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HIGHLIGHTS

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G2 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

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FutureLab: A Unique Interactive Strategic Planning Event for Lab Managers

Oct. 24, Washington, DC

www.lableadershipsummits.com

Artificial Intelligence: An Automated New World for Labs & Pathology

Artificial intelligence (AI) and machine learning are making significant inroads in the diagnostics realm. Here are four ways the technology is changing the field and the business of pathology.

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The End Comes for Theranos

Just five years ago, Theranos was a Silicon Valley sensation with a valuation of over $9 billion. While black-turtlenecked Elizabeth Holmes supplied the charisma, the heart of the Theranos phenomenon was its finger-stick blood test technology offering not only accuracy but groundbreaking convenience. But it was all a mirage. And now it's coming to an end.

The Theranos Deception

As documented in the recent *60 Minutes* piece, the technology proved unreliable. Theranos often used analyzers from other companies to test consumer blood samples sometimes modifying those analyzers in unapproved and potentially illegal ways. Because of the modifications, test results were often inaccurate.

Financial Fallout

As a result of testing issues, an agreement with Walgreens, which had been the company's steppingstone to the consumer market unraveled. The drugstore chain sued the company for breach of contract and won damages.

In April 2017, Theranos settled charges with CMS agreeing to a $30,000 fine and two-year Medicare exclusion.

Determined to carry on, Theranos refocused its business, shedding CLIA lab testing and concentrating on technology. Layoffs followed. The company, which once reportedly employed 800, was down to fewer than 25 employees earlier this year.

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Artificial Intelligence: An Automated New World for Labs & Pathology, *from page 1*

1. Diagnostics

The traditional method of reviewing tissue slides is time-consuming and subjective. Two pathologists assessing the same slide will only agree approximately 60% percent of the time, studies show. By contrast, deep learning tools can identify abnormalities with as much as 100% accuracy.

2. Analysis

Because it relies on algorithms, AI continually builds a library of knowledge. This ever-growing library is accessed each time the tools are used. As a result, pathologists, even those with extensive experience, have access to far more information than they otherwise would. This library also serves as a resource for long-term analysis, and new recommendations and protocols.

3. Detection

AI tools allow for faster review, and therefore earlier detection. Likewise, greater accuracy leads to fewer false positives. These advantages have important implications for patient health. They also have the potential to reduce costs. In addition, AI can be used to enhance radiology tools, in some instances eliminating the need for a tissue sample.

4. Treatment

Early detection and greater accuracy help clinicians identify the onset of disease, and better plan for treatment. Among the treatment options for which a patient may qualify are clinical trial enrollment.

Practical Impact & Applications

In terms of practical impact, applications of AI in the diagnostic field include:

- Use by researchers in a recent study to predict patient survival from pathology images in lung cancer;
- Development of new computational pathology software leveraging deep learning AI to aid in prostate and ovarian tumor tissue identification;
- Use of computer-aided diagnosis (CAD) powered by AI to assess diminutive colorectal polyps with 98% accuracy, according to a recent study;
- Development by Johns Hopkins researchers of a deep learning AI system to diagnose pancreatic cancer early.

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

A mid back to school season, companies were back to making diagnostic deals. Here's a recap of the key activity from mid-August through the third week of September.

M&A and Asset Sales

This month, Proteomics International, based in Australia, agreed to sell back its shares in CPR Pharma Services for A$928,399 ($666,000) in cash. Earlier this year, the two companies entered into a strategic alliance focused on clinical trials and related research. As part of the deal, Proteomics acquired 10% of CPR's share capital in exchange for 4 million of its shares.

M&A highlights for this period include Qiagen's acquisition of NeuMoDx for $224 million. The merger agreement gives Qiagen the right to acquire the remaining 80% of NeuMoDx it doesn't currently own.

