G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 38th Year of Publication

Vol. 17, Iss. 2, Febuary 2017

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Conferences:

Lab Leadership Summit: Designing, Implementing & Managing a High-Profit Lab Outreach Program
May 11, 2017 – 8 a.m.-5 p.m.
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October 25-27
Hyatt Regency Washington on Capitol Hill, Washington, DC
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Health Care Organizations Urge Congress to Update LDT Oversight

Late last year, the U.S. Food and Drug Administration (FDA) announced that it would not finalize its 2014 proposed guidance on agency oversight of laboratory developed tests (LDTs) but would work with the new administration and Congress "to get our approach right." (See "No Final LDT Framework in 2016: FDA Seeks Further Input from Stakeholders, New Administration," *NIR*, Nov. 26, 2016.) But that doesn't mean the FDA is passively waiting for the new administration to act—it issued a discussion paper in January outlining a possible alternative approach to FDA regulation of LDTs.

Shortly thereafter, health care organizations emphasized the urgency of addressing LDT safety with a letter urging Congress to act soon-

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The 7 Things Labs Need to Know About the Trump Travel Ban

We'll leave it to others to argue whether the Trump travel ban is legal, moral or wise. What we can tell you is that while it may be on temporary hold, the travel ban and the policy it embodies are challenges that labs are likely going to have to deal with sooner or later. Here are the six things you need to know about the travel ban and its practical impact on your lab.

1. What Is It?

The so called "travel ban" is an Executive Order (EO) issued on Jan. 27 to temporarily bar individuals from designated countries (restricted countries) from entering the U.S. The EO would actually impose three different entry bans:

Duration	Entrant Status	Entrant Nationality
120 days	Refugees	All nationalities
Indefinite	Refugees	Syria
90 days	Citizens, both immigrant and non-immigrant	Iran, Iraq, Libya, Somalia, Sudan, Syria, Yemen

Continued on page 8

FDA Discussion Paper Synthesizes Stakeholder Feedback on LDT Regulation, *from page 1*

er rather than later in addressing oversight. Calling the current regulatory system for LDTs "inadequate and in urgent need of updating," the American Cancer Society Cancer Action Network and 32 other organizations sent a letter to U.S. Senate leaders urging them to update the oversight framework for all molecular diagnostic tests, with an emphasis on LDTs.

"It is imperative that patients and physicians are assured of the accuracy and reliability of these test results when making vital health decisions," write the letter's signees. "Currently, diagnostic tests undergo widely different levels of oversight depending on whether they are submitted to the U.S. Food and Drug Administration for review or are offered as LDTs."

Citing the increased complexity of current LDTs and the fact these tests are increasingly performed in reference laboratories with national reach, the organizations, representing patients, scientists, advocates, caregivers, and health care professionals, say that CLIA regulation does not adequately address the "safety and effectiveness" of LDTs.

Under CLIA, laboratories are required to demonstrate the analytical validity of the tests they offer (the test's reproducibility), but CLIA does not ensure consistent performance for measuring the same analyte across laboratories, the Cancer Action Network says. Additionally, the organizations stress that CLIA does not evaluate the clinical validity of a test—the test's ability to accurately diagnose a condition.

"There is no systemic way to be sure of the accuracy and reliability of these tests," say the signees. "The current oversight framework creates inconsistencies in oversight and can leave FDA with limited options to catch and address problematic LDTs."

The letter cites Theranos' invalidation of thousands of test results as "an example of why proactive oversight by FDA based on a risk-based approach paradigm is necessary." As further evidence of the need for updates to the oversight framework, the organizations cite a Dec. 15, 2016 study in *JAMA Oncology* that reported "markedly" different test results from two different commercially available, next-generation sequencing-based tumor profiling tests. The letter explained that in the study, "[r]esearchers sent samples from the same cancer patients to different LDT providers for cancer testing, and found only 25 percent of the drug recommendations based on test results overlapped."

That study compared results from the tissue-based FoundationOne test (F1; Foundation Medicine) with the blood-based Guardant360 (G360; Guardant Health) test in nine patients seen at a community oncology practice. Previous published studies have shown that both the F1 and G360 tests have high specificities (above 99 percent), but lower sensitivities. The level of concordance between the platforms was compared among two men and seven women (mean age, 61 years). In addition to comparing identified genomic alterations, test results were compared regarding recommended drugs.

For eight patients with identified alterations, 36 drugs were recommended, in total. However, only one-quarter of the drugs were recommended for the same

NIR

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National Intelligence Report (ISSN 2332-1466) 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.

