Your Independent Source for Business & Financial News

LABORATORY INDUSTRY REPORT™

Vol. 16, Iss. 20, December 29, 2016

HIGHLIGHTS

Abbott, Molecular Lab Acquisitions Dominate the Year in Diagnostics Industry M&A

Although volume of diagnostics industry mergers and acquisitions was up slightly in 2016, the big story of the year was the deals that did not go through—at least not yet.

Abbott Steals the Headlines…

No diagnostic company generated more attention in the M&A realm over the past year than Abbott. The Illinois diagnostics giant's $25 billion acquisition of medical device maker St. Jude Medical was, by far, the biggest deal of the year. But it was touch and go for a while. In October, St. Jude announced that it was having problems with its implantable cardioverter defibrillator and resynchronization devices, sending both companies' stock prices sharply down.

Continued on page 8

Palmetto Latest Medicare Contractor to Loosen Up on Covering Molecular Dx Testing

Advanced diagnostic tests are emerging faster than the clinicians can document their clinical utility. All of this creates an interesting dilemma for payors as far as coverage is concerned. Normally the most cautious of payors, Medicare has demonstrated an increasing willingness to cover newfangled tests—at least in certain circumstances—with the expectation that they do work and that the studies will eventually catch up. The recent local coverage determinations (LCDs) issued by Palmetto, GBA, one of Medicare's most important contractors, is an excellent illustration of where things seem to be evolving with regard to Medicare coverage of new molecular diagnostic tests.

What's at Stake

First, a quick refresher on LCDs. Medicare covers only services that are "reasonable and necessary." Each Medicare contractor has discretion to decide which services meet those criteria. LCDs

Continued on page 2

Palmetto Latest Medicare Contractor to Loosen Up, *from page 1*

set out the particular contractor's coverage rules. So-called draft LCDs typically contain proposed revisions and updates to coverage rules and are open to comment for at least 45 days. Once the comment period ends, the contractor issues a final LCD.

The lab test LCDs discussed in this article are draft LCDs that Palmetto issued on Dec. 23. The comment period runs between Feb. 6 and March 23. So you should have plenty of time to respond if you want to weigh in.

Let's go through the 8 key coverage changes.

1. Eliminate Coverage of Vectra DA for Rheumatoid Arthritis (DL37024)

Test: Vectra DA generates a test score based on 12 biomarkers associated with rheumatoid arthritis inflammation that is used to track disease activity and a patient's response to treatment.

Proposed Change: The draft LCD proposes to end Medicare coverage of Vectra DA.

Explanation: Palmetto says there is conflicting evidence on Vectra DA's effectiveness, citing, among other things, a recent study suggesting that test scores yielded are unreliable and should not be used to guide treatment. Palmetto also notes that 2015 American College of Rheumatology treatment guidelines recommend "functional status assessment using a standardized, validated measure" and do not even mention biomarker testing.

Financial Impact: Vectra DA is manufactured by Myriad Genetics' subsidiary Crescendo Biosciences. Myriad "strongly disagrees" with the proposal and claims the cited study is flawed. There is a lot on the line. Ending Medicare coverage of Vectra DA could cut Myriad's revenues by $35 million to $40 million, according to one report (by a Piper Jaffray analyst cited in GenomeWeb).

2. Coverage of Prolaris for Intermediate-Risk Prostate Cancer Patients (DL37043)

Test: Prolaris measures the aggressiveness of prostate cancer by analyzing 31 cell cycle progression genes.

Proposed Change: The LCD proposes to cover the test for men who have favorable intermediate risk of prostate cancer under National Comprehensive Cancer Network (NCCN) guidelines.

Explanation: Palmetto acknowledges the current lack of evidence supporting Prolaris's clinical utility among men at intermediate risk of prostate cancer but says that prospective studies supporting the test's effectiveness for identifying low-risk patients who can then avoid unnecessary invasive procedures is enough to justify coverage. Last year, Palmetto and another Medicare contractor Noridian issued a final LCD covering Prolaris for patients meeting NCCN criteria for low- and very-low-risk prostate cancer.

