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IN THIS ISSUE

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Compliance Perspectives: Can You Require Lab Workers to Get the COVID-19 Vaccination?

Although it's clearly a positive development for the world at large, the almost miraculous emergence of a vaccine for COVID-19 in less than a year poses legal challenges for employers in general and labs and other healthcare providers in particular. **The Question:** Can labs require their workers to get the vaccine?

Bottom Line on Top: The answer is probably but not 100 percent certainly YES. And even if a mandatory vaccine policy is justifiable, it's also subject to strict restrictions.

The Legal Justification for Mandatory Vaccination Policies

Even though the COVID-19 situation is new and unprecedented, we can still discern the boundaries with regard to employers' rights to demand that workers get vaccinated. Specifically, we know that OSHA, courts and arbitrators have historically upheld mandatory flu vaccination policies (as well as their slightly less restrictive cousin, the vaccination-or-mask policy requiring all employees to either

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Court Dismissed: The Quest Case and Medical Malpractice Liability Risks of Genetic Testing Labs

For years, Quest Diagnostics has been embroiled in a poignant lawsuit testing the liability of genetic labs for faulty DNA test results. In 2018, Quest struck a decisive blow by getting the South Carolina Supreme Court to toss the wrongful death claims on a technicality, namely, the fact that the case was filed after the statute of limitations had expired. On Nov. 4, the South Carolina federal court wrote the latest and perhaps last chapter in the drama by dismissing the remaining claims against Quest.

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get vaccinated or wear a mask during flu season) as a legitimate workplace health and safety measure.

The starting point is the broad general authority of employers to adopt policies to police the workplace and deal with health and safety hazards. For labs and other healthcare facilities, such policies are not only justifiable but also legally required to protect to protect workers' and public health and safety. Moreover, because most employment is "at will," workers can be fired for disobeying these policies.

OSHA's Policy on Mandatory Flu Vaccination

OSHA has also given the green light to mandatory *flu* vaccination. No OSHA standard specifically addresses the subject. But the "general duty clause" of the OSHA statute (*OSHA Act* (Act), Section 5(a)(1)) requires employers to keep the workplace free from "recognized hazards." Coronavirus infection is clearly a "recognized hazard," especially in lab settings.

In addition, OSHA guidelines on influenza preparedness for healthcare facility employers say it's "advisable" for such facilities to "encourage and/or provide seasonal influenza vaccination for their staff, including volunteers, yearly, during October and November." Admittedly, this language is pretty wishy-washy. But an OSHA Interpretation Letter from 2009 (during the influenza pandemic) not only reiterates the "encouragement" line but also adds the following: "Although OSHA does not specifically require employees to take [seasonal and H1N1] vaccines, an employer may do so." Significantly, the Letter specifically addresses healthcare facility employers [OSHA *Interpretation Letter*, Nov. 9, 2009].

Do Flu Vaccination Rules Apply to COVID-19?

OSHA policy (and the pro-flu vaccination bent of courts and arbitrators) is based on three indisputable facts:

- **Fact 1:** Influenza is contagious and spreads via human-to-human contact;
- **Fact 2:** When a lab worker gets the flu, it poses a hazard to not just co-workers but everybody in the workplace, including patients, vendors, visitors and guests; and
- **Fact 3:** Flu vaccinations have been proven to be safe and effective in preventing the flu.

The first two facts clearly apply to COVID-19 as well. However, the same cannot necessarily be said about Fact 3. **Explanation:** Flu vaccines which have received normal non-emergency FDA clearance; current COVID-19 vaccinations have only received emergency use authorization (EUA) and thus lack long term data supporting their safety and effectiveness. And this casts doubt on whether the rules and guidelines for mandatory flu vaccination policies apply to COVID-19.

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The 4 Legal Restrictions on Mandatory Vaccination Policies

But even with this limitation in mind, the current rules for flu vaccination still offer the best source of guidance on COVID-19. Accordingly, most legal experts believe that mandatory workplace COVID-19 vaccination is justifiable as a necessary health and safety measure. But as with flu, mandatory COVID-19 vaccination is subject to the following four key restrictions:

1. Policy Can't Violate Worker's Contract or CBA

Forcing workers to get vaccinated would be invalid if it violates the terms of lab workers' employment contract, including the applicable collective bargaining agreement (CBA) of any workers represented by a union.