"Since both the F1 and the G360 tests are performed in thousands of patients with cancer each year, these findings are clinically relevant."

— Nicole M. Kuderer, M.D.

patients by both platforms. In five patients there was no overlap between the drugs recommended by the two tests. Concordance among recommended drugs improved to 62 percent (8 of 13 drugs), when reported mutations were also concordant.

In seeking an explanation for the discordant test results, the authors cite differences in timing between the two tests as a possible source, but note that seven of the eight patients with reported alterations underwent both tests within a 2.5-month period. Other potential sources of the discordance are tumor heterogeneity and differences in the variant-interpretation process.

"Since both the F1 and the G360 tests are performed in thousands of patients with cancer each year, these findings are clinically relevant," write the authors led by Nicole M. Kuderer, M.D., from University of Washington, Seattle. "In-depth comparisons of next-generation sequencing tests across larger numbers of patients with cancer are needed to improve concordance and clinical utility."

The authors note that theirs was not the first to identify "significant discordance." Two studies comparing tissue-based next-generation sequencing tests and another report also comparing the F1 and G360 tests, all found discordant test results.

Takeaway: As a recent study compares results of different sequencing platforms, health care organizations argue there's an urgent need for oversight of LDTs.

Flu Antigen Tests Reclassified as Class II Devices

Effective this month, the U.S. Food and Drug Administration (FDA) has reclassified antigen-based, rapid influenza virus antigen detection test systems (RIDTs) used directly on clinical specimens from Class I to Class II devices. Further, the FDA is introducing special controls aimed at improving the overall quality of flu testing and reducing the number of misdiagnosed cases.

Given that misdiagnosis of the flu could lead to inappropriate use of antibiotics, failure to use antiviral therapy, and ineffective infection control measures, the FDA believes premarket notification is necessary for these tests "to provide reasonable assurance of safety and effectiveness."

RIDTs are widely used in non-clinical laboratory settings, such as physicians' offices, and evidence from the U.S. Centers for Disease Control and Prevention and the Association of Public Health Laboratories showed the tests were performing poorly in medical practice, resulting in many misdiagnosed cases.

In addition to the reclassification, special controls were established to mitigate health risks. These special controls include new minimum performance criteria; use of FDA-accepted comparator method for establishing the performance (currently, either an FDA-cleared nucleic acid-based test or a correctly performed viral culture method); and annual analytical testing of cir-

culating strains, based on the CDC's annual standardized seasonal influenza virus test panel, as well as emergency analytical reactivity testing of newly emerging strains, when needed.

Additionally, the FDA's final order requires that the results of the last three years of annual analytical reactivity testing be included as part of the device's labeling. The FDA is giving manufacturers one year to come into compliance with the final rule.

Takeaway: Manufacturers have one year to come into compliance with new FDA regulations of RIDTs, including reclassification and implementation of special controls.

Fraud and Abuse Efforts Face Declining ROI

The federal government's return on investment (ROI) in the fight against health care fraud continues a steady decline according to the latest numbers reported for the Health Care Fraud and Abuse Control Program (Program). Every year the Department of Health and Human Services and the Department of Justice must jointly report to Congress on the Program's successes and its expenditures. Those agencies issued a report on accomplishments for fiscal year 2016—the Program's 20th year—in January. While the successes are significant, the costs are as well. Here is a rundown on some details revealed in the report:

- DOJ opened 975 criminal health care fraud investigations and 930 civil health care fraud investigations during FY 2016
- Prosecutors filed 480 criminal cases and gained convictions for 658 defendants
- OIG investigations during FY 2016 led to 765 criminal actions and 690 civil actions.
- OIG excluded 3,635 individuals from participating in federal programs
- $282.1 million in mandatory funding (after $20.6 million in mandatory sequester reductions), and $681.0 million discretionary funding

The bottom line revealed in the report, however, indicates a decline in the ROI for the Program for the third year in a row. For FY 2016 the report reveals an ROI of $5.00 for every dollar spent, for the three year period 2014-2016. "Because the annual ROI can vary from year to year depending on the number and type of cases that are settled or adjudicated during that year, DOJ and HHS use a three-year rolling average ROI for results contained in the report," the agencies explain in their report every year. Here's how that ROI compares to the ROI reported in the annual reports going back to 2011 (reported for three year period ending in that FY year):

FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
$7.20	$7.90	$8.10	$7.70	$6.10	$5.00

Takeaway: Although enforcement efforts remain aggressive, the return on investment has faced decline in recent years.

