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HIGHLIGHTS

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Upcoming Events

Lab Institute 2018

Surviving Disruption: Rethinking Business Models, Technologies, and Competitive Strategies in a Changing Lab Market

Oct. 24-26, Washington, DC
www.labinstitute.com

FDA Watch: Agency Issues New Guidance to Ease Approval of NGS Tests & IVD Devices

April 13 was a red letter day for FDA guidance with the agency issuing a pair of final guidances on the design, development and validation of next-generation sequencing (NGS) tests, as well as a draft guidance outlining a proposed new voluntary, streamlined submission process for evaluating the risks of investigational in vitro diagnostics (IVDs) being codeveloped alongside a trial cancer drug. Here is the lowdown on all three sets of guidance:

Final Guidance 1: Using Public Genetic Variant Repositories to Show Clinical Validity of NGS Tests

The two final guidances are designed to make it easier and more efficient to develop NGS tests. The first final guidance, which bears the catchy title "Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic & Genomic-Based In Vitro Diagnostics," explains how test developers can rely on FDA-recognized public genetic variant repositories to support the accuracy of their tests and related marketing claims.

A "genetic variant database" means a publicly accessible database of human genetic variants that aggregates and curates reports of human genotype-phenotype relationships to a disease or condition with publicly available documentation of evidence

Continued on page 2

Market Report: 2018 Shaping Up as Record Year for Healthcare Industry Mergers & Acquisitions

While healthcare industry merger and acquisition activity has been on the rise for several years, the early returns suggest that 2018 will be the biggest M&A year in over a decade. According to Bloomberg, $156 billion in deals have been done so far this year. And that number exceeds $200 billion if you count Takeda Pharmaceutical Company's pending $45 billion acquisition of Shire.

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FDA Watch: Agency Issues New Guidance to Ease Approval of NGS Tests & IVD Devices, *from page 1*

supporting those linkages, the guidance explains. While as a best practice, such databases should follow an open-access model, databases that use licensing models and charge fees for commercial use may also qualify and be used to support clinical validity of genetic or genomic tests, the guidance continues.

Criteria of reliability includes a genetic variant database that:

- Operates so as to provide sufficient information and assurances regarding the quality of source data and its evidence review and variant assertions;
- Offers transparency regarding its data sources and operations, particularly on how variant evidence is evaluated;
- Collects, stores and reports data and conclusions in compliance with all applicable requirements regarding protected health information, patient privacy, research subject protections and data security; and
- Houses genetic variant information generated by validated methods.

Final Guidance 2: Design of NGS Tests for Diagnosing Germline Diseases

The other final guidance ("Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing (NGS)–Based In Vitro Diagnostics (IVDs) Intended to Aid in the Diagnosis of Suspected Germline Diseases") explains to test developers the types of data the FDA is looking for in premarket submissions for such tests. Such tests do not include NGS-based tests for aid in the diagnosis of microbial infection, cell-free DNA testing, direct-to-consumer uses, fetal testing, microbial genome identification and detection of antimicrobial resistance and virulence markers, pre-implantation embryo testing, risk assessment, risk prediction, RNA sequencing, screening, stand-alone diagnostic purposes, tumor genome sequencing or use as a companion or complementary diagnostic, the guidance explains.

The guidance then lists recommendations covering different aspects of NGS test development and quality including:

- NGS test design considerations;
- Test performance and accuracy;
- Test run quality metrics;
- Performance and evaluation studies;
- Supplemental procedures;
- Variant annotation and filtering;
- Presentation of test performance in labeling; and
- Test reports.

Draft Guidance: Determining Risk of Investigational IVDs

The new draft guidance lays out a streamlined process for evaluating investigational IVDs in oncology drug trials, specifically whether the investigational IVD is considered significant risk (SR), nonsignificant risk (NSR) or exempt. The guidance says that the FDA device division would make this risk determination alongside the drug division's evaluation of the investiga-

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tional new drug application. It also calls on sponsors to submit information on how the test results will be used in the clinical trial, discuss the prevalence of the biomarker in the patient population and any risks the biopsy collection process has on study subjects.

