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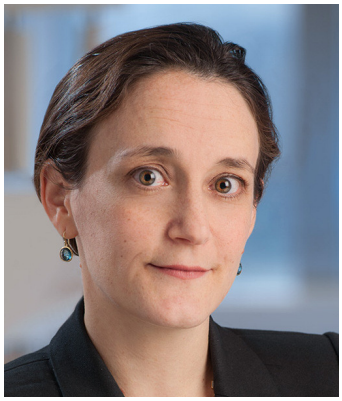
Helping piece together the life sciences puzzle

Alison Fethke



Kim B. Nemirow

In this Q&A on M&A, two Ropes & Gray experts gauge the biotech, pharma and medical markets

BY LAUREN P. DUNCAN
Law Bulletin staff writer

Setting up a regulation compliance program for a global pharmaceutical or medical device company is no simple puzzle to piece together.

Thanks in part to a few busy years of mergers and acquisitions in the life science sector, companies in many instances are turning to outside counsel to help set up their compliance programs, according to two Ropes & Gray LLP attorneys who work in healthcare compliance and investigations.

In 2016, there was about $177 billion worth of mergers and acquisitions in the pharma, medical and biotech industries worldwide, down from a record high of $298 billion in deals in 2015, according to a recent report from Mergermarket.

Despite a slow year in 2016, the U.S. remains a significant part of M&A activity in the global life sciences and health-care market, contributing to nearly 60 percent of that $215 billion last year, according to an analysis by accounting firm Deloitte.

A few of those deals that closed in recent years include the $14 billion Zimmer-Biomet merger, Pfizer's $16 billion purchase of Lake Forest-based Hospira and the recent $25 billion acquisition of medical device company St. Jude Medical, Inc. by Lake Bluff-based Abbott Laboratories.

As life science companies expand, so do their compliance programs. Ropes & Gray partner Kim B. Nemirow and counsel Alison Fethke, who work in the regulation compliance arena, weighed in on the challenges that pharmaceutical and medical device companies face as they expand.

Nemirow has experience working on both internal and Department of Justice and Securities and Exchange Commission investigations regarding compliance matters involving pharmaceutical and medical device companies. Fethke, who previously worked in-house at Abbott, advises clients on regulatory issues in a variety of healthcare-related areas.

The following interview has been edited for brevity.

Law Bulletin: What are some of the biggest issues you two are dealing with in life science regulation compliance?

Nemirow: One of the biggest overall trends relates to the globalization of companies. Though life science companies have been expanding globally for a while, over the past several years we've seen U.S. companies increasingly focusing resources on the creation of integrated global compliance programs. Historically, companies have grown the business first in a particular country and then compliance or legal has to catch up later. More recently, we've seen the international legal and compliance infrastructure begin to catch up with the globalization that has been going fast and furious for a while.

Fethke: To some degree we're also seeing some consolidation in the industry, which can lead to complications, particularly when you consider company integration. Sometimes, in a merger or acquisition, one company has a stronger ex-U.S. presence than another, but by combining them everything just gets bigger and more complicated. That applies to the compliance infrastructure as well and, in some cases, not only is the program getting bigger, but the two companies' differing styles and approaches have to mesh together.

LB: What are some of the essential components for a life science company to consider in creating a new compliance program?

"There is no one way to do a compliance program because every company is different."

Nemirow: Infrastructure and resources, resources, resources. Whether it is a major multinational or a smaller company with a manufacturing facility in one country in Europe, all companies need to have a capable compliance infrastructure in place to mitigate risks. While we can write a policy, and we can write a program, if you don't have the internal resources to implement it, it's not going to be successful. And we of course mean compliance headcount, but also the systems and controls necessary to implement the program, including finance capabilities, the necessary software, and third party vendors. These systems are critical to the success of compliance programs, particularly for domestic companies entering international markets.

Fethke: I think there's a pretty set model for how to do this within a domestic company. I think one of the very important components — and you see this all throughout the writings both on the anti-corruption laws and on the U.S. fraud and abuse laws — is the government views tone at the top and the buy-in of an executive team into the compliance program as a totally essential element of how a compliance program has to operate, because if your executives and leaders don't believe in it, aren't going to resource it, aren't going to enforce discipline, aren't going to message about it on a continual basis, your program isn't going to be effective, and so in reality, in an ideally operating compliance program you have that strong tone from the top and you have a shared ownership of compliance from everyone at your nstitution.

Nemirow: There is no one way to do a compliance program because every company is different. A program must be tailored to the specific business, culture and needs of each company. But, the whole reason these compliance programs exist is generally in response to government regulation, so your compliance

program should be such that you should be prepared to present it to the U.S. Department of Justice and the SEC.

LB: How important is it that these global compliance programs educate employees across the world on U.S. laws?

Fethke: The goal of a compliance program is not to eliminate misconduct. It happens. We say to people all the time, if you have a compliance program or you have a hotline, and you don't get any reports or complaints, your program's not working. The goal is that you catch it first. It's critical that companies build a compliance program preemptively, as opposed to when they urgently need one, and educate employees across the globe.

Nemirow: You think of the place like a super-remote part of Chengdu Province in China, an employee there has never been to Illinois, has never even met anyone from the company headquarters, and is selling only to local hospitals. You have to convince that person who is so far removed from headquarters about the importance of complying with laws from the United States. They've never heard of the U.S. Department of Justice. How challenging is it for companies to do that? It's very hard, and so what companies need to be doing, the best practices of the company, is getting to a place so that their systems are strong enough and their training program and their monitoring program are strong enough that if an issue arises with that person in Chengdu, they can go to the Department of Justice and say, this issue happened, this guy was going rogue, we trained him, we monitored him and he was defrauding us.

Fethke: Most companies try to set out a compliance framework that is heavily based on U.S. law but also incorporates globally understood standards.

Nemirow: Part of the whole international legal compliance structure has to be getting the right advice in the right country in every country. They all have slight nuances, and sometimes significant nuances.

LB: Are you dealing with more investigations these days as these companies become more global?

Nemirow: It's increased significantly over the last five years. A huge part of our practice is doing global investigations.

Fethke: And companies have built some of that capacity internally, but they have also continued to rely heavily on outside counsel. For instance, we recently helped a medical device company strengthen its compliance infrastructure following a DOJ inquiry.

LB: Amid impending administrative changes, what's the future look like for life science compliance?

Fethke: It's not entirely clear, but a lot of what companies do every day — at least in the drug and device space — the [Good Manufacturing Practices], shipments, making sure your supply chain is safe, your product is stable, sterilized, none of that is going to change.

Nemirow: There is a lot of speculation right now on the enforcement side, in the government, DOJ, SEC, criminal and civil enforcement, speculation about what the future is going to look like.