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Feds, Private Actors Increasing Scrutiny of Anti-Competitive Activity

Labs should review their conduct and relationships with others, now that there's been a renewed interest in whether they are engaging in unlawful antitrust activity.

Antitrust lawsuits involving labs have been making news this summer. In August, the class action suit against Quest Diagnostics and three health insurance companies brought by Hunter Laboratories and Surgical Pathology Associates settled for an undisclosed amount just five days before the lawsuit was to go to trial. The lawsuit had originally also been brought by Rheumatology Diagnostic Laboratories and Pacific Breast Pathology Medical Corporation; their claims had been dismissed earlier. The plaintiffs had alleged that Quest offered below cost lab pricing in exclusive agreements to Aetna, Blue Cross Blue Shield Association and Blue Cross of California to injure the smaller labs and destroy competition among labs in California.

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DOJ Memo Emphasizes Focus on Individual Liability for Corporate Misconduct

Given the number of individuals charged in the Biodiagnostic Laboratory Services case it should be no surprise that the government is interested in holding individuals and not just entities accountable for wrongdoing. A recent government memo to prosecutors and others involved in enforcing federal laws reinforces that commitment. What is being referred to as the Yates memorandum addresses "Individual Accountability for Corporate Wrongdoing" and emphasizes that "[o]ne of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing."

The memo discusses "challenges unique to pursuing individuals for corporate misdeeds" and seeks to promote consistency in enforcement efforts. Those challenges include difficulty proving "beyond a reasonable doubt" that individuals had the required criminal intent when corporate decision-making is often "made at various levels" and high-level executives in particular may be distanced from "day-to-day activity in which the misconduct occurs."

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DOJ Memo Emphasizes Focus on Individual Liability for Corporate Misconduct, *from page 1*

Addressed to US Attorneys, the FBI director and assistant attorneys general for the civil, criminal, antitrust, tax and other divisions of the Department of Justice, the memo describes six "steps to be taken in any investigation of corporate misconduct"—some new and others already in use. The memo's guidance is intended to apply not just to criminal but civil cases as well. Here's an explanation of the six measures the memo says those involved in enforcement should be taking to ensure culpable individuals are held accountable for corporate misdeeds.

Hinge cooperation credit on identification of culpable individuals. Corporations must provide "all relevant facts relating to individuals responsible for the misconduct" to receive any credit for cooperating with an investigation. The memo emphasizes that companies "cannot pick and choose what facts to disclose" but must provide all facts regarding the misconduct and identify all individuals involved or responsible "regardless of their position, status or seniority." This applies to civil cases as well as criminal cases. But, the memo warns, attorneys should not wait for or rely on the company's disclosure but should be "proactively investigating individuals at every step of the process."

Criminal and civil investigators should be communicating with each other about corporate investigations, allowing the government to consider "the full range of … potential remedies."

Plea agreements and settlements that occur before cases against individuals have been fully resolved must also include requirements that the company provide information about all culpable individuals and impose penalties for failure to comply with that obligation.

The memo's focus on cooperation reiterates statements made earlier this year by Assistant Attorney General Leslie R. Caldwell who explained entities seeking benefits of cooperation must conduct their own internal investigation and share with prosecutors "all available evidence of wrongdoing" including identification of all culpable individuals, even high level executives. (See *GCA*, July 2015, p. 4).

Begin with a focus on individual liability. Civil and criminal investigators should start looking for culpable individuals from the very beginning of their investigations. The memo asserts that "a corporation only acts through individuals" so starting investigations with a focus on individuals "is the most efficient and effective way to determine the facts" and increases the chances of identifying the individuals involved at the higher levels of corporate organizations.

Coordinate civil and criminal investigations. Criminal and civil investigators should be communicating with each other about corporate investigations, allowing the government to consider "the full range of … potential remedies." The memo advises civil and criminal attorneys to alert each other to potential claims the other branch may have with regard to individuals and engage in early coordination of efforts on potential concurrent civil and criminal investigations.