If the drug and device divisions find that an investigational IVD in a particular study confers non-significant risk, the FDA will issue a letter instructing sponsors to proceed with the trial ensuring that biopsy procedures do not carry significant risks and report any unanticipated adverse events. If the test is found to carry significant risks, FDA will tell the sponsor to submit an IVD exemption application and wait to start the trial until it is approved. Trials of invasive biopsy procedure presenting serious health risk to study participants would not be eligible for the new streamlined submission process, the guidance notes.

The deadline to comment on the draft guidance is 60 days from the April 13 publication date.

New FDA Approvals

Meanwhile, here's a rundown of the key new FDA approvals announced from late March through mid-April:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Roche	*Premarket approval for expanded use of Cobas EGFR Mutation Test v2 as companion diagnostic test with AstraZeneca's Tagrisso (osimertinib) for non-small cell lung cancer*
Roche	510(k) clearance for Cobas CT/NG assay for use on Cobas 6800 and 8800 systems
Cancer Genetics	Special 510(k) clearance for Tissue of Origin gene expression test
EKF Diagnostics Holdings	510(k) clearance and CLIA waiver for use of DiaSpect Tm hand-held reagent-free hemoglobin analyzer in point-of-care settings
AESKU Group	Clearance of AESKUSLIDES ANCA Ethanol and ANCA Formalin vasculitis test on the Helios automated IFA system
Curetis	De novo clearance of Unyvero molecular diagnostic platform
Curetis	De novo clearance of multiplex lower respiratory tract infections detection test, the first such test to be cleared by FDA
DarioHealth	Clearance of iPhone-compatible blood glucose monitoring system, enabling users to access firm's Dario app on iPhone 7, 8 and X mobile devices
Ortho Clinical Diagnostics	Clearance of Ortho Connect V2.0 integrated and customizable middleware system
DiaSorin	Clearance of Simplexa HSV 1 & 2 Direct assay for running on Liaison MDx instrument for detection and differentiation of herpes simplex virus DNA in lesion swabs
Cepheid	Clearance for Xpert CT/NG Assay running on GeneXpert instrument for automated detection and differentiation of genomic DNA from Chlamydia trachomatis and/or Neisseria gonorrhoeae
Siemens Healthineers	Clearance for received clearance for Atellica IM Total hCG human chorionic gonadotropin assay for early pregnancy detection run on Siemen's Atellica IM Analyzer
Runbio BioTech	Clearance for David Home Pregnancy Test Cassette, over-the-counter lateral flow immunoassay for early pregnancy detection
Guangzhou Wondfo Biotech	Clearance for Preview Digital Pregnancy Test used to detect human chorionic gonadotropin in urine for early pregnancy detection
Phadia	Clearance for Elia PR3s immunoassay for measuring IgG antibodies targeting proteinase 3 in human serum and plasma

Continued on page 4

NEW FDA APPROVALS, *Cont'd.*

Manufacturer(s)	Product(s)
Phadia	Clearance for Elia MPOs immunoassay for measuring IgG antibodies targeting myeloperoxidase in human serum and plasma
Phadia	Clearance for Elia GBM assay for measuring IgG antibodies to α3 chain of collagen IV in human serum and plasma
Diazyme	Clearance for latex particle enhanced immunoturbidimetric assay for determination of lipoprotein(a)
Becton Dickinson	Clearance for BD Veritor System rapid chromatographic immunoassay for influenza A and B viral nucleoprotein antigens
Immco Diagnostics	Clearance for ImmuLisa Enhanced RNA POL III Antibody ELISA to detect anti-RNA POL III IgG antibodies in human serum
Hardy Diagnostics	Clearance for Granada Medium agar to detect Group B streptococcus after18 to 24 hours of incubation of Lim broth
Liofilchem	Clearance for MIC Test Strip, a quantitative method that determines antimicrobial susceptibility of bacteria

