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Compliance Perspectives: The 5 Things to Do When Implementing a Vaccine Passport Policy at Your Lab

Like many labs and other health providers, you might have been undecided about whether to mandate that your employees get the COVID-19 vaccine. However, now that the FDA has fully approved a coronavirus vaccine, namely, the Pfizer BioNTech, you are on much stronger legal ground in requiring that employees get vaccinated. One strategy that may work, especially for labs that aren't administering the vaccine for their own employees, is to implement a vaccine passport, i.e., a policy requiring personnel to present proof of their vaccination status to gain entry to the workplace.

What Is a Vaccine Passport?

A "vaccine passport" is a commonly accepted means of showing that a person has received the COVID-19 vaccine.

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Enforcement Trends: Federal Courts Split on Government Dismissals of *Qui Tam* Claims

In 2018, the Justice Department (DOJ) ordered US Attorneys to aggressively seek dismissal of *False Claims Act* (FCA) whistleblower qui tam lawsuits that lack merit or don't serve the government's interests. However, actual attempts to implement the controversial policy have proven tougher than expected with the courts split over how much discretion the government has to toss *qui tam* cases it doesn't like.

The Granston Memo

Under the FCA, lawsuits by whistleblowers (aka, "relators") must be filed under seal to give the DOJ time to decide whether to intervene in the case. Although the case doesn't end if the DOJ declines, the decision reduces the relator's

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Some foreign governments are creating official, uniform cards that individuals must display. (Go to page 3 for a visual summary of vaccine passport laws in each state.) However, passports can take many forms, both digital and hard copy, including a signed letter from a doctor, certificate from a vaccine provider or even a personal attestation.

In the workplace context, employers may require employees and perhaps customers, vendors and other visitors to produce their "passport" to gain entry into the facility. Those who cannot or will not do so aren't allowed in.

Are Vaccine Passports Legal?

The first thing you need to do is check the laws of your state. There are seven states (Alabama, Florida, Iowa, Kansas, North Dakota, South Dakota and Texas) where it's illegal for businesses, including labs, to implement a vaccine passport. A few other states, including Georgia and Missouri, are considering adopting similar legislation. But in most states, including those that have banned governments from using them, vaccine passports are allowed—or at least not prohibited. (In three states, New York, North Carolina and Hawaii, they're actually required.)

Even so, there are limitations under personal privacy and discrimination laws. Essentially, where it's not legally banned, a lab could have a vaccine passport policy under five conditions:

1. There's an evidence-based need to verify vaccination status to prevent transmission at your lab workplace;
2. There are no less restrictive alternatives;
3. You comply with privacy laws by requiring no more personal information than you need to verify vaccination status;
4. You comply with the *Americans with Disabilities Act* (ADA) and other discrimination laws by making reasonable accommodations to the point of undue hardship; and
5. You constantly monitor and revise your policy as public health guidelines and the pandemic situation evolves.

Unless and until courts bar vaccine passports, the states must decide whether to establish—or ban—passport systems within their own boundaries. Here's a visual depiction of where each state currently stands on the vaccine passport issue:

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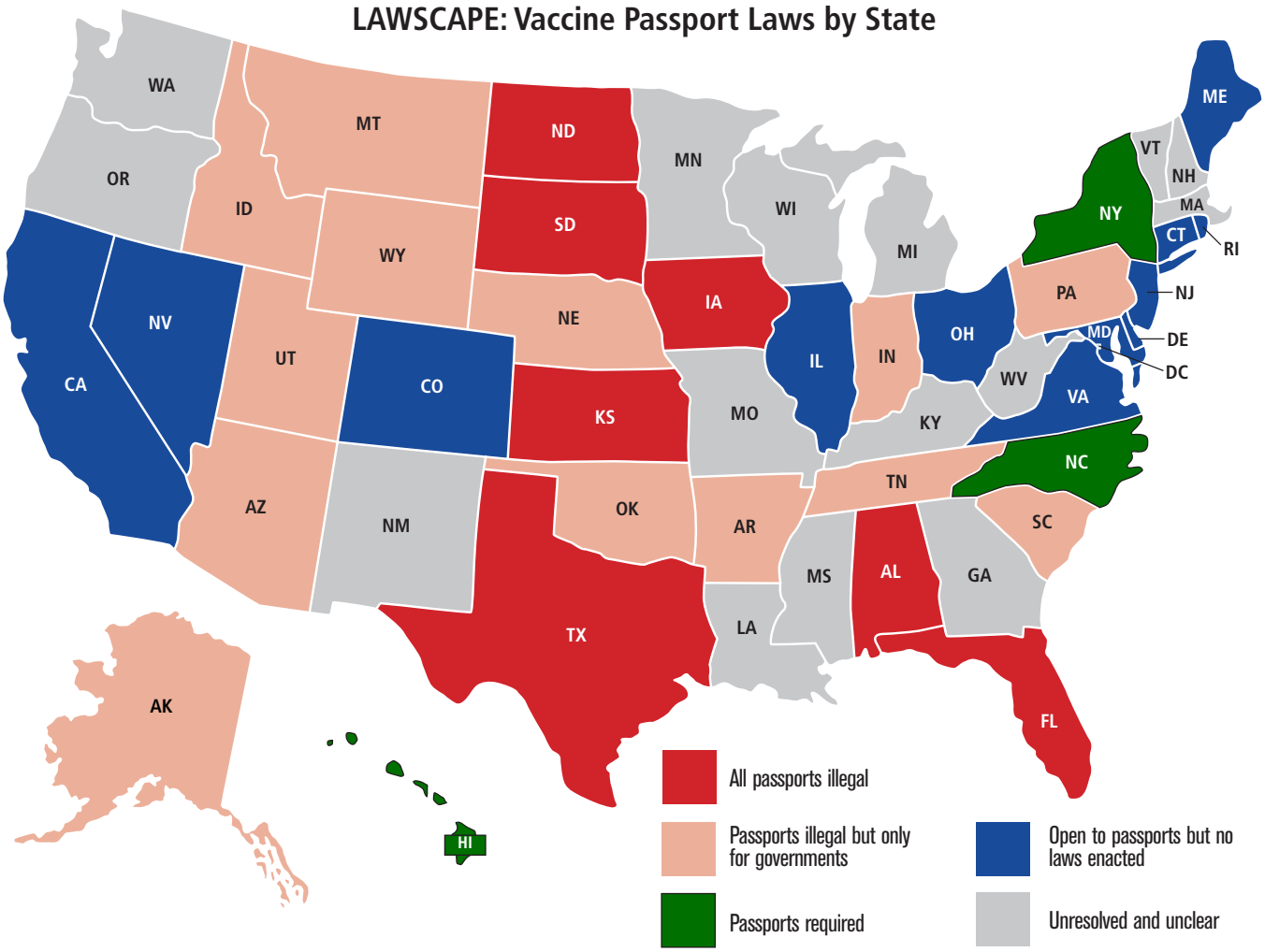

The 5 Legal Guidelines

Until courts weigh in, all of what we know about the legality of vaccine passports in states where they're not expressly banned comes not from statutes or regulations but government guidance. From almost the moment the public health emergency began, the U.S. Equal Employment Opportunity Commission (EEOC), public health departments and other government agencies have made it clear that, at least for the time being, normal privacy and discrimination protections give way to the imperative to stop COVID-19.

And that means private sector labs (outside Alabama, Florida, Iowa, Kansas, the Dakotas and Texas) may have some leeway to implement mandatory vaccine policies in the workplace. According to the EEOC, "under the ADA, an employer may require an individual with a disability to meet a qualification standard applied to all employees, such as a safety-related standard requiring COVID-19 vaccination, if the standard is job-related and consistent with business necessity."

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Even so, privacy and discrimination laws remain very much in play and there are limits to how far labs can go to prevent COVID-19 from spreading in the workplace. The key to compliance is keeping your vaccine passport protocols within these boundaries. There are five things you must do to accomplish that goal.

1. Ensure Vaccine Passports Are Needed to Prevent Workplace Infection Risks

While medical screening of any kind is privacy invasive, public health guidelines call on employers to perform it to ensure persons with infections, symptoms or recent exposure don't get into the workplace and infect others. Vaccination passports are essentially an extension and different form of medical screening.

However, you can't just take it for granted that a passport system is necessary in your own workplace. Guidelines stress the need for making "evidence-based" decisions based on an assessment of the actual transmission risks at the particular facility based on risk factors like:

- Whether employees work alone or with others or work inside or outside;
- The available ventilation;
- Frequency and duration of direct interaction employees typically have with others at the lab;
- The number of partially or fully vaccinated individuals already in the workplace;
- Whether employees wear masks or undergo routine screening testing;
- The space available for social distancing; and
- Current CDC and other public health guidelines.

