

CONTENTS

The FDA Speaks Out on Drug Safety

BY JO CAVALLO

After a number of highly publicized drug recalls, the Food and Drug Administration is coming under heavy scrutiny to enact reforms to ensure drug safety. *CURE* asked Karen Weiss, MD, deputy director of the Office of Oncology Drug Products in the Center for Drug Evaluation and Research at the FDA, what the reforms may mean for cancer drug approval and how changes could impact cancer patients.

***CURE:* How many cancer drugs come up for review each year?**

Dr. Weiss: We have an Oncologic Drugs Advisory Committee meeting two to three times a year, and usually there are three to four drugs [under review]. Oncology approvals per year range from three to seven for new drugs, but add new indications and it's about double that number. The review process for oncology drugs is a very active area. But it raises the question of how much do we know about these drugs at the time they come to approval? You have to ask yourself, what are these drugs being approved for and what is the net benefit? And how do you weigh that against the toxicities that are known as well as those that might yet be discovered with greater use?

.....

***CURE:* How will the FDA Revitalization Act affect cancer treatment?**

Dr. Weiss: The problem with drug approvals, in the general sense, is that the post-marketing studies that include safety studies don't have a lot of teeth behind having those studies. Very few post-marketing studies are required to be done. You don't have consequences for not conducting post-marketing studies that aren't required by law, so I think that having more force to have post-marketing studies done will help. As opposed to other disease settings where there's a lot of concern about protecting patient safety, in the cancer population it's almost the opposite. In the cancer world, much like in the HIV/AIDS setting, patients have very serious, progressive diseases, and you know what the ultimate outcome will be without treatment. You want to make the best decision at the most opportune time, and it's a very difficult struggle.

.....

***CURE:* As more cancers are treated as chronic diseases, will there be different regulations for drugs used long-term, or will they be studied differently?**

Dr. Weiss: Cancer drugs are becoming more targeted, and a lot of the serious toxicities seen over the last several decades will be minimized. The ultimate goal is to turn cancer into a chronic disease where patients take some pill and it won't

disrupt their lifestyle and they can live a normal life.

.....

CURE: Is the FDA planning to educate the public on newly discovered risks of drugs already on the market?

Dr. Weiss: Absolutely. We've already put initiatives in place to provide greater transparency and information to the public on emerging drug safety issues even before they've been fully evaluated. It's been put in place in the past couple years with public documentation issued by the FDA, public health advisories, questions and answers about drugs and their toxicities that we make public, and press releases and media calls. There's a greater effort to target consumers and physicians when emerging information starts to come to light, and then to update that information as we continue to evaluate drug data.

.....

CURE: Is the FDA undergoing internal reforms to ensure consumer safety?

Dr. Weiss: We're trying to expand the group that looks at post-marketing safety. The types of data and expertise it takes to look at post-marketing safety information is oftentimes very different from the pre-marketing safety information. So we're formalizing our process for how these two groups are going to interact and work together to review and discuss safety information.

.....

CURE: How does the FDA balance drug safety with the approval of new therapies?

Dr. Weiss: It's important to get new drugs to market. It's also important to protect the safety of the public. Those are the things people wrestle with every day, both inside and outside the agency. Everybody wants the same thing, but how best to do this is really an evolving art.