

Clinical ColLABorative

Legal Insights in Laboratory Compliance

What To Do When The Government Knocks On Your Lab's Door

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The volume of federal enforcement actions involving laboratories has increased dramatically over the last few years. Not a month seems to pass without a press release from the United States Department of Justice (DOJ) trumpeting a conviction of, or multi-million-dollar settlement with, a lab, lab owners, or lab personnel. In late April, for example, the DOJ announced a nationwide coordinated effort aimed at COVID-19 testing fraud, which encompassed target labs in California, New York, Florida, Maryland, and other states, and resulted in criminal charges against 21 defendants across nine federal districts [You can read the DOJ's Press Release at this [link](#)]. While the government certainly has invested significant resources in pursuing pandemic-related issues, the scope of enforcement in the lab space is far broader with regard to COVID-19 issues.

The potential consequences of an enforcement action mean that few events are more disruptive to a laboratory than a knock on the door from federal or state government investigators. The "knock" is really an attempt by the government to obtain information and documents, and there are three methods typically used:

- Informal Requests,
- Subpoenas or Civil Investigative Demands (CID), and
- Search Warrants.

Although the first two methods do not create the same public spectacle as the execution of a search warrant, all three should be treated with equal seriousness and care, as each may signal the start of a lengthy legal ordeal. Oftentimes, how the lab responds initially could alter the course of events to follow, for better or worse.

Any discussion of strategies for responding to a government investigation must begin with the caveat that the potential consequences of enforcement actions are so severe that companies and individuals should always seek the advice of competent legal counsel rather than trying to respond on their own. Nonetheless, there are certain key considerations for lab ownership, management, and personnel to keep in mind when the government knocks.

1. Informal Requests

One of the most common investigation tactics is also the least formal. On the federal side, for example, agents from the FBI, but possibly from other agencies such as HHS, the IRS, or Treasury, can appear at a lab's office asking to meet with certain individuals in management or operations to ask "just a few questions." The agents' demeanor may be disarmingly polite, friendly, and low-key, all of which have the tendency to mitigate anxiety and thereby induce a dialogue.

While there is generally nothing illegal or unethical about informal requests, it must be understood that the interviewee is often very nervous, if for no other reason than the fact that he or she is speaking with law enforcement agents, who appear to have the power to cause the individual to be imprisoned. Those nerves and the normal human desire to match the agents' casual demeanor may cause the interviewee to provide information that is less than accurate on its own or is shaded by the influence of the interrogators. Those

inaccurate or inartful responses may come back to haunt the interviewee and the lab. Simply put, the informal request is usually not a level playing field.

Time and time again, individuals, including senior executives, voluntarily participate in such an informal interview out of a concern that refusing would make them “look guilty.” While that possibly exists, the agents are equally aware of how serious the circumstances are and should respect an individual’s very reasonable preference that any cooperation with federal authorities be coordinated through the company’s legal counsel.

Instead of accepting the interview, it is reasonable and sufficient to respond to the request with a statement along the lines of, “Thank you for stopping by today. Let me ask you to contact our company counsel, [name of lawyer], at [phone number], and [he or she] will work with you on what you need in terms of documents, information, or interviews. I will let [him or her] know right after this that you will be calling.” Competent counsel will know how to engage appropriately with the government and to level the playing field for the laboratory.

2. Grand Jury Subpoenas, HIPAA Subpoenas, and Civil Investigative Demands

The main formal information-gathering method used by the federal government in a health care fraud investigation is a subpoena or civil investigative demand (CID). A subpoena directs a witness to appear in person to give testimony and produce documents, although the personal appearance/testimony component is routinely waived by the government so long as documents are produced in a timely manner. In this context, the subpoena is typically either a grand jury subpoena or a subpoena issued pursuant to HIPAA. (Of note, a HIPAA subpoena is used by the government to request broad categories of information relating to health care fraud and allows sharing of responsive documents and information between government lawyers on the civil and criminal sides.) A CID serves the same purpose as a subpoena. In fact, most federal health care fraud is pursued under the federal False Claims Act (the Act), and the Act expressly authorizes the government to use CIDs to investigate suspected violations.

A common error labs and other businesses make in dealing with subpoenas and CIDs is not taking them seriously enough. It begins with respecting the compliance date. These formal requests include a specific date by which the lab or individual must appear or produce documents. That deadline is mandatory, and noncompliance can be punished severely. While counsel can often negotiate an extension with the government, no one should presume it will be given automatically, especially if the request is made the day before the deadline or sometime thereafter.

The substance of the response to a subpoena or CID should be approached thoughtfully and strategically. As with the compliance deadline, the scope of the requests may be subject to negotiation with the government, particularly with regard to the burdens that would be imposed without any modifications. Regardless, recipients are expected to conduct a thorough and diligent search for responsive materials, which begins by identifying the appropriate sources of data and the individuals who have that data. Formal efforts should be made to preserve potentially-responsive records, including by issuing hold notices to relevant subject matter personnel and ensuring that IT takes steps to prevent data deletion or destruction.