Financial Impact: Like Vectra DA, Prolaris is manufactured by Myriad Genetics. If approved, the draft LCD proposal would expand coverage for

LIR

Kelly A. Hardy, JD, Editorial Director

Glenn S. Demby, Contributing Editor

Catherine Jones, Contributing Editor and Social Media Manager

Barbara Manning Grimm, Managing Editor

David van der Gulik, Designer

Randy Cochran, Corporate Licensing Manager

Myra Langsam, Business Development

Michael Sherman, Director of Marketing

Jim Pearmain, General Manager

Pete Stowe, Managing Partner

Mark T. Ziebarth, Publisher

Laboratory Industry Report (ISSN 1060-5118) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 1-888-729-2315
Fax: 1-855-649-1623
Web site: www.G2Intelligence.com.

about 15 percent of men or roughly 30,000 per year, according to an official company statement. Prolaris coverage in intermediate-risk patients is a $65 million market, according to the aforementioned Piper Jaffray analyst.

3. Limited Coverage of Xpresys for Lung Cancer Screening (DL37031)

Test: Xpresys is a molecular blood test in which expression levels of two proteins are assessed against five clinical risk factors to identify which lung nodules are likely benign and which patients are eligible for surveillance via noninvasive CT scans rather than invasive surgical procedures.

Proposed Change: Palmetto would cover Xpresys Lung version 2 (XL2) but only in limited circumstances. Under the LCD, XL2 would be covered only:

- To assess lung nodules of between 8 and 30 mm in diameter;
- For patients over age 40 who have a pre-test cancer risk of 50 percent or less.

Explanation: In Feb. 2015, CMS announced that Medicare would cover lung cancer screening. But while it can save lives and minimize the need for costly treatment, low-dose computed tomography screens also detect intermediate lesions that cannot be defined as benign or malignant without costly and sometimes dangerous additional testing.

Financial Impact: So the capacity to detect benign tumors noninvasively makes biomarker tests like Xpresys, which is manufactured by Seattle-based Integrated Diagnostics and has been on the market only since 2014, potentially valuable. By the same token, only a few of these tests are commercially available; and they have yet to be adopted for routine clinical use. Accordingly, Medicare has been wary about covering them, as reflected in the LCD.

4. Limited Coverage of DecisionDx-UM for Metastatic Cancer Risk (DL37033)

Test: DecisionDx-UM is a gene expression profile test assessing the expression levels of 15 messenger RNA transcripts to evaluate whether patients newly diagnosed with uveal melanoma (UM) are at risk for metastatic disease.

Proposed Change: Palmetto proposes limited coverage of DecisionDx-UM for patients diagnosed with UM when there is no evidence of distant metastatic disease at the time of diagnosis for purposes of determining whether the patient should be referred to a specialist for further surveillance. Physicians should not order the test unless they intend to act upon the results.

Explanation: Although there is enough clinical evidence to support clinical utility for now, the LCD stipulates that continued coverage will depend on publication and/or presentation of clinical utility evidence. This is in line with LCDs of other contractors, such as Noridian which began covering DecisionDx-UM last year.

Financial Impact: DecisionDx-UM was developed by an ocular oncologist and exclusively licensed to Castle Biosciences in 2009. The test is "now used as a standard of care by over 95 percent of ocular oncologists in the U.S.," according to the company website.

5. Coverage of Comprehensive Genomic Profiling (CGP) for Specific Cancers

Test: CGP cancer analysis is a single test that uses tissue from a tumor to detect genomic alterations and information that can guide diagnosis and individualized treatment.

Proposed Change: Palmetto issued LCDs covering CGP for patients with three different types of cancers: i. metastatic melanoma (DL37041); ii. metastatic colorectal cancer (DL37039); and iii. advanced primary peritoneal, fallopian tube and ovarian cancer (DL37045). All three of the LCDs include the same basic coverage conditions, including the requirement that:

- The patient be newly diagnosed with the cancer involved;
- The patient has not received CGP (or, in the case of metastatic melanoma, CGP or polymerase chain reaction (PCR)) testing for genomic alterations;
- The test is capable of detecting all four types of DNA alterations associated with cancer; and
- The test meets Palmetto's Analytical Performance Specifications for CGP (APS).

