

EXPERT GUIDE

Trends in Compliance for the Life Sciences Industry

An interview with Jacob Elberg, previous Chief of the Health Care & Government Fraud Unit in the U.S. Attorney's Office for the District of New Jersey

MEET OUR EXPERT



Jacob Elberg

Jacob Elberg spent the majority of his law career in the U.S. Attorney's Office in the District of New Jersey, where he focused primarily on life sciences and healthcare organizations. During his time in the U.S. Attorney's Office, Elberg served as the Chief of the Health Care & Government Fraud Unit. There, he led one of the country's largest and most impactful healthcare units, supervising a team of 15 AUSAs and directing all of the Office's criminal and civil investigations and prosecutions of healthcare fraud offenses.

Elberg currently holds the position of Faculty Director at the Center for Health and Pharmaceutical Law at Seton Hall Law School, where he teaches classes covering healthcare fraud and data analytics. In addition, he holds the title of Faculty Advisor for Seton Hall's Healthcare Compliance Certificate programs around the world.



How have you seen the risks evolve over the last decade around interactions between life sciences companies and HCPs and HCOs, particularly as it relates to kickback and bribery-related risks in the US and globally?

JACOB ELBERG: Most significantly, I would say that risks have increased largely because the enforcement environment has increased. What we've seen at the Department of Justice, both at Main Justice in Washington and U.S. Attorney's Offices around the country, is an increased dedication of resources to healthcare fraud. That's happened across administrations as more and more folks have seen it as a problem that needs to be addressed. Just from that perspective, there is an increase in risk. We can also see increased risk over the last decade of dealing with third parties. While that's an issue in the U.S. it's even more prevalent outside of the U.S.

In your experience, as a former prosecutor and someone who has studied corporate resolutions widely, where do breakdowns typically occur in life sciences companies in compliance program controls around these risks?

The real challenge from a compliance perspective is that breakdowns happen at all levels. There are certainly companies, including companies that I prosecuted, where the issues went all the way up to the CEO and Board level. At the same time, in other cases, even if things were happening largely as they should from a leadership perspective, there were real breakdowns in control as you got further away from leadership. So, it is, unfortunately, a real challenge and a problem that is not easily solved.

When you were a former federal prosecutor, how would you have assessed a company before you with substantiated issues related to kickbacks and bribery in terms of their remediation steps? Let's cover this first from a process and controls perspective. What would you have expected to see within that organization in terms of putting into place better preventative and detective controls?

JACOB ELBERG: It's a real challenge from a DOJ perspective to determine whether a company's remediation efforts are substantial and sufficient, as well as whether they are sincere. There are two parts to this.

1. Even if they are taking the necessary steps, if a company's efforts are not sincere, prosecutors will be understandably concerned that the new processes

will go away as soon as they are no longer under a monitorship or are no longer “under a microscope.”

2. In terms of making sure the changes are necessary, part of it is looking at the particular issue that happened. There are some issues where the company does what it should be doing; completes a root cause analysis, and tries to understand why the problems occurred. They’re trying to figure out if there’s a process they can put in place that would address their specific problem. And this process certainly needs to happen.

As a prosecutor, you look at if the company has figured out how to make sure that this specific problem doesn’t happen again. However, it needs to go beyond that. The understanding needs to be from both the company and DOJ perspectives.

In terms of whether what the companies put in place works and is sufficient, every company is different. There is no one-size-fits-all, but resourcing is a big part of it. Spending money isn’t the only way to measure whether it works, but it is certainly a test. And seeing a company devoting resources and putting money into it is certainly one way of judging sincerity.

Second, how would you assess remediation of bribery or kickback issues from a culture and people perspective? What behavioral, cultural, or structural changes would you have been looking out for?

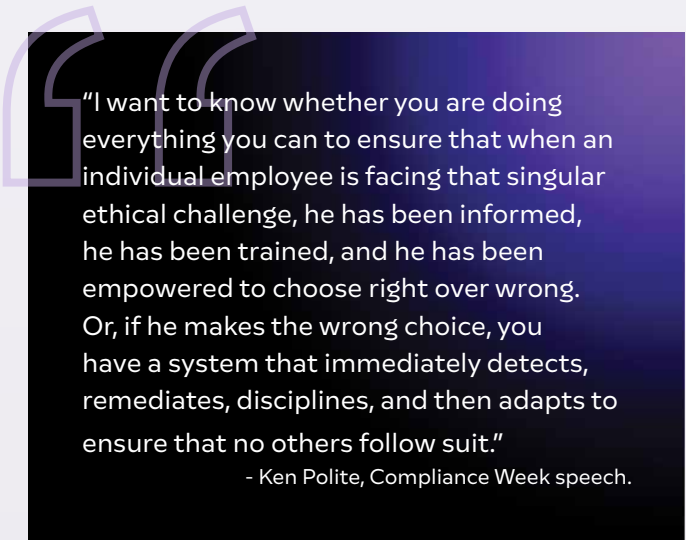
I regularly speak, both in my role as a professor and as faculty director to our compliance programs, about the connection between compliance and ethics. You can’t just be talking about processes and controls; you really do need to have a cultural change in any culture that is trying to support compliant behavior going forward. That, unfortunately, can be a difficult thing to measure. I like to look out for companies that have made efforts to shape it in the right ways with the appropriate messaging from the top all the way down to the bottom, and also try to measure where things stand from a culture perspective. They should be asking themselves, “Are we headed in the right direction or not?”