Example: A Washington hospital requires workers to get a flu vaccination to be considered "fit for duty." Nurses sue and the court rules that unilaterally implementing the policy violates the hospital's CBA duty to collectively bargain all employment terms and conditions [*Virginia Mason Hospital v. Washington State Nurses*].

2. Policy Must Be as Minimally Invasive as Possible

Even where mandatory vaccination is justifiable for a lab or other setting, there must be a clear, written policy, like the Model Policy on the *Lab Compliance Advisor* (LCA) website, whose terms are limited to the minimum necessary to accomplish the health and safety purpose. If possible, the vaccination requirement should be based on job description and limited to workers for whom having COVID-19 would pose unusually significant hazards, as opposed to being staff-wide. Also consider the possibility of alternatives, such as a vaccination-or-mask policy, and leave room for religious and other exemptions, as we'll explain below.

3. Policy Can't Discriminate on the Basis of Religion, Disability or Other EEO Grounds

Mandatory vaccination might also violate employment discrimination laws. According to EEOC guidance, forcing a worker to get vaccinated might violate his/her "sincerely held religious belief, practice or observance;" the *Americans with Disabilities Act* would also kick in if workers have a disability that prevents them from taking the vaccine. In either case, exempting the worker from the policy might be one of the "reasonable accommodations" you'd have to make to accommodate the worker's religion/disability. In either case, you'd have to engage the worker and determine what accommodations to offer, which could include:

- Exempting the worker from the policy, which could be conditioned on his/her agreement to wear a mask;

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- Temporarily reassigning the worker to another position where lack of immunization would pose less of a hazard to others; and/or
- Letting the worker work from home or take a leave of absence until the pandemic ends.

Discrimination & the "Anti-Vax" Movement

The discrimination or human rights codes of some states protect not only religion but also creed, which is typically defined as a set of sincerely held religious beliefs or practices which need not be based on the edicts of an established church or particular denomination. That opens the door for a challenge by workers who subscribe to the so-called "anti-vax" philosophy that objects to vaccinations of any kind. The question of whether mandatory vaccination is a form of creed discrimination will depend on the actual caselaw and regulatory guidance of the particular state.

4. Policy Can't Violate OSHA Whistleblower Discrimination Rule

Section 11(c) of the Act makes it illegal to "discharge or in any manner discriminate against" a worker for filing a safety complaint or exercising other rights under the OSHA law. As noted by OSHA in the 2009 Interpretation Letter mentioned above, firing a worker for defying a mandatory vaccination policy could violate the whistleblower protections of Sec. 11(c) if the worker's refusal is based on a "reasonable belief" that she has a medical condition, e.g., an allergy, that could result in serious injury or death if she gets the shot.

How to Manage Liability Risks

Vaccination is clearly one of the best ways to prevent outbreak of COVID-19 at your lab. But requiring lab workers to be vaccinated and disciplining them if they refuse is fraught with legal risks, especially given that the COVID-19 vaccination isn't backed by long term scientific studies the way the flu vaccine is. A better option may be to encourage workers to get shots without ordering them to do so. Some of the ways to do that:

- Provide the vaccination yourself at no cost to workers;
- Vaccinate workers right on the worksite and at convenient times; and
- Educate workers about the benefits of the vaccination and address any concerns they raise about its safety.

For More Help

See page 9 for Model Policies you can use to implement either a mandatory or voluntary vaccination policy at your lab.

Labs IN COURT

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

LabCorp Can Sue Physician to Collect $117K Worth of "Pass-Through" Charges for Uninsured Patients

Case: Labs like LabCorp typically enter "pass-through" arrangements with physicians covering patients that lack insurance or are otherwise self-pay. The way it works: The lab bills the physician who ordered the results. The physician then pays the bill and seeks reimbursement from the patient. Thus, the charges "pass through" the physician to the patient. LabCorp contends that this was the case with a New Mexico physician liable for $117,210 of unpaid charges on a pair of accounts. But the physician disagreed, claiming that the accounts were set up solely to facilitate billing for insured patients and that he had never agreed to pay for any services rendered to uninsured patients. So, he asked the federal court to dismiss the claim.