FOCUS ON:

Emphasis on Individual Responsibility Likely to Continue Even After Yates Departure

Pursuing False Claims Act (FCA) and Anti-Kickback (AKS) prosecutions against labs is just one of the things the U.S. Department of Justice does to crack down on corporate wrongdoing. On Sept. 9, 2015, the DOJ increased the pressure when then-Deputy Attorney General Sally Quillian Yates issued a memo (commonly known as the Yates Memo) calling on prosecutors to focus not just on the corporation but the individuals responsible for its transgressions. Now that a new administration has begun and Yates has been replaced by newly-confirmed Attorney General Jeff Sessions, some in health care may be wondering if the policy in the Yates memo will be pursued as vigorously.

Labs no longer qualify for leniency based on cooperating with law enforcement unless they furnish "all relevant facts relating to the individuals responsible for the misconduct."

While nobody can be sure what's going to happen, here are a few things we do know about the Yates Memo and some predictions for what its future may hold.

The 3 Key Changes in Prosecution Policy

While the Yates memo is best known for its emphasis on holding individuals accountable for corporate wrongdoing, it's worth a reminder that it has several practical implications beyond simply that policy on individual accountability. Here are three important ways the memo impacted DOJ enforcement policy:

1. Labs no longer qualify for leniency based on cooperating with law enforcement unless they furnish "all relevant facts relating to the individuals responsible for the misconduct."
2. Absent "extraordinary circumstances," DOJ settlements with corporations would no longer release the individuals responsible for the transgression from liability.
3. The DOJ will sue individuals for money damages regardless of their ability to pay.

(For more about these changes and their practical implications for labs being investigated, see Compliance Perspectives for an in-depth article about the Yates memo in the December 2015 issue of *GCA*.)

Health Care Prosecutions in the Aftermath of the Yates Memo

Roughly 17 months after the memo was issued, it is clear that the DOJ has embraced the policy as evidenced by a discernible pattern of bringing fraud cases against not just health care organizations but their individual execs/directors/managers. Three recent examples:

FOCUS ON:

Tenet: In October 2016, Tenet Healthcare Corporation and two of its hospitals agreed to pay $513 million to settle claims of paying bribes and kickbacks in exchange for patient referrals. Under previous policy, the settlement would have likely released not just Tenet but the individuals involved. But the DOJ stayed true to the Yates Memo and on Jan. 24 indicted Tenet's former senior vice president of operations for his alleged role in the $400 million scheme, claiming that he caused the bribes and kickbacks to be paid and actively concealed the scheme by falsifying financial records and circumventing internal accounting controls.

NAHC: In September 2016, the board chairman and a senior vice president of North American Health Care (NAHC) paid $1 million and $500,000, respectively, to settle claims they had a role in the skilled nursing company's alleged billing of medically unnecessary rehabilitation services provided to residents. A week later, NAHC concluded its own separate $30 million settlement with the DOJ. Consistent with Yates Memo principles, the settlements covered only the parties involved and expressly excluded any other individuals from the release of liability, thus leaving the door open for further prosecutions.

The DOJ has also been faithful to the Yates Memo mandate of pressuring health care organizations into playing ball with the government by turning on their execs/directors/managers in exchange for leniency.

Tuomey: In October 2015, Tuomey Healthcare System agreed to shell out $72.4 million to settle claims of paying part-time specialists for referrals of hospital patients and falsely billing Medicare $39 million. But in accordance with Yates Memo policy, the settlement did not release the South Carolina system's individual executives. One of those executives was former CEO Ralph "Jay" Cox III, whom the DOJ claimed was the driving force behind the "sweetheart deals," undertaken despite attorneys' warnings, designed to keep physicians from referring outpatients to a new freestanding surgery center. In September 2016, Cox agreed to pay $1 million and accept a four-year ban to settle charges stemming from his personal involvement in the scheme.

The DOJ has also been faithful to the Yates Memo mandate of pressuring health care organizations into playing ball with the government by turning on their execs/directors/managers in exchange for leniency. The clearest evidence for this is the growing prevalence of inserting into settlement agreements a "cooperation clause" requiring the settling health care organization to:

- Fully cooperate with investigations into the allegations covered in the settlement, including into "individuals and entities" that the settlement does not release from liability;
- Make "former directors, officers and employees available for interviews and testimony"; and

FOCUS ON:

- Furnish non-privileged documents to the government concerning the conduct covered in the settlement.