Often the problem is one of the overall compliance atmosphere and overall problems of culture that are broader than the individual wrongdoing issue at the time. So, we expect companies to be consistently doing the same kind of real, introspective analysis, even when they have not gotten themselves in trouble.

How would you ferret out organizations making deep and lasting changes versus those checking a box for you?

It really depends on the organization. Sometimes, it’s an issue—as we’ve discussed—of adding additional resources or putting different things in place. Other times, it’s an issue of specific personnel. Frequently, it can be solved by bringing in a person or a team of people with credibility but also the reputation for being unwilling to tolerate a lack of compliance.

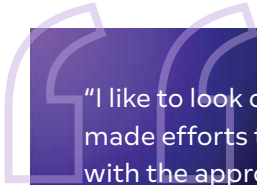
The DOJ 2020 compliance program guidance updates crystallized expectations on healthcare organizations to test the effectiveness of their programs. Various DOJ officials have since spoken about how they expect companies to use data analytics more aggressively to do just that. Kenneth Polite has gone a step further to set an expectation that organizations “immediately” detect wrongdoing.



“I want to know whether you are doing everything you can to ensure that when an individual employee is facing that singular ethical challenge, he has been informed, he has been trained, and he has been empowered to choose right over wrong. Or, if he makes the wrong choice, you have a system that immediately detects, remediates, disciplines, and then adapts to ensure that no others follow suit.”

- Ken Polite, Compliance Week speech.

Can you provide your perspective on where organizations should be headed in terms of using data analytics internally from a continuous monitoring perspective to detect wrongdoing in the kickback and bribery space?




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What "immediately" means is going to depend on the circumstance. My interpretation is that companies need to make sure they are doing what they can to address issues as quickly as possible. Being able to do something immediately—meaning in real-time—is probably going to be more applicable in the financial services industry than it is from a healthcare perspective if we're talking about addressing something in the same minute, in the same hour, on the same day.

When you think about kickbacks, companies should have systems in place where it's not years or months later that they're digging into and understanding if there are payments that don't make sense or that shouldn't have been made.

One of the things that the DOJ has increasingly recognized is that companies are doing more with data. Putting compliance aside for a moment, we're able to use data to see things immediately from the business side of things—from a marketing and sales perspective. Companies are able to detect if sales are going up or down and they can figure that out immediately. If there's the ability to put a data system in place that's going to enable that same sort of prompt and effective analysis, then companies should be as willing to invest in the compliance side as much as they are on the sales and marketing side of the house.



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You have researched and written extensively on how regulators have in the past not been as clear in terms of the benefits of compliance programs in some DOJ resolutions. Can you share a little more about what you are hoping to see more of in those resolutions from regulators?

There are two parts to this, and I think both are happening.

1. What does the resolution itself look like? Is the DOJ making sure that resolutions with a company that has tried really hard—having a pre-existing compliance program (where wrongdoing occurred despite their best efforts) and implementing remedial measures—look different than a resolution with a company that has not done as well in those areas or hasn't put the effort into their compliance program before the wrongdoing occurred. This should also look different if the remedial measures were not as strong as they should be.

So, part of it is making sure that those resolutions look very different. The DOJ has increasingly talked about it and has made them look different, whether in terms of monitor or no monitor, the type of resolution on the criminal side or—most relevant from a healthcare perspective—domestically having differences in the multiplier from the false claims act perspective. Those resolutions are not coming out the same way.

2. To be able to do those things, the DOJ needs to be able to distinguish between companies that have an overall effective compliance program before the wrongdoing occurs and have made proper remedial measures and investments in compliance—and those that have not. That's not easy, which is something DOJ has increasingly recognized in recent years. Because of this, we are seeing increased investment in training DOJ folks on compliance issues, as well as increased investment in hiring at the most senior levels of the DOJ and at the level of the folks that will be investigating and prosecuting the cases. This is all to try to employ more people that actually understand compliance and can make those distinctions.

