing concerns from legal and genetic experts.