Sponsored article

A Q&A with Raymond Bonner, Sidley Austin

The life sciences industry faces greater scrutiny from government regulators, putting enormous pressure on companies to comply. *LMG Life Sciences* Editor Kevin Matha discussed that issue and more with Raymond Bonner (pictured, below), who has dedicated his practice to handling some of the industry's toughest problems.

How did you get into the industry?

After a couple of years in private practice, I went to the US Attorney's Office in the District of Maryland where a number of major government agencies are located, including the FDA, CMS, and NIH.

All three of these institutions are important to the healthcare and drug regulatory process. Little did I know, when I went to do "cops and robbers" cases in the hope of a lot of trial work, that after a couple of months I would be spending at least 60-70% of my time on FDA-related investigations.

How has the industry changed since you joined private practice?

Three major things happened: First, government enforcement of the pharmaceutical and medical device industry increased enormously. Second, the "whistleblower," or *qui tam* litigation, also started increasing. The convergence of government enforcement actions and "whistleblower" False Claims Act cases put the entire industry under the microscope. And a third thing that happened over the last 10 to 15 years is that the industry went truly global—with public authorities in numerous countries monitoring industry activities.

There are always going to be government investigations and at Sidley we are well equipped to handle these complex matters. We have represented numerous companies in a variety of cases and thus are positioned well to advise clients on the legal, regulatory, science, and technical issues.

In the second area, the "whistleblower" False Claims Act cases, we once again have handled a significant number of these cases, and this broad-based experience coupled with our appreciation of the regulatory background, allows us to defend matters in a much more sophisticated, strategic way.

Fortunately for our clients, we've had a significant number of what I call "quiet wins" in cases that are declined by the government. I've probably had more of those cases than anybody at Sidley. We handle so many of them, but unfortunately, although our clients appreciate the work and retain us again and again, I can't discuss the specifics of any such matter.

You mentioned that Sidley Austin handles certain matters in a "sophisticated, strategic way." Can you elaborate?

First of all, I think that given our firm's deep experience in certain areas—marketing, Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Quality System Regulation (QSR), and drug and medical device reporting—we have considerable experience working with so many companies that I think factually, we are in a position where we can present strong company defenses.

Given the diversity and depth of our regulatory work, I believe we are able to present factual arguments rooted in regulatory law, guidance, and history that present the government with factors that are important as they exercise their enforcement/prosecutorial discretion.

For example, in the oncology sector, we have handled oncology-related cases, so we know how oncologists review emerging clinical data to make independent judgment decisions regarding oncology product usage, including decisions to use multiple products in a cocktail approach. We know how oncology products are reviewed during the FDA approval process. We also appreciate the approach the government takes regarding the pricing of oncology products. All of these are important factors when we discuss issues with the government. Indeed, the government appreciates a fulsome discussion regarding these types of issues—so that they can make an informed judgment regarding the matter.

So, by having credibility with the government, it lends weight to your arguments.

Yes! We go in and say, Listen, I think it's important to weigh this information and evidence to determine whether the government should really bring a particular case. The prosecutor has a lot of discretion in life science cases and, in my experience, they are careful in weighing evidence presented to them.

Having formerly been a prosecutor in this area, and knowing the industry and the prac-

tices so well, I am very aware that there are a lot of factors for the government to weigh. It is so important that you are credible with the government, so much so that in some situations you concede certain issues because that is what the facts dictate.

You need to be strategic and sophisticated but, most importantly, credible.

Are there typical problems life sciences companies run into?

Let's start with the pharmaceutical sector. Right now, the number one issue, from the DOJ's perspective and from the FDA's perspective, is off-label promotion. Many investigations boil down to the following case focus: Is the company orchestrating an off-label marketing promotion "scheme" and are they systematically driving company profits by promoting the drug off-label?

The number two issue for the pharmaceutical industry would be GMP enforcement. The FDA regularly inspects manufacturing sites to ensure products are being produced according to acceptable quality/safety standards. Many companies have manufacturing sites throughout the world. Sites that do not comply with GMP requirements face significant regulatory, financial, and business consequences.