2. Consider Less Intrusive Alternatives

Vaccine passports must also be "proportional" to the risks they address, and resorted to only when there are no less intrusive methods available for containing infection risks. Less intrusive alternatives may include social distancing, face masks and allowing employees to work from home.

3. Minimize Privacy Intrusions

Whether a person has received a vaccination would be deemed protected health information (PHI) that HIPAA and other privacy laws ban employers from collecting, using or disclosing without consent. **Exception:** Employers generally don't need consent to collect PHI to carry out legitimate and essential employment functions. Requiring proof of vaccination may also constitute an inquiry about a person's disability banned by the ADA.

However, during the pandemic, government guidelines have consistently allowed pre-entry medical screening as a legitimate and, in many cases, required infection control measure. These same principles also apply to requiring proof of COVID-19 vaccination. **Caveat:** You're allowed to use only the minimum PHI necessary to accomplish this purpose. Example:

- **OK:** Asking employees if they've been vaccinated for COVID;
- **Not OK:** Asking employees if they have any non-COVID-19 related medical conditions or what medications they use.

Strategic Pointer: Keep a list of employees who produce verification of vaccine rather than ask them to produce a passport each time they seek entry into the lab.

4. Make Necessary Accommodations

Differentiating between employees who are and aren't vaccinated involves risk of illegal discrimination, especially when the reason they're not vaccinated is due to disability, pregnancy, religion or other personal characteristic protected by federal, state or local equal opportunity laws, rather than a mere personal preference. Accordingly, employers must accommodate people who are unable to get the vaccine due to a protected characteristic to the point of undue hardship. Accommodations may include letting employees work from home or allowing them in but requiring them to self-isolate, wear a mask at all times and/or engage in medical self-monitoring.

The EEOC says you can still bar protected persons from the workplace because they're not vaccinated if you determine that allowing them to enter would pose a "direct threat" in the workplace. **Condition:** You must first make "an individualized assessment of the employee's present ability to safely perform the essential functions of the job" based on four risk factors:

- The duration of the risk;
- The nature and severity of the potential harm;
- The likelihood that the potential harm will occur; and
- The imminence of the potential harm.

5. Constantly Monitor and Modify Your Policy

If you do implement a vaccine passport policy, keep it in effect for the shortest possible length of time. You also need to constantly monitor the most recent public health guidelines and health situation and change the policy accordingly. It's a dynamic equation that you must constantly revisit as the situation changes.

TOOL MODEL LAB WORKPLACE VACCINE PASSPORT POLICY

Although courts have yet to weigh in on the issue, guidelines from the US Equal Employment Opportunity Commission and other regulatory agencies indicate that employers may implement vaccine passports if they perform a workplace assessment and determine that limiting entry to the vaccinated is a necessary health and safety measure to prevent an imminent risk. Employers must also ensure that their passport policies comply with anti-discrimination and privacy protection requirements. Here's a Model Policy that you can adapt for use at your own lab, depending on the workplace-specific circumstances involved.

WORKPLACE VACCINE PASSPORT POLICY

1. POLICY STATEMENT

The scientific evidence clearly shows that the COVID-19 vaccinations currently available in the U.S. are safe and effective. They are also provided free of charge. XYZ Laboratories strongly urges all employees to receive the COVID-19 vaccination if they are able to do so. XYZ Laboratories will provide education, information support and assistance [*including paid time off from work*] as necessary to enable employees to get the vaccination.

2. MANDATORY VERIFICATION OF VACCINATION STATUS

COVID-19 coronavirus is highly contagious and ensuring that persons who are actually infected, symptomatic or at undue risk of being infected do not enter the facility is essential to the health and safety of all in the workplace. Based on an assessment of the health and safety risks of its specific facilities and worksites and current public health guidelines, XYZ Laboratories has determined that it is necessary to implement a COVID-19 vaccine passport system until the health and safety situation improves. Accordingly:

Until further notice, no person may enter an XYZ Laboratories work site or facility without a COVID-19 vaccine passport.

