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Upcoming Conferences

Lab Revolution
April 6-8, 2016, Sheraton Wild Horse Pass Resort & Spa, Chandler, AZ
www.labrevolution.com

Lab Institute 2016
October 26-28, 2016
Hyatt Regency Washington on Capitol Hill, Washington, DC

Recent Lab Cases Spotlight Continuing Enforcement Trends: Individual Responsibility, Medical Necessity, Kickbacks

Laboratories saw aggressive enforcement by federal agencies in 2015 and can expect continued scrutiny in 2016. Some recent settlements between federal agencies and laboratories and laboratory owners occurred as 2015 closed and 2016 began that demonstrate continuing themes in enforcement efforts affecting labs.

Individual Responsibility. The increased focus on individual responsibility, highlighted by last year's release of the Yates Memo, is borne out by a recent Department of Justice (DOJ) settlement with the former owner of a Virginia-based laboratory. Dr. David G. Bostwick, founder, owner and chief executive officer of Bostwick Laboratories between 1999 and 2011, agreed to settle allegations that his laboratory violated the False Claims Act by billing Medicare and Medicaid for medically unnecessary cancer detection tests and provided incentives to physicians in exchange for Medicare and Medicaid referrals.

"This case shows that the Department will not hesitate to hold accountable both the companies and the individuals who order or perform excessive, non-patient specific tests and provide inducements to physicians that lead to unnecessary costs being imposed upon our nation's health care programs," said Benjamin C. Mizer, principal deputy assistant attorney general for the Civil Division of the DOJ, in a statement announcing the settlement.

The settlement arrangement includes an agreed payment of $2.6 million plus additional payments up to $1.125 million to be paid "if certain financial con-

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Dx Industry Joins Global Call for Incentives to Combat Antibiotic Resistance

Global representatives of the diagnostics and pharmaceutical industries issued a joint declaration at the World Economic Forum in Davos, Switzerland calling on governments to take action, along with private companies, to support investment in the development of products to combat antimicrobial resistance (AMR).

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Recent Lab Cases Spotlight Continuing Enforcement Trends, *from page 1*

tingencies occur within the next five years," according to the DOJ announcement. The laboratory itself previously settled allegations in the case for $6.5 million.

> *"Pathway admits no wrongdoing as part of the settlement and is neither an admission of liability or wrongdoing by the Company, nor a concession by the United States that its claims are not well founded. Pathway has fully cooperated with the inquiry and was not required to enter into a corporate integrity agreement. We now consider this matter closed."*
>
> — Pathway Genomics

Whistleblowers. As with several other cases G2 Intelligence has reported on recently, the Bostwick case developed from a whistleblower's allegations. That whistleblower will receive more than $2.5 million from the settlements with Dr. Bostwick and Bostwick Laboratories, the DOJ said.

Pathway Genomics ended 2015 by settling a whistleblower suit with the federal government for $4.03 million. The San Diego-based Pathway and the U.S. Attorney's Office announced the settlement on Dec. 30. It involves not only the federal government, but 29 states and the District of Columbia. The case arose from a whistleblower claim brought by former Pathway employee Monique Gipson, the government said. She filed a *qui tam* suit against the company in April 2014. Pathway issued a statement denying wrongdoing: "Pathway admits no wrongdoing as part of the settlement and is neither an admission of liability or wrongdoing by the Company, nor a concession by the United States that its claims are not well founded. Pathway has fully cooperated with the inquiry and was not required to enter into a corporate integrity agreement. We now consider this matter closed."

The Pathway and Bostwick settlements were the third and fourth involving a laboratory entangled in a whistleblower suit since late November. On Nov. 30, the government announced Piedmont Pathology Associates, Inc. and Piedmont Pathology PC in Hickory, N.C., agreed to pay $500,000 to settle false claims charges. A former Piedmont salesperson had sued, claiming the organization had exchanged medical software licenses for patient referrals. On Dec. 1, it was announced that Wisconsin-based Pharmasan Laboratories and a corporate affiliate agreed to pay $8.5 million to settle allegations that it had submitted claims for ineligible food sensitivity tests to Medicare—using CPT codes for fluorescent antibody assays and other tests that are covered by the program. Pharmasan Labs, Inc. and the affiliated NeuroScience, Inc. in Osceola, Wis., and the owners of the two companies, Gottfried and Mieke Kellermann, agreed to pay $8.5 million to settle False Claims Act allegations. That included $2.85 million seized by federal agents in March of last year, and another $5.66 million the businesses and the Kellermanns will pay directly. The case began as a *qui tam* action, brought by an insurance billing manager.