Don't let individuals off the hook when resolving corporate liability. Culpable individuals can't be released from liability when either a civil or criminal matter is resolved as to the corporation except in extraordinary circumstances or due to an approved policy. That means any resolution or civil settlement of the corporation's liability can't include immunity deals, dismissed charges or civil releases that compromise the government's ability to pursue individuals.

In civil cases, attorneys shouldn't consider an individuals' ability to pay when deciding whether to pursue individual liability.

Memorialize plans to pursue individuals. If the government resolves matters with a corporation before it has completed investigations of individuals, DOJ attorneys should do so only with a documented "clear plan to resolve related individual cases." Therefore, details of the status of individual investigations and what remains to be done as well as a plan for completing those investigations should be stated in the resolution of corporate investigations. Any decision not to pursue individuals must be explained and approved by the U.S. Attorney or Assistant Attorney General involved in the investigation.

Don't focus on individual financial solvency. In civil cases, attorneys shouldn't consider an individual's ability to pay when deciding whether to pursue individual liability. The memo emphasizes two "equally important" objectives of enforcement efforts are to return funds to the government and deterrence of future misconduct. Therefore, decisions should be based on the seriousness of the conduct, the sufficiency of evidence and whether pursuing a case is consistent with federal interests and resources.

Takeaway: Laboratory executives and compliance professionals should take heed that the government will be looking to hold individuals accountable for any corporate wrongdoing.

Federal Appeals Court Rebuffed Unfair Competition Claims But Didn't Decide Stark, AKS Liability

The Eleventh Circuit Court of Appeals ruled that a federal court didn't have jurisdiction to hear state law claims of unfair competition in a lawsuit that led to a multi-million dollar jury award against Millennium Health. But it didn't issue any opinion on whether the conduct in dispute violated the federal Anti-kickback Statute or Stark law (See *GCA*, February 2015, p.1). The appeals court explained that Ameritox had really raised state law issues when it argued that point-of-care testing (POCT) cups Millennium supplied to referring physicians for free violated *state* unfair competition laws because those practices violated the *federal* AKS and Stark law. Declaring that the federal trial court's decision to hear the "novel and complex state-law claims" was an abuse of discretion, the appeals court said it "resulted in the needless creation of new law for nine states and permitted parties that were either ignorant of the law or disingenuous to waste scarce judicial resources."

Millennium and Ameritox are competitors who provide drug testing to physicians' patients. POCT cups include chemically activated strips that detect drugs in urine samples, allowing physicians to obtain limited information in their office about whether drugs are present in the urine. They then send the sample in the POCT cup to the laboratory for confirmatory testing. Physicians can bill Medicare for the testing performed in office using the POCT cups. Using a standard specimen cup would not allow such billing because the physicians wouldn't be performing a test. Millennium provided the POCT cups for free to physicians who signed Free Cup Agreements (FCA) agreeing to send those used cups to Millennium for confirmatory testing and agreeing not to bill federal programs for the in-office test. The provision of these cups could violate AKS and Stark if considered remuneration in exchange for referrals. Millennium's position was that because the physicians agreed not to bill for the in-office test, these arrangements didn't violate the AKS or Stark. Ameritox filed a lawsuit in federal court alleging

Millennium's arrangements violated state unfair competition laws and involved kickbacks in violation of state and federal law. The jury found Millennium tortiously interfered with Ameritox business in multiple states and its conduct was unfair competition under state law and awarded more than $14 million in damages. Millennium appealed.

> ***"It certainly does not require any great leap of logic to believe that a company that profits by declining to comply with government regulations enjoys an unfair advantage vis-à-vis its competitors who choose to obey the law."***
>
> **— 11th Circuit Court of Appeals**

The issue on appeal was whether a violation of AKS or Stark law proved unfair competition or deceptive business practices in violation of state laws. The appeals court said, "Allowing the state-law claims to be tried using the Stark/AKS theory was egregious, constituting a clear error of judgment." The court said Ameritox either didn't know it would base its state law claims on violations of federal AKS and Stark law or it concealed that intention. Thus, the court said Ameritox was responsible for waste of judicial resources and it would create "perverse incentives" to allow Ameritox to claim the case should now stay in federal court to avoid a waste of resources by starting all over again in state court.