Explanation: The new CGP LCDs are significant for what they do *not* include, namely, the requirement that labs submit testing and patient data through registries, a burdensome obligation that has appeared in previous Palmetto CGP coverage policies.

Financial Impact: As in the brand-specific LCDs, Palmetto acknowledges the current lack of evidence supporting the clinical utility of CGP for metastatic melanoma but states its belief that the test works and will be validated by forthcoming studies.

Takeaway: Medicare Is Coming to Accept Molecular Testing. Palmetto is only one Medicare contractor. But far from being a blip on the radar screen, the new Palmetto LCDs are a reflection of how CMS and its other contractors are coming around on newly developed molecular diagnostic testing—despite the current lack of evidence supporting their clinical effectiveness. In other words, the Medicare payor community is moving ahead with coverage in the expectation that the justifying scientific studies will eventually catch up and not the other way around.

G2 INTELLIGENCE *INSIDE THE* LAB INDUSTRY

New Laws: Civil Monetary Penalties Get More Expensive—and Easier to Dish Out

One aspect of the Affordable Care Act (ACA) that is not likely to be repealed is the enhancement of penalties for Medicare and Medicaid fraud and abuse. That includes the new Regulation on civil monetary penalties (CMPs) that the OIG adopted on Dec. 7. Here is a quick overview of the new rules and their potential impact on business.

How CMPs Work

The Civil Monetary Penalties Law (CMPL), which dates back to 1981, allows the government to impose CMPs on providers for various offenses. CMPL violations can also get providers excluded from Medicare, Medicaid and other federal health care programs.

In 2010, Congress upped the ante by putting language in the ACA authorizing the OIG to impose CMPs for "false and fraudulent claims and similar misconduct." As if potential penalties under the False Claims Act, Anti-Kickback Statute and/or Stark Law were not already tough enough, such violations would now expose labs to the risk of tack-on CMPs. But the ACA changes were not self-actuating. The OIG had to adopt specific regulations to put its new CMPs powers into effect. And that is what the Dec. 7 Regulation does.

4 Ways the New CMP Rules May Impact You

Here are the four aspects of the new rules that labs and other diagnostics providers should be concerned about, listed in order of importance.

1. More Ways for OIG to Sock Labs with CMPs

Change: Current rules authorize CMPs for six basic offenses; the new rules nearly double that total to 11, as summarized in the table below.

Offenses Justifying Imposition of CMPS—Before & After

Original CMP Offenses	New CMP Offenses
■ Knowingly presenting or causing to be presented false claim for services ■ Knowingly giving or causing to be given false or misleading info reasonably expected to influence decision to discharge patient ■ Offering or giving remuneration to federal health care program beneficiary likely to influence receipt of reimbursable items or services ■ Arranging for reimbursable items or services with entity excluded from a federal health care program ■ Knowingly or willfully soliciting or receiving payment for referral of beneficiary ■ Using a payment intended for beneficiary for another use	■ Failure to grant OIG timely access to reasonably requested records ■ Ordering or prescribing while excluded when excluded person knows or should know that item/service may be paid for by federal health care program ■ Making false statements, omissions or misrepresentations in an enrollment or similar bid application to participate in federal health care program ■ Failure to report and return an overpayment ■ Making or using false record or statement that is material to a false or fraudulent claim

Practical Impact: Labs will be at greater risk of CMPs, particularly by the new overpayment offense. Under the new rules, failure to report and return overpayments within 60 days of identifying them can result in CMPs of up to $10,000 *per item or service* overpaid. The "per-service" language is especially scary for labs and other diagnostics providers that submit a high volume of low-value claims.

