Put It on the Board, 1/16

2016 may be year of action on laboratory-developed tests

During a session at the Association for Molecular Pathology's annual meeting in November, Rep. Michael Burgess, MD (R-Tex.), said he expects the Food and Drug Administration to issue its long-awaited final guidance on laboratory-developed tests during the first quarter of 2016.

FDA officials, meanwhile, have been more circumspect in their public statements. In a recent meeting of the CDC's Clinical Laboratory Improvement Advisory Committee, Alberto Gutierrez, PhD, director of the FDA's Office of In Vitro Diagnostics and Radiological Health, described the agency's potential action on LDTs in 2016 using the conditional "if."

When the FDA released its proposed regulatory framework for LDTs in July 2014, it sparked criticism from virtually every side. What perhaps few expected was that 2015 would slip by without agency action on the matter.

The FDA's November 2015 release of a report designed to make the case for stricter oversight of LDTs garnered coverage in The *New York Times* and elsewhere, and to some eyes it presaged a definitive move in the new year, or at least aimed to offer Congress some support for legislative action on the matter. It was released the day before a hearing on LDTs held by the House Energy and Commerce Committee's health subcommittee.
"We examined events involving 20 LDTs that illustrate, in the absence of compliance with FDA requirements, that these products may have caused or have caused actual harm to patients," said the FDA report's executive summary.

The AMP has issued a report in response (http://j.mp/amp20cases), arguing that the FDA often mischaracterizes the nature of the tests, how they were used—or misused—by clinicians, and whether the problems detailed were ones that stricter FDA oversight could have prevented. In an interview, AMP Professional Relations Committee chair Roger Klein, MD, JD, says the agency's case studies too often rely on news media reports rather than peer-reviewed literature. In one specific case, he says the FDA appears to have failed to do "due diligence" by not talking with the laboratory and institution at issue to learn their depiction of the facts underlying the news report on which the agency relied.

The AMP says the Centers for Medicare and Medicaid Services should use third-party reviewers to scrutinize the clinical validity of high- and moderate-risk LDTs, and that FDA oversight of the tests would do more harm than good.

The FDA's regulatory plan for LDTs "is a major step and has sweeping implications that the agency is only beginning to understand," says Dr. Klein, medical director of molecular oncology at Cleveland Clinic.

"If they were to go ahead and finalize that document, it would seemingly shut down next-generation sequencing for oncology at most major academic medical centers. The reason it would is because FDA's claimed highest-risk procedures are those tests that are used to select targeted drug therapies. NGS tests are, in fact, used to guide drug therapy in oncology patients for tumors and drugs for which FDA-approved tests are available." As currently written, he says, the FDA's draft guidance would appear to require laboratories to obtain premarket approval for such tests, which generally requires clinical trials. Such a course would prove cost-prohibitive for academic hospital laboratories.

Dr. Klein says he remains skeptical that the FDA will finalize its 2014 proposal, at least in anything like the form in which it was presented initially. "It's a big trigger to pull," he says. "It's like the nuclear option."

The American Clinical Laboratory Association has already said it will take legal action to stop the FDA if the agency acts to finalize its LDT proposal. ACLA says the agency must pursue its proposal using the federal rule-making process, rather than through guidance.
Dr. Klein says participation in litigation is something the AMP would be willing to consider. Apart from the FDA's "highly questionable" jurisdiction to regulate LDTs, he says, the FDA's proposal requires issuance of new regulations as opposed to a nonbinding guidance document because it is "more than a mere policy change…it involves implementation of an entirely new regulatory scheme." *—Kevin B. O'Reilly*

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Kaiser Permanente to acquire Group Health

Kaiser Permanente's announced acquisition of Seattle-based Group Health Cooperative is big, adding nearly 590,000 covered lives to Kaiser's already extensive reach on the West Coast, in the Pacific Northwest, and beyond. Among the many things that remain unknown about the joining of the two integrated health care organizations is how the deal will affect Group Health's laboratory operations.

Group Health, which does not operate inpatient facilities, employs a mixed model for laboratory services for its dozens of full-service clinics and other health care operations.

"We do have our own laboratory services, but we also partner with local laboratories," Group Health spokesperson Heather M. Griesbach said in an email. One of those partners is Seattle-based Bloodworks

Northwest, which has long met the integrated health care organization's need for pretransfusion testing services for outpatients and at the various Seattle area hospitals where inpatient care is provided.

Bloodworks Northwest CEO James AuBuchon, MD, says he would be surprised to see big changes in how Group Health handles its laboratory operations. He has not heard anything regarding Bloodworks Northwest losing its business, for one.

"I don't know what Kaiser would intend to do with respect to transfusion services, and that's the part of the laboratory services we're involved in," Dr. AuBuchon tells CAP TODAY. "We can provide pretransfusion testing services at a lower cost than what it costs hospitals. And since Group Health is interested in keeping costs low, I don't expect that to change."

Griesbach said it is far too soon to comment on potential laboratory consolidation as a result of the Kaiser purchase.