According to Bloomberg BNA, in 2016, 46% of FCA settlements included a cooperation clause; by comparison, cooperation clauses appeared in only 17% to 32% of FCA settlements made between 2008 and 2015.

> *"[S]ometimes, it seems to me that the corporate officers who caused the problem should be subjected to more severe punishment than the stockholders of the company who didn't know anything about it."*
>
> — Jeff Sessions, Attorney General

What Happens Next?

Internal federal government policies are always subject to change, especially when a new President takes office. Many may be wondering if this enforcement policy emphasizing individual accountability will continue under a new administration and new Attorney General. While no one can predict the future, based on what we know so far, it looks like the Yates Memo is going to be around for at least a little while longer.

In fact, the early indications are that the DOJ will continue to follow Yates Memo policy, at least for the time being. Here are a few reasons labs and their executives can expect to see continued emphasis on holding accountable not only labs but also the individuals running them:

- New Attorney General Jeff Sessions is a former prosecutor with a track record of aggressively pursuing corporations and white collar crime. As Washington D.C. attorney John F. Wood predicts in a November 30, 2016 article for *Inside Counsel* "[C]orporate America should not expect a weakening of corporate criminal prosecutions."
- During his confirmation hearings, Sessions said he intended to increase FCA enforcement and continue the current emphasis on charging individuals tied to corporate wrongdoing. "[S]ometimes, it seems to me," Sessions testified, "that the corporate officers who caused the problem should be subjected to more severe punishment than the stockholders of the company who didn't know anything about it."
- Last but not least, as Ms. Yates noted in one of her last speeches, holding individuals accountable for corporate wrongdoing is not based on political party or ideology. It is a core principle of criminal justice that continues regardless of which party is in power. Moreover, in its short existence, the policy has proven both potent and effective in bringing corporate wrongdoers to justice.

Takeaway: The Yates Memo has made a discernible difference in federal fraud enforcement and signs indicate that the DOJ is likely to continue following the Yates Memo policies under the new administration.

The 7 Things Labs Need to Know About the Trump Travel Ban, *from page 1*

2. What is the Current Status of the Ban?

Critics have challenged the travel ban on constitutional grounds. The underlying lawsuit will take time to adjudicate but on Feb. 3, a federal district court granted a temporary restraining order (TRO) banning enforcement of parts of the ban pending resolution of the underlying lawsuit.

It is worth noting that in the government's latest brief filed before the order to put litigation on hold pending a revised EO, the government argued that the language of the initial EO and its intended scope was misunderstood.

The administration immediately appealed but the U.S. Circuit Court of Appeals for the 9th Circuit upheld the lower court ruling, leaving the administration to decide whether to give up on the ban, appeal to the U.S. Supreme Court, fight in district court or revise the EO. The administration chose to revise the EO. As we went to press, the 9th Circuit had issued an order acknowledging that President Trump "intends to issue a new Executive Order and has urged the Court to 'hold its consideration of the case until the President issues the new Order.'" Therefore, further court action with regard to the TRO and the constitutionality of the EO is on hold pending the new order.

It is worth noting that in the government's latest brief filed before the order to put litigation on hold pending a revised EO, the government argued that the language of the initial EO and its intended scope was misunderstood. The government brief explained that the EO's "principal focus is on aliens who have never entered this country and have no connection to it." The government's brief argued the court had concluded that the EO affected lawful permanent residents, aliens already in the U.S. and aliens who sought asylum from persecution.

The government's brief argued the EO did not violate constitutional rights because those intended to be affected had not yet entered the U.S. and thus were not protected by the U.S. Constitution. "Properly construed, the Order falls well within the President's statutory authority to 'suspend the entry of all aliens or any class of aliens,' 8 U.S.C. § 1182(f), and the U.S. Constitution," the brief asserts.

Therefore, it is reasonable to suspect that perhaps the revision will seek to more definitively draw this distinction in order to argue there is no constitutional bar to the order. Stay tuned to see how this plays out. But in the meantime it is wise to understand what a similar EO could mean for your lab. The following points help you gain some insight into the EO.

3. Could the EO Affect Your Lab?

The ban would affect your lab directly if, like many other labs, you have employees (or want to recruit employees), contractors or business associates who are citizens of the restricted countries.

4. What Is Its Practical Effect?

The term "travel ban" is a bit misleading. Technically, the EO doesn't prevent anybody from *leaving* the U.S.; it simply bars them from getting back into the country later. Practical impact on your lab:

- It would deter individuals from restricted countries who are currently in the U.S., including your own employees, contractors and business associates, from leaving the country, e.g., traveling to an international conference or meeting;
- It would bar employees, contractors and business associates from restricted countries who are currently abroad from entering the U.S. to do business with you.