But it could have been much worse. In its Interim Rule, the OIG proposed penalizing providers $10,000 *per day* for each day they fail to report and return an overpayment. Fortunately for labs, the daily penalty did not make the final cut. However, the OIG did suggest that long delays in failing to report and return overpayments could be an "aggravating factor" justifying higher CMPs.

Overpayment is hardly the only concern. Other key new CMP offenses potentially affecting labs include:

- Not giving the OIG access to requested records;
- Use of false records or statements in false claims; and
- Accepting test orders from excluded providers.

2. CMPs Will Be Higher

Change: Not only will it become easier to get fined but fine amounts will be higher. You need a little context to understand why.

The U.S. Department of Health and Human Services (HHS) is only one of many federal agencies that impose CMPs to punish violations of the laws under their jurisdiction. Some of these agencies have not done a good job of keeping their CMP schedules in line with inflation. So last year, Congress passed a law called The Bipartisan Budget Act of 2015 (BBA) mandating that federal agencies adjust their CMPs for inflation. The so-called "catch-up adjustment" had to be based on the difference between the CPI in October 2015 and the month the agency last increased its CMPs. Thereafter, agencies had to adjust their CMPs annually for inflation.

Practical Impact: HHS had not adjusted its own CMPs in decades. As a result, its "catch-up adjustments" were significant—as high as 150% in some cases. The table below shows key CMP adjustments that HHS made in the initial 2015 adjustment.

2015 CMP Adjustments

CMP Offense	Pre-Inflation Amount	Post-Inflation Amount	Percentage Increase
Offering remuneration to induce program beneficiaries to use particular providers	$10,000	$15,024	50.24%
Employing or contracting with excluded individual	$10,000	$14,718	47.17%
Knowing and willful solicitation, receipt, offer or payment for referring individual for service ... paid for by federal health care program	$50,000	$73,588	47.17%
Submitting or causing to be submitted claims in violation of Anti-Kickback Statute or Stark law	$15,000	$23,863	59.09%

And because BBA mandates annual inflation adjustments, HHS had to increase the 2015 numbers again in 2016.

3. Risk of CMPs for Labs that Deal with Medicare Advantage and Part D Plans

Change: CMPs can be assessed against Medicare Advantage (MA) or Part D contracting organizations that:

- Enroll individuals without their consent
- Transfer enrollees for the sole purpose of making a commission
- Transfer enrollees from one plan to another without their consent
- Fail to apply with applicable marketing rules
- Employ or contract with persons who engage in marketing violations.

Practical Impact: Enrollment and marketing of health plans are not activities in which labs typically get directly involved. But the "employ or contract" offense may be broad enough to cover labs that do business with MA or Part D plans.

4. Clear Factors for Setting CMP Amounts

Change: The OIG has discretion to set the amount of CMPs. The Regulation adds transparency by listing the five factors the OIG will use to make such determinations, including:

- The nature and circumstances of the violation
- Whether the provider has a history of offenses
- The person's "degree of culpability"
- Other wrongful conduct
- Other matters "as justice may require."

Practical Impact: Knowing the aggravating and mitigating factors can help you manage CMP risks. For example, one insight that is especially worthy of noting is the OIG's acknowledgement that in assessing "degree of culpability," it will treat "appropriate and timely" corrective action as a mitigating factor. To get credit, though, the provider must disclose the violation under the OIG Self-Disclosure Protocol.

Takeaway: Three Ways to Protect Yourself. The new CMPs Regulation does not change the substance of your compliance obligations; but it does make the potential consequences of not living up to those obligations more costly. Some of the specific things to put on your to-do list:

1. *Minimize risk of CMPs for overpayments by ensuring your lab meets the requirements of the Feb. 2016 CMS Final Rule on complying with the 60-day deadline for returning Medicare overpayments (G2 Compliance Advisor, April 2016)*
2. *Take advantage of the new "degree of culpability" mitigating factor for CMPs by familiarizing yourself with and, if necessary, implementing the OIG Self-Disclosure Protocol (G2 Compliance Advisor)*
3. *Avoid CMPs for employing or contracting with excluded providers by performing background checks on job applicants, current employees and referring physicians (G2 Compliance Advisor, Oct. 2016)*