During the period, the following FDA CLIA waiver was announced:

NEW FDA CLIA WAIVERS

Manufacturer(s)	Product(s)
EKF Diagnostics Holdings	DiaSpect Tm hand-held reagent-free hemoglobin analyzer for use in point-of-care settings

New CE Marks & Global Certifications

Notable European CE certifications:

NEW CE CERTIFICATIONS

Manufacturer(s)	Product(s)
Curetis	CE/IVD marking for Unyvero UTI test cartridge diagnosing severe urinary tract infections run on company's Unyvero platform
Mobidiag	CE/IVD marking for Amplidiag CarbaR+MCR single test to detect main carbapenemase-producing organisms and colistin resistance markers
Mobidiag	CE/IVD marking for Novidiag Bacterial GE+ molecular diagnostic test concurrently identifying common enteric pathogens from stool samples
Beckman Coulter Diagnostics	CE marking for DxH 520 hematology analyzer
CareDx	CE marking for Olerup QType real time human leukocyte antigen typing test
Now Diagnostics	EC Design Examination Certificate authorizing over the counter sale of AdexusDx hCG pregnancy test
Novosanis	CE marking for Colli-Pee self-sampling urine collection device
Emosis	CE marking for HIT Confirm cytometry-based heparin-induced thrombocytopenia test
Seventh Sense Biosystems	CE marking for Tap, one-step push-button TAP blood collection device
Siemens Fast Track Diagnostics	CE marking for real-time PCR assay detecting 14 human papillomavirus subtypes in high-risk patients

Other international clearances announced in the past month:

Manufacturer(s)	Product(s)	Product(s)
Curetis (via its Southeast Asian partner, Acumen Research Laboratories)	Singapore	Clearance to market Unyvero blood culture cartridge to detect more than 103 diagnostic targets associated with sepsis
Myriad Genetics	Japan	Approval to market and manufacture its BRACAnalysis Diagnostic System

Diagnostic Deals: A roundup of the key mergers, acquisitions, alliances, licenses and other strategic transactions from the past month

While M&A activity in the wider healthcare industry is heating up (see related story on page 1) deal making in the diagnostics space remains relatively light, not so much in terms of volume but in size, at least compared to the same period in 2017. Still, the diagnostic industry remains strategically active, particularly in forging new alliances and collaborations. Here is an overview of what happened from late March to mid-April.

M&A

The biggest deal of the period, and for all of 2018 so far, was the closing of Roche's $1.9 billion acquisition of Flatiron Health. The oncology EHR software developer will continue to operate as a separate entity under its current business model while retaining its network of community cancer clinics, academic research centers and therapeutic oncology companies. Also closing was BioMérieux's acquisition of protein biomarker developer Astute Medical for $90 million in cash.

On April 17, Hong Kong-based Prenetics made a move into consumer genomics by acquiring UK firm DNAFit for $10 million, which will continue to maintain its own brand and London HQ.

Meanwhile, Amarantus Bioscience announced that it has reacquired the rights to three neurology tests from Avant Diagnostics, including MSPrecise, NuroPro and LymPro Test. Under the deal, Amarantus will cancel $722,000 of liabilities owed by Avant and issue it 1 million shares of its common stock. In return, Avant will issue an additional 32 million shares of its common stock to Amarantus to repay the debt.

Strategic Alliances

Key alliances during the period paired leading diagnostic providers with major pharmaceuticals and biopharm companies, including:

- A pair of deals involving Illumina, one with Bristol-Myers Squibb aimed at developing new companion diagnostics tests for use with drugs in the BMS pipeline, and another with Loxo Oncology for creating sequencing-based pan-cancer diagnostics for Loxo's targeted oncology drugs;
- PATH and Mologic's collaboration to develop and commercialize a rapid diagnostic test for treating *Plasmodium vivax* malaria; and
- Personal Genome Diagnostics's agreement to work with Five Prime Therapeutics to develop a blood-based companion assay for use with the bemarituzumab investigation drug.

