FDA Review of Drug Ads Doesn’t Add Up
Shortcomings Concern Congress

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Continuing concerns about drug advertising on television may prompt Congress to consider legislative remedies, especially since the TV drug-advertising review program that the House and Senate agreed on in 2007 was never implemented. It was Representative Rose DeLauro (D-Conn.), chairman of the House FDA appropriations subcommittee, who refused to fund the FDA ad-review program, authorized in the FDA Amendments Act (FDAAA) and signed by President Bush last October. The failure of that program to get off the ground, the continued airing of questionable TV advertisements for major drugs, and the latest Government Accountability Office (GAO) report on the FDA’s inadequacy in administering its current drug ad review program have combined to move the matter to Congress’s front burner.

The FDA’s current limitations were the main meal at hearings on May 8 in the House Energy and Commerce Committee’s oversight subcommittee. Last year, this committee was chiefly responsible for the drug-advertising provisions in the FDAAA, which would have allowed the FDA to require a pharmaceutical company to submit an ad before airing it on TV or on the radio. Under the FDA’s current authority, companies can voluntarily submit an ad, ask for the FDA’s opinion (i.e., is the ad fair and reasonable?) and then incorporate the FDA’s suggestions into the final ad—or not. If the company ignores the FDA, which it can do, the company then becomes subject—possibly, if the FDA is paying attention—to civil penalties, which are generally weak.

The problem, according to the GAO, is that the FDA is not paying attention, and by the time it figures out that new TV ad has serious shortcomings, the advertisement has already been playing for six months. The damage has been done.

Marcia Crosse, a director of health care for the GAO, portrayed the FDA as a kind of “Keystone Kops” operation. The FDA finally, after years of GAO nagging, has developed criteria it uses to determine which drug ads it should review, either after they are voluntarily submitted or after someone complains about an ad that was not voluntarily submitted. But the FDA still does not systematically apply its criteria to all of the direct-to-consumer (DTC) materials it receives. Ms. Crosse explained:

... GAO noted in its 2006 report that FDA could not determine whether a particular material had been reviewed. GAO recommended in that report that the agency track which DTC materials had been reviewed. FDA officials indicated to GAO in May 2008 that the agency still did not track this information. As a result, the agency cannot ensure that it is identifying and reviewing the highest-priority materials.

Representative Bart Stupak (D-Mich.), chairman of the subcommittee, hauled three pharmaceutical companies up to Capitol Hill. All three (Merck/Schering-Plough, Pfizer, and Ortho Biotech) had recently put controversial TV ads on the tube but then subsequently pulled them. James Sage, Senior Director and Team Leader of Lipitor at Pfizer, admitted that there were some problems, at least from a public perception standpoint, with the way in which Pfizer used Robert Jarvik, MD, in ads for Lipitor. Dr. Jarvik is not a practicing physician. Mr. Sage admitted that the Lipitor (atorvastatin) ads “created misimpressions and distractions.” He added, “Going forward, we are committed to ensuring that there is greater clarity in our advertising regarding the presentation of spokespersons.”

Ensuring “clarity” in drug advertising—with regard to spokespersons and more—was what section 503b of the FDAAA was all about. It would have allowed the FDA to require an ad to be reviewed. The agency would have had to make sure that the ad would not be “false or misleading” and that under the stated conditions of use, the major statement relating to side effects, and any contraindications would be presented in a “clear, conspicuous, and neutral” manner.

Section 503b called for drug companies to pay user fees totaling $11 million to set up the new FDA ad-review program. Many companies agreed. The $11 million was there; however, Rose DeLauro refused to allow that money to be transferred to the FDA budget for the reviews, and the program never got off the ground.

The American Medical Association is prodding Congress to resurrect legislation on drug advertising. The American Association of Retired Persons (AARP), the powerful lobby for senior citizens, did not testify at the Stupak hearing, but it presented a statement that tied increases in drug prices to DTC ads. The AARP is pushing for (1) a two-year ban on the advertising of new drugs, a prescription that Congress had considered in 2007 for inclusion in the FDAAA but then discarded, and (2) a requirement that all drug ads be submitted to the FDA for approval before they are aired—a much more radical proposal that Congress never considered.