The EO does not deport anybody; but there are concerns that subsequent orders may. [See the Box on page 10 for the EO's impact on visa holders.]

If the citizen of the restricted country is also a legal U.S. citizen, the EO does not apply.

5. Does It Cover Green Card Holders?

One question that has caused confusion is whether the ban would still apply if the person from the restricted country is a legal permanent resident with a green card.

The short answer: Although having a green card will be a big help, it does not guarantee entry.

Explanation: On Jan. 29, the Department of Homeland Security issued a press release stating that in applying the EO, it will "deem the entry of lawful permanent residents to be in the national interest." But the next sentence opens a disturbing loophole. "Absent the receipt of significant derogatory information indicating a serious threat to public safety and welfare, lawful permanent residence status will be a dispositive factor in our case-by-case determinations" (emphasis added).

Translation: Although green card holders will get the benefit of the doubt, the DHS can still bar entry if it has evidence that the individual poses a serious threat.

6. Does It Cover Dual Citizens?

If the citizen of the restricted country is also a legal U.S. citizen, the EO does not apply. However, dual citizens who hold passports of both a restricted and non-restricted country outside the U.S. are covered even if the latter country is a U.S. ally such as the United Kingdom, Canada, Australia or Germany.

7. What Can You Do about It?

The key to insulating your lab from the harmful effects of the EO is to keep employees from restricted countries inside the U.S. But be careful about how you deal with the affected employees:

Wrong Way: One approach is to not let employees from restricted countries travel abroad. While it may be well-intentioned, any policy that imposes an employment restriction on a group of employees based on their country of origin would likely be deemed a form of nationality discrimination banned by federal Equal Employment Opportunity laws. The fact that the policy is designed to protect employees against themselves is no defense. "In the area of civil rights, employees [should be left to] make their own personal risk decisions" without the employer's "paternalistic" interference, according to one court.

Right Way: Recognize that you can't prevent employees from travelling and respect their right to make their own personal decisions. But do everything in your power to encourage them to make the right decision. For example, consider cancelling all international trips involving affected lab personnel through the period in which the travel ban remains in effect.

Takeaway: Issue Written Statement of Support. In addition, you might want to do what so many other leading companies across the U.S. have done in response to the EO and issue a written statement to affected employees. Although there is no one-size-fits-all formula, your statement should:

- *Express your support for immigration and employees affected by the EO;*
- *Explain the EO and risks of travelling abroad while it remains in effect;*
- *Make it clear that you will neither require nor expect affected employees to engage in international business travel for as long as the EO is in effect; and*
- *Assure affected employees that they will suffer no adverse employment consequences for not travelling.*

Suspension of Visa Interview Waiver Program

One part of the Jan. 27 Executive Order that has flown under the radar is the suspension of the State Department's Visa Interview Waiver program, which allows frequent visitors to the U.S. to renew their visas without an in-person interview.

The combination of restoring the interview requirement with expected government staff hiring freezes and cuts will make it harder to renew visas and may force visa holders to cut their stays short. Moreover, the visa issue affects visa holders from *all* countries, not just the seven countries covered by the travel ban.

What Labs Should Do: Labs can get out in front of the issue by warning employees with valid nonimmigrant visa status of the risk of significant delays in scheduling visa interviews and post-interview processing.

H-1B Visas

Many labs employ skilled temporary foreign workers under the H-1B visa program. Although the EO does not cover H-1B visas, the President has repeatedly criticized the program for allegedly crowding out American workers and plans to cap the number of visas granted are rumored to be in the works. Stay tuned...

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Quest Pays $315K for Self-Disclosed Rent Kickbacks to MDs. **Case:** Quest Diagnostics agreed to pay $315,093 for allegedly paying kickbacks to a referral source. Quest self-disclosed the conduct which the OIG alleged involved rent payments made by one of its New Jersey labs to a medical practice at above fair market value. **Significance:** Although there's not much information available about the case, the apparent takeaway is that Quest caught the problem and used the OIG self-disclosure protocol to minimize its resulting liability. The other lesson is the need to ensure that your leases with referral sources provide for fair market value rent.