Significance: The court refused. Even though the agreement didn't specifically mention it, the court concluded that LabCorp had presented evidence showing that the physician's open accounts amounted to a pass-through arrangement. Specifically, LabCorp contended that it told the physician as part of its standard practice in setting up accounts that account holders are held liable for any charges not paid by insurance. It also claimed it performed "in-services" to review the physician's billing terms the way it does will all account holders. The physician also knew that pass-through arrangements were a customary practice in the industry. While not ruling on whether all of this proved that there was a pass-through arrangement in place, the court concluded that the evidence created enough of a question to warrant a trial.

[*Lab. Corp. of America v. McMahon*, 2020 U.S. Dist. LEXIS 227956, 2020 WL 7125249]

Texas Hospital Pays $48 Million to Settle False Claims and Kickback Charges

Case: In one of the largest kickback settlements of 2020, Texas Heart Hospital of the Southwest, a partially physician-owned hospital, and its management company subsidiary (which we'll refer to collectively as Heart Hospital) have agreed to shell out $48 million to settle federal healthcare fraud charges. The first thing Heart Hospital allegedly did wrong was requiring physicians to satisfy annual 48 patient contacts per year to maintain ownership in the hospital, in violation of the *Anti-Kickback Statute and Stark Law*. By subsequently billing Medicare for services provided to patients as a result of those illegal arrangements, Heart Hospital then violated the *False Claims Act*.

Significance: The case began when two former physician owners, Mitchell Magee and Todd Dewey, brought a whistleblower lawsuit against Heart Hospital. As a reward, they will split a $13.9 million share of the recovery.

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Labs in Court *from page 5*

Georgia Physician Pays $36,000 to Settle HIPAA Right of Access Violation Charges

Case: In April 2019, the HHS Office for Civil Rights (OCR) received a complaint about a primary care physician practice's failure to respond to a patient's request for access to his medical records. A month later, OCR provided technical assistance to the practice on the HIPAA right of access requirements and closed the complaint. But in October 2019, the agency received a second complaint alleging that the practice still hadn't given the patient access to his medical records. So, OCR investigated and determined that the practice's failure to provide the requested medical records was a potential violation of the HIPAA right of access standard. In addition to eventually giving the patient access, the practice agreed to settle the complaint for $36,000 and agreement to take corrective actions and undergo two years of OCR monitoring.

Significance: This is the 13th settlement of an investigation under the OCR's HIPAA Right of Access Initiative, which began in the spring of 2019. Here's a Scorecard of all announced settlements to date. For more on the Initiative, see *National Intelligence Report* (NIR), Nov. 18, 2020.

OCR Right of Access Initiative Settlements Scorecard
(as of Dec. 29, 2020)

Provider	Settlement*	Allegations
St. Joseph's Hospital and Medical Center	$160,000	Phoenix hospital refused to provide PHI to patient's mother even though she was his legal representative
NY Spine Medicine	$100,000	Neurology practice refuses patient's multiple requests for copies of specific diagnostic films
Bayfront Hospital	$85,000	Florida hospital didn't provide expectant mother timely access to the PHI of her unborn child
Korunda Medical	$85,000	After first refusing to provide it at all, Florida primary care and interventional pain management services provider sent patient's PHI to third party in the wrong format and charged him excessive fees
Beth Israel Lahey Health Behavioral Services	$70,000	Massachusetts provider ignored request of personal representative seeking access to her father's PHI
University of Cincinnati Medical Center, LLC	$65,000	Ohio academic medical center failed to respond to patient's request to send an electronic copy of her medical records maintained in its electronic health record EHR to her lawyers
Housing Works Inc.	$38,000	New York City non-profit services provider refused patient's request for a copy of his medical records

Provider	Settlement*	Allegations
Peter Wrobel, M.D., P.C., dba Elite Primary Care	$36,000	Georgia primary care practice failed to provide patient access to his medical records
Riverside Psychiatric Medical Group	$25,000	California medical group didn't provide patient copy of her medical records despite repeated requests and OCR intervention
Dr. Rajendra Bhayani	$15,000	NY physician didn't provide patient her medical records even after OCR intervened and closed the complaint
All Inclusive Medical Services, Inc.	$15,000	California multi-specialty family medicine clinic refused patient's requests to inspect and receive a copy of her records
Wise Psychiatry, PC	$10,000	Colorado psychiatric firm refused to provide personal representative access to his minor son's medical record
King MD	$3,500	Virginia psychiatric practice didn't provide patient access to her medical records even after OCR intervened, provided technical assistance and closed the complaint

*In addition to the monetary settlement, each accused provider had to agree to implement a corrective action plan and allow the OCR to conduct close monitoring for one to two years

New York Court Tosses Case against Lab Accused of Drug Test Tampering and Falsification

Case: After his court-ordered hair follicle tests came back positive for cocaine, Mr. S, a man accused of child abuse sued the testing lab for fraud and mental distress. "I don't use drugs of any kind," he insisted, contending that the lab tinkered with the sample and falsified the results. The test lab filed a motion to dismiss all claims without a trial. **Result:** Motion granted.