A pair of deals involving Illumina, one with Bristol-Myers Squibb aimed at developing new companion diagnostics tests for use with drugs in the BMS pipeline, and another with Loxo Oncology for creating sequencing-based pan-cancer diagnostics for Loxo's targeted oncology drugs;

Here's a summary of the key diagnostic deals from late March through mid-April:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
Roche	Flatiron Health	■ Price: $1.9 billion ■ Status: Closed ■ Roche already held 13% stake in Flatiron ■ Acquisition of Flatiron's oncology technology assets boosts Roche's personalized healthcare infrastructure
Agilent	Lasergen	■ Price: $105 million ■ Status: Agreement exercising option to acquire remaining shares of NGS tech firm with no closing date announced ■ In 2016, Agilent acquired a 48% equity stake in company ■ Plan is to combine Agilent's engineering expertise with Lasergen's sequencing chemistry to build entire clinical sequencing workflow ■ Newly merged firm to be called LaserGen
Prenetics	DNAFit	■ Price: $10 million ■ Status: Closed ■ Acquisition of UK-based wellness genetics company represents entry of Prenetics, known for pharamacogenomics and reproductive testing, into consumer genomics market
Aurora Diagnostics	Cascade Pathology Services	■ Price: Undisclosed ■ Status: Closed ■ In addition to Oregon physician-owned multispecialty pathology practice, Aurora acquires Cascade Cytology Reference Laboratories, an affiliated lab providing cytology support services to physician groups ■ Aurora now owns 32 physician practices
BioMérieux	Astute Medical	■ Price: $90 million in cash ■ Status: Closed ■ Astute produces tests for identifying and validating protein biomarkers of medical conditions, including Nephrocheck, an FDA cleared test assessing risk of kidney injuries
UCB	Element Genomics	■ Price: $30 million, including upfront and short-term success-based milestone payments ■ Status: No closing date announced ■ Acquisition of Duke Univ. biotech spinout bolster UCB's biopharm development pipeline ■ Element to remain based in Durham, NC, while working with UCB international research teams
Thompson Street Capital Partners (private equity firm)	Transnetyx	■ Price: Undisclosed ■ Status: No closing date announced ■ Thompson Street to acquire YX Genomics Holding, the holding company of Transnetyx, lab management services firm YX Services, and robotics company RobotYX
Apax Partners	Minority stake in Vyaire Medical held by Becton Dickinson	■ Price: $435 million in cash ■ Status: Expected to close by end of April ■ BD to use proceeds in line with its broader capital allocation strategy and says that divestiture will not no material impact on FY 2018 revenue or adjusted earnings
Mars Petcare	OptiGen	■ Price: Undisclosed ■ Status: Closed ■ Mars acquires DNA diagnostics company specializing in canine inherited disorders, exclusive licenses to genetic disease tests and biobank of over 150,000 samples

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Quest Diagnostics	Humana + Multiplan + UnitedHealth Group's Optum + UnitedHealthcare	■ Objective: Create national alliance to use blockchain technology to improve quality data and cut administrative costs ■ Dynamic: Launch of pilot program ■ evaluating how sharing data across healthcare organization on blockchain technology can improve data accuracy, streamline administration and improve access to care
Mologic	PATH	■ Objective: Develop rapid diagnostic test (RDT) to support treating and eliminating Plasmodium vivax malaria ■ Dynamic: International nonprofit PATH to support Mologic in commercializing and getting regulatory approvals for RDT