"We are very early on in the initial announcement about a potential future acquisition by Kaiser," she said. Members must first vote to approve the deal, and then it must traverse state and possibly federal review.

“We anticipate these two actions will require at least nine to 12 months,” Griesbach said. “Until the acquisition is approved, we are operating business as usual.”

A Group Health statement announcing the deal said that, “like other Kaiser Permanente regions, the Washington region will be managed locally while taking full advantage of Kaiser Permanente’s national resources.”

Dr. AuBuchon says it is hard to predict what the deal will mean for the Seattle area health care scene. But he shares the view that it represents a joining of like-minded health care operations.
“These two organizations appear to be structurally similar and interact with their patients in very much the same way,” he says. “I would expect that a merger of the operations, to the extent that it occurs, wouldn’t yield a dramatic change in the way that patients receive their care or the kind of care they receive.” *—Kevin B. O’Reilly*

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Tango Infinity cleared

Bio-Rad Laboratories has received FDA clearance to market its Tango Infinity system that automates routine blood typing and screening testing procedures. Key features of the system include seven-day onboard storage, high capacity, continuous monitoring of critical processes and reagent shelf life, optical liquid verification of sample and liquid reagent dispense volumes, a small footprint, and a touchscreen monitor.
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Beckman sells genomic services business

South Plainfield, NJ-based Genewiz has signed a definitive agreement to acquire the genomic services business of Beckman Coulter.

Beckman Coulter Genomics’ Sanger sequencing, next-generation sequencing, bioinformatics, and CLIA/clinical services will complement Genewiz’s existing genomics services and support its expansion strategy. The boards of directors of both companies have approved the agreement.
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Clearance for Luminex respiratory panel

Luminex has received FDA clearance for its NxTag Respiratory Pathogen Panel that detects 20 clinically relevant viral and bacterial respiratory pathogens, including the atypical bacteria Chlamydophila pneumoniae and Mycoplasma pneumoniae. The respiratory assay panel is designed to enable laboratories to simultaneously detect 20 respiratory pathogens in a single closed-tube system in a format that scales to accommodate throughput changes needed to respond to seasonal changes in demand.

The accompanying Synct Software provides a comprehensive approach to data analysis and reporting and enables the NxTag Respiratory Pathogen Panel to be integrated into any laboratory. Any of a number of targets can be selected to customize the panel.
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LabCorp to buy Pathology Inc.

Laboratory Corporation of America has entered into a definitive agreement to acquire substantially all of the operating assets of Pathology Inc.’s medical testing and services business. Pathology Inc. is a full-service, independent women’s health laboratory, providing expertise in FDA-required reproductive donor testing as well as anatomic, molecular, and digital pathology services.

The transaction, which includes the acquisition of Pathology Inc.'s patient service centers, is subject to customary closing conditions. It is expected to close in the first quarter of this year. Upon the closing of the transaction, Pathology Inc. will cease operations.
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CLIA waiver for Cepheid's POC flu/RSV test

The FDA has granted 510(k) clearance and a Clinical Laboratory Improvement Amendments waiver for Cepheid's Xpert Flu+RSV Xpress test for use on the GeneXpert Xpress System. The system is composed of a single module and a tablet computer with an ATM-like interface for the CLIA- waived environment. Xpert Flu+RSV Xpress is the first PCR panel test to achieve a CLIA waiver, and the first in a series of reference-quality molecular tests that Cepheid intends to deliver to the point-of-care market over the next several years.

The Flu+RSV Xpress test uses the same design as the company's laboratory-based Flu/RSV XC test. The new test includes high-level multiplexing, redundant target segments, and extended coverage for human and avian influenza strains. Cepheid's Xpert Flu/RSV XC test has been available for CLIA moderate-complexity customers since November 2014. The Xpert Flu+RSV Xpress test uses the same test cartridge as the Xpert Flu/RSV XC test and was made available in December for customers in CLIA-waived settings. Both tests detect and differentiate between influenza A, influenza B, and RSV in about one hour.
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Case-based guide to practice management

A new book captures the experience and wisdom of pathologist leaders, practice managers, and respected consultants in practice, legal, and billing matters.

Titled *Pathology Practice Management—A Case-Based Guide,* the book is "designed for the pathologist or pathology resident who wants or needs a broad overview of the pathology practice environment," says Michael L. Talbert, MD, one of the book's editors.

"It is particularly helpful for those pathologists and trainees who are seeking positions, moving into leadership roles, or facing changes in their practice environment," adds Dr. Talbert, who is the Lloyd E. Rader professor and chairman of the Department of Pathology, College of Medicine, University of Oklahoma Health Sciences Center.

Lewis A. Hassell, MD, professor and director of anatomic pathology at the University of Oklahoma Health Sciences Center, and Jane Pine Wood, of McDonald Hopkins LLC, are co-editors. The publisher is Springer.

The chapters cover such topics as coding and billing, practice sales and mergers, contracts, corporate and general liability, and market and valuation risks. Didactic reviews of a subject are followed by illustrative cases drawn from the experiences of the 10 authors. "The book can be read by chapter or topic, or used as an educational tool in a structured training program," Dr. Talbert says.
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