What the court refused to decide was whether the conduct at issue did violate the Stark law or AKS or other state law or whether violations of the Stark law and AKS should support claims of unfair competition under state law. However, while claiming it expressed "no opinion whatsoever" about violations of Stark, AKS or state law and "no view as to whether it would be wise" to allow Stark law and AKS violations to prove violations of state law, the court did say: "It certainly does not require any great leap of logic to believe that a company that profits by declining to comply with government regulations enjoys an unfair advantage vis-à-vis its competitors who choose to obey the law." The court also left the door open for the parties to litigate their claims "in a proper forum."

Takeaway: Federal court rules in favor of Millennium on procedural issue but leaves some uncertainty by refusing to decide whether conduct violated AKS and Stark law.

Reminder: ICD-10 Launches October 1

After much delay, ICD-10 implementation will finally be a reality October 1, 2015. The Centers for Medicare & Medicaid Services' ICD-10 Ombudsman Dr. Bill Rogers issued a release heralding the event and praising ICD-10 as a resource to help better identify and treat patients' medical issues, coordinate care, and "support new payment methods that drive quality of care."

While many may be skeptical, CMS promises it is ready for implementation of ICD-10 technologically speaking and will be monitoring their systems so the ICD-10 Coordination Center can address any glitches. "As we come to October 1st, CMS wants to assure the medical community that we've tested and retested our systems, and we're prepared to solve problems that may come up," said Rogers.

CMS has provided a ICD-10 Coordination Center and ICD-10 Ombudsman to handle questions and problems that may arise and earlier this year provided guidance indicating flexibility with regard to claim denials during the transition.

COMPLIANCE PERSPECTIVES

Take Heed: Strike Force Takedowns Signal Aggressive, Coordinated Fraud Enforcement

Gina L. Simms, Esq.
Principal, Ober Kaler

Robert E. Mazer, Esq.
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Earlier this year, the U.S. Department of Justice, the Department of Health and Human Services- Office of Inspector General (HHS-OIG), the Federal Bureau of Investigation, and other state and local law enforcement agencies collaborated to carry out the largest criminal "takedown" in Strike Force history, involving 243 individuals in connection with alleged Medicare fraud schemes involving more than $700 million in alleged false billings. This isn't the first and won't be the last such coordinated, aggressive enforcement initiative, and laboratories remain a top target for investigative and enforcement efforts according to the FY 2015 HHS-OIG Work Plan and other government enforcement agencies' statements. So laboratories need to be on alert, spot and address potential compliance issues before they become targets, and understand what to do if they do find themselves the subject of investigation. *G2 Compliance Advisor* has consulted two health care attorneys, Gina L. Simms and Robert E. Mazer of Ober Kaler, for their Perspective on the issues raised by this takedown. For more in-depth discussion of these government enforcement initiatives and tips for dealing with internal and external investigations, you can also join Gina and Robert on a G2 Intelligence webinar on Oct. 22, 2015. To register for the webinar, visit http://www.g2intelligence.com/take-down-webinar or contact customer service at 1-888-729-2315.

Q: While the Strike Force takedown earlier this year was the largest to date in the number of individuals prosecuted, it's not the first large scale "takedown." Is this large scale takedown enforcement strategy new? What's behind this focus on large, coordinated and even nation-wide investigations?