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Illumina	Bristol-Myers Squibb	▪ Objective: Develop companion DX tests for BMS' cancer drug pipeline ▪ Dynamic: Create diagnostic version of Illumina's TruSight Oncology 500 biomarker assay to run on Illumina's NextSeq 550Dx platform
Illumina	Loxo Oncology	▪ Objective: Develop sequencing-based pan-cancer companion diagnostics for two of Loxo's targeted oncology drugs ▪ Dynamic: Companies to use Illumina's TruSight 170 panel to create test for Illumina's NextSeq 550Dx platform ▪ Plan is to validate NTRK fusions and RET fusions/mutations assays as Class III FDA-approved diagnostic in conjunction with Loxo's larotrectinib and LOXO-292, respectively
Thermo Fisher Scientific	Biocept	▪ Objective: Form broad commercial collaboration ▪ Dynamic: As first step, Biocept's lab to validate Thermo Fisher's Oncomine NGS liquid biopsy panels ▪ Thermo Fisher intends to designate Biocept as a Center of Excellence clearing way for oncology liquid biopsy initiatives
Agilent Technologies	BioTek Instruments	▪ Objective: Develop integrated product for cellular metabolic analysis and imaging ▪ Dynamic: Integrate Agilent's Seahorse XFe96/XFe24 Analyzers with BioTek's Cytation 1 Cell Imaging Multi-Mode Reader
RTI International	PierianDx	▪ Objective: Promote PierianDx's genomics platform ▪ Dynamic: RTI also to make undisclosed investment and provide other strategic support to advance PierianDx's growth plan
DiaCarta	MIODx	▪ Objective: Develop test to predict immunotherapy response based on MIODx's ClonoMap immune sequencing technology ▪ Dynamic: Test to be developed and validated at DiaCarta's San Francisco Bay Area and Nanjing, China labs
PerkinElmer	Helix + NorthShore University Health System	▪ Objective: Develop two new DX applications for Helix's online genomics marketplace ▪ Dynamic: PerkinElmer to develop and launch first app used to report pathogenic variants in 59 genes linked to serious diseases on marketplace ▪ NorthShore to apply its genetic risk scoring tech to create method of assigning polygenic prostate cancer risk score on marketplace
PerkinElmer	Biotechnology Industry Research Assistance Council	▪ Objective: Promote India-led biomed, biotech and public health startups ▪ Dynamic: Parties sign letter of intent agreeing to work together for five years
UgenTec	Serosep	▪ Objective: Add Serosep's EntericBio assays to UgenTec's FastFinder platform ▪ Dynamic: Partnership similar to UgenTec's existing arrangements with MDxHealth, Fast Track Diagnostics and SpeeDx
UgenTec	Hamilton Robotics	▪ Objective: Remedy lab automation issues in molecular diagnostics industry ▪ Dynamic: Launch of New Molecular Automation Network, consortium to promote partnerships facilitating exchange of business and technical info between labs and manufacturers of automated liquid handling workstations, real-time PCR devices and software ▪ UgenTec and Hamilton Robotics to exchange technical expertise and integrate their software and hardware systems
IncellDx	CellMax Life	▪ Objective: Develop and market circulating tumor cell tests ▪ Dynamic: CellMax to combine its CTC isolation technology with IncellDx's BioINK microfluidic reagents ▪ Tests to be processed at CellMax's California lab and jointly marketed in US by CellMax's sales force
ArcherDX	Washington University in St. Louis	▪ Objective: Study minimum residual disease in pediatric acute myeloid leukemia patients ▪ Dynamic: Researchers to use ArcherDX's sequencing technology to analyze patients in clinical trial analyzing different treatments of pediatric AML patients with Down syndrome
ArcherDX	Ambry Genetics	▪ Objective: Provide immune repertoire sequencing services to biopharms ▪ Dynamic: Ambry to use ArcherDX's Immunoverse and VariantPlex NGS assays for immune repertoire sequencing and chimeric antigen T cell receptor manufacturing characterization
Protagen	Gustave Roussy Institute of Oncology	▪ Objective: Identify biomarkers for immune system-related side effects in cancer patients treated with checkpoint inhibitors ▪ Dynamic: Protagen's SeroTag platform for simultaneously measuring autoantibody levels for different antigens to be used to test cancer immunotherapy patients for markers linked to immune-related adverse events ▪ Ultimate goal is to develop risk-profiling test for immunotherapy patients
PathoQuest	Charles River Laboratories	▪ Objective: Expand previously announced partnership for delivery of NGS services to biologics industry ▪ Dynamic: Charles River to directly invest unspecified amount in PathoQuest