Significance: The issue wasn't necessarily the truth of the charges. The reason the New York federal court tossed the claims is that in all three cases Mr. S's *legal theory* was faulty:

- **The fraud claim** was invalid because Mr. S left a vital element of the fraud tort out of his complaint, namely, that the lab made any intentional misrepresentations to him;
- **The intentional infliction of mental distress** claim failed because even if the allegations were true, the lab's actions didn't amount to conduct "so outrageous in character, and so extreme in degree, as to go beyond all possible bounds of decency, and to be regarded as atrocious, and utterly intolerable in a civilized society," which is the standard required to prove that tort; and
- **The negligent inflection of mental distress** claim was defective

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Labs in Court, *from page 7*

because, again, Mr. S left an essential element of the tort out of his pleading, i.e., the "guarantee" that his alleged distress was "genuine."

[*Spencer v. Lab. Corp. of Am. Holdings*, 2020 U.S. Dist. LEXIS 223451, 2020 WL 7024381]

Technician Who Never Complained Can't Sue Lab for Supervisor's Alleged Sex Harassment

Case: He dismissed her as a "typical millennial" and "Princess Diana" (Diana happened to be her first name). He asked her why she didn't wear stiletto heels and low-cut tops. Above all, he constantly (and falsely) referred to her as a lesbian and a "softball player," a derogatory term for lesbians. But at the end of the day, none of these things that her supervisor allegedly did turned out to be enough for a lab technician to make out a legal case for creating a hostile work environment against the lab. But while dismissing the sex harassment case, the Illinois federal court allowed the lab technician to go to trial on her claim that the supervisor retaliated against her for exercising her *Family and Medical Leave Act* (FMLA) rights.

Significance: This was a fairly complex case with a lot of context, most of it involving issues other than sex harassment. The key facts that worked to the lab's advantage with regard to the sex harassment claim:

- The lab had a clear and strongly worded sex harassment policy;
- The technician was good at her job and did productive work;
- She worked well with the supervisor and while there was some back and forth between, it appeared mutual and mostly playful; and
- Most important of all, the technician never once went to HR or anybody else to complain about sex harassment.

[*Trahanas v. Northwestern Univ.*, 2020 U.S. Dist. LEXIS 241663]

MODEL TOOL
MANDATORY COVID-19 VACCINATION POLICY

It behooves you to ensure that lab workers get vaccinated against COVID-19 to protect not only themselves but also co-workers, patients and others at your facility. But what if workers neglect or just plain refuse to be vaccinated? There are two basic options:

- **Option 1:** Require lab workers to be vaccinated
- **Option 2:** Encourage lab workers to be vaccinated voluntarily

Here's a Model Policy you can use to implement Option 1. For a Model Voluntary Policy, see page 9; and for an analysis of the legal implications of mandatory v. voluntary vaccination policies, see the related story on page 1.

COVID-19 VACCINATION POLICY

PURPOSE

The purpose of this policy is to ensure that all XYZ Laboratories (XYZ) staff are vaccinated against COVID-19 vaccines to protect their own health and safety, as well as the health and safety of their co-workers, XYZ patients and others who may be exposed to infection risks while at XYZ facilities.

XYZ management has chosen to implement this policy after considering the costs, risks and benefits of vaccination. We recognize that vaccination is personally invasive and that some individuals may object to it. However, we also recognize that all responsible and knowledgeable experts in public health agree that the benefits of the COVID-19 vaccination exceed the risks of receiving it.

POLICY

All XYZ workers are required to obtain initial and necessary subsequent COVID-19 vaccinations according to schedules that XYZ establishes for each particular year. Vaccinations will be made available to staff members free of charge.