Answer by Gina L. Simms (GLS):

No, it is not new. The June 2015 nationwide "takedown" marks, I believe, the seventh or eighth such takedown led by the Medicare Fraud Strike Force during the past several years. Since the late 2000s, the U.S. Department of Justice (DOJ) and the U.S. Department of Health and Human Services-Office of Inspector General (HHS-OIG) have formally collaborated to prosecute individuals and entities whom the government believes have engaged in Medicare and/or Medicaid fraud. This collaboration has been under an initiative called "HEAT," and these Strike Forces are one component of the initiative. While the number of cities that have Strike Forces present investigating fraud has grown over the years, this recent takedown represents a continuation of a now fairly long-standing DOJ and HHS-OIG approach.

I believe that the "takedowns" are designed to put health care providers everywhere on notice that the federal government has the resources to aggressively investigate and pursue fraud. I also believe that it is also about pooling resources (federal, state and local law) under these interagency task forces to catch those who commit fraud.

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Q: These large takedowns return millions of dollars back to federal programs. Does this mean that the government won't be looking at smaller providers who may not yield such large return on investment for their investigative dollar?

"Following the issuance of the Yates memo, it would be a mistake for corporate executives and individuals to assume that a DOJ resolution with a company means that individuals will escape prosecution."

—Gina L. Simms, Esq.
Principal, Ober Kaler

Answer by Robert E. Mazer (REM):

Unfortunately, I think that the answer to your question is "no." I think that it would be a mistake for a "smaller" provider to conclude that his/her actions are of no interest to law enforcement. You have to remember that the government is obligated by law to evaluate every qui tam complaint that it receives to determine whether it is worth intervening in that action. Thus, a "smaller" provider may find itself subject to a government investigation. Also, under the False Claims Act, recovery is available on a per claim basis, and a small provider could have thousands and thousands of claims. Laboratories and individuals who do business with them should be concerned/not presume that they are beyond scrutiny. The latest string of criminal prosecutions related to laboratories, for instance, the prosecutions of individuals who did business with Biodiagnostic Laboratory Services, LLC, illustrates that neither individuals nor companies are beyond the reach of the government.

Q: Do you see a shift in focus with the government seeking prosecution of more individuals rather than pursuing corporate entities? For example, a significant number of individuals were targeted in the latest takedown and the DOJ recently released a memorandum that addresses "Individual Accountability for Corporate Wrongdoing" (see page 1 for further discussion of this memorandum).

GLS: *I'm not sure that I would say that there has been a shift in focus towards prosecuting more individuals, rather than companies. For quite some time, DOJ and various U.S. Attorney's Offices have been pursuing individuals for violations of both civil and criminal statutes. As Rob mentioned, there are the Biodiagnostic Labs criminal prosecutions. On the civil enforcement side, one cannot forget about the $26.1 million settlement with Dr. Steven J. Wasserman, in 2013, which may still be one of the largest False Claims Act settlements with an individual. However, during the past several years, there have also been so many significant False Claims Act settlements with companies, like the settlements with Health Diagnostic Laboratory and Singulex, Inc.*

With regard to the recent DOJ policy memorandum related to holding individuals accountable for corporate wrongdoing ("Yates memorandum"), I surmise that the DOJ would say that the memo builds upon existing DOJ policies and mostly repeats what it has been saying to corporations and individuals for a long time. What is different is that federal investigations of corporate wrongdoing will now focus at the outset on individuals.

Following the issuance of the Yates memo, it would be a mistake for corporate executives and individuals to assume that a DOJ resolution with a company means that individuals will escape prosecution.

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Q: When the latest takedown was announced HHS Secretary Burwell said in a statement: "With increased resources that have allowed the Strike Force to expand and new tools, like enhanced screening and enrollment requirements, tough new rules and sentences for criminals, and advanced predictive modeling technology, we have managed to better find and fight fraud as well as stop it before it starts." **Could you explain what is meant by these new tools such as enhanced screening and predictive modeling technology? What are some other ways government investigations have changed given sophisticated technology available today?**

> ***"One of the first things that a health care provider should do if it finds itself the subject of a government investigation, is to contact competent counsel to assist in marshalling a response and building a defense."***
>
> **—Robert E. Mazer, Esq.**
> **Principal, Ober Kaler**