What can happen if they find something wrong or irregular?

If the company has a difficult inspection, it can lead to a FDA 483 inspection report (the name of the government inspection form). The FDA will officially report major problems and if the company does not address those problems, the FDA can issue a warning letter that can then lead to an injunction case and a lengthy consent decree. Most importantly, it can hold up further application approvals.

Stop and think from a risk standpoint: Many pharmaceutical companies, given the enormous increased GMP enforcement, have identified this as a major company or enterprise compliance risk.

If the company does not resolve the issues post-warning letter, the government may pursue an injunction case against the company and a consent decree. A consent decree will require the company to bring in a third party consulting firm to do what they call a baseline audit of all manufacturing facility issues. The consent decree will require certification by the third party that you have corrected the issues, after which they will require the third party to be involved for five years to handle ongoing reviews.

At the same time, the FDA will return to your plants on a more frequent basis to inspect them, and if they find additional problems, they can move for further enforcement action in court, including contempt related to the consent decree violations. Now, while this warning letter is pending or, in some cases, while the consent decree is pending, the FDA puts your product applications on hold if those new products are going to be manufactured at the site subject to the warning letter or, alternatively, the consent decree.

> "Right now, the number one issue, from the DOJ's perspective and from the FDA's perspective, is off-label promotion."

This presents a significant problem. A company may have promised shareholders that significant product approvals are expected, however, and now suddenly, as a result of your GMP problems, you can't move forward from an application standpoint. In many of these cases, the FDA may have the consent decree cover multiple sites.

Maintaining quality systems and processes, and thus maintaining the company's products supply chain, is critical. If a warning letter is issued and you have to shut down your facility, the costs can run, for example, well over $500 million. If a consent decree is entered into and you have to, essentially, restart your manufacturing operations, again you're talking about enormous financial loss and costs. It is critical that companies regularly monitor and review the compliance status of their manufacturing establishments.

How often do you handle these types of cases?

I actually handled a lot of GMP cases when I was a prosecutor. I have been doing GMP work for about 20 or so years now, and we have numerous attorneys who have been doing GMP work for 10 plus years. At Sidley, we know the law, the regulations; we know the technical and science issues. We have lawyers on our team who have engineering backgrounds, so they can address validation, equipment, HVAC, and water system-related issues.

Because of the volume of the work we do in the GMP area for pharmaceutical companies and medical device companies, we probably, this is an estimate, have the largest practice in the world from a law firm standpoint. And as a result of companies having sites throughout the world, we probably travel internationally as much as any group in the firm. We have been in Europe extensively at a number of sites, including Belgium, Germany, the UK, Sweden, Austria, and Italy, as well as sites in Australia, China, and Japan.

We truly have a global, worldwide practice at Sidley where companies routinely call on us to assist them in terms of preparing for FDA inspections, responding to FDA inspections and warning letters, and then conducting audits to make sure they are in continuous compliance. You really have to accumulate experience in this area to make a difference with these companies that are sophisticated consumers of legal and regulatory services.

When dealing with some of the multinational corporations it seems likely that foreign laws will be in play. Is it important to have a firm with a global reach?

You're absolutely right! We have a number of offices with significant regulatory experience, particularly in Brussels, London, Tokyo, and in Beijing. Those offices have lawyers in them who are knowledgeable about life science issues with respect to the EU, Asia or their particular countries.

One of the things that we've done, given our GMP practice, is that we have trained people in numerous offices regarding major GMP issues and investigations. So, if something arises in a different part of the world, we can coordinate with those offices and related government authorities and deal with the issues in terms of a communications plan, regulatory reporting, and, essentially, crisis management. Internally, there is constant communication with those offices on new

developments. It's a very productive, cohesive process.

It's more about managing the crisis, and tackling the issue quickly?

Yes, that's why our group is pretty flexible and dynamic. On any given day or in any given week, I may have a to-do list in terms of numerous matters. But when the phone rings and there's a major issue at a manufacturing plant, or there's a need to consider a recall, or there's some signal out there that the drug is acting differently, we travel immediately—either to company headquarters or to the factory facility—to assist our client on the review.