Abbott, Molecular Lab Acquisitions Dominate the Year in Diagnostics Industry M&A, *from page 1*

The deal also hit regulatory snags in Europe. The European Commission eventually gave antitrust approval, but only on the condition that St. Jude sell off its Angio-Seal and Fermoseal vascular closure assets, including a manufacturing plant in Puerto Rico, and that Abbott divest itself of the Vado steerable sheath it acquired as part of its acquisition of Kalila Medical in February. Japanese company Terumo Corp. has agreed to acquire all of the affected assets for $1 billion. But despite the challenges, the deal has been approved by St. Jude shareholders.

Abbott contends that Alere has lost "substantial value" as a result of lost billing privileges, government subpoenas, recalls and other business setbacks suffered since February.

The same cannot be said for Abbott's other big strategic play of 2016: the ill-fated $5.8 billion mega-merger with Alere. When the deal was announced in February, it looked like a coup for both sides with the merged entity to become the leading diagnostics provider in the US. But things started going wrong almost immediately. In March, Alere's foreign business practices drew unwanted attention from the U.S. Justice Department. Abbott offered a bailout payment but Alere refused. After months of claims and counterclaims, things came to a head in December when Abbott asked a Delaware Chancery Court to let it out of the deal.

Abbott contends that Alere has lost "substantial value" as a result of lost billing privileges, government subpoenas, recalls and other business setbacks suffered since February. But Alere refuses to go away, claiming that nothing in Abbott's lawsuit justifies terminating the deal and expressing confidence that the merger will proceed.

As hopes for a settlement fade, it will be up to the courts to determine the fate of the deal. Meanwhile, there are indications that the negative publicity and fallout from the Alere mess has already compromised Abbott's reputation and desirability as a strategic position in the eyes of other potential targets. See *LIR*, Nov. 25, 2016. Having to go through with a shotgun marriage to Alere would only add insult to injury.

…But Other Companies Struggled with M&A Deals Too

Abbott was hardly the only diagnostics company to struggle with M&A. Several of the year's biggest deals hit unexpected snags along the way to consummation, including:

- Thermo Fisher Scientific's $1.3 billion acquisition of cellular and genetic analysis company Affymetrix in March. To complete the deal, Thermo Fisher had to overcome not one but a pair of competing bids by Origin Technologies, a new company created by Affymetrix former executives.
- Qiagen's $103.5 million acquisition of a 95 percent stake in Danish molecular diagnostics company Exiqon via tender offer in June. Qiagen had to amend the terms of its bid three times to meet the threshold for shareholder acceptance. And even then, Exiqon had to twist shareholders' arms and warn of profitability risks for the deal to go down.

The deal pattern of 2016 was largely consistent with previous years with established diagnostics companies acquiring smaller firms to beef up their strategic positions in the emerging molecular diagnostics market.

- Luminex Corp.'s acquisition of point-of-care molecular diagnostics company Nanosphere, Inc. for roughly $90 million in cash. The deal closed in June but Luminex had to raise its initial offer from $1.35 to $1.70 per share after an unexpected and unsolicited third party stepped in and offered $1.50. (See *LIR*, June 2, 2016.)

Molecular DX Remains Center of M&A Activity

Although the Abbott deals were the richest, most of the M&A energy from 2016 focused on relatively smaller deals involving small cutting edge molecular diagnostics and genetics firms. GenomeWeb reports that the number of mergers and acquisitions involving these companies increased for the second year in a row. However, the rate of increase, from 48 to 51, or six percent, was significantly less than the 33 percent jump in M&A deals in 2015.

The deal pattern of 2016 was largely consistent with previous years with established diagnostics companies acquiring smaller firms to beef up their strategic positions in the emerging molecular diagnostics market. Thermo Fisher, Laboratory Corp. of America and Myriad Genetics were among the established companies that engaged in multiple acquisitions during the year. The chart below summarizes the 10 biggest deals of 2016, both closed and pending.