REM: *My experience thus far has been that details on the specifics of these tools has been sparse for obvious reasons—the government does not want the public to know exactly how these tools work because the less scrupulous individuals will look for ways to thwart these analytics tools. My general understanding is that the Centers for Medicare and Medicaid Services uses an analytics system called the Fraud Prevention System (FPS), which employs different technologies to find so-called problematic billing patterns and outliers in claims. In addition, the Strike Forces that Gina mentioned earlier also use sophisticated tools to do "real time" tracking of claims submitted as well as the identification of suspected fraud trends.*

Don't forget various DOJ officials have started speaking publicly about how DOJ will use in white collar fraud the "old school" technology and investigative techniques that were more widely used on the criminal side for mob prosecutions and drug prosecutions: undercover agents, body wires, surveillance, and wiretaps.

Q: How does an entity or individual usually learn they are the subject of a government investigation? What are the first things a pathology practice or laboratory should do if it finds itself the subject of a government investigation?

REM: *Some of the more traditional ways that an entity or individual learns that he or it is the subject of a government investigation are via a subpoena, a request for documents or via the execution of a search warrant. A laboratory may also learn that physicians or other clients have been contacted by government investigators asking questions about the laboratory or its sales representatives.*

One of the first things that a health care provider should do if it finds itself the subject of a government investigation, is to contact competent counsel to assist in marshalling a response and building a defense. At the outset of a government investigation, a provider wants to take as many steps as possible to preserve all possible legal privileges. In addition, the provider should institute a litigation hold. The provider must produce all relevant and responsive documents, and not exacerbate an already-invasive and significant situation by inadvertently destroying or failing to produce documents called for by a subpoena.

Q: We recently reported in *GCA* that the Department of Justice's Assistant Attorney General for the Criminal Division, Leslie R. Caldwell, commented earlier

this year on the importance of cooperation. How far must a laboratory or other provider go to be considered cooperative in an investigation? In other words, what types of activity gain "points" as cooperation?

GLS: *The Yates memo makes clear that corporations will not receive any "cooperation credit" without providing to DOJ all relevant facts about individuals involved in alleged corporate wrongdoing.*

> ***"A good corporate compliance plan, that is being properly implemented, should provide substantial protection."***
>
> **—Robert E. Mazer, Esq. Principal, Ober Kaler**

Speaking at a conference on September 22, 2015, AAG Leslie Caldwell cited to a few recent prosecutions of corporations and individuals that predate the Yates memo as examples of what some companies have done to receive cooperation credit. What you see in those cases is companies who voluntarily disclose wrongdoing, or made witnesses available for interviews, or gathered and analyzed evidence, or fired the wrongdoers, ostensibly get "cooperation credit" in the form of lesser penalties. I note that some of the companies who decided not to be as cooperative often paid heavier fines. At that September 22 conference, AAG Caldwell also said that the Yates memo calls for companies to conduct independent and thorough investigations to identify culpable individuals, and that investigations that reveal only general corporate misconduct will not suffice. She also invites companies who are unclear about what all of this means to just call DOJ and ask what this all means. I do believe that we will have to watch the post-Yates corporate and individual prosecutions to help us identify if there are more specific steps that a company should take.

Q: What do you find most providers don't know about government fraud investigations or are surprised to encounter when they are the subject of an investigation?

GLS: *One thing that immediately springs to mind is that some providers are surprised about the amount of information and claims data that the government has amassed about them before the government decides to contact them.*

Q: As Rob mentioned earlier, the government has to investigate every *qui tam* or whistleblower complaint it receives, which means whistleblowers are often a trigger for an investigation. Are there ways that laboratories can find out potential compliance risks before a whistleblower draws government attention to the laboratory?

