

IMPROVING COMPLIANCE IN THE WORLD OF BIOTECHS: HELPING SMALL COMPANIES AVOID BIG PROBLEMS

by John Watson

During the 2007 Biotechnology Industry Organization, speakers at a roundtable discussed the guidelines regulating the sales of prescription medications, the legal risks drug companies face, and provided ideas to help small companies move toward compliance.

Although emerging biotechnology companies often define themselves as being in opposition to the monoliths of Big Pharma, they are nonetheless at risk of encountering some of the same legal difficulties as their more established peers. Yet, unlike the major pharmaceutical companies operating today for whom robust profits can make even substantial fines and penalties appear to be the cost of doing business, a fledgling biotech can be undone almost overnight if they face the wrong lawsuit at the wrong time.

The Noncompliance Risk

The risks encountered when navigating the various laws and guidelines regulating the sale and marketing of prescription medications have been well-known by every major drug company for some time now.

“By 2000, it was very clear that the government was looking at the pharmaceutical industry as one of the biggest influencers, if not actors, in what it thought to be a considerable potential for fraud, abuse, and waste in federal healthcare programs,” said Ted Acosta, JD, National Leader, Health Sciences, Investigative & Dispute Services, Ernst & Young LLP, and moderator of the recent business roundta-

ble, “Commercialization Readiness–Sales & Marketing Compliance,” held during the BIO CEO & Investor Conference on February 12, 2007 in New York City.

According to Acosta, the former Senior Counsel in the Health & Human Services Office of the Inspector General, it took some time for the federal government to become familiar with pharma’s business model and to fully understand how drugs went to market and the extent of the interaction between sales reps and prescribers. Once this preliminary education was complete and the ramifications were immediately clear, a series of high-level prosecutions took place for allegations ranging from kickbacks and inappropriate inducements to influencing prescribing patterns and promoting off-label use. As time went on, inquiries conducted almost exclusively by federal investigators have now also become the province of state and international authorities.

“What has happened is that you’ve had an amazing transformation take place within the industry, with an increased focus on what’s happening on the commercial side particularly,” said Acosta.

“What does this mean for biotech?” Acosta asked. “It means a lot, because in this industry you often have the same model, the same needs for communication with customers, for approval of products, and for going to market. And the government doesn’t really make a distinction, nor should it, when it comes to the responsibilities of a biotech company with respect to their influence on how, ultimately, their products will be reimbursed by federal programs. From the government’s perspective, it is going to view you the same and expect the same from you.”

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In order to combat the risk of legal malfeasance within their organizations, biotech companies will have to emulate, if not exactly copy, the examples set forth by the major pharmaceutical companies, who have developed efficient compliance programs to identify and deal with possible problems before they threaten to lead to significant fines or worse.

Defining Compliance

By their nature, biotech companies are ambitious upstarts staffed with a wide variety of employees from all different sectors of the industry. When designing a compliance program in this setting, it is important to take stock of the disparate personalities at work within the organization. Those coming from Big Pharma may have a pre-existing definition of compliance not shared by their counterparts fresh to the industry.

“You have to ask yourself—what is your culture and how can you build an environment of compliance where you have individuals coming from different backgrounds to a place where they’re working together,” observed panel member Elizabeth Lewis, Vice President of Commercial Law at Millennium Pharmaceuticals, Inc. “That’s a really fundamental question. If you don’t figure that out right away or soon, you start having a clash where there are individuals who come from a very compliance-oriented environment who may feel they’re being asked to do something wrong or in a noncompliant way. That’s how whistleblowers are made and that’s where biotech faces a risk.”

Fortunately, the relatively small size of these companies makes settling upon a definition of compliance a much easier task. In fact, the size of these companies remains their greatest attribute, giving them a distinct advantage over larger organizations, according to another roundtable panel member, Robert J. Perez, Senior Vice President of Commercial Operations at Cubist Pharmaceuticals, Inc.

Perez said that, at Cubist, they’ve built upon the belief that these new compliance rules and

their enforcement allows a small company such as theirs to compete very effectively and very aggressively within those boundaries—in fact, much more easily than a large company they’re competing with like Pfizer or a Big Pharma firm with thousands of people to manage. “We can make sure we’re absolutely within the rules and that we’re building a compliance culture, so that it’s not the chief compliance officer trying to catch people and be the police, and the sales force trying to hide what’s going on. That’s a recipe for disaster,” he said.