Additionally, within the last few weeks, Thermo Fisher Scientific agreed to acquire Becton Dickinson's Advanced Bioprocessing business for an undisclosed amount. The deal, expected to close in early 2019, will allow Thermo Fisher to integrate Advanced Bioprocessing into its life sciences solutions segment.

Strategic Alliances

Quite a few new alliances were announced this past month, including a strategic venture between Predicine and Flagship Biosciences that will combine Predicine's GeneRADAR molecular insights platform with Flagship's artificial intelligence-enabled cTA digital pathology, allowing for complementary and comprehensive biomarker profiling to empower clinical trials in the immuno-oncology (IO) space.

Two companies, Fluidigm and Evotec, each entered into multiple alliances. (See the chart below for details.)

In addition to all the new partnerships, there were also a few breakups like Quanterix's decision to terminate its 2012 license agreement with BioMérieux for commercialization of Quanterix's Simoa immunoassay technology for *in vitro* diagnostic purposes. Quanterix regains control of its intellectual property as a result of the termination.

Here's a summary of key diagnostic deals from mid-August through the third week in September:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
Qiagen	NeuMoDx	▪ Price: $234 million ▪ Status: Merger agreement signed giving Qiagen right to acquire remaining 80% of NeuMoDx it doesn't currently own ▪ Merger accompanied by strategic alliance under which Qiagen to market NeuMoDx 288 (high-throughput) and NeuMoDx 96 (mid-throughput) systems in Europe and other markets outside US

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
Thermo Fisher Scientific	Becton Dickinson's Advanced Bioprocessing business	■ Price: Undisclosed ■ Status: Expected to close in early 2019 ■ Thermo Fisher to integrate Advanced Bioprocessing into its life sciences solutions segment
10x Genomics	Epinomics	■ Price: Undisclosed ■ Status: Closed ■ Acquisition of Stanford Univ. startup to commercialize technology for mapping chromatin regions across the genome
Summit Health (Quest Diagnostics wellness sub)	Hooper Holmes, dba, Provant Health	■ Price: $27 million ■ Status: Stalking horse bid entered before and to be completed after bankruptcy auction in Oct. ■ Target filed for Chapter 11 after 2017 merger of Hooper Holmes and Provant Health left combined company with a working capital shortfall and over-leveraged balance sheet
Bruker	Hain Lifescience	■ Price: Undisclosed ■ Status: Bruker to acquire 80% interest with 2021 option for remaining 20% ■ Bruker strengthens its tuberculosis and mycobacteria testing and human genetics capabilities by acquiring German molecular DX firm
Canon Medical Systems	ACTmed	■ Price: Undisclosed ■ Status: Closed ■ Canon acquires majority interest in Japanese joint venture between ACTmed and Taiwanese molecular DX firm ACT Genomics, including latter's NGS technology
Cancer Genetics	NovellusDx	■ Price: Undisclosed ■ Status: Merger agreement signed ■ CGI's cancer test products to be combined with NovellusDx's NGS and machine-learning cancer treatment response prediction technologies
Medicover	Center for Human Genetics and Laboratory Diagnostics + IMGM Laboratories affiliate	■ Price: Undisclosed ■ Status: Expected to close in Jan 2019 ■ Medicover acquires German labs known for genetic testing, pathology, transfusion medicine, microbiology and virology
Inscripta	Solana Biosciences	■ Price: Undisclosed ■ Status: No closing date given ■ Acquisition boosts Inscripta's efforts to commercialize its gene editing tools