REM: The traditional ways that we commonly talk about in the compliance arena that most providers already have in place for employees to report possible wrongdoing: hotlines, open door policies, anonymous reporting. In addition, laboratories should periodically conduct internal audits—analytics are available to help labs to spot potentially aberrant arrangements, like a substantial increase in the number of tests ordered by certain clients without any obvious explanation as to why that occurred. A good corporate compliance plan, that is being properly implemented, should provide substantial protection.

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Feds, Private Actors Increasing Scrutiny of Anti-Competitive Activity, *from page 1*

Another class action antitrust lawsuit against Quest, brought by several consumer-patients in California, was dismissed in June because the complaint lacked sufficient information about the alleged anticompetitive behavior. The court granted the plaintiffs time to amend the complaint, but they did not do so.

In addition to this antitrust attention, the Federal Trade Commission (FTC) issued a policy statement Aug. 13 clarifying its "standalone" authority to enforce unfair competition even when the activities involved don't specifically violate the antitrust laws but contravene the "spirit" of the laws and could violate them if allowed to mature or complete. The "Statement of Enforcement Principles Regarding 'Unfair Methods of Competition' under Section 5 of the Federal Trade Commission Act" asserts that the FTC has such "standalone" authority since the laws themselves were written generally to accommodate changing markets and business practices and enable the FTC to challenge activities on a case-by-case basis. While the FTC did not explain the reason for or timing of the policy statement, it may be a sign that the agency intends to ramp up its enforcement activities.

Expect more private challenges

There's been an increase in agreements and transactions in health care in the past few years, especially as the Affordable Care Act and improved economy has fueled more business deals among providers, according to attorney Jonathan Lewis, with Baker & Hostetler in Washington, DC.

But the improved economy is also spurring more private antitrust lawsuits by aggrieved competitors or customers challenging a deal, relationship or other type of conduct, as evidenced by the lawsuits against Quest. Unlike some laws, like the Health Insurance Portability and Accountability Act, where private citizens cannot file lawsuits for violations of the law, there is no such restriction for challenging possible anticompetitive conduct.

> ***"Many of the deals that are challenged in private litigation are smaller, local situations that are less likely to come to the attention of the government."***
>
> **—Jonathan Lewis, Attorney, Baker & Hostetler**

And while there was a downtick in private antitrust litigation during the recession because people were more careful about spending their money on lawsuits, private antitrust litigation is on the rise again, according to attorney Bill Berlin, with Hall, Render, Killian, Heath & Lyman in Washington, DC.

Entities are also more likely to be sued privately for antitrust violation allegations than be investigated by the government. Many of the deals that are challenged in private litigation are smaller, local situations that are less likely to come to the attention of the government, says Lewis. While the FTC and the Department of Justice (DOJ) have increasingly been targeting health care deals, and apparently FTC is extending its authority further, the government tends to focus on larger deals, such as the Humana/Aetna and Cigna/Anthem health plan mergers announced this summer, points out Berlin.

Moreover, usually the government is content to let a private litigant bring an antitrust challenge without joining the fray unless it had also been investigating the activity that is the subject of the litigation, which was the case when the FTC joined in the lawsuit against St. Luke's Health System's acquisition of Saltzer Medical Group in Idaho. That lawsuit had been initially brought by a competitor of St. Luke's, says Berlin. The court in that case ruled against the providers and ordered the health system this past February to unwind the deal.

"A challenge [via a private lawsuit] is not necessarily invalid or less credible [to the government] but the FTC and DOJ have limited resources," Berlin explains.

Unfortunately, many labs don't realize that a deal or conduct they're considering or engaged in violates the antitrust laws.

However, don't think that you only need to worry about lawsuits and can fly under the government's enforcement radar. It's common for competitors, individuals and managed care plans to file complaints with the FTC for perceived antitrust violations rather than filing a private lawsuit, and anyone is fair game. "You're not immunized because you're smaller. Sometimes the FTC or DOJ will pick a small antitrust matter to use as an example," Berlin warns.