Top 10 Biggest M&A Deals of 2016 in Diagnostics

Rank	Acquiring Company	Target Company	Price
1	Abbott	St. Jude Medical	$25 billion*
2	Abbott	Alere	$5.8 billion*
3	Thermo Fisher Scientific	FEI Company	$4.2 billion
4	Danaher Corp.	Cepheid	$4.0 billion
5	Thermo Fisher Scientific	Affymetrix	$1.3 billion
6	Myriad Genetics	Assurex Health	$410 million—$225 million upfront + $185 million milestones
7	Laboratory Corp. of America	Sequenom Laboratories	$371 million (See *LIR*, Sept. 6, 2016)
8	Varian Medical Systems	PerkinElmer (medical imaging business line)	$276 million*
9	Takara Bio USA Holdings	Rubicon Genomics	$75 million*
9	Boston Scientific	Neovasc (15% equity stake + bio tissue business line)	$75 million*

* Deal still pending and not yet closed at time of publication
Note: Only includes deals in which price and other financial terms were disclosed.

FDA Watch: Next-Gen Sequencing Companion Test Wins Approval

Last month, the U.S. Food and Drug Administration shelved its long-awaited/dreaded (depending on your point of view) final guidance on laboratory-developed tests. (For the details, see, LIR, Nov. 2016). This month, it was back to business as usual—although a piece of significant new legislation will have a lasting impact on the FDA in the long-term.

New FDA Approvals

Arguably, the most noteworthy FDA Section 510(k) approval of the month was for Foundation Medicine's FoundationFocus CDxBRCA, a next-generation sequencing-based companion diagnostic test. The FDA approved the test for use in identifying advanced ovarian cancer patients with BRCA mutations. Not coincidentally, the agency has or shortly will approve pharmaceutical products for treating ovarian cancer patients with the gene mutations detected by CDxBRCA, including Clovis Oncology's PARP inhibitor Rubraca.

At least three other diagnostics products received Section 510(k) clearance from the FDA in December, including:

Manufacturer(s)	Product(s)
Statlife	DenSeeMammo breast density assessment software based on BI-RADS guidelines that can be used in combination with Statlife's MammoRisk risk assessment tool
Animas Corporation (a subsidiary of Johnson & Johnson)	One Touch Vibe Plus insulin pump and continuous glucose monitoring system
Cepheid	Xpert MRSA NxG test for MRSA (methicillin-resistant Staphylococcus aureus) infection

New Applications

Companies that submitted new 510(k) clearance applications during the month include:

- Biocartis for its Idylla molecular diagnostics platform
- Biocartis and Janssen Diagnostics for Janssen Idylla Respiratory IFV-RSV Panel for detecting influenza and respiratory syncytial virus using the Idylla platform
- GenMark Diagnostics for ePlex, a respiratory pathogen panel based on the company's eSensor electrochemical detection technology
- Great Basin Scientific for its molecular panel assay for stool pathogens.

21st Century Cures Act Draws New Lines on FDA Authority

The month's most significant FDA development in the long-term was the passage of the new 21st Century Cures Act legislation which imposes new rules on FDA oversight of drugs, devices and biologics. Key items:

- New language "clarifying" that the FDA is not responsible for regulating health care software targeting health care facility administrators or functions, e.g., software for transferring lab data;
- Similar clarification that the FDA lacks responsibility for regulating consumer-facing applications, including but not limited to apps for "maintaining and encouraging a healthy lifestyle";
- New approval pathway allowing for smaller and faster clinical trials for antibacterial drugs that treat infections resistant to existing treatments; and
- $500 million in funding for new administrative and enforcement activities—although Congress must adopt actual legislation to appropriate that money.

False Claims Act Cases Continue to Be a Cash Cow for the Feds

Easy liability; High penalties; Private individuals willing to do the heavy lifting by bringing *qui tam* whistleblower lawsuits.