Kickbacks. Both the Bostwick and Pathway cases included allegations that incentives were provided to referral sources. In the Bostwick case, the government alleged that Bostwick violated the Anti-Kickback Statute by offering discounts and billing arrangements to treating physicians to encourage referrals of federally reimbursed services.

The Pathway Genomics agreement settled allegations that Pathway violated federal anti-kickback laws by paying physicians as much as $20 for each saliva sample of a patient it remitted for genetic testing pertaining to medication sensitivity. Pathway no longer pays any fees for physicians to submit tests. "[This] settlement should make it abundantly clear that the FBI and our law enforcement partners will not allow kickbacks and bribes to influence patient care decisions," said Eric S. Birnbaum, the FBI agent in charge of the Pathway Genomics investigation, in a statement.

Medical Necessity. A familiar issue for laboratories, medical necessity, was at issue in the Bostwick case. The government claimed that, during 2006-2011, Bostwick caused the laboratory to bill Medicare and Medicaid for Fluorescent In Situ Hybridization (FISH) tests and other tests not medically necessary, without a treating physician's consent or order.

Sister publication, *G2 Compliance Advisor (GCA)*, surveyed counsel for laboratories about the top compliance issues to be concerned about in 2016 and medical necessity was the top issue named. Those surveyed also indicated it may not be just the government that laboratories need to be worried about but that private payers may also raise medical necessity challenges as well. To learn more about top compliance issues for laboratories in 2016, see the January issue of *GCA* which highlights the top 10 issues identified by those surveyed, including the 60-day deadline for repayment of overpayments, and aggressive sales and marketing tactics—which can give rise to kickback allegations like those in several of the cases highlighted above.

Takeaway: Recent settlements indicate aggressive enforcement of false claims cases continues and key issues are medical necessity of test orders, incentives to referral sources and identifying the individuals responsible for decisionmaking related to the challenged activities. G2

CMS Reports ACO Participation Continues to Grow

During his remarks at the J.P. Morgan Annual Health Care Conference, Jan. 11, 2016, Centers for Medicare & Medicaid Services (CMS) Acting Administrator Andy Slavitt addressed not just meaningful use (see page 6) but also praised recent data on ACOs as "strong evidence that ACOs will be part of ushering in the new wave of alternative payment models." That same day, CMS reported that 121 new participants were joining the Medicare ACO program. Those new participants bring the total participation numbers to 477 ACOs serving 8.9 million beneficiaries. Sixty-four of those ACOs are risk-bearing. The ACO models currently in effect include the Shared Savings Program, Pioneer, Next Generation, and Comprehensive ESRD Care ACO models.

Next Generation ACOs are leading the way with regard to risk sharing alternatives allowing participants to take on up to 100% risk. This ACO model involves prospectively set benchmarks and, as Slavitt noted in his Jan. 11 remarks, they include "innovative options like telemedicine, home visits, and direct consumer incentive and engagement options."

The Medicare Shared Savings program added 100 new ACOs. Twenty-two of the MSSP ACOs have opted to transition to Tracks 2 and 3, which allow for more risk sharing. Thirty-nine MSSP ACOs will now be participating in the ACO Investment Model (AIM) which involves pre-paid shared savings to encourage ACO formation in rural and underserved areas and transitions to performance-based risk sharing models. Slavitt summed up the numbers on ACOs, praising the progress made and promising continued improvement: "[ACOs] have demonstrated improvements in quality, patient experience and have been certified to reduce costs," said Slavitt. "There will still be progress and setbacks and we will continually improve."

Takeaway: Participation in ACOs continues to grow with participants increasingly moving to accept more risk. G2

FDA Ramps Up Its Efforts to Ensure Cybersecurity Risks Are Addressed in Medical Devices

As federal agencies including the U.S. Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services encourage interoperability and increased sharing of patient information to inform and improve quality of care and decrease costs, the risks inherent in that connectivity are also a significant concern. Laboratories are central to the discussion of interoperability and connectivity as easy transmission and sharing of laboratory test orders and results are critical to treatment decision-making. In the December 2015 issue of *National Intelligence Report*, we highlighted the OIG's 2016 Work Plan which included a new project indicating the OIG is concerned about how well the FDA has ensured that networked medical devices at hospitals safeguard electronic protected health information (ePHI) and beneficiary safety. That article indicated that in light of the OIG's focus, Lisa Gallagher, vice president, Technology Solutions, Healthcare Information and Management Systems Society (HIMSS) North America, predicted the FDA would heighten scrutiny of computerized medical device cybersecurity. The FDA has in fact now issued new draft guidance and held a recent public workshop addressing cybersecurity risks raised by networked medical devices.