3. DEFINITIONS

For purposes of this Policy:

"COVID-19 symptoms" include [monitor and revise this list as CDC guidelines change]:

- **Fever or chills;**
- **Cough;**
- **Shortness of breath or difficulty breathing;**
- **Fatigue;**
- **Muscle or body aches;**
- **Headache;**
- **New loss of taste or smell;**
- **Sore throat;**
- **Congestion or runny nose;**
- **Nausea or vomiting;**
- **Diarrhea.**

"Vaccine passport" means a form of acceptable verification showing that a person has received both doses of an approved COVID-19 vaccine. Such forms may include (*without limitation*):

- An official digital or hard copy passport of vaccination issued by a federal, state or municipal governmental agency;
- A signed letter from a physician indicating that the person has received the vaccination;
- A certificate of vaccination from a vaccine provider; and
- A personal written attestation of vaccination.

4. SCOPE

This Policy applies to XYZ Laboratories employees and others seeking entrance to XYZ facilities,

including but not limited to contract workers, couriers, clients, customers and visitors. These requirements will not be waived and those seeking to avoid them may do so by not seeking to enter the facility. However, XYZ will make accommodations to the point of undue hardship in accordance with the requirements of applicable anti-discrimination laws, as set forth in Section 6 below.

5. VACCINE PASSPORT PROCEDURE

5.1 Initial Presentation of Passport

Employees must provide their vaccination passport to the HR department for photocopying. The HR department will maintain a list of all employees who have furnished an appropriate passport (*the "passport list"*) and provide that list to security personnel stationed at facility entrances.

5.2 Entry Procedure

Rather than having to display their passports each day, employees will only have to provide their name and ID to security upon entering the premises for verification that they are on the passport list. Employees on the passport list will be allowed to enter the facility without undergoing medical screening unless they exhibit COVID-19 symptoms.

5.3 Admittance Criteria

Employees who are not listed on the passport list or who exhibit COVID-19 symptoms will not be allowed to enter the facility, subject to Section 7 below.

6. PRIVACY PROTECTIONS

XYZ Laboratories will neither ask for nor allow HR or security screening personnel to ask for any medical information other than verification that an individual has received two doses of an accepted COVID-19 vaccination as listed in the vaccination passport. XYZ Laboratories will retain the photocopy of the vaccine passports that employees provide in a confidential personnel file. The vaccination list will also be kept confidential. None of such records will be used or disclosed except in accordance with this Policy and the XYZ Laboratories Employee Privacy Policy. All such records will also be kept secure in accordance with the XYZ Data Security Policy.

7. EMPLOYEES' ACCOMMODATION RIGHTS

Reasonable accommodations, possibly including exemptions, to the point of undue hardship will be made for employees who notify XYZ Laboratories and verify that they cannot receive the COVID-19 vaccine due to disabilities, pregnancy, age, national origin or other characteristics protected from discrimination under applicable anti-discrimination laws. Refusal to receive the COVID-19 vaccine due to personal preference is not a protected characteristic, particularly when that personal preference is based on misinformation or misunderstandings of scientific information. Accommodations will be based on an individualized assessment of the employees' circumstances and whether allowing them to enter without being vaccinated would pose a direct threat to others in the workplace.

XYZ Laboratories will also honor the terms of applicable collective bargaining agreements and external circumstances that may make it difficult or impossible for employees to get vaccinated.

8. TEMPORARY POLICY

This is a temporary policy that will expire when the health and safety purpose justifying its implementation no longer applies. XYZ Laboratories also reserves the right to revise this Policy as public health guidelines, pandemic situation and scientific information changes and evolves.

Labs IN COURT

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

Use of Hospital's NPI Enough to Establish Testing Labs' Liability for Pass Through Billing

Case: Licensees of Blue Cross and Blue Shield Association sued individuals and entities allegedly involved in a pass-through scheme for toxicology and blood tests billed from a small rural hospital in Putnam County, Missouri. The question in this particular ruling was whether the hospital CEO, whom had already pleaded guilty to criminal conspiracy charges in connection with the scheme, could be liable for civil fraud claims. The federal district court said yes and granted summary judgment, i.e., judgment without a trial.

Significance: The CEO himself didn't contest the motion. The defense came from the testing labs whose own liability was on the line. The labs contended that they had no connection with the hospital since they didn't identify it in the billing. But the court brushed aside the argument, noting that the labs did use Putnam's National Provider Identifier and Tax Identification Number to bill claims on behalf of patients who had no connection to Putnam. And that was more than enough to establish the connection required to prove liability.

