FDA vs. free speech over drug promotions

- New rules aim to legitimize alternative drug uses
- Agency restricts conferences, press releases

Washington

In a clash that pits the constitutional rights of industry against government responsibility to regulate drugs, the Food and Drug Administration (FDA) is battling the pharmaceutical industry over the promotion of products for uses other than those for which they were approved.

In recent months, FDA has cracked down on industry-sponsored scientific conferences and drug company press releases that the agency says are actually advertising aimed at promoting uses that have not been approved. Agency officials have angered the pharmaceutical industry by proposing rigid new guidelines to define what FDA considers an acceptable industry-sponsored scientific conference, rather than a cloaked promotion for a company's products (see sidebar).

This week, FDA commissioner David Kessler is expected to announce new rules he hopes will quell the controversy by allowing drug companies to circumvent the normal long approval process for alternative drug uses. What the agency has settled on, Kessler said last week, is a way to speed the transition from 'off-label' to approved status for secondary uses by reducing the amount of data and documentation a company must submit to gain agency approval. "Once it's on the label," Kessler said, "you can promote it all you want." Kessler is expected to announce the new policy at a meeting on off-label drug uses this week at the Institute of Medicine.

Part of what pushed the FDA to take new measures is the explosion of industry-sponsored symposia. In 1988, the drug industry spent $85.9 million on funding 34,688 scientific conferences. That, according to the Congressional Research Service, is more than a 13-fold increase from 1974.

In the past year, Kessler has doubled the size of the division that regulates marketing and has started to crack down on the industry. On 26 October, FDA issued a draft 'concept paper' listing 20 criteria a scientific conference should fulfil to be considered 'independent'. FDA also wrote to pharmaceutical companies, telling them to send the agency copies of all their press releases and 'video news releases', short videotapes that many companies produce and send to television stations to promote their products.

Now, FDA is itself facing scrutiny, as critics charge that the agency's new rules deprive companies of their constitutional right to free speech. "There is a real feeling of paranoia out here," says Susan Sauer, director of communications for the pharmaceutical company Sigma Tau. To ensure that the FDA does not accuse them of a violation for undue promotion of unapproved drug uses, some companies have taken to sending FDA drafts of the press packages for approval before release. Other companies are just not talking. One reporter recalls a recent case in which drug company researchers stopped cooperating on a story about a new drug use, fearing that the FDA would see their quotes and call it promotion.

Kessler said last week that he is not going to back down on restricting drug promotions if they go beyond approved uses. Particularly in cancer treatment, many drugs are approved for a single disease, although they are often also prescribed for other, related conditions, a practice known as 'off-label' use. Acne drug Retin-A gained international attention several years ago when it was promoted as an off-label way to reduce wrinkles. Although FDA cracked down on that use, arguing that there was no evidence it was effective, officials estimate that some 20 per cent of off-label uses are actually the best available therapy for the relevant condition. Doctors may freely prescribe drugs for such secondary uses, although many insurance companies often refuse reimbursement for off-label drug prescriptions.

Although FDA can do nothing about the off-label drug prescriptions, it can stop drug companies from promoting such use in the absence of data to show its efficacy. "If you can promote the secondary use without approval," Kessler asked, "where's your incentive to do the testing and the [clinical] trials? The problem we have here is one of hype."

But with the pharmaceutical industry up in arms, FDA decided to find a compromise that does not sacrifice public health for industry's right to free speech. According to William Hubbard, FDA's assistant commissioner for policy coordination, the new rules will allow companies to submit journal articles, unpublished clinical trial data and any other evidence they may have acquired to suggest that an approved drug may have another effective use. At the moment, drug companies are required to go through the same elaborate approval process for secondary uses as for primary use, something that few were willing to do, considering that they could sell the drugs without it.

"We believe that companies won't have to go out and get new data," Hubbard says. "The fact that an [off-label] use is popular means that the data are out there." He says that the agency hopes to have all the major unapproved cancer uses "on the label" within a year, by encouraging the companies to come in from the cold, bearing any data they happen to have.

Christopher Anderson

When is a conference independent?

Washington

In seeking to ensure that industry-sponsored scientific conferences are not advertising campaigns in disguise, the FDA is preparing to issue some tough new rules on what is, and is not, an 'independent' symposium. An FDA 'concept paper' issued on 26 October proposed some rigid new definitions of what FDA considers science, rather than salesmanship.

To escape sanctions, FDA says that industry-sponsored conferences should:

- include independent experts. "The drug company should play no role in the selection of presenters or authors."
- disclose their finances. Organizers should reveal "the actual source of funding ... and relationships between individual presenters and the drug company."
- not focus on a specific drug. Conferences "should be on broad aspects of a disease and on a variety of treatments."
- separate the sponsors from the substance. The industry sponsor should agree not to engage in "scripting, ghostwriting of papers, preparation of visual aids, training of presenters, or targeting of points for emphasis." Nor should there be any promotion, such as distribution of material, "in proximity to educational activity".
- not be repeated. Holding a conference more than once "enables drug companies to judge content and to selectively support repeat presentation only of programmes favourable to its product."

Not surprisingly, the Pharmaceutical Manufacturers Association (PMA) is up in arms over the proposed rules. It said that the rules, if adopted, would "severely and unnecessarily limit the continued and timely dissemination of medical and scientific information". By listing 20 "essential" criteria for an acceptably independent conference, the FDA concept paper "goes well beyond what is appropriate and reasonable." **C.A.**