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Personal Genome Diagnostics	Five Prime Therapeutics	▪ Objective: Develop blood-based companion DX assay for use with Five Prime's investigational drug candidate, bemarituzumab ▪ Dynamic: PGDx to create and validate circulating tumor DNA test to identify patients eligible for treatment with drug ▪ Five Prime to use to select patients for Phase 3 of its registrational FIGHT trial evaluating bemarituzumab in combination with chemotherapy as front-line treatment in patients with advanced gastric or gastro-esophageal junction cancer with FGFR2 amplification
3D Signatures	MDxHealth	▪ Objective: Evaluate 3DS's Telo-PC test for prostate cancer for use on TeloView software platform ▪ Dynamic: Companies to share study costs ▪ 3DS to also grant MDxHealth an exclusive licensing option for Telo-PC test
Agena Bioscience	Simcere Diagnostics (subsidiary of Simcere Pharmaceutical)	▪ Objective: Develop and market companion DX and pharmacogenomic tests in China ▪ Dynamic: Simcere to develop panels based on Agena's MassArray mass spectrometry-based genetic analysis system for Chinese market with Agena to provide commercial support
Biodesix	Checkmate Pharmaceuticals	▪ Objective: Biomarker research studying circulating proteome of patients with advanced melanoma treated with CMP-001 in combination with pembrolizumab ▪ Dynamic: Researchers to use Biodesix's Diagnostic Cortex AI-based biomarker discovery platform
Laboratory Corporation of America	Appalachian Regional Healthcare	▪ Objective: Form multiyear lab partnership ▪ Dynamic: LabCorp Diagnostics to provide technical services for the health system's hospital-based labs and reference testing for its entire network ▪ Appalachian to also gain access to LabCorp Diagnostics' info technology and data analytics services to improve patient care
GenePOC	Primerdesign (molecular testing division of Novacyt)	▪ Objective: Develop molecular influenza and respiratory virus assay ▪ Dynamic: Primerdesign to develop test for influenza A, influenza B and respiratory syncytial virus to be run on GenePOC's Revogene instrument ▪ GenePOC will to seek CE-IVD marking and FDA clearance for test

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
Twist Bioscience	Recenttec KK	▪ Products: Twist's synthetic DNA and NGS products including new exome and custom target enrichment product ▪ Territory: Japan
Twist Bioscience	LnCBio (subsidiary of DNA Link)	▪ Products: Twist's synthetic DNA and NGS products including new exome and custom target enrichment product ▪ Territory: Korea
Twist Bioscience	Premas Life Sciences	▪ Products: Twist's synthetic DNA and NGS products including new exome and custom target enrichment product ▪ Territory: India
Twist Bioscience	BioArrow Technology	▪ Products: Twist's synthetic DNA and NGS products including new exome and custom target enrichment product ▪ Territories: Hong Kong and Macau
Rellergen Biotech	ALK	▪ Product: Rellergen Biotech's Bio-IC allergy diagnostic technology ▪ Territory: China
Ortho Clinical Diagnostics	Thermo Fisher Scientific	▪ Products: 14 assays for monitoring therapeutics, immunosuppressants and drugs of abuse for use on Ortho's Vitros 4600 chemistry system and Vitros 5600 integrated system ▪ Territories: North America, Europe, Africa, and Middle East
Interpace Diagnostics Group	Acupath Laboratories	▪ Products: Interpace's ThyGenX and ThyraMIR tests ▪ Territories: Undisclosed
OncoDNA	PromTest	▪ Products: OncoDNA's tumor profiling products ▪ Territory: Armenia
Streck	Van Xuan Medical Technology	▪ Products: Streck's cell stabilization and molecular products ▪ Territory: Vietnam ▪ Three-year distribution agreement

