Prescription Drug Ads Put FDA on the Spot

It has asked companies to hold off advertising directly to consumers while it studies the legal and ethical implications

Faced with increasing competition in the pharmaceutical industry, some drug companies want to try a new and controversial approach to selling their wares. They have proposed advertising prescription drugs directly to the public, in the hope that consumer demand will cause physicians to alter their prescribing habits. In the past, drug companies have directed their advertising almost exclusively to doctors and other health professionals.

The proposal has put the Food and Drug Administration (FDA) on the spot, because it raises several practical and ethical problems. FDA has asked drug companies to hold off on direct consumer advertising while it gives the matter more thought. The agency is planning a series of public meetings, the first of which was held in Washington, D.C., on 28 March, and it hopes to make a decision by the end of the year.

A major practical difficulty is that the food and drug law requires that all ads include information on the side effects and contraindications of the drugs—the so-called "fair balance" requirement. Obviously, it would be impossible to include all this information in a 30- or 60-second radio or television spot. FDA commissioner Arthur Hull Hayes, Jr., says that one issue that must be decided is "whether fair balance will need to be redefined in order to meet the demands of the media or whether fair balance as we have known it is even possible using electronic media."

But the fair balance requirement is not the only problem. As Hayes explained at the recent meeting, it is not at all clear that consumers will get adequate information in these ads to reach a decision about what to ask a physician for. And, said Hayes, "We at FDA have a major concern about the public's ability to evaluate what we call the risk/benefit ratio of a drug. If you purchase most products advertised on TV (toothpaste, deodorant, and so forth) you are able to generally decide how well it's working and if you think it's causing any unexpected side effects such as a rash or burning sensation. If, however, you take a cardiac medication, will you be able to determine that it may also cause other major medical problems?"

Physicians, too, have their doubts about the wisdom of such advertising. Robert H. Moser, executive vice president of the American College of Physicians, says it is his personal opinion that "the business of prescribing drugs is difficult enough without this extra dimension." He worries that physicians may end up spending an unreasonable amount of time explaining away a sales pitch and that drug company ads "may be less than candid in presenting possible adverse side effects." Neither the American College of Physicians nor the American Medical Association has taken an official position on this issue.

Arthur Hull Hayes, Jr.
FDA Commissioner

But competition is forcing drug companies to a clear view. According to Lloyd G. Millstein, director of prescription drug labeling and advertising at the FDA, "There are many more new products on the market. Years ago, a product would have a relatively long market life and a good market penetration before it had any competition. Today, as soon as a new product is introduced, many other products that differ from it in only minor ways come tumbling after."

Companies have tried to get an edge up on their competitors by increasing their advertising to doctors and other health professionals. Medical journals that in the 1960's were 50 to 60 pages long are now more than 100 pages because of increased ads. The pharmaceutical companies spend more than $2 billion a year on advertising. But the market, says Millstein, is such that, "The companies need a new approach to get physicians to prescribe their products."

There is reason to believe that advertising to consumers might be inordinately effective. "It takes but a little snippet of an article in a newspaper [about a new treatment] to bring patients banging on doctors' doors," says Hayes.

The extraordinary story of Oraflex, a drug for arthritis, illustrates just how much sales can increase when patients request a drug. "With Oraflex, I saw for the first time physicians prescribing due to patient demand," Millstein says. But the Oraflex story also gives some companies pause when they think of the potential hazards of generating consumer demand for their own drugs.

Oraflex came out last spring. It was not directly advertised to consumers, but it was indirectly promoted by means of an unprecedented media campaign. Eli Lilly & Company, the drug's manufacturer, sent out 6500 press kits and supplied all the television networks with file films and tapes on the drug. According to Millstein, all the appropriate cautionary information was in the press kits, but the press releases were written in such a way that a person without scientific training would be misled into believing that Oraflex was not only extremely effective for arthritis sufferers but that it may even arrest the disease. The media picked up this message and patients clamored for the drug.

In the 12 weeks that Oraflex was on the market, doctors wrote a half a million prescriptions for it. But the FDA, in the meantime, reprimanded the company for providing "false and misleading" information in its press kits and ordered it to send out corrections informing reporters that the drug could cause serious adverse reactions and that it was not that different from its competitors. In addition, with the huge number of people taking Oraflex, there was a corresponding increase in the number of adverse reactions, including 70 deaths that were reported. Oraflex began to get bad publicity from the same media that had so recently hailed it. Lilly voluntarily withdrew the drug from the market.

No other company has tried to generate the intense consumer demand seen with Oraflex, but a few companies have experimented with advertising to patients in a limited, cautious way.

Merck Sharp & Dohme took out ads last year in *Reader's Digest* and in some daily newspapers and senior citizens'

publications telling people over age 65 that its pneumonia vaccine, Pneumovax, is available and that Medicaid will reimburse for it. A Merck spokesman said the company cannot comment on whether it plans to repeat such ads but that the results were "satisfactory." The company views advertising the availability of its vaccine as a public service and notes that public health agencies frequently advertise the availability of pediatric vaccines. "The distinction between this and general ads for drugs is very clear," says the Merck spokesman.