Handling these issues requires an understanding, not only of the law and regulatory issues, but also of science and technology. That's why our goal is to get on top of the issues as fast as possible for two reasons. First, if a product is not performing correctly, the company needs to deal with it in the market right away. Secondly, the company wants to communicate with all the appropriate government agencies because, if there's a real issue, the company and regulatory authorities must develop a clear action/communication plan. But if there is not a credible issue, you might actually be doing the wrong thing by taking the product off the market. In other words, if the evidence is not compelling, there's always a risk-benefit analysis by regulatory authorities and it may be more important to keep the product on the market. The important step is that you gather as much information as possible in an accurate and thorough way.

The great thing about this practice is that everybody wants to do the right thing. I actually find the process to be collaborative and productive because the company and the public health authorities are trying to do the right thing.

With such sophisticated science in an ever-evolving industry, what trends are you seeing and how are you handling the resulting issues?

There are two areas. The first area would be the sophisticated word for drug safety: Pharmacovigilance, which essentially means monitoring drug safety. We do a lot of work with companies who are starting to see a change in information relating to adverse events reports or, for medical device companies, medical device reports.

If you start to see information becoming a possible trend, a signal, you have an obligation to look at that issue in a much more comprehensive way to determine if the drug is truly acting differently post-launch. If it is, how is it acting differently? The company can communicate those issues to the public health authorities and reach an appropriate decision.

Secondly, what other action does the company have to take if there is a material change in the drug safety or medical device safety profile? Now, it can be difficult to rapidly determine whether there is a trend or a signal, but the positive aspect of this process is that you have smart researchers and scientists, both internally and externally, addressing the issue. So the company is trying to figure out, with the regulatory authorities, what to do with developing information for drugs and devices that are important to patients.

As America gets older, and as America gets heavier, many people are facing enormous health challenges and many patients are going to be taking multiple drugs. How do those drugs interact with one another? Is there a full understanding of the mechanism of action? How do those drugs interact in certain patients? Whether it is personalized medicine or more drugs consumed by the public, these are new challenges and new issues for everybody. So, I am interested to see how public health authorities adapt their approval processes to meet patient needs.

Are you monitoring those lifestyle changes in American culture? Are there other prevalent issues?

Oh yes! I would say it's fascinating. Baby boomers are going to live longer, live better quality lives as a result of the medicines that are now available. So you also have to consider the issue from just a purely demographic standpoint.

The other thing that is interesting from my perspective is that you have government agencies that are much more active and are much more powerful in terms of making decisions. On the flipside of that, you have patient advocacy groups that understand medical science and drive regulatory authorities to be responsive to their important needs. So you have this enormous collision of medical interests occurring over the next decade or two.

It is going to be an amazing phenomenon and that's why there is so much at stake. When you look at government—and there is a lot of intervention—or when you look at the health industry in general, it is one of the biggest industries out there. The next two decades are going to be fascinating. It is critical for public health authorities to recruit and retain highly skilled scientists, physicians, and yes, attorneys, to make independent, responsive decisions.

With that said, what do you think is your favorite part of your job?

There are a number of them. When you're working for a company and you defend them in a very credible way, whether in a criminal investigation or a government enforcement proceeding, and there is a good result, that can be very satisfying in terms of both how it impacts the company and its ongoing relationship with the government.

I think that just from a cultural standpoint, my experience overall with the companies (and I know big pharma gets knocked) has been positive. When it comes to trying to address issues from a science standpoint, companies proceed in a thorough, ethical manner to address issues. I really like that about the industry.

Also, there are mid-level companies in the pharma sector and medical device sector. Working for these companies is incredibly interesting and satisfying because they don't have huge in-house legal departments. Working for mid-size companies creates an opportunity to meaningfully partner with legal and regulatory departments and to become part of their team.

We have several clients in that space. It is an enormously satisfying practice. Many times those companies have the more interesting, developing pipelines. So, in some way, it is much like pharma 20 to 30 years ago, and that's really interesting work.