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
Genedrive	Arkray Healthcare	▪ Products: Genedrive HCV ID kit and platform ▪ Territory: India ▪ Genedrive responsible for product development, quality management and manufacturing; Arkray responsible for sales, marketing, customer support and distribution in India
Akers Biosciences	Diagnostica Stago	▪ Product: Akers Biosciences' PIFA PLUSS RF4 Rapid Assay for heparin-induced thrombocytopenia ▪ Territory: US ▪ Three-year distribution agreement
LICENSES		
Licensor	**Licensee**	**Deal Summary**
SUNY Upstate Medical	Quadrant Biosciences	▪ Property: Undisclosed epigenetic biomarker technology for autism spectrum disorder ▪ Expansion of existing collaboration
Penn State University	Quadrant Biosciences	▪ Property: Undisclosed epigenetic biomarker technology for concussion and Parkinson's disease ▪ Expansion of existing collaboration
System Biosciences	Qiagen	▪ Property: SBI's ExoQuick exosome isolation technology for research use ▪ Worldwide, non-exclusive ▪ Qiagen to use technology in its precipitation-based miRcury Exosome Kits, complementing its spin column-based exoEasy and exoRNeasy products
SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Servicer	**Client**	**Deal Summary**
Owlstone Medical	AstraZeneca	▪ AstraZeneca gets access to Owlstone's Breath Biopsy Services to help in identifying breath-based biomarkers and classification algorithms for COPD with aim of identifying disease phenotypes and the best treatments
Theradiag	Biogaran	▪ Theradiag to supply its Lisa Tracker monitoring kits for use in monitoring responses to biosimilar drugs sold by Biogaran

New Laws: Congress Doubles Penalties for Medicare Fraud & Abuse

Sneaky may be too strong a word. But what is fair to say is that the new hikes in federal health care fraud violation penalties have flown totally under the radar despite their obvious and immediate ramifications for labs, pathology practices and other providers. Here is the rundown of what you need to know.

How It Happened

As is often the case when significant amendments are made to existing legislation, the new penalty provisions were tacked onto a larger bill addressing a totally different topic—in this case, the new federal budget, aka the *Bipartisan Budget Act of 2018* (BBA) that was officially signed into law on Feb. 9, 2018.

Which Laws Were Affected

Of course, funding the federal government is the perfect occasion for tweaking just about any and all activities the budget pays for, including enforcement of health care fraud and abuse laws. Among the laws amended by the BBA are the *Civil Monetary Penalties Law* (CMPL) and the *Anti-Kickback Statute* (AKS). If you want to look them up, the changes are contained in Section 50412 of the BBA.

Higher Civil Penalties Under the CMPL

The CMPL is the foundation of federal health care enforcement because it authorizes the OIG to impose civil monetary penalties and other punishments for Medicare and Medicaid fraud and abuses, including AKS and Stark Law offences. The CMPL lists a schedule of fines for different types of offenses. The BBA doubles (and in some cases more than doubles) those amounts:

New CMPL Civil Penalties

Offense Type	Previous Penalty	New Penalty[1]
Knowingly filing an improper claim for a medical or other item or service	Maximum of $10,000 per claim	Maximum of $20,000 per claim
Knowingly making or causing to be made a false statement, omission or misrepresentation of a material fact in any application, bid or contract to participate or enroll a federal health care program provider or supplier	Maximum $50,000 per false statement	Maximum $100,000 per false statement
AKS violation	$50,000 per violation	$100,000 per violation
Payments made to induce reduction or limitation of services[2]	Maximum $2,000	Maximum $5,000

NOTES:

[1] The numbers are actually less dramatic when you take into account that previous budgets mandated that penalty amounts be indexed for inflation

[2] In addition, some payments to induce reduction or limitation of services that once carried a $5,000 maximum were also increased to a $10,000 maximum

Higher Criminal Penalties Under the AKS

The BBA also jacks up the maximum criminal penalty for an AKS violation from $25,000 to $100,000 while doubling the maximum prison sentence from five to 10 years.