Anticompetitive behavior takes many forms

There is a multitude of ways to violate the antitrust laws. Some of the most common anticompetitive issues affecting labs include:

- Deals by the larger labs. These include bundled/discount pricing that smaller labs can't offer, "most favored nations" clauses in managed care contracts, which force the smaller labs to lower their prices to meet the discount set by the "most favored" lab provider, or exclusive contracts that shut out the competition, which was the allegation in the lawsuits against Quest.
- Acquisitions, mergers and joint ventures, which can create market power in a geographic area.
- Unlawful concerted activity, such as joint price fixing with other labs, joint boycotting of managed care contracting unless the plan meets a certain threshold compensation, or other anti-competitive collusion.

Unfortunately, many labs don't realize that a deal or conduct they're considering or engaged in violates the antitrust laws. And while some transactions are clearly anticompetitive—such as independent labs banding together to set prices—many deals fall more into a gray area and may not necessarily be hurting competition, depending on the context, market power of the parties, and other factors. "It's not cut and dried," Lewis explains.

For instance, exclusive contracts, which are common in health care, are not inherently unlawful. "There's nothing wrong with them as long as they are up for bid at regular intervals and terminable on short notice," Lewis explains. But if the exclusive contract enables one provider to lock up a lot of volume with more than one contract and those contracts are staggered, so that there's no real opportunity for others to bid for the global business, then the exclusive contract can be an unlawful barrier.

Five steps to reduce risk of antitrust violation, challenge

Many activities are permissible under the antitrust laws. Very few deals are "dead on arrival," but sometimes they do need to be reviewed and possibly tweaked or restructured, says Lewis.

And of course, even a deal that passes legal muster can be costly to defend. To protect themselves, labs should consider these five tips:

1. **Assess the benefits and risks of a deal from an antitrust standpoint, ideally with an antitrust attorney.** If deal is procompetitive, such as providing increased efficiency, improving quality of care and reduction of costs, it's more likely to be lawful. "Have a real motive for the conduct. If you're signing a contract just to get bargaining leverage, it's indicative of anticompetitive effect. If there are procompetitive justifications, it's more likely to be legitimate," says Berlin.

2. **Document any deal/conduct carefully.** Make sure your legal documents, emails and the like contain language that addresses the legitimate reasons for the activity, says Berlin. You want evidence to help you defend your actions.
3. **Watch your market share.** A deal in an area where there's a lot of competition for laboratory services is less likely to be problematic from an antitrust perspective, says Lewis. "It's more complicated the bigger you are," he warns.
4. **If you're merging or forming a network, check to see if there's a market for it.** "From a practical matter, will a payor want to buy [from the new entity]? If so, it's less risky and less likely to raise an antitrust risk. But if it will really aggravate a payor or competitor, then it's more risky and more likely someone will challenge it," says Berlin.
5. **Be careful when deals or relationships go sour.** These often lead to antitrust claims from the aggrieved party, even though many of these are unsuccessful, warns Lewis.

Takeaway: Laboratory compliance officers should assess whether a proposed or existing relationship, activity or agreement with other providers or entities could invoke antitrust concerns and, if so, determine how to reduce the risk that the lab will have to defend itself in court or to the government.

G2 Compliance Corner

Avoid Common Investigation-Related Compliance Mistakes

In our discussions with health care lawyers Gina L. Simms and Robert E. Mazer for their *Perspectives* on the government's fraud enforcement initiatives (see pages 5-8), they revealed some compliance do's and don'ts that laboratory compliance officers should heed.

To be proactive and avoid becoming the subject of a government investigation of any size, Mazer recommends that laboratory compliance officers should be asking: "Do the arrangements that [the laboratory] currently has with clients, e.g., physician practice groups, comply with Stark and the Anti-Kickback Statute? How recently have these arrangements been scrutinized by counsel?" Mazer explains, "I have found that, over time, sometimes these arrangements start out compliant, but out in the field, get 'morphed' so that they no longer reflect the business arrangements that were carefully put together to satisfy applicable legal and regulatory requirements." "Compliance is an ongoing activity," he advises.

