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FDA's Risk-Benefit Plan May Drive More Drug Approvals

By **Rachel Slajda**

Law360, New York (March 13, 2013, 9:36 PM ET) -- The Food and Drug Administration's proposal for a new, more structured method for weighing the benefits and risks of a new drug could result in a more transparent and consistent approval process, more patient input and even more drug approvals if all goes as planned, experts say.

The agency is looking to implement a new risk-benefit framework for new drugs and biologics, according to a draft of a five-year plan it released last week. Under the plan, the agency would create templates for reviewers to use as they weigh benefits and risks, publish the information from the templates after it approves a drug, and incorporate patients' perspectives on risk and benefit into the review process.

These elements of the FDA's plan — more consistency, more clarity for sponsors and more input from patients — could work together to make drug approvals quicker, smoother and more certain, industry observers say.

Not only will the plan standardize the way reviewers balance risks against benefits, but it will also open a window into how the FDA makes its decisions, giving drug sponsors a better idea of what it is looking for in new drug applications, according to experts.

"In some ways, history is the greatest teacher," said Diane Bieri, a partner in Arnold & Porter LLP's FDA and health care practice group and former general counsel for the Pharmaceutical Research and Manufacturers of America, the industry's main trade group.

"There's no such thing as a risk-free drug," she added. "It's really all about that balance."

Industry experts hope the standardization will make the review process more consistent across reviewers and types of diseases.

"Templates for the reviewers, so there's more consistency and so people have a checklist — that's all to the good," said Stephen Mahinka, chair of Morgan Lewis & Bockius LLP's life sciences and health care interdisciplinary group. "You will get some improvement in speed of review from having a manual like this and having templates and training."

The FDA's plan also outlines the first steps to getting more patient input into the review process. Patient advocates have been pushing for an official seat at the table for years, and in last year's user fee legislation, Congress ordered the agency to include patient representatives in the process.

The agency will hold a series of public meetings focusing on specific groups of diseases, in order to round up patient input on the conditions and the current available treatments.

Although the paragraph outlining the patient initiative is vague, Marc Boutin, chief operating officer of the National Health Council, said his group was happy with the FDA's plan. The council, an umbrella organization of patient groups, pharmaceutical companies and health professionals, had lobbied for the patient representative provisions.

“We asked the FDA to hold these 20 meetings with patient reps to really understand their benefit-risk tolerance. And the goal for that ... was to develop a methodology to understand the perspective of the patient community,” he said.

Boutin hopes the agency will eventually develop a process for drawing input from a range of patients who could benefit from a proposed drug.

That would be a sea change, he said. Patient advocates and drug companies have long complained that the FDA doesn't do enough to consider how much risk actual patients are willing to tolerate, especially for diseases that aren't yet treatable.

And drug companies are on board too, according to Bieri.

“Incorporating patient views is critical. … Patients are the ones that take the medicines and should have a say in whether they're willing to bear certain risks to get certain benefits,” Bieri said. “Patients have a unique perspective. You don't know how desperate a situation is until you've experienced it.”

The increased transparency that comes with the FDA's publication of its review templates will also benefit patients, Boutin said, helping them give the agency more and better input.

“When we, as patient advocates, are on the outside ... we don't know what assumptions were used when making the judgment. So you can't have a rational discussion of whether it's correct or not,” he said.

Patient input will influence where drugmakers focus their resources in research and development, with an eye to developing the drugs patients want to see, Boutin said.

--Editing by Kat Laskowski and Chris Yates.