EXCEPTIONS

XYZ personnel who have been recently vaccinated elsewhere may satisfy this requirement by providing written documentation of the vaccination they received. Such personnel may also be excused from this requirement if they have legitimate religious objections to being vaccinated. XYZ will also make reasonable accommodations up to the point of undue hardship for disabilities, religious preferences and other protected grounds as required by federal and state anti-discrimination and human rights laws.

CONSEQUENCES OF NON-COMPLIANCE

XYZ reserves the right, at its sole discretion, to impose disciplinary actions on workers who refuse to receive a vaccination as required by this policy up to and including termination in accordance with applicable laws, contracts and collective bargaining agreements.

MODEL TOOL

VOLUNTARY COVID-19 VACCINATION POLICY

It behooves you to ensure that lab workers get vaccinated against COVID-19 to protect not only themselves but also co-workers, patients and others at your facility. But what if workers neglect or just plain refuse to be vaccinated? There are two basic options:

- **Option 1:** Require lab workers to be vaccinated
- **Option 2:** Encourage lab workers to be vaccinated voluntarily

Here's a Model Policy you can use to implement Option 2. For a Model Mandatory Policy, see page 8; and for an analysis of the legal implications of mandatory v. voluntary vaccination policies, see the related story on page 1.

COVID-19 VACCINATION POLICY

PURPOSE

COVID-19 coronavirus is a highly contagious and potentially fatal respiratory illness caused by the SARS-CoV-2 virus. Vaccination is the most effective way to prevent COVID-19 infection. Vaccination protects you, your co-workers and your patients.

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Model Tool: Voluntary COVID-19 Vaccination Policy, *from page 9*

POLICY

XYZ Laboratories (XYZ) will develop, implement and evaluate a program to offer regular COVID-19 vaccination for XYZ personnel on an annual basis in accordance with public health guidance. In the event of limited vaccine availability, COVID-19 vaccination will be allocated on the basis of regulatory requirements and occupational risks. All XYZ personnel are required to either receive initial and subsequent COVID-19 vaccination or complete a statement (attached to this Policy as Exhibit A):

- Acknowledging that they were offered vaccination;
- Indicating that they voluntarily declined it; and
- Listing the reasons for declining vaccination.

EXHIBIT A: COVID-19 VACCINATION DECLINATION FORM

I HEREBY ACKNOWLEDGE THAT:

• COVID-19 is a highly contagious and potentially fatal respiratory disease that has killed roughly 300,000 Americans to date.

• The SARS-CoV-2 virus that causes COVID-19 may be shed for up to 48 hours before symptoms begin, increasing the risk of transmission to others.

• Some people with COVID-19 have no symptoms, increasing the risk of transmission to others.

• COVID-19 vaccine cannot transmit COVID-19 and it does not prevent all disease.

• I have declined to receive the COVID-19 vaccine.

* I acknowledge that COVID-19 vaccination is recommended by the U.S. Centers for Disease Control and Prevention for all healthcare workers in order to prevent infection from and transmission of COVID-19 and its complications, including death, to patients, my co-workers, my family, and my community.

• I am required to wear a mask at all times while in any XYZ Laboratories clinical area during the pandemic as defined by the Chief Medical Officer.

• My supervisor and manager, including division and departmental leadership will be notified that I declined.

PRINT NAME: _____ DOB _____

Knowing these facts, I choose to decline vaccination at this time. I may change my mind and accept vaccination later, if vaccine is available. I have read and fully understand the information on this declination form. I decline vaccination for the following reason(s). (Please list)

Print Name _____ Signature _____ Date_____

Phone Number _____

Department _____ Manager's Name_____

MODEL TOOL

LAB WORKER'S ACKNOWLEDGEMENT OF DECISION TO DECLINE COVID-19 VACCINATION

It behooves you to ensure that lab workers get vaccinated against COVID-19 to protect not only themselves but also co-workers, patients and others at your facility. But what if workers neglect or just plain refuse to be vaccinated? There are two basic options:

- **Option 1:** Require lab workers to be vaccinated
- **Option 2:** Encourage lab workers to be vaccinated voluntarily

If you select Option 2, require workers to sign a form acknowledging that they were offered the vaccine and voluntarily declined to accept it and list the reasons for doing so. Here's a Model Policy you can adapt.

COVID-19 VACCINATION DECLINATION FORM

I HEREBY ACKNOWLEDGE THAT:

• COVID-19 is a highly contagious and potentially fatal respiratory disease that has killed roughly 300,000 Americans to date.