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Predicine	Flagship Biosciences	■ Objective: Offer integrated molecular and contextual tissue biomarker solution for immuno-oncology pharm customers ■ Dynamic: Combine Predicine GeneRADAR combined liquid biopsy assay with Flagship's artificial intelligence-enabled cTA digital pathology platform
IDbyDNA	Fleury Group (Brazil)	■ Objective: Offer IDbyDNA's Explify platform for clinical metagenomic testing in South America ■ Dynamic: Fleury to integrate Explify into its lab workflow to develop full suite of Explify-based clinical testing, starting with Explify Respiratory
Qiagen	NeuMoDx	■ Objective: Commercialize NeuMoDx's PCR-based molecular diagnostic systems ■ Dynamic: Qiagen to initially distribute the NeuMoDx 288 (high-throughput) and NeuMoDx 96 (mid-throughput) systems in Europe and other non-US markets ■ Parties also signed a companion merger agreement (see M&A above)
Natera	Bristol-Myers Squibb	■ Objective: Determine if Natera's circulating tumor DNA assay, Signatera, can identify non-small cell cancer patients who may benefit from BMS's Opdivo (nivolumab) immunotherapy ■ Dynamic: BMS researchers to use Signatera to select patients with minimal residual disease to receive standard of care adjuvant therapy or adjuvant therapy plus Opdivo

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Definiens	Merck KGaA	■ Objective: Biomarker development ■ Dynamic: Merck's to use Definiens' web-based collaboration software platform to support its use of Definiens' Tissue Phenomics image-analysis technologies for biomarker quantification including immuno-profiling
Celmatix	Ferring Pharmaceuticals	■ Objective: Research women's response to *in vitro* fertilization treatment ■ Dynamic: Use Celmatix's knowledgebase to investigate whether a woman's response to ovarian stimulation during IVF treatment is linked to genomic characteristics
Fluidigm	Visiopharm	■ Objective: Comarket automated image analysis for imaging mass cytometry ■ Dynamic: Copromote Visiopharm's Phenomap image-analysis software with Fluidigm's Hyperion imaging system, MCD Viewer software and Maxpar antibodies and kits
Fluidigm	GenomOncology	■ Objective: Create Immuno-Oncology Gene Expression Workflow for developing checkpoint immunotherapies and identifying predictive biomarker signatures for therapeutic response ■ Dynamic: Combine Fluidigm Advanta Immuno-Oncology Gene Expression Assay with Genom-Oncology's data analysis software
Prescient Medicine	Metabiomics	■ Objective: Develop microbiome diagnostic assays for colon cancer ■ Dynamic: Use Metabiomics MultiTag NGS technology and microbiome analytics platform to develop stool-based test for precancerous colon polyps ■ Sides will also work together to develop diagnostics for other GI diseases including Crohn's disease, colitis and irritable bowel syndrome
Novacyt	Applied Microarrays (AMI)	■ Objective: Develop microarray-based SNP assays ■ Dynamic: Novacyt's Primerdesign molecular testing division to help AMI design probes for customized SNP microarrays used in point-of-care and lab settings
BioArctic	Brain Biomarker Solutions	■ Objective: Develop biomarkers and diagnostics for Alzheimer's disease ■ Dynamic: Sides to identify and measure new blood- and cerebrospinal fluid-based biomarkers that can be used to diagnose and monitor the effects of investigational treatments for Alzheimer's ■ Each side to bear its own costs, jointly own rights to resulting products and evenly split licensing revenues
MRM Proteomics	Exactis Innovation	■ Objective: Develop proteomic test for guiding cancer immunotherapy ■ Dynamic: Use MRM's immunoMALDI system to analyze breast and colorectal cancer samples in Exactis' Personalize My Treatment patient registry to identify and validate protein markers predictive of patient response to cancer immunotherapies
Foundation Medicine	Incyte	■ Objective: Develop and commercialize companion diagnostics ■ Dynamic: Start with a CDx for Incyte's FGFR1/2/3 inhibitor, pemigatinib, for treating cholangiocarcinoma patients CDx for Incyte's FGFR1/2/3 inhibitor, pemigatinib, to treat patients with cholangiocarcinoma, to be incorporated into Foundation's FoundationOne CDx assay
Seven Bridges Genomics	E-Nios (Greece)	■ Objective: More efficient extraction of biomarker signatures from NGS and multi-omics data ■ Dynamic: Combine machine learning and physiology to automate at least part of laborious process of interpreting potential biomarkers
Lunaphore Technologies	A. Menarini Diagnostics	■ Objective: Market system for personalized immunohistochemistry (IHC) treatment ■ Dynamic: System to use Lunaphore's LabSat Frozen technology for rapid enabling of IHC assays
Exact Imaging	Cambridge Consultants	■ Objective: Improve prostate cancer detection and diagnosis ■ Dynamic: Combine Exact Imaging's ExactVu micro-ultrasound platform for urologist to assess and target suspicious regions during biopsy with Cambridge's AI and deep learning expertise
Evotec	Celgene	■ Objective: Targeted protein degradation drug discovery ■ Dynamic: Use Evotec Panomics genomic, transcriptomic, and proteomic data platform to identify difficult-to-track drug targets ■ Celgene to get exclusive rights to all drug candidates and pay Evotec undisclosed upfront payment, milestone payments and potential double-digit royalties
Evotec	Centogene	■ Objective: Develop high-throughput platform for evaluating novel small molecule treatments for rare hereditary metabolic diseases ■ Dynamic: Combine Evotec's induced pluripotent stem cell-based drug screening platform with Centogene's patient access and biomarker expertise

