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5 questions raised at the FDA's off-label hearing

One physician believes that changing regulations to allow off-label communications would mean there is less of an incentive for drugmakers to take their therapies through the FDA approval process.

That view and others were shared Wednesday at the first day of the FDA's public hearing to solicit input from pharma companies, insurers, patient advocates, and others as the agency reviews its policies regarding off-label communications.

The hearing — held at the FDA's headquarters in Silver Spring, Maryland — is the latest episode in the long tug of war between the industry and the FDA on whether truthful and non-misleading information may help or hinder healthcare providers and payers in their decision making.

Here are five issues raised at the FDA hearing.

Sharing off-label communications may lessen the incentive to conduct a randomized well-controlled study.

If the floodgates open for off-label communications, there may no longer be an incentive for drugmakers to take therapies through the FDA's approval process, according to Dr. Aaron Kesselheim, an associate professor of medicine at Harvard Medical School. During his testimony, he said that the requirement for FDA approval for each indication of a drug incentivizes drugmakers to undertake rigorous clinical trials. If all truthful and non-misleading information can be legally shared, the case for the FDA approval process for drugmakers becomes less clear, he noted.

It's unclear what information about a product can be considered medical evidence.

Dr. Soumi Saha, assistant director of pharmacy and regulatory affairs for the Academy of Managed Care Pharmacy, proposed that drugmakers should be able to share information with healthcare decision makers — like payers — prior to an FDA decision date. But Rachel Sherman, associate deputy commissioner at the FDA, questioned that proposal, asking when information or data becomes evidence.

Physicians may not have time to discern what information shared by drugmakers is misleading.

Dr. Robert Califf, the FDA commissioner, noting how busy physicians' days are, said it is difficult for doctors to discern what information is misleading. How confident are drugmakers that physicians can determine what information is misleading? And if it is misleading, how likely is it that physicians would report that information to the FDA? “As a practitioner, I've had multiple visits from reps,” he said. “This seems to be a tough thing to figure out in those circumstances.”

Patients need an accessible resource to find information about experimental drugs and ongoing clinical trials.

Zoe Dunn, principal at Hale Advisors, described GlaxoSmithKline's online database of its own clinical research as a good example of how patients need access to better information about experimental medicines and ongoing clinical trials. She said, however, in response to a question from Dr. Sherman that ClinicalTrials.gov “falls short from being patient and health literacy friendly. This [information] needs to be more publicly accessible.”

Communicating with payers about experimental drugs raises the question of when is the right time to allow that communication.

Sherman asked at what stage in the drug development process is it appropriate to discuss new drugs with payers, given the high attrition rate of drugs in development, suggesting the potential

risk of drugmakers sharing information about experimental drugs that has not yet been fully understood.