Although the focus of the investigation is often unclear, experienced counsel may be able to provide some insight for the laboratory on the focus of the government’s investigation based upon the requests included in the subpoena or CID. Furthermore, counsel may be able to develop a positive line of communication with DOJ lawyers through which additional information can be gleaned about the investigation and a dialogue initiated to drive the matter toward a favorable outcome.

That insight can be very valuable, particularly if it reveals a need for the lab to conduct its own internal investigation “parallel” to the government’s investigation. Although these internal investigations need to be mindful of practices designed not to improperly interfere with the government’s work, they often yield useful benefits to the lab, including with respect to resolving the government’s concerns in the most advantageous way possible.

3. Search Warrants

The execution of a search warrant can be a painful, public experience for a lab. It purposefully comes without warning, and agents have the ability to roam through the facility in search of documents and data. As the most serious of the investigatory methods, it indicates that the government is likely concerned that lab and its personnel have engaged in criminal conduct.

A search warrant, which must be signed by a judge, allows law enforcement agents to enter into private property to search for and seize evidence. To obtain the warrant, agents must tell the judge exactly where they want to

look and what they expect to find. They have to give the judge probable cause to believe that the search is likely to turn up that evidence. By the time the agents arrive at the lab's door with the warrant, they have obtained the judge's approval for the search. This does not mean, however, that the lab and its personnel are without rights.

In the incredibly stressful first few minutes of a warrant execution, as agents begin to swarm the facility, clear thinking can be a challenge. It is important that the lab has already designated in advance an employee to be the point person for such an event, and that person must remain calm and polite in dealing with the agents (even if the agents are neither calm nor polite). There will be an officer in charge for the government, who will identify himself or herself. That officer should be asked for their business card and a copy of the warrant to be read before the search commences. It is also worthwhile to ask that the search not begin until the lab's legal counsel can arrive.

At the earliest opportunity during the execution of the search warrant, a call should be made by the designated employee to the lab's legal counsel in order to obtain specific guidance. That call should be made from a private area, outside of the presence of agents. The warrant does not give the agents the right to listen to any attorney-client conversation.

It is possible that the officer will provide the warrant copy but refuse to wait to begin the search. If that happens, no effort should be made to physically obstruct the agents' efforts. Doing so may violate the law and result in stand-alone criminal charges.

It is a common misconception that employees must remain on premises during the search. Absent an arrest warrant for an individual, he or she is free to leave. More importantly, it is likely in the laboratory's best interests to send all employees home with a message such as:

"As you can see, the government is here to search our offices. Given the disruption, we are closing for today. Please take the rest of the day off with pay and plan to return at your scheduled time tomorrow. We will communicate about today's events tomorrow. Of course, if you have any questions, please let me know and we can set a time to speak this evening or as early in the day tomorrow as possible."

The officer in charge should be informed of that directive. Although the officer in charge may be upset, that displeasure may be better than having the employees remain on site. Oftentimes, while executing the search warrant, the agents also will seek informal interviews of employees, and with such interviews there is the risk of the employees potentially making statements that are panic-driven and imprecise or inaccurate (as discussed above). Of course, while employees have their own right to remain silent, the lab may **not** direct employees to refrain from speaking with the agents. Giving such an instruction may also result in stand-alone criminal charges.

The warrant will specify in writing which areas can be searched. The agents may not exceed the specified boundaries, *absent the lab's consent*. This is an important consideration because in the fog of the moment, that consent can sometimes be given thoughtlessly. To be clear, if there were valid legal grounds to search a part of the lab, that part would be noted in the warrant. If the agents want to expand their search, that request should first be discussed with the lab's legal counsel.

It can be useful to visually monitor (but not interfere with) the search. Written notes of the areas searched, and the items seized can prove helpful with the short- and long-term efforts to respond to the government's investigation. Be sure to write the words, "Attorney-Client Privileged / Confidential" at the top of any such note pages in order to designate them as protected from discovery since they will be provided to counsel.

The government must create its own inventory, and a copy should be requested from the officer in charge. There is no reason to respond to a request to confirm the accuracy of that inventory during the warrant execution. Such confirmation should not be provided until after a discussion with counsel.

Counsel also will help draft an appropriate communication to employees about the day's events, to be used the following day to help ease general anxieties about the future of the business.

It bears repeating that the execution of a search warrant can be an extraordinarily stressful event. Remember, however, that the disruption and turbulence will conclude in a matter of hours. Remaining calm and professional while staying focused on the actions of the lab's employees and the law enforcement agents on site is essential. Spending even a moment during the execution of the search speculating what the government's suspicions might be is wasted time. If a criminal prosecution follows from the search, there will be plenty of time to analyze the charges and the evidence.

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