And while there is still a long way to go, I think the DOJ is sincerely committed to doing that and is headed in the right direction. I think companies can expect that the DOJ is going to be doing a better job at figuring out whether their compliance programs were and are where they're supposed to be.

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You've trained a lot of in-house folks, and many companies are dealing with the same data analytics challenges. Are there more opportunities to collaborate across the industry with the use of data to strengthen compliance?

So I think what is going on to some degree, when we are talking about data in particular, is just a level of data literacy spreading across organizations. The more it increases, the better it will be. There obviously are and are always going to be folks that are real experts in data.

For some companies that's housed in-house and others look externally to find those people. I think that's always going to be necessary. Everybody is not going to be a data person, but I see some companies making increase efforts at doing the sort of thing that I try to do with my law students in my data analytics class, which is which is get folks to a point of data literacy and understanding some basics of how it works, what's possible, and what's not possible.

The benefit of that, in terms of collaboration across industry, is that the more folks (including those who aren't the pure data folks) that engage and understand those discussions, the more can happen when they're together at compliance conferences and other trainings. While those people who are the data experts are always going to be necessary, from my perspective, a lot of the creative work at figuring out what we could be doing, what sources we could find, and what we can be doing with it not only needs to come from those true data experts but also from those who are more veteran, "non-data-focused" compliance people.

The more there is data literacy, the more increased discussion. We're seeing more and more panels talking about data analytics at industry conferences and other places. I think that's a positive for collaboration.

As a prosecutor and someone who has worked a lot with in-house folks and companies, where have you seen compliance organizations do well in terms of collaborating outside of compliance?

I think the answer is a little bit counterintuitive. You frequently will see well-intentioned folks who want the compliance program to do well and want to do the right thing say, "Well, we need to go and hire and train our compliance people to be bulldogs and tough."

The problem is that it can really lead to siloing. You want the compliance folks, obviously, to be focused on making sure that things are being done in a compliant way. But, they have to do that from a teamwork perspective, seeing themselves as partners that want the business to succeed and looking to add things that are good for the business and compliance. The best entities aren't necessarily the ones with the most aggressive compliance people; they're the ones where the compliance people have really become integrated.

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We've seen a shift in companies that we work with. They're using the business as the first line of defense to these issues and compliance data and automation are more of a backstop to monitor actions. They believe that in most cases, people will make the right call, but in some cases, they're going to find where they're going off track through data. As a prosecutor, how would you have viewed an approach like that? How would you have assessed and tested whether that balance had gone too far for the business?

I'll often say when talking to compliance folks that as much as you want to be necessary, the ultimate goal is that the conversation with business folks looks no different whether you're on the call or not. You want to empower folks with the information, understanding, and desire to really do the compliance person's role. Data can be a significant part of making sure that the format can be understood by all. A business person shouldn't have to say, "I need somebody from compliance to translate this data for me so that I can understand what's going on."

Folks can use it together, and I think everybody wins from that perspective. Business folks are not happy when they're surprised by something that compliance folks are seeing, so giving them the opportunity to engage with the data is only a positive.

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Your entire program starts with risk assessment. The previous, traditional approach to risk assessment was fairly crude and broad. We are seeing more and more companies wanting to go another level down. Are you seeing a similar movement in the industry to have more granular risk assessments? Do you agree with that approach? Do a lot of companies still have a ways to go with that approach?

What makes it difficult is that it's a company-by-company problem. Depending on how the company, the leadership decisionmaking, and compliance program is structured may mean you need to break it down differently. It may mean not only different risks but risks that are going to be targeted more for one company than another. I think it is great when you think about the idea that different companies are doing it differently. It's an opportunity for all those companies to ask themselves, "Are we doing it the right way or should we be doing it more the way somebody else is?"

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The Problem We're Solving

We focused on the challenges every compliance team faces:



Employees lacking sufficient tools to assess risk and own their own compliance



Interfaces for the business that are not user-friendly or intuitive



Too few legal or compliance resources to support the business



Disorganized and disparate data stores, making insights difficult to generate



Risks managed in multiple systems that do not talk to each other



Not having real-time analytics and monitoring, leading to missed anomalies

ABOUT CASE IQ

Case IQ offers an end-to-end compliance and case management solution that consolidates compliance monitoring, whistleblower solutions, third-party risk oversight, investigative case management and compliance approval and disclosures workflows. Lextegrity was acquired by Case IQ in 2025 and is now offered as an end-to-end suite of compliance tools.

Case IQ's software has been before enforcement agencies globally in 12 separate company engagements and was even recognized by the SEC as a remediation factor in a client's FCPA resolution. It has been chosen by several companies after the appointment of compliance monitors or after the start of an investigation and has been a factor in resolving those matters, including helping to secure a DOJ declination.

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