Also last year, Peoples Drug Stores purchased a full page ad in the Washington *Post* to announce that it carries the Burroughs Wellcome drug, Zovirax, which can be used to treat herpes. Joseph Pollard of Peoples Drug Stores says that this advertisement, too, was meant as a public service to make consumers aware of the drug. "We filled a number of prescriptions but not enough to pay for the ad," Pollard remarks.

Another type of promotion is Pfizer's "Healthcare" series, run as advertisements in *Time*, *Newsweek*, the *New York Times*, and the *Wall Street Journal*. Although it does not mention specific drugs in its "Healthcare" ads, Pfizer describes diseases such as angina which can be treated with Pfizer's drugs.

In addition, companies have been filing into Millstein's office to show him proposed ads directed toward the public. Hayes has said some of the proposed ads were appalling, but others were quite impressive. Ciba-Geigy, for example, who is considered a forerunner in the push to advertise to consumers, received a letter from the FDA saying its presentation to the agency was "interesting and provocative" and that its plan "represent a major initiative."

But if the recent FDA meeting is any indication, outside of industry, vocal supporters of prescription drug advertising to the general public are hard to find. Most participants were neutral or opposed to the idea and some companies—Ciba-Geigy for example—were reluctant to come on strong in a public forum, in part because neither the companies nor the FDA are ready to discuss specific proposed ads.

Even the Pharmaceutical Manufacturers Association has not yet reached a consensus among its members on the issues.

Among opponents who spoke at the FDA meeting, Fred Wegner, representing the 14 million member American Association of Retired Persons, said, "Drug industry advertising and promotion is harmful to the national health. Who wants it anyway?" Americans already take too much medicine and the proposed ads would only make matters worse, he noted. Other countries, including Great Britain, Canada, West Germany, France, and Italy prohibit advertising prescription drugs to consumers, Wegner said, although, when asked, he confessed he did not know why. Representatives from the American Pharmaceutical Association and the Consumer Federation of America also spoke out against direct-to-consumer advertising.

Charles Adams, executive vice president of the American Association of Advertising Agencies, suggested modifying the fair balance regulation for broadcast media so that an ad need only state that the drug is a prescription product, that "Almost all pharmaceutical products have side effects and limited use," and that only a physician can determine who should take the drugs.

Taylor of Ciba-Geigy was one participant who favors a new ad policy. "The question we've been asking is, Is there information that encourages patients to go to physicians for treatment when they need it? Advertising would serve an important need if it encourages noncompliant patients or if it encourages patients to work with their physicians. If advertising can play a role in meeting these needs, I think it's something that should be explored."

Although he kept silent at the meeting, Jerald A. Breitman, who is manager of the department of public policy planning at Hoffmann–La Roche, told *Science* that his company, like Ciba-Geigy, is seriously interested in advertising prescription drugs to consumers.

He suggests that a possible way to make consumers aware of Hoffmann–La Roche's drugs would be to discuss a disease, such as hypertension or heart disease, and then end the ad with a list of drugs that Hoffmann–La Roche makes to treat the disease. A Lederle spokesman, who was not at the FDA meeting, told *Science* that he would like to see ads detailing the cost of developing drugs and the effort and care his company takes. Specific Lederle drugs would also be listed, he said.

One thing that was clear at the FDA meeting is that no one—not even the drug companies—wants to rush into advertising prescription drugs to consumers. "This particular question does not admit easy or obvious solutions," Hayes said. "It is important that we have a substantive dialog. We do not want to make decisions on an ad hoc basis. The issue is too broad and too profound."

—GINA KOLATA

Opposition Sends OMB Back to Drawing Board

The Office of Management and Budget (OMB) has withdrawn proposed regulations which nonprofit organizations insisted would have stifled their ability to communicate with government.

OMB's initiative was directed specifically at organizations that receive federal contracts and grants. The stated aim of the regulations was to prevent both industry and nonprofits from using federal dollars directly or indirectly for political advocacy. Nonprofits complained vehemently that the restrictions would bar them from legally permissible advocacy activities using private funds.

In OMB's usage, political advocacy covered both lobbying in the familiar sense of seeking to influence legislation and activities intended to sway other decisions in government.

In recent years, industry, particularly defense contractors, have been accused of using federal funds to lobby for decisions beneficial to their own business interests. Conservatives have complained that public interest groups use federal funds in a variety of ways to achieve political or ideological aims.

OMB publication of proposed revisions of its Circular A-122, "Cost principles for nonprofit organizations" in the 24 January *Federal Register* triggered an outpouring of protest from nonprofits and formation of a coalition of such organizations to oppose the draft regulations.

A general objection by the nonprofits was that the proposals by OMB far exceeded the powers delegated to it by Congress for rule-making and seemed to be in conflict with existing law. Advocacy activities of nonprofits are governed principally by the Tax Reform Act of 1975. The act sets dollar limits on lobbying activities by tax-exempt nonprofits that elect to operate under its provisions and defines more clearly than had been done in the past the types of such activities allowed.

The sharpest specific objection to the proposed rules was that they required a separation of advocacy from other activities so complete as to be impracticable for many nonprofits,