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SCHERING BROADCASTS MISLEADING LORATADINE (CLARITIN) DIRECT-TO-CONSUMER TV ADS

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Predictably, it has taken only 11 days for a major drug company to violate Federal law and regulations with misleading direct-to-consumer (DTC) TV ads for a prescription drug, supporting the contention that the true purpose of TV ads for prescription drugs is to sell products, not, as the drug industry would have people believe, to educate consumers.

In a letter dated August 19th, just 11 days after the Food and Drug Administration (FDA) announced guidelines for DTC advertisements on television (August 8th), Schering Corporation of Kenilworth NJ was cited by the FDA for violations of the Federal Food, Drug, and Cosmetic Act for two misleading TV commercials for the widely prescribed antihistamine loratadine (Claritin). The FDA letter to Schering stated that "both advertisements are misleading because the risk information disclosed as part of the required 'major statement' is not presented in a manner comparable to that used to present the information relating to efficacy." The agency asked Schering to "immediately discontinue the use of the advertisement[s]".

In the first part of both 30-second ads, Schering hyped the benefits of loratadine clearly and slowly in easy-to-understand language. But when it came time to tell consumers about the adverse effects of loratadine, the company skillfully hid them from public view. While the adverse effects of loratadine were being read by the announcer, there was a competing message on the screen and the description of the drug's adverse reactions were read so quickly that it was difficult for the typical consumer to understand.

In one ad, consumers were told that additional information on loratadine's adverse effects could be found in a *Newsweek* magazine ad for the drug, but the message was obscured at least half the time by using white letters on a white background (neat trick).

In the other commercial, consumers were told that they could get more information about loratadine on the Internet, but gave no other sources for obtaining

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adverse reactions information. The Internet is the last place that consumers should be looking for accurate drug information and a company's web site is only another vehicle for misleading advertising.

Guidelines announced by the FDA on August 8 gave voluntary ground rules for the first time to allow drug companies to broadcast direct-to-consumer (DTC) radio and TV commercials for prescription drugs. The move was hailed by the FDA as providing "realistic standards" for radio and TV ads and as part of their efforts to provide consumers with better, more understandable drug information. Realistically, the FDA should have written DTC advertising regulations before allowing prescription drug TV commercials. The agency has been promising to write such regulations for 15 years.

The drug industry loves the new guidelines. Alan F. Holmer, president of the Pharmaceutical Research and Manufacturers of America, a drug industry trade group, is quoted as saying the FDA was "striking a blow for patients." The only blow that has been struck has been against consumers who still have no easily available, objective source of comprehensive adverse reaction information about prescription drugs and, instead, are going to be barraged with an increasing crescendo of false and misleading information on TV and in DTC print ads.

Of three DTC TV ad campaigns which have run so far, two were reviewed in advance by the FDA and thought to meet the regulations and guidelines. For the third, the Claritin ads were not sent to the FDA in advance for approval and have been found to be "violative of the Federal Food, Drug, and Cosmetic Act and its implementing regulations." It is unlikely that as the volume of such TV ad campaigns increases the FDA will be able to keep up with the ones which are voluntarily submitted for prior review and those which are caught after the fact. It is likely that millions of people saw the violative Claritin ads in the 5 days between the ad first running during a National Football League game on August 15th on the Fox network and when the FDA letter was sent asking that the ads be immediately stopped.

When we learned about FDA's new policy to open up the gates for much more TV advertising of prescription drugs by issuing guidelines which were relatively easier to meet than previous interpretations of what drug companies have to do to get their ads on TV, we were very concerned and voiced strong opposition to the plan. We stated that this new policy is a set-up for pushing drugs with misleading information. We have not changed our minds.