FDA Releases Guidance on Safety of Interoperable Devices

Connectivity and interoperability raise not only security issues but also clinical safety and effectiveness issues as well. The FDA issued draft guidance on interoperable medical devices addressing pre-market submission recommendations for devices that interact with other devices or systems, including electronic health record systems. The FDA release announcing the draft guidance stated: "The FDA believes that the use and development of standards that support interoperability of medical devices is vital to creating interoperable systems that are reliable and safe." The FDA is concerned with the devices' ability to "safely and effectively exchange and use the exchanged information" and provides manufacturers with issues to consider when designing interoperable medical devices and drafting pre-market submissions and labeling for those devices. The benefit of interoperability, says the FDA, is the "potential to foster rapid innovation at lower cost." The risk, however, is that without "appropriate functional, performance, and interface requirements" interoperable devices "may lead to the exchange of inaccurate, untimely, or misleading information," device malfunction or patient injury or death. Therefore, the FDA draft guidance outlines for manufacturers the following considerations: anticipated users of the device and their need to understand clinical use and risks of the device and performance needs; device capabilities, security, verification, and validation considerations; labeling containing functional and performance requirements; and consensus standards for design of devices.

The draft doesn't address compatibility issues and connectivity but rather offers recommendations for what to include in the pre-market submission and labeling for an interoperable device.

FDA Guidance

The FDA's draft guidance, "Postmarket Management of Cybersecurity in Medical Devices," notes that a "growing number of medical devices are designed to be networked to facilitate patient care" and necessarily include software that "may be vulnerable to cybersecurity threats." Thus, the agency encourages medical device manufacturers to "address cybersecurity throughout the product lifecycle, including during the design, development, production, distribution, deployment and maintenance of the device."

The FDA provides guidance for medical devices containing "software (including firmware) or programmable logic" and software that constitutes a medical device on its own but the guidance doesn't apply to experimental or investigational medical devices. It addresses post-market surveillance of cybersecurity vulnerabilities. While the majority of "routine updates and patches" won't require advance notification or reporting, remedies addressing a "small subset of cybersecurity vulnerabilities and exploits that may compromise the essential clinical performance of a device and present a reasonable probability of serious adverse health consequences or death" would require agency notification. Among examples of vulnerabilities having impacts that require remediation, the FDA includes a hypothetical hospital report that a medical device fails to operate as intended leading to patient harm. The guidance includes as an appendix a list of elements for an effective postmarket cybersecurity program.

Not all vulnerabilities however are fatal—the FDA "recognizes that medical devices and the surrounding network infrastructure

cannot be completely secured" and there can be inadvertent incorporation of vulnerabilities into software and devices. The FDA is concerned rather with the impact of those vulnerabilities on "essential clinical performance of the device" which trigger patient safety concerns. Public comments will continue to be accepted regarding the draft guidance through April 21, 2016.

Public Workshop

FDA also held a two-day workshop Jan. 20-21, 2016, titled "Moving Forward: Collaborative Approaches to Medical Device Cybersecurity." The workshop addressed "the current state of medical device cybersecurity" and what can be done to improve security. One focus of the discussion was implementation of a "voluntary, risk-based framework for achieving enhanced cybersecurity" developed by the National Institute of Standards and Technology (NIST) with public and private sector collaboration. Compromised medical devices can malfunction, disrupt services or provide inappropriate access to patient information or endanger integrity of electronic health records and risk adversely affecting patient care.

Suzanne Schwartz, MD, MBA, associate director for Science and Strategic Partnerships and Acting Director of Emergency Preparedness/Operations and Medical Countermeasures of the FDA's Center for Devices and Radiological Health, analogized the workshop in her introductory remarks to a soundstage upon which the participants could come together like the members of an orchestra to change a "cacophony" of different stakeholders' efforts to a "symphony," coordinating "the richness and the diversity of efforts in medical device cybersecurity." She emphasized the importance of cybersecurity to patients who "are at the very heart of everything that we do."