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
NRGene	RCK (Israeli cannabis producer)	■ Objective: Develop DNA biomarkers for medical cannabis breeding and strain identification ■ Dynamic: Use NRGene's computational tools to develop the biomarkers for commercial use
LTS Health	The Project Santa Fe Foundation	■ Objective: Create online platform to serve as a knowledgebase to crowdsource ideas from health professionals and institutions in lab diagnostics ■ Dynamic: Platform to launch in Nov.
Agendia	GeneCast Biotechnology	■ Objective: Bring Agendia's breast cancer tests to China market ■ Dynamic: GeneCast gets exclusive right to market Agendia MammaPrint and BluePrint tests in China referred by local physicians to be performed at GeneCast's oncology laboratory
Congenica	Digital China Health Technologies (DC Health)	■ Objective: Bring Congenica's Sapientia genome analysis platform to China market ■ Dynamic: DC Health to market platform which will be tailored for Chinese market
Biocartis	Wondfo Biotech	■ Objective: Bring Biocartis' Idylla platform to China market ■ Dynamic: Form 50/50 joint venture to license Idylla in China starting by end of 2018
Clearbridge Health's SAM Laboratory subsidiary	Indonesian firms PT Kreasi Putra Nusantara + PT Indo Genesis Medika	■ Objective: Provide diagnostics services to public hospitals in Indonesia ■ Dynamic: Multiple contracts under which SAM acquires proposed subscription of a controlling stake in Indo Genesis for $2.8 million
Sienna Cancer Diagnostics	Royal Melbourne Hospital (RMH)	■ Objective: Evaluate Sienna's cancer hTERT for detecting telomerase biomarker for thyroid cancer ■ Dynamic: Study to be conducted at RMH will run the test on fine needle aspirate thyroid biopsies with matched thyroid nodules after removal to determine whether it can accurately differentiate benign from cancerous nodules
Biocept	Highmark Health	■ Objective: Study clinical and economic impact of Biocept's Target Selector liquid biopsy in patients with non-small cell lung cancer ■ Dynamic: 12-month study conducted through Highmark's Vital Innovation Program
Abreos Biosciences	ResearchDx	■ Objective: Make co-developed moNATor test for monitoring Tysabri (natalizumab) available to clinicians and researchers ■ Dynamic: Test to be available through ResearchDx's Pacific Diagnostics reference laboratory
BGI	Xing Technology (Australia)	■ Objective: Optimize DNA nanoball technology to improve quality and throughput of sequencing data to lower costs ■ Dynamic: Collaborate on integrating circulating tumor cell isolation, characterization and sequencing to accelerate technology's use for disease screening and monitoring ■ Jointly research and manufacture a diagnostic product developed by Xing