Pain Management Clinic Owner Settles False Billing Charges for $20 Million. **Case:** Pain management physician and businessman Dr. Robert Windsor may have to sell off his real estate holdings, two boats and four jet skis to come up with the $20 million he agreed to pay to settle fraud charges. The case, which started as a whistleblower suit, contends that over a four-year period, pain clinics owned by Dr. Windsor in Kentucky and Georgia billed Medicare, Medicaid and other government programs for medically unnecessary balance tests, qualitative drug screens, nerve conduction and electromyography procedures. **Significance:** The unnecessary diagnostic services are just part of the story. The government also alleges that the clinic falsely billed for online, real time intraoperative monitoring of surgeries that were not monitored by any physician, let alone by Dr. Windsor personally, despite false representations to the contrary.

FISH Testing FCA Claims Yield Another Million Dollar Settlement. **Case:** A *qui tam* lawsuit alleged that a lab owned by 21st Century Oncology billed Medicare and Tricare for medically unnecessary fluorescence in situ hybridization (FISH) tests. The government claimed the tests were ordered by four Fort Myers-based urologists who allegedly received bonuses from the integrated cancer center based on the number of tests they ordered. In January 2016, 21st Century paid $19.75 million to settle the civil charges and the whistleblower who initiated the case, a medical assistant of one of the urologists, received $3.2 million of the recovery as a share. Two of the urologists have also already settled for $1.05 million and $250,000 each. Feb. 1, 2017, the Department of Justice announced another settlement with a third urologist for $3.81 million bringing the total recovered in the case so far to more than $24 million. This latest settlement resolves claims by the government that the urologist submitted claims for FISH tests that were not medically necessary. The government further alleged that this urologist ordered over 13,000 FISH tests and was the "number one referring physician in the country with respect to FISH tests," receiving bonuses of approximately $2 million in bonus payments in connection with those referrals. In addition to the settlement, the urologist also agreed to a three-year corporate integrity agreement. **Significance:** The case and this latest settlement are an excellent illustration of whistleblower suits against labs under current OIG medical necessity guidelines and Department of Justice enforcement policy.

HHS Temporarily Barred from Enforcing Gender Identity Parts of ACA Antidiscrimination Rule. **Case:** Section 1557 of the Affordable Care Act bans Medicare participants from committing discrimination on the basis of, among other things, gender identity. A group of religious hospital systems and medical groups challenged the law claiming that it forced medical professionals to provide gender transition and abortion services in violation of their medical judgment and religious beliefs. A federal district court in Texas agreed and issued a preliminary injunction to block HHS from enforcing the rule in a case called *Franciscan Alliance v. Burwell*. **Significance:** As the name implies, a preliminary injunction is a temporary measure rather than a final disposition of the case. A trial still needs to take place to determine if the gender identity protections of Section 1557 are a violation of doctors' constitutional rights. In fact, some legal experts believe that the court was wrong to conclude that Section 1557 forces providers to furnish gender transition services and abortions and that the ruling will be overturned. But even if that does happen, it will probably take a long time. In the meantime, unless the preliminary injunction is lifted, HHS will be unable to enforce the gender identity nondiscrimination parts of the rule unless and until the court decides that it is enforceable. (For more on Section 1557, see "Complying with ACA's Nondiscrimination Requirements," *GCA*, Nov. 7, 2016.)

Labs in Court, *continued from page 11*

Physician Indicted and Salesman Sentenced in BLS Bribery Case. Case: The list of individuals charged and sentenced in the Biodiagnostic Laboratory Services (BLS) bribery case continues to grow. On Jan. 10, the Justice Department indicted a Passaic County doctor for taking bribes in exchange for test referrals, making him the fifth physician charged in the scheme. According to the indictment, from February 2009 through April 2013, the doctor received $130,000 from BLS employees and associates in the form of sham monthly rental, service agreement and consultation payments in exchange for referring roughly $525,000 worth of Medicare lab business. Additionally, on Jan. 18, a salesman was sentenced to 20 months in prison for allegedly bribing a physician for referrals to the lab. The salesman previously pleaded guilty to one count of conspiring to bribe a physician and one count of money laundering. **Significance:** The BLS case is a perfect illustration of the ruin that a kickback scheme can inflict on all involved. BLS had to shut down and forfeited all its assets after pleading guilty in June 2016 to kickback charges. The investigation has also generated what is believed to be a record number of prosecutions against medical professionals in a bribery case, yielding 41 guilty pleas, 27 of them from physicians. One physician has been sentenced to 37 months in prison and the other two await trial. (For more on the BLS case, see "Lab Implicated in Long-Running Kickback Case Pleads Guilty, Forfeits Assets," *NIR*, July 14, 2016.)