RightCHOICE Managed Care, Inc. v. Hosp. Partners, Inc., 2021 U.S. Dist. LEXIS 153605

Medical Group Pays $94.4K to Settle HDL Process and Handling Payment Anti-Kickback Law Charges

Case: A physician and his Texas medical group have agreed to fork over $94,440 to the OIG for accepting kickbacks from now defunct Health Diagnostic Laboratory, Inc. (HDL) in the form of processing and handling payments for collecting patient blood samples in exchange for referrals of Medicare patients for lab testing.

Significance: This case is the most recent in a long line of enforcement actions against providers on the receiving end of the biggest lab testing kickback scheme in history. In April 2015, HDL paid $47 million to settle its role in the scheme. Chapter 11 bankruptcy followed shortly thereafter. In February 2021, the U.S. Court of Appeals for the Fourth Circuit upheld a massive $114.1 million jury whistleblower case verdict against a former blood lab CEO and two sales consultants who acted as principles. Settlements with downstream physicians have been in the range $60,000 to $150,000, depending on the volume of referrals generated.

Court Rules that Hologic Didn't Steal Minerva's Patented Technology

Case: Minerva Surgical Instruments sued Hologic for illegally incorporating Minerva's patented technology for endometric ablation into its NovaSure ADVANCED and CLASSIC devices. Hologic argued that it based its NovaSure devices on a plasma delivery system that had already been reduced to practice for at least a year. The federal district court

agreed and tossed Minerva's claim for a declaration of the validity of its patent.

Significance: Under the so-called "on-sale bar" of patent law (35 U.S.C. § 102(b)), a person is entitled to a patent unless the invention was "in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." The evidence clearly demonstrated that the technology had been reduced to use for years before the NovaSure products launched. Minerva itself displayed a prototype of what would later become its Aurora product incorporating the technology at the American Association of Gynecologic Laparoscopists trade show in 2009. As a result, it granted Hologic's motion for summary judgment on the invalidity of the Minerva patent.

Minerva Surgical v. Hologic, Inc., 2021 U.S. Dist. LEXIS 138474, 2021 U.S.P.Q.2D (BNA) 789, 2021 WL 3161477

Texas Toxicology Lab Settles Self-Disclosed Anti-Kickback Law Charges for $1.54 Million

Case: The American Institute of Toxicology, Inc., d/b/a AIT Laboratories has agreed to pay $1,541,062 to settle charges of violating the anti-kickback law. OIG alleges that AIT, through its agent, paid remuneration by placing specimen collection personnel in 18 sober home clients. The problem is that the AIT specimen collectors performed those services free of charge. The OIG also claims that AIT's agent forged contracts and lab test orders for federal health care beneficiaries residing in the sober homes.

Significance: OIG has repeatedly warned that placing personnel who perform free services in the facilities of referral sources raises a bright red flag under the anti-kickback laws. The good news for AIT is that it likely saved itself a lot of money by self-disclosing the violations to OIG, especially when you consider that the rogue practices involved no fewer than 18 different client facilities.

Enforcement Trends: Federal Courts Split on Government Dismissals of *Qui Tam* Claims, *from page 1*

leverage significantly. The FCA also includes what had been a rarely used provision, Section 3170(c)(2)(A), allowing the government to actively seek to have cases that it doesn't believe serve its interests dismissed.

In January 2018, then DOJ Civil Fraud Section Director Michael Granston issued an internal memorandum instructing US Attorneys to exercise their Section 3170(c)(2)(A) powers more aggressively. The Granston memo calls on federal prosecutors to act as "gatekeepers" to preserve enforcement resources, protect government interests and prevent weak cases from resulting in adverse judgments that weaken government enforcement powers.

The DOJ's 7 Grounds for Seeking Dismissal of *Qui Tam* Claims

The Granston memo instructing US attorneys to use their Section Section 3170(c)(2)(A) dismissal powers more aggressively lists seven kinds of problematic *qui tam* claims that they should target for dismissal:

1. Meritless Claims, i.e., where a *qui tam* complaint appears to be lacking in merit because the relator's legal theory is "inherently defective," or because his/her "factual allegations are frivolous."

2. Parasitic or Opportunistic Claims, i.e., *qui tam* actions that duplicate pre-existing government investigations and add no useful information to the investigation and bestow the relator with an unwarranted windfall in taxpayer dollars for providing merely duplicative information.