It is not hard to understand why few federal government ventures generate a more handsome return on investment than enforcement of the False Claims Act (FCA). After sagging a tad in recent years, FCA recoveries bounced back in fiscal year 2016, generating their third highest total in over a decade. As usual, most of that money came from the health care industry.

FCA Recoveries by the Numbers

Here are some of the key numbers from the year in FCA recoveries as reported by the U.S. Department of Justice (DOJ) on Dec. 14.

- **$4.7 billion:** Total FCA recoveries in FY 2016, the third highest since the government has been keeping track of these numbers;
- **$2.5 billion:** Total recoveries against health care providers in FY 2016—not including state Medicaid;
- **$31.3 billion:** Total FCA recoveries between 2009-2016;
- **$4 billion:** Average annual FCA recoveries between 2009-2016;
- **$19.3 billion:** Total FCA recoveries from health care providers between 2009-2016;
- **$2.4 billion:** Average annual FCA recoveries from health care providers between 2009-2016;
- **702:** Total *qui tam* (whistleblower) lawsuits filed in FY 2016—an average of 13.5 cases per week;
- **$2.9 billion:** Total recoveries in *qui tam* lawsuits in FY 2016;
- **$519 million:** Total recoveries paid to whistleblowers in FY2016.

The biggest FCA recovery against a lab for the year was the $260 million paid by Millennium Health (formerly Millennium Laboratories) to settle allegations of billing Medicare for unnecessary urine and genetic tests and giving free items to physicians to induce referrals of costly tests.

Beyond the Numbers

The DOJ FY 2016 FCA report is noteworthy not just for the numbers but the enforcement trends it cites, including:

Voluntary Compliance: U.S. Health and Human Services Inspector General Daniel R. Levinson emphasized that the big dollar values belie the "collateral benefits" achieved via "voluntary observance of federal laws through corporate integrity agreements addressing compliance weaknesses and self-disclosures that encourage health care providers and other entities to voluntarily report suspected violations."

Executive & Individual Accountability: The DOJ also continued its determination to go after not just entities but the individuals running them in pursuit of the policy announced in the September 2015 Yates memorandum. Of the 11 individuals the DOJ cites as being held personally liable for alleged false claims in 2016, nearly half were connected with laboratory testing, including:

Congress to CMS: Catch Medicare Fraud Before It Happens

Despite the enforcement successes reflected in the Department of Justice's announcement of $4.7 billion in recoveries in fiscal year 2016, there is concern that more needs to be done before false claims are paid. In September 2016, Members of Congress sent a letter to Andrew Slavitt, Acting Administrator of the Centers for Medicare and Medicaid Services, stating that "the billions of dollars lost to Medicare fraud each year underscore the importance of stopping potentially fraudulent payments before they are made." The letter eschews the so called "pay and chase" efforts to recover improper payments after the fact and supported increased use of methods such as the Fraud Prevention System (FPS) to use predictive analytics to "identify claims and providers that present a high fraud risk to the Medicare program." The Congressional members expressed a concern that despite the use of FPS, CMS was still relying "too heavily" on efforts to identify and recover improperly paid claims rather than preventing them from happening. The letter requested information regarding the types of schemes FPS has identified and total investigations for the past three years.

- Dr. Jonathan Oppenheimer, a former executive with a Nashville drug testing laboratory who agreed to a $9.35 million settlement;
- Gottfried and Mieke Kellerman, founders of Pharmasan Labs, Inc. and NeuroScience, Inc., who settled for $8.5 million;
- Dr. David G. Bostwick founder and former owner and CEO of Bostwick Laboratories, who entered into a $3.75 million settlement; and
- Dr. David Spellberg and Robert A Scappa, urologists who settled allegations of billing Medicare for medically unnecessary FISH testing.

Takeaway: The DOJ's reporting of FY 2016 fraud recoveries indicates large scale and individual enforcement efforts continue unabated and that laboratory testing is a fruitful target for enforcement agencies.