• The SARS-CoV-2 virus that causes COVID-19 may be shed for up to 48 hours before symptoms begin, increasing the risk of transmission to others.

• Some people with COVID-19 have no symptoms, increasing the risk of transmission to others.

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• I have declined to receive the COVID-19 vaccine.

* I acknowledge that COVID-19 vaccination is recommended by the U.S. Centers for Disease Control and Prevention for all healthcare workers in order to prevent infection from and transmission of COVID-19 and its complications, including death, to patients, my co-workers, my family, and my community.

• I am required to wear a mask at all times while in any XYZ Laboratories clinical area during the pandemic as defined by the Chief Medical Officer.

• My supervisor and manager, including division and departmental leadership will be notified that I declined.

PRINT NAME: _____ DOB _____

Knowing these facts, I choose to decline vaccination at this time. I may change my mind and accept vaccination later, if vaccine is available. I have read and fully understand the information on this declination form. I decline vaccination for the following reason(s). (Please list)

Print Name _____ Signature _____ Date_____

Phone Number _____

Department _____ Manager's Name_____

Consumer Fraud: OIG Warns Medicare Beneficiaries Not to Fall for COVID-19 Scams

Pharma companies, diagnostics manufacturers, labs and other parts of the healthcare industry have done a commendable job in pivoting in response to the current public health industry. Sadly, it seems that you can say the very same thing can also be said about the scammers. On Nov. 23, the OIG issued a new alert warning the public about fraud schemes related to COVID-19.

The Face of COVID-19 Fraud

The OIG says that scammers are taking advantage of the coronavirus pandemic to collect personal medical information of Medicare and Medicaid beneficiaries to commit identity theft and fraudulently bill federal health care programs. And if Medicare or Medicaid denies the claim for an unapproved test billed, the beneficiary could also end up being responsible for the cost.

OIG describes the different methods fraudsters have been using to target beneficiaries, including telemarketing calls, text messages, social media platforms, and door-to-door visits. The alert cites examples of actual schemes, including:

- After hacking social media accounts, fraudsters are sending direct messages to beneficiaries posing as a friend or government employee notifying beneficiaries of their eligibility for government grants, and urging them to call a phone number to collect the funds. Upon calling, the beneficiary is asked to pay a "processing fee" (using bank account information, gift cards, bitcoin) to receive the grant money.
- Fraudsters are offering COVID-19 tests to beneficiaries in exchange for personal information, including their Medicare and Medicaid information.
- Scammers posing as medical labs are targeting retirement community residents with offers of COVID-19 tests so they can draw blood and bill federal health care programs for medically unnecessary services.
- Some scammers have been offering people $200 Medicare prescription cards when no such cards currently exist.

8 Ways Consumers Can Protect Themselves

The OIG alert lists recommendations for consumers to avoid being scammed:

1. Being suspicious of unsolicited requests for Medicare or Medicaid numbers or personal/medical/financial information or offering COVID-19 tests or supplies;

2. Understanding that Medicare doesn't call beneficiaries to offer COVID-19 related products, services, or benefit review.
3. Not responding to or opening hyperlinks in text messages about COVID-19 from unknown individuals.
4. Not responding to offers or advertisements for COVID-19 testing or treatments on social media sites.
5. When making an appointment for a COVID-19 test online, confirming that the location is an actual testing site.
6. Being mindful of the fact that only physicians or other trusted healthcare providers should assess medical condition and approve requests for COVID-19 testing.
7. Not providing personal or financial information to anyone claiming to offer HHS grants related to COVID-19.
8. Being on the lookout for scammers posing as COVID-19 contact tracers. Legitimate contact tracers will never ask for Medicare numbers, financial information, or attempt to set up a COVID-19 test and collect payment information for the test, the alert notes.

Court Dismissed: The Quest Case and Medical Malpractice Liability Risks of Genetic Testing Labs, *from page 1*

What Happened

Amy Williams was and is a sympathetic plaintiff with a highly compelling story. In 2007, the Myrtle Beach mother's 2-year-old son Christian began experiencing regular seizures. Suspecting a mutation in the SCN1A gene, doctors sent Christian's DNA for genetic testing to Athena Diagnostics (which Quest Diagnostics would later acquire in 2016). The test detected a glitch in the gene which the report described as a "#4: variant of unknown significance" (VUS) that, according to Athena's classification "often has no effect" on normal gene activity. Sadly, though, it turned out that Christian had a rare and more dangerous condition called Dravet syndrome.