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
Arbor Biosciences	Tataa Biocenter	■ Products: Arbor's NGS and synthetic biology products ■ Territories: Sweden, Denmark, Norway, Slovakia, Czech Republic ■ Arbor to provide reagents and support to Tataa for its education course on NGS applications
Ranomics	Axil Scientific	■ Product: Ranomics' VariantFind DNA libraries ■ Territory: Singapore
HalioDx	Gencell Pharma	■ Product: HalioDx's Immunoscore Colon assay ■ Territory: Colombia ■ HalioDx made distribution deals for assay in Mexico and Israel in July
Lucence Diagnostics	Mascots Medical and Laboratory Center	■ Products: Lucence's blood-based cancer diagnostic tests and treatment in ■ Territory: Myanmar ■ Lucence has deals already in place for Philippines, Thailand and Singapore
Todos Medical	Orot+	■ Products: Todos' blood-based breast cancer screening tests TM-B1 and TM-B2 ■ Territories: Romania (5 years) and Austria (3 years) ■ Exclusive

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
NovellusDx	Primetech	▪ Product: NovellusDx's functional annotation for cancer treatment (FACT) assay ▪ Territory: Japan ▪ Exclusive
LICENSES		
Licensor	**Licensee**	**Deal Summary**
Illumina	Premaitha Health	▪ Property: Illumina's NIPT patent pool ▪ Premaitha to offer testing in Europe and other countries and develop a version of its Iona test ▪ Premaitha to also pay up to £1 million ($1.3 million) to settle its UK litigation with Illumina
Broad Institute and ERS Genomics	Thermo Fisher Scientific	▪ Property: CRISPR technologies patents ▪ Global, non-exclusive
Hospital Del Mar + two individual researchers from University of Torino	Biocartis	▪ Property: EGFR ectodomain mutations that have been shown to determine responses to targeted therapy for metastatic colorectal cancer ▪ Global, exclusive
Nanosys	BioDirection	▪ Property: Patents for technologies BioDirection is using to develop its development of its Tbit sepsis diagnostic platform ▪ Extension of 2012 agreement between the parties ▪ Global, exclusive
SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Servicer	**Client**	**Deal Summary**
NeoGenomics	Premier	▪ Group purchasing agreement providing Premier network members access to NeoGenomics clinical reference lab testing services at pre-set rates
Expedeon	PaxGenBio (South Korea)	▪ 3-year license and supply agreement under which Expedeon to supply PaxGenBio colloidal gold for use in multiplexed polymerase chain reaction-based universal lateral flow assays for simultaneous detection of sexually transmitted diseases and tuberculosis

FDA Watch: New LDT Proposal Is Much Different from One Negotiated with Industry

The lab industry played an active role in the drafting of the *Diagnostic Accuracy and Innovation Act* (DAIA), a bill designed to establish a new regulatory regime for laboratory developed tests (LDTs). But last month, without consulting anybody, the FDA sent a Technical Assistance document (TA) proposing a DAIA re-write in the interest of "public health."

FDA's 5 Proposed DAIA Changes

Among the notable differences between the current DAIA and the FDA's new TA proposal:

1. Definition of IVCTs

The DAIA defines in vitro clinical tests as a laboratory test protocol or finished product, which is used in disease detection, screening, prediction, and monitoring, and for selecting treatment based on analysis of human samples. The TA definition includes test platforms and software used for these same purposes as IVCTs and doesn't specifically mention "finished product," "laboratory test protocol" or "laboratory-developed test."

2. Risk Categories

The DAIA establishes a process for determining whether a test is low-risk, moderate-risk or high risk, and outlines regulatory requirements consistent with a test's risk level. The TA defines high and low risk tests but leaves out moderate-risk.

3. Timelines

The DAIA contains strict review timelines that FDA must meet to avoid having the test automatically approved. The TA contains no timelines for review.