Acting FDA Commissioner Dr. Stephen Ostroff declared the topic of "vital importance" noting that technology "is in a constant state of evolution and change" which offers "great promise" but also requires "tremendous vigilance in response to potentially dangerous or risky applications." He therefore exhorted the attendees that "as the devices become increasingly sophisticated and more interconnected and more interoperable, it is really vital that we work to make sure that these systems are protected from intrusions and exploitations just like other types of devices." "We know for instance that the risk that the entire healthcare network could be compromised has grown exponentially over time." He also reminded attendees that this is not the FDA's initial efforts to address cybersecurity, noting the workshop and the recently released guidance build on discussions held in 2014 and the NIST voluntary "Framework for Improving Critical Infrastructure Cybersecurity." In 2014, the FDA also released Final Guidance on Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

Takeaway: While laboratories and other providers seek to attain interoperability and data sharing, the FDA highlights the security risks posed by medical devices that facilitate this goal. G2

CMS Transitions Away from Meaningful Use As We Know It

Centers for Medicare & Medicaid Services (CMS) Acting Administrator Andy Slavitt announced Jan. 11 at the J.P. Morgan Healthcare Conference in San Francisco that the CMS Meaningful Use program that awards incentives for using certified electronic health records to improve patient care will be ending in 2016. "The Meaningful Use program as it has existed, will now be effectively over and replaced with something better," said Slavitt. He indicated CMS would explain the next stage over the next few months.

About a week later, on Jan. 19, Slavitt co-authored a CMS Blog entry with Karen DeSalvo, acting assistant secretary for health at the Department of Health & Human Services, discussing a "transition from the staged meaningful use phase to the new program as it will look under MACRA." The blog backed away from the "end" of meaningful use, however, stating that MACRA "continues to require that physicians be measured on their meaningful use of certified EHR technology for purposes of determining their Medicare payments."

MACRA, the Medicare Access & CHIP Reauthorization Act of 2015, signed into law April 16, 2016, emphasizes the new Merit-Based Incentive Payment System (MIPS) and incentive payments for participation in certain Alternative Payment Models (APMs). As Slavitt explained in his remarks Jan. 11, MIPS measures physicians based on "four categories: quality, cost, the use of technology, and practice improvement." Slavitt indicated that this move away from the meaningful use program "as it has existed" will be guided by four themes:

- Greater focus on patient outcomes physicians achieve rather than their use of technology.
- More user-centered focus that allows providers "to customize their goals so tech companies can build around the individual practice needs, not the needs of government."
- Leveling the technology playing field and enable "apps, analytic tools, and connected technologies to get data in and out of an EHR securely."
- Interoperability—Slavitt says "we are deadly serious about interoperability" and CMS wants to engage patients in their care and close referral loops. Data blocking "won't be tolerated."

Those themes are also discussed in the Jan. 19 blog. Both the Jan. 19 blog and Slavitt's Jan. 11 comments promise further details will be forthcoming about implementation of MACRA and the transition from meaningful use. The Jan. 19 blog emphasized, however, that existing regulations, including stage 3 meaningful use regulations are still in effect. Some relief is provided, however, for those seeking hardship exceptions to meaningful use requirements. New application processes allow groups of providers to submit a single application for the exception rather than individual applications.

Takeaway: Meaningful use is transitioning to an outcomes-focused methodology for assessing health care delivery.

Slavitt Spotlights CMS 2016 Agenda

In addition to causing a stir about Meaningful Use, Centers for Medicare & Medicaid Services Acting Administrator Andy Slavitt highlighted CMS top agenda items for 2016. Besides the transition in store for meaningful use, Slavitt discussed the following agenda items:

- **ACOs.** Noting the increase in participants in Accountable Care Organizations, he declared that "in 2016, we have not only more ACOs, but better ACOs."
- **Medicaid.** Modernization of Medicaid will continue, with CMS' priority being "to attract new innovative companies to invest in the Medicaid IT space."
- **Health Insurance Marketplaces.** Indicating the marketplaces are moving from the "startup stage to a more mature stage," Slavitt indicates an intention to make the marketplaces attractive to consumers, to "create a healthy, stable, and balanced risk pool" and make sure "risk adjustment works as it is intended to allow coverage of individuals with pre-existing conditions" and "proper incentives exist to insure sicker populations."