Ms. Williams and her attorneys claimed that Athena should have detected that the VUS was pathogenic and that the doctors relied on the report to rule out Drevet and treat Christian with sodium-channel-blocking medications, which worsened his condition and intensified his seizures. A proper diagnosis would have prevented the fatal seizure Christian suffered on Jan. 5, 2008, according to the complaint.

The Statute of Limitations Stumbling Block

After initially blaming herself for Christian's death, Ms. Williams finally decided to sue Athena and its now parent company Quest (which for

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Court Dismissed: The Quest Case and Medical Malpractice Liability Risks of Genetic Testing Labs, *from page 13*

simplicity's sake, we'll refer to collectively as "Quest") in 2017, 10 years after the fateful genetic testing lab report. That was a problem because in South Carolina, the statute of limitations for medical malpractice is six years. The apparent good news for Ms. Williams' legal team was that the statute of limitations for negligence and wrongful death is three years from the date the plaintiff discovers that he/she has a cause of action. Accordingly, Ms. Williams contended that she didn't discover that she had a legal case against Quest and thus still had time to file her suit as a wrongful death action.

The moral of this story is that genetic testing labs can be sued for money damages if they make mistakes.

Not so fast, countered Quest, who claimed the case was essentially a wrongful death case based on medical malpractice and thus subject to the hard six-year cap. **The key question:** Was Quest acting as a licensed healthcare provider when it performed genetic testing on Christian? If so, the six-year medical malpractice statute of limitations would apply.

The 2018 Ruling

On June 27, 2018, the South Carolina Supreme Court ruled 4 to 1 in favor of Quest. "A genetic testing laboratory that performs genetic testing to detect an existing disease or disorder at the request of a patient's treating physician is acting as a 'licensed health care provider' under [state law]," the Court reasoned. As a result, the medical malpractice case was time-barred.

The 2020 Case

Having lost on the wrongful death front, Ms. Williams still had some legal cards to play, including ordinary negligence and deceptive trade practice. And those were the actions the South Carolina federal court dismissed without a trial in its Nov. 4 ruling.

No Case for Negligence: Although medical malpractice was no longer on the table, Ms. Williams was still able to claim that the failure to detect that the VUS in the SCN1A gene was pathogenic constituted ordinary negligence. But the claim had a fatal flaw, namely, the lack of evidence showing that the treating physician had ever read, let alone relied on the

2007 report. The report wasn't located in his file, and the doctor didn't recall reviewing it. So, the negligence claim failed.

No Case for Deceptive Trade Practices: Like most states, South Carolina has a law banning businesses from engaging in deceptive or unfair trade practices that have an impact on the public interest. Ms. Williams' theory was that Athena crossed that line because at the time of the 2007 report, it was in violation of several different CLIA requirements relating to the analysis and reporting of positive test results. But the court pooh-poohed the arguments. First, there was no evidence that Athena violated the CLIA regulations. And even if it had, CLIA violations can't be the basis of a deceptive trade practices claim because CLIA is enforced by HHS and CMS and doesn't provide for a "private right of action." In other words, private persons can't sue a lab for money damages based on a CLIA violation.

Belser v. Quest Diagnostics, Inc., 2020 U.S. Dist. LEXIS 207217, 2020 WL 6526084

Takeaway

The moral of this story is that genetic testing labs can be sued for money damages if they make mistakes. While Quest ended up prevailing on all counts, the legal victories are of limited legal significance because they don't get into the substantive issues governing a lab's liability for inaccurate genetic testing, analysis and reporting. Thus, Quest won on wrongful death in 2018 because the statute of limitations had tolled. It won on negligence in the new case not because the lab didn't commit negligence but because the plaintiff couldn't show that the treating physician relied on the allegedly faulty test report. The one novel takeaway from the 2020 ruling is that a CLIA violation can't be the basis of a state deceptive trade practices claim. But even that applies only to South Carolina.