4. Regulation of IVCTs

The DAIA would create a new center for IVCTs within the FDA. The TA proposes creation of collaborative communities of private and public stakeholders who advise the FDA on mitigating measures and performance standards for IVCTs.

5. Raw Data

The TA makes explicit that raw data should be submitted for high-risk, cross-referenced, or first-of-a-kind tests, and that the Department of Health and Human Services secretary can request raw data for any other test.

New FDA Approvals

Here's a look at some of the key FDA approvals announced at the end of August through the third week of September:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Roche	Approval of Cobas EGFR Mutation Test v2 as companion diagnostic test with AstraZeneca's cancer drug Iressa (gefitinib) for non-small cell lung cancer patients

Manufacturer(s)	Product(s)
Cepheid	510(k) clearance for Xpert Xpress Flu Assay on new software version of GeneXpert Instrument System
Thermo Fisher Scientific	Clearance for addition of Plazomicin at concentrations 0.06 to 128 µg/mL to Sensititre 18-24 MIC for susceptibility testing of non-fastidious gram-negative organisms
InBios International	510(k) clearance for DENV Detect NS1 ELISA, an antigen detection assay providing presumptive dengue virus diagnosis before IgM antibodies are present
DiaSorin Molecular	510(k) clearance for Simplex Bordetella Direct real-time PCR assay system for direct amplification, detection and differentiation of Bordetella pertussis and Bordetella parapertussis DNA from unprocessed nasopharyngeal swabs
Microbiologics	Clearance for BD Max CT/GC/TV 20-Day QC Panel to monitor in vitro laboratory nucleic acid testing procedures for qualitative detection of Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis in genitourinary specimens
Assure Tech	Clearance for AssureTech Panel Dip Tests and AssureTech Quick Cup Tests urine drug tests for qualitative and simultaneous detection of amphetamine, oxazepam, cocaine, marijuana methamphetamine, morphine, oxycodone, secobarbital, buprenorphine, methylenedioxy-methamphetamine, phencyclidine, methadone, EDDP, nortriptyline and d-propoxyphene
Biokit	Clearance for Advia Centaur Herpes-2 IgG assay for qualitative determination of IgG antibodies to herpes simplex virus type 2 in human serum and plasma
Quidel	Clearance and CLIA waiver for Sofia 2 Lyme FIA assay to detect antibodies to the bacterial pathogen that causes Lyme disease

New CE Marks & Global Certifications

Notable European CE certifications:

NEW CE CERTIFICATIONS IN EUROPE

Manufacturer(s)	Product(s)
Cepheid	CE-IVD marking for Xpert HCV VL Fingerstick for detecting RNA levels of HCV directly from blood
Co-Diagnostics	CE marking for Logix Smart MTB Test for tuberculosis diagnosis
Qiagen + DiaSorin	CE marking for Liaison QuantiFeron-TB Plus workflow
Optrascan	CE-IVD marking for firm's on-demand desktop scanning systems
Asuragen	CE marking for QuantideX, a new NGS oncology panel

Other international clearances announced in the past month:

Manufacturer(s)	Product(s)	Product(s)
Beckman Coulter	Canada	Health Canada Medical Device License approval for DxH 900 Hematology Analyzer and its Early Sepsis Indicator
Illumina	China	China National Drug Administration regulatory clearance for MiSeqDx system

The End Comes for Theranos, *from page 1*

Criminal Conduct Alleged

Things went from bad to worse. According to *The Wall Street Journal*, Holmes and her ex-boyfriend, Ramesh "Sunny" Balwani, who served as Theranos president and chief operating officer until he retired from the company in May 2016, have been indicted on nine counts of wire fraud and two counts of conspiracy to commit wire fraud.