If the government does target your laboratory for investigation, make sure you respond appropriately. We asked Simms, a former federal prosecutor, what mistakes providers commonly make when faced with an investigation. Simms indicated common missteps include "not responding quickly enough to a subpoena or government inquiry," and "failing to view the government's subpoena as a possible red flag that further internal investigation into certain practices might be warranted." She also notes that providers sometimes "fail to preserve all relevant and responsive documents." Furthermore, she says that she has seen, on some occasions, that "after a government subpoena is issued, a company's employees start communicating openly in emails about the conduct under investigation by the government, sometimes with the view of trying to make sure that everyone 'gets their stories straight' on what exactly happened." This is problematic for many reasons, one of which is that colluding or conspiring to create a version of what happened is what prosecutors call lying or obstructing an investigation.

News at a Glance

FDA Establishes First Patient Engagement Advisory Committee. Recognizing the shift to "patient-centered medicine," the U.S. Food and Drug Administration (FDA) is establishing the first-ever Patient Engagement Advisory Committee (PEAC) to advise the FDA Commissioner on issues regarding medical devices, their regulation and use. In a recent *FDA Voice* blog announcing the new committee, Nina L. Hunter, Ph.D., a regulatory scientist in the FDA's Center for Devices and Radiological Health and Robert M. Califf, M.D., deputy commissioner for Medical Products and Tobacco, wrote: "Americans are becoming increasingly active consumers of health care, making choices about their doctors, diagnostics, treatments, and health care experiences rather than simply allowing health care providers to make the decisions for them." The authors cautioned, however, that while patients can help the agency "define meaningful benefits or unreasonable risks" of new devices, patient preference information won't be used "to justify approval of unsafe or ineffective devices." Nominations for voting members are due by Nov. 20, 2015 to receive first consideration for membership. Nominations received after that date will be considered for future vacancies. The FDA is soliciting comments through Nov. 20, 2015 regarding potential topics for the Committee to address.

CMS Releases Proposed Rule Implementing PAMA. As we went to press, the Centers for Medicare & Medicaid Services (CMS) announced a proposed rule, to be published Oct. 1 in the Federal Register, implementing the Protecting Access to Medicare Act of 2014 and requiring Applicable Laboratories to report private payer reimbursement data regarding laboratory testing. Applicable Laboratories would be those receiving at least $50,000 under the Clinical Laboratory Fee Schedule and "more than 50% of Medicare revenues from laboratory and physician services." Such laboratories would need to report private payer payment rates and volume of services. If an organization includes multiple facilities, not just laboratories, that 50% threshold is calculated based on the Medicare revenue for the entire organization—so the organization must receive more than 50% of its entire revenue for all components, not just its laboratories, from payments under the Clinical Laboratory Fee Schedule and Physician Fee Schedule. Comments on the proposed rule are due by Nov. 24, 2015. We will address the proposed and eventual final rules in more detail in future issues.

Two FDA Workshops Focus on Precision Medicine Issues. The Food and Drug Administration announced two workshops that will follow-up on issues discussed at a February workshop addressing next-generation sequencing. The first workshop, to be held Nov. 12 will focus on potential analytical standards for next-generation sequencing based in vitro diagnostic tests, including laboratory developed tests. The FDA seeks "sufficiently flexible assay performance standards that can accommodate innovation, including test modifications, while assuring NGS test safety and effectiveness." The FDA promises a white paper in advance of the workshop that will cover its "current thinking for a standards-based approach to analytical performance evaluation of NGS diagnostic tests." A second workshop will be held the next day, Nov. 13, addressing use of databases to establish clinical relevance of human genetic variants. The workshop will focus on development, operation and curation, and use of databases of genetic variants. For both workshops, attendees must register for in person or webcast attendance by Oct. 30, requests to make public comment must be made by Oct. 26, and written comments on the issues can be submitted until Nov. 25, 2015. Registration, agendas and other information for both workshops can be found on the FDA's website.

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