Wrongful Birth' Litigation

The Quest case is hardly the first time a genetic testing lab has been sued for medical malpractice. However, most of the cases have alleged not wrongful death but wrongful birth, i.e., failure to diagnose pre-natal genetic disorders resulting in births that would have been aborted had the correct genetic information about the fetus been provided. Here's a quick summary of some of the notable cases.

Florida: Plaintiff Wins $21 Million Malpractice Award

Parents sue Univ. of South Florida doctor for failing to diagnose their son's genetic disorder (called Smith-Lemli-Optiz syndrome) impairing

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his ability to synthesize cholesterol, leading couple to have a second child with same disorder. Ruling: Jury finds malpractice and awards couple $21 million but state law caps damages at $200K.

Virginia: LabCorp Can Be Sued for Malpractice

Parents who are both "carriers only" of thalassemia beta decide to continue their pregnancy after genetic testing confirms that their unborn fetus is also "carrier only." But when the results turn out to be wrong and the child has the more serious "affected person" version of the disorder, they sue LabCorp for "wrongful birth" malpractice. **Ruling:** The federal court refuses to dismiss the case but also finds that LabCorp is a "health care provider" and thus covered by the medical malpractice damages caps under state law.

Montana: Giving Pregnant Mom Pamphlet Defeats Claim of Negligently Failing to Provide Screening Test Info

After giving birth to a daughter with cystic fibrosis, a mother sues her doctor and prenatal care nurse for $14 million for not providing her any information on the availability of cystic fibrosis carrier screening testing. **Ruling:** The jury doesn't buy it and finds the defendants did meet the standard of care in delivering prenatal treatment, including giving the patient a cystic fibrosis pamphlet during her first appointment that she did not read.

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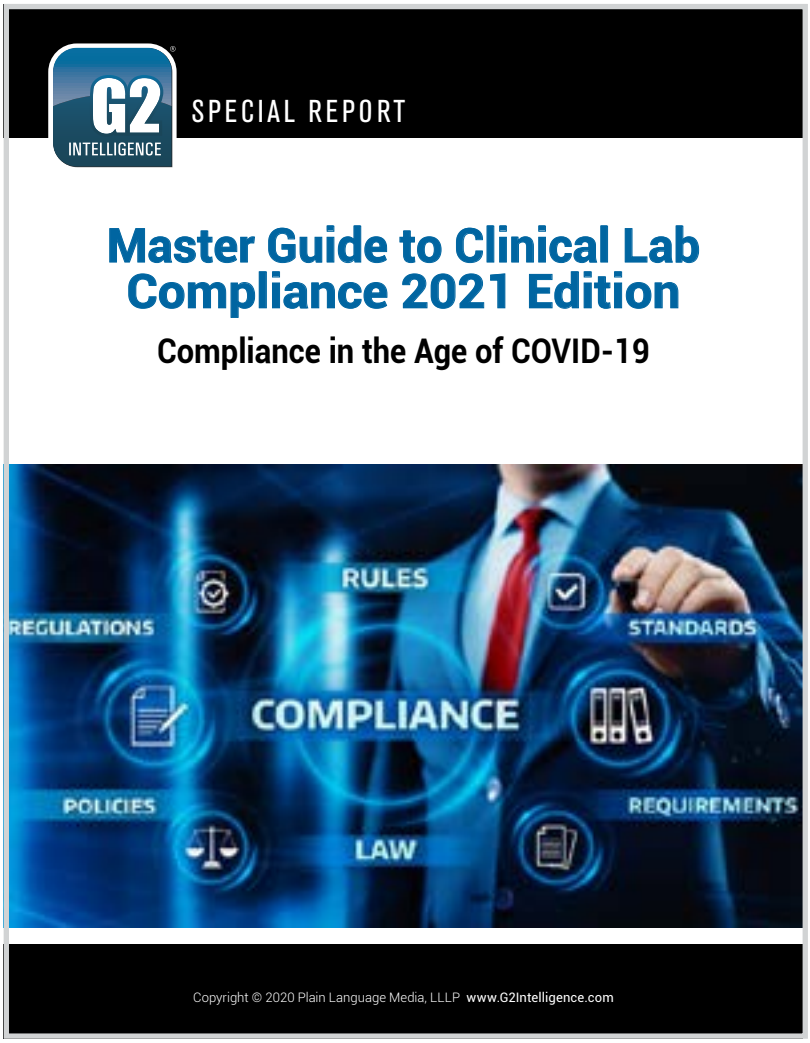

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