If convicted of charges, which allege that they defrauded investors out of hundreds of millions of dollars, while also defrauding doctors and patients, Holmes and Balwani each faces up to 20 years in prison and a fine of $250,000, plus restitution to those found to have been defrauded—on each count.

Corporate Dissolution

Against this backdrop, it perhaps comes as no surprise that in an email to shareholders the company announced it has ceased operations and will formally dissolve. Before arriving at this decision, it pursued a sale. But none of the 80 potential buyers reportedly contacted showed any interest.

The company owes at least $60 million to unsecured creditors, according to the email. As part of its dissolution, Theranos will distribute its remaining cash, estimated to be approximately $5 million, to unsecured creditors.

Latest Legal Challenge to ACA May Mean a Hot Mess for Insurance Markets

After a series of setbacks, Republicans challenging the constitutionality of the *Affordable Care Act* (ACA) and its individual mandate are back at it. And this time they may win. Here's a look at the latest case and what it means for the future of ACA and the insurance markets.

Beating a Dead Horse?

Six years ago, the U.S. Supreme Court found the mandate constitutional. *Reasoning:* mandate + penalty for not having health insurance = federal tax. And Congress has the constitutional power to tax [*National Federation of Independent Business v. Sebelius*].

Why the Horse *Isn't* Dead

What's changed since *Sebelius*? On Dec. 20, 2017, Congress passed the *Tax Cuts and Jobs Act* establishing a $0 mandate penalty starting in 2019. The plaintiffs in the new case contend that a $0 penalty is *not* a tax and thus no longer supportable as an exercise of Congressional taxing powers. And since the individual mandate isn't severable from the rest of the ACA, they say the entire ACA should be struck down.

Another big difference is who's leading the defense. Needless to say, the Trump DOJ is less dedicated than its predecessor to defending the ACA. But while the DOJ says that 16 parts of the ACA should be struck down, it deems the parts under attack in the latest suit constitutional and worth defending. But with such a lukewarm endorsement, attorney generals from 16 states and the District of Columbia have intervened in the lawsuit to bolster the defense.

The Texas Showdown

The venue for the new case, Texas v. United States, is the federal district court in the Northern District of Texas. On Sept. 5, Judge Reed O'Connor held a hearing to deal with the plaintiffs' request for a preliminary injunction (PI) barring enforcement of the law pending the case's outcome. A PI would effectively freeze the ACA unless and until either an appeals court overturned it or the court ultimately ruled on the merits in favor of the law's constitutionality.

But getting a court to issue a PI is a stiff task requiring the plaintiffs to prove four things:

1. They'll likely to succeed on the merits;
2. They'll likely suffer "irreparable harm" if the PI isn't granted;
3. The balance of equities favors their argument;
4. Granting the PI is in the public interest.

What's At Stake

Obviously, there's a lot on the line in both the short- and long-term:

Short-Term: Issuing a PI would create a hot mess in insurance markets. Accordingly, the DOJ has asked the court to limit any ruling on the mandate's constitutionality to beginning in 2019. The DOJ also cited the need

for additional briefing on the timing and impact of an injunction on state insurance markets, as well as the need to potentially issue new regulations and address the multi-year process by which insurers must get their products approved for sale.

Long-Term: Invalidating the *entire* ACA would adversely impact, among other things:

- Protections for people with pre-existing conditions;
- ACA Medicaid expansion;
- Children under 26 who get insurance through their parents' plan;
- Annual and lifetime coverage limits; and
- Caps on out-of-pocket expenses.

Accordingly, the DOJ has asked the court to defer any ruling on severability, i.e., whether invalidation of the mandate takes down the entire ACA, until 2019 after the close of the next open enrollment period and mid-term elections.

More to Come

Don't expect any immediate resolutions one way or the other. No matter how the court rules, an immediate appeal to the Fifth Circuit of Appeal is all but assured. And no matter how the Fifth Circuit rules, the U.S. Supreme Court will be asked to intervene—although there's no guarantee it'll accept the case.