When the New Penalties Take Effect

The penalties went into effect on the same date that the BBA did, Feb. 9, 2018 and apply only to offenses committed on or after that date.

Market Report, *from page 1*

Big Pharma Leads the Way

Much of the impetus for this frantic activity has been supplied by pharmaceutical giants. Big deals in 2018 include:

- GlaxoSmithKline's purchase of Novartis AG's stake in a consumer health joint venture for a reported $13 billion;
- Celgene's $9 billion acquisition of Juno Therapeutics and separate $1.1 billion acquisition of Impact Biomedicines; and
- Multiple acquisitions by Sanofi valued at roughly $15 billion.

Hospital Health Systems

M&A at the hospital health system level has been just as hot and heavy, including:

- A likely merger of Catholic Health Initiatives and Dignity Health that would create the second largest nonprofit health system in the US;
- The pending merger of Jefferson Health and Einstein Health;
- The full-asset-merger of Massachusetts-based Care Group System, which includes Beth Deaconess Medical Center, Lahey Health and a standalone hospital in Newburyport.

The Big One

As heated as things have been so far this year, it appears that 2018's biggest healthcare M&A deal is still in the offing—namely, the proposed $69 billion merger of Aetna and CVS Health. This month, the deal moved one step closer to fruition with shareholders of both principles approving the transaction. Of course, regulatory approval remains the potential fly in the ointment. So, stay tuned...

The Dx Pipeline: A Roundup of the Month's Key New Product Launches

Fluidigm, Qiagen and MNG Laboratories launched multiple products. Here's a rundown of the key diagnostic product launches from late March through mid-April:

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)
Fluidigm	Maxpar Human Immune Monitoring Panel Kit for immune cell profiling in cancer and immune-mediated diseases
Fluidigm	Advanta CFTR NGS Library Prep Assay for sequencing the CFTR gene
Qiagen	AdnaTest ProstateCancerPanel AR-V7 kit detecting androgen receptor splice variant 7 in circulating tumor cells of prostate tumor origin isolated from blood samples
Qiagen	AdnaTest LungCancer for analyzing molecular mechanisms of lung cancer
NanoString Technologies	Breast Cancer 360T (BC 360) research panel
MNG Laboratories	MNGenome whole-genome sequencing assay

Continued on page 12

NEWLY LAUNCHED PRODUCTS & SERVICES, *Cont'd.*

Company(ies)	Product(s)
MNG Laboratories	MNG Xpress Actionable Epilepsy DNA-sequencing assay for sequencing the coding regions of exons
CareDx	HeartCare comprehensive rejection surveillance solution for heart transplant recipients
Golden Helix	May launch of VSClinical to help labs automate clinical interpretation of variants based on ACMG guidelines
Swift Biosciences	Accel-NGS Unique Dual Indexing Kit
LifeMap Sciences	Version 3.0 of its TGex clinical genomics platform
Human Longevity	Health Nucleus X and Health Nucleus X Platinum, direct-to-consumer membership-based products combining whole-genome sequencing with MRI and other modalities to reveal insights into cancer, cardiac, metabolic and neurodegenerative/neurovascular diseases
Color	Hereditary Heart Health Test this week detecting mutations in 30 genes associated with hereditary heart conditions
Foundation Medicine	US launch of FoundationOne CDx
Horizon Discovery	Edit-R CRISPRa arrayed crRNA (CRISPR RNA) libraries, addition to its CRISPR activation reagent platform from recently acquired Dharmacon business
Omics Global Solutions	PromarkerD test predicting diabetic kidney disease
MDNA Life Sciences	Mitomic Prostate Test Real-Time PCR Kit for research use only in Europe