Dx Industry Joins Global Call for Incentives to Combat Antibiotic Resistance, *Continued from bottom of p.1*

Commercial drug and diagnostic developers agreed on a common set of principles for global action to promote antibiotic conservation and the development of new drugs, diagnostics, and vaccines. Prominent in the declaration was a call for increased usage of rapid, point-of-care diagnostics to improve antibiotic stewardship.

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"The in vitro diagnostics (IVD) sector is ready to stand shoulder to shoulder with colleagues from across industry to tackle the threat of AMR to human health," said Doris-Ann Williams, chief executive of the British In Vitro Diagnostics Association, in an accompanying press release. "IVDs have a critical role to play in preventing unnecessary prescriptions of antibiotics or accurately targeting their use."

Calling the increase in AMR "dramatic," the signees say combatting AMR needs to be a top priority for global public health policymakers. Efforts to combat AMR to date, the group says, have failed because of an "innovation gap" that results from a combination of scientific and commercial barriers.

"The scientific difficulties are formidable and traditional R&D approaches have largely failed: companies, private and public funders have invested billions of dollars over the last 20 years to discover new antibacterials, yet no new class of antibiotic for Gram-negative infections has reached approval in over 40 years," the declaration says. "Therefore, we call on governments to commit to allocating the funds needed to create a sustainable and predictable market for these technologies while also implementing the measures needed to safeguard the effectiveness of antibiotics."

The signees, 85 companies and nine industry associations from 18 different countries, believe that a combination of appropriate incentives, coupled with safeguards to support antibiotic conservation, is needed for companies to invest in R&D. Among the specific requests, the declaration calls for:

- Governments to commit funding and support to develop and implement "transformational commercial models."
- Enhanced conservation of antibiotics through integration of fast and accurate point-of-care and laboratory diagnostics to ensure appropriate antibiotic stewardship.
- Prompt reimbursement decisions at prices that reflect value, for new drugs and diagnostics.

"The value assigned to antibiotics and diagnostics often does not reflect the investment required for their creation or the benefits they bring to society, and we stand ready to work with payers and policymakers on new valuation mechanisms and commercial models that specifically address the unique challenges of this market," the signees commit.

Takeaway: Diagnostics industry calls for governments worldwide to provide safeguards and incentives, including adequate reimbursement for diagnostics, to fight antibiotic resistance. G2

More FDA Workshops Focus on NGS Technology

Last year the FDA held workshops to discuss analytical standards for next-generation sequencing (NGS) and use of curated databases for establishing clinical relevance of genetic variants. The FDA continues its engagement with stakeholders regarding NGS technology, this year fostering public discussion regarding patient and provider perspectives about what to do with genetic test results in a March 2 workshop. Recognizing the vast amount of information that can be yielded from NGS, the difficulty in interpreting results of NGS testing and lack of evidence in some cases linking genetic variants to specific diseases the FDA workshop will discuss how best to make use of the results of NGS testing—based on patient and provider preferences.

The goal, the notice of the workshop announced, is "to learn, when results are generated in a CLIA-compliant laboratory, which results are of importance to patients and providers, how these results should be returned and how much and what types of evidence supporting interpretation of those results is necessary."

Specific questions to be addressed are what patients and providers want reported "when there is no medical action that can be taken," what patients would like to be reported "when there is limited or conflicting evidence supporting the results," how best to present results, what should be included in reporting results, and what providers don't need/want to know. The agency said it will provide case studies to spur the conversation and will make those available on its website in advance of the workshop.

Another workshop to be held Feb. 25, 2016 will also focus on NGS but with specific attention to analytical and clinical validation approaches to NGS-based oncology panels. The FDA notice of the workshop cites the potential for NGS technology to find numerous biomarkers in a patient's tumor specimen and increasing use of NGS tumor panels to screen a cancer patient for several mutations at the same time. The purpose of the workshop is to gain public comment on "approaches to establish performance characteristics of NGS-based oncology panels that include variants that are intended to be used as companion diagnostics, as well as other variants that may be used for alternative therapeutic management of patients who have already been considered for all appropriate therapies."

The agency will accept written comments until March 28, 2016 for the oncology panel workshop and until March 31, 2016 for the genetic test result reporting workshop. Registration is free for both workshops but advance registration for in person attendance is recommended. Live streaming webcasts are offered for both workshops.

Takeaway: The FDA continues to engage in public conversations about how best to ensure quality, efficacy and appropriate use of genetic testing and NGS technology. G2

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