3. Threats to Policies or Programs, i.e., *qui tam* actions that threaten to interfere with a government agency's policies or programs.

4. Actions Interfering with Other FCA Cases, e.g., a separate qui tam case in which the government has already chosen to intervene.

5. Cases Threatening Harm to National Security, e.g., *qui tam* actions that may compromise classified information, involve intelligence agency operations or military contracts.

6. Cases Where Costs Will Exceed Gain, the calculation of which should include the "opportunity cost" of utilizing resources on other matters of higher priority with a surer probability of recovery.

7. Claims that May Frustrate an Investigation, i.e., whether there are issues, such as procedural errors, with the relator's action that frustrate the government's effort to conduct a proper investigation.

The Courts Split

Even so, government attempts to implement its Section 3170(c)(2)(A) powers have encountered firm resistance from not only relators but also

the courts. All agree that, as the "real party in interest," the US government can seek dismissal. However, even before Granston, the federal courts have split on what the government must do to get a case dismissed under Section 3170(c)(2)(A).

Unfettered Discretion: In a case decided in 2003, the DC Circuit, found that the government has unfettered discretion to get a *qui tam* case dismissed (*Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003).

Rational-Relation Test: By contrast, two Circuits, the Ninth (*United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998) and Tenth (*Ridenour v. Kaiser-Hill Co.*, 397 F.3d 925, 936 (10th Cir. 2005) have required the government to hold an evidentiary hearing and meet a two-part test:

1. First, the government must identify "a valid government purpose" for dismissal; and
2. Then, it must show that dismissing the case accomplishes that valid purpose.

When and if the government meets that purpose, the burden shifts to the relator to prove that "dismissal is fraudulent, arbitrary and capricious, or illegal."

Note: The Seventh Circuit subscribes to neither of these views and has held that a Section 3170(c)(2)(A) *qui tam* dismissal is no different from dismissal of any other lawsuit subject to the Federal Rules of Civil Procedure (*United States ex rel. CIMZNHCA v. UCB, Inc.*, 970 F.3d 835, 839 (7th Cir. 2020)).

The Health Choice Case

In July, the Fifth Circuit became the fifth court to weigh in on this question. The case began when Health Choice and another entity created by a legal and consulting firm to file *qui tam* lawsuits against pharmaceutical companies and health care providers sued Eli Lily and Bayer for paying physicians kickbacks in the form of patient-education services for prescriptions that were subsequently billed to Medicare. Having done its own two-year investigation into the matter, the government concluded that the case had no merit. A year after declining to intervene, it sought dismissal of the case under Section 3170(c)(2)(A).

The lower court agreed and tossed the cases. Health Choice appealed but to no avail. After acknowledging the courts split, the Fifth Circuit sided with the Ninth and Tenth in deciding that the rational-relation test applied. But it also found that the government met the test in this case:

- **Valid purpose:** The government demonstrated two valid reasons for dismissal: i. the claims lacked the merit sufficient to justify the cost of

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investigation and prosecution; and ii. litigation over free patient education services would "undermine practices that benefit federal healthcare programs by providing patients with greater access to product education and support";

- **Rational relation:** The government also showed that because the case lacked merit, the expected recovery wouldn't be enough to recoup its litigation expenses if the case were to proceed; and
- **Arbitrary:** Once the government met both parts of the test, the burden shifted to Health Choice to show that the motion to dismiss was "fraudulent, arbitrary and capricious, or illegal." But the court rejected its argument that the DOJ had a personal animus against the organization and deliberately waited a year into discovery to seek dismissal as "conclusory."

United States ex rel. Health Choice All., L.L.C. v. Eli Lilly & Co., 2021 U.S. App. LEXIS 20175, ___ F.5th ___, 2021 WL 2821116

What It Means

Granston is gone but his memo remains. Thus, much the way the DOJ's Yates memo policy of targeting individual corporate officers, directors and leaders for the fraud committed by their organizations before it, the Granston memo policy of making greater use of Section 3170(c)(2)(A) to seek dismissal of cases the DOJ deems weak or counter to government interests is likely to survive the loss of its author and transition in administrations. At the same time, it appears that at least some federal courts will hold the government's feet to the fire and make a solid case for dismissal rather than grant it unfettered discretion to dismiss any case it doesn't like.