Compliance and Co-Promotion

For emerging biotechs with promising agents in the pipeline, the question of entering into a co-promotional partnership with a more established company is ever present. Ultimately, the decision on whether to sign off on such an arrangement comes down to several key economic variables, although even in these matters the issue of compliance proves to have significant import.

“Companies do consider compliance when they think about developing co-promotion with a small biotech,” said Garry O’Grady, Senior Vice President of Sales Practice at Campbell Alliance Group, Inc. “They don’t necessarily hinge their decision on that, but they certainly are looking at that company and its culture to see if it’s someone they want to do business with.”

If a biotech company does decide to enter into a co-promotional arrangement, compliance will remain an issue far after due diligence has been completed, explained Lewis.

“As you’re thinking about co-promotion, you have to think where the other company is at with compliance,” she said. “Do they have a Corporate Integrity Agreement (CIA) with the government that dictates how they operate and what their compliance processes are, and how does that line up with your process? The biggest problem of tension between a large company and a biotech is that they have mandated policies that they have to go through that are fairly rigid. In a biotech [cont. on pg 56 >>](#)

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company, it's not that we care less about compliance, we care just as much, but we don't have the same rigid requirements," Lewis commented.

Designing Effective Compliance Programs

The panel agreed that even if a biotech's research has yet to yield the kind of late-stage clinical results that can signal its arrival as a legitimate competitor, it would still need to develop an initial compliance program to protect itself.

"It's not that you first consider compliance once you're in a Phase 3-setting, this is something you scale up over time," said Natasha Leskovsek, Special Counsel for Heller Ehrman LLP. "The minute you hit the clinic, you start having a relationship with potential prescribers of your product. If you get that far, you need to start having reasonable policies in place that guide your financial relationships with key healthcare providers. The first question that we ask in due diligence are what types of standard operating procedures do you have in place. It's not something you just drop into place once you're ready to launch."

For biotechs further along in clinical development, an effective compliance program can eliminate the time constraints seen in larger organizations and make for a more responsive sales force.

"From a consultant's viewpoint, the ability to be more nimble in response to some of the queries you get can be a competitive advantage," said O'Grady. "Having the processes in place that are within guidelines allows your reps to get that information through the network to the medical science liaison. Getting reps back in front of the querying physician very quickly can be a competitive advantage over some of the large, more traditional pharma companies."

To achieve that nimbleness, the panelists recommended that biotechs integrate their compliance processes within the existing infrastructure of the company, rather than separating compliance into another department and adding another layer of communication and bureaucracy, as is commonly observed in larger companies. These initial efforts do not require expanding your overhead by creating new posts within the company, and assigning someone to exclusively act as a compliance officer is often unnecessary in these early stages.


"I find with a launch, there are several opportunities to leverage individuals within the organization without creating any new head count by building upon the experiences that people have," said Lewis.

She recommended potentially using someone already within the organization such as general legal counsel or medical director, for example, to oversee compliance issues. Yet whoever the company chooses to serve in this role, it is important for them to look beyond their own department to survey the rest of the employees when developing a compliance plan. This leads to the creation of a plan that better reflects the unique challenges of each employee. Nowhere is this more essential than with the sales force, whose members often find themselves walking the razor's edge of improving profits while trying to remain within the strict ethical boundaries set forth by compliance officers.

"I believe it's our jobs as executives and for those in the home office to weigh these risks and come up with the appropriate ways for the company to behave," said Perez. "Then we have to say to the reps, 'here's where we're going to allow you the freedom and here's where we're not. If you stay within the rules we define you'll be fine, but if you go out of them, we're going to have your head, because you've been trained on it and we're going to talk about it often.'"

It is also important not to make the opposite mistake of creating an overly comprehensive plan in the early stages, focusing instead on the greatest risks facing the company.

"For a pharma company or biotech with a product on the market, or if you're moving towards that goal, your biggest risk areas are always going to be around your sales force, marketing practices, your relationships with physicians, your promotional material, and what you're doing from a scientific communications standpoint," said Lewis. "These might be the areas where you build first, and then you start migrating out as your organization gets bigger, looking at what your specific risk areas are."

Whatever a biotech determines to be of most importance, directing these early efforts throughout the company, from the CEO on down, will begin to create an environment necessary for reducing future risks. In doing so, biotechs will ensure that their fate will be left to their data, not to the investigators. 



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