Ms. Stokes says companies need a safety plan, one that includes efficacy and safety data as well as risk-benefit information, before a drug reaches the market.

Drug Safety Alliance's **CATHY STOKES** defines safety expectations

As CEO and President of Drug Safety Alliance Inc., Cathy Stokes is focusing on helping clients put in place comprehensive safety plans. She discusses the challenges pharma companies face with product submissions and how they can improve their odds of success.

From the standpoint of safety, Cathy Stokes believes there are several things a company can do earlier rather than later before submitting compounds to the NDA.

FDA EXPECTATIONS

What do companies need to do to manage safety issues and to get drugs to market? And what is the FDA looking for?

STOKES: The FDA has a huge volume of work that has to be done internally and a small budget with which to do it, so this is always a challenge. But the agency does have a way of looking at aggregate data that some of the small and mid-sized companies, and even some of the larger companies, don't have. For example, agency reviewers can compare similar products of the same class that perhaps already are in the database. They also can do a lot more data mining than most pharmaceutical companies are able to do. Drawing on this vast array of information, the FDA is able to evaluate trends in the data, and as such, this information has become more important to the agency's operations.

The agency wants companies to address some of the risk-benefit aspects of their drug registrations before submission. Regulators are expecting companies to develop a way to demonstrate not only efficacy and safety data, but also the risk-benefit of the product. Regulators want companies to be able to show that the benefits of their products outweigh the risks; show that they have explored and understood the risks; and that they have a plan in place that will be followed when the drug goes to market.

SAFETY STEPS

In light of the FDA's expectations, what steps do companies need to take to improve their odds for timely approval?

STOKES: Safety seems to be a stopping point for many products, and it's not always easy to determine what the exact safety issues are. The difficulty is because often there is limited information from study results, and certainly there is no real-life information when a product is introduced in the market. Companies need to get a better understanding about the safety profiles of their drugs and manage their safety data in a way that provides aggregate pools of information, which enables them to look for potential safety signals. This approach also allows companies to mark the data and look for any interesting information that might rise to the surface, giving them a better chance of understanding what their risk profile is going to look like should the drug reach the market.

Once a drug is introduced to patients in Phase II and III clinical studies, companies can take a more proactive look at the risk-benefit profile that arises from the safety data. If the safety data are all in one place — and this is a big advantage — this improves the chances of being able to mine and evaluate data across different protocols and programs. As time progresses, it becomes easier to understand what those risks are going to look like. For example, maybe the data flag potential liver damage, in which case the company needs to develop trials that are better able to capture information about the liver, which in turn provides a much better way of explaining that information when the drug is submitted to the agency.

EARLY SIGNALS

How can early market research and early signal detection benefit companies?

STOKES: Having better-designed trials where the outcome is a key priority will benefit companies in the long run. Having better guidelines within the protocols will help investigators understand what they truly need to look for and will help to better define what the end product is going to look like. And being able to track trends or signals throughout the lifecycle of development will be important.

In the past it was difficult to analyze data in a way that made sense. That's because in clinical trials, data are gathered, put into a database, and looked at after the trial finishes; it may be a year or two before the product enters the NDA submission phase. This is too long of a delay because issues could develop during a trial that perhaps weren't obvious. Companies go through development, spend millions and millions of dollars, and then at the end of Phase III and into submission they have a problem. So early detection is very important to make sure that the drug is viable and resources are not wasted. There are ways to mine data in a very proactive way. For example, safety software companies have tools that enable data to be aggregated without freezing the database. There are also signal detection tools that allow companies to use proprietary data from the safety database as well as being able to compare the information with external databases, including the FDA's Adverse Event Reporting System (AERS) and Vigibase, which is the European safety database.

BALANCING OPTIONS

How is the global economy affecting pharmaceutical companies?

STOKES: Companies are assessing different options. The layoffs have been massive, and these have really affected safety departments — probably for the first time — as companies are looking for ways to reduce their costs. Outsourcing is one option, although it's not always a solution for every company. Other cost-saving options include looking for redundancies within departments. Smarter companies are investigating more efficient ways to get the work done by using electronic workflow and effective metrics for productivity. Companies are taking a more broad-minded approach to business. There is greater transparency with regard to data, which gives external regulatory bodies greater access to public health and safety information. And there's more collaboration, which could still be taken further to generate a wealth of knowledge that can be shared, which would be extremely beneficial. Collaboration also could help to cut costs and would also be better for public health. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

CAREER Highlights

Catherine C. Stokes is President and CEO of Drug Safety Alliance Inc. (DSA), which she launched in 2000. DSA provides drug safety and risk management services. Before founding DSA, Ms. Stokes worked at GlaxoWellcome as Section Head in Drug Safety and Surveillance for nine years. She also held positions in clinical research and medicinal chemistry for four years. She has an M.S. in medicinal chemistry from the University of North Carolina, Chapel Hill, and a B.A. in biology from Hollins College. Ms. Stokes is a supporter of Senior PHARMAssist, a nonprofit organization that assists senior citizens with prescription drug costs and Medicare prescription drug plans. Ms. Stokes is affiliated with the Healthcare Businesswomen's Association (HBA) and serves on the UNC School of Pharmacy Board of Visitors.

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