The GAO report, although not a binding document, provides conclusions and recommendations that will help shape Congressional debate on the proper role of FDA in reviewing direct-to-consumer advertising.

The Government Accountability Office recently submitted a report to Congress evaluating FDA’s regulation of direct-to-consumer advertising and recommending improvements FDA can make to improve its oversight.

The GAO report, although not a binding document, provides conclusions and recommendations that will help shape Congressional debate on the proper role of FDA in reviewing direct-to-consumer advertising.
In November 2006, the Government Accountability Office (GAO) submitted a final report to Congress titled “Prescription Drugs: Improvements Needed in FDA’s Oversight of Direct-to-Consumer Advertising.” See http://www.gao.gov/new.items/d0754.pdf. The report was prepared at the request of Senators Bill Frist, Charles Grassley, and Herbert Kohl. GAO was asked to examine five issues related to FDA’s oversight of prescription drug advertisements. The following is a brief summary of what GAO recommends as to each issue and what practical impact those recommendations may have.

**Trends in Drug Company Spending on DTC Advertising**

GAO concludes that from 1997 to 2005 pharmaceutical companies increased spending on direct-to-consumer (DTC) advertising close to 20 percent from $1.1 billion to $4.2 billion. In 2005, 94 percent of all DTC advertising came in the form of television and magazine ads. DTC advertising increased “twice as fast as spending on promotion to physicians or on research and development.” Despite this growth, pharmaceutical companies still spend more dollars on research and development and promotion to physicians than they do on DTC advertising.

**Relationship Between DTC Advertising and Drug Spending and Utilization**

GAO concludes that DTC advertising “increases prescription drug spending and utilization.” GAO explains that DTC advertising increased utilization of drugs by leading more patients to ask their doctors for advertised drugs and more doctors to prescribe them. Furthermore, DTC advertising of one drug has been found to increase the sales of other drugs that treat the same condition. One study determined that every $1,000 spent on advertising for allergy drugs yields 24 new prescriptions for one specific allergy drug.

**What DTC Materials FDA Reviews**

GAO states that although FDA has increased the amount of DTC material it reviews, FDA still reviews only a “small portion” of the DTC materials it receives. FDA tries to focus its time and energy on DTC advertising that has “the greatest potential to impact public health.” FDA, however, does not have formal guidelines that reviewers must apply in determining which DTC materials to review. GAO criticizes FDA’s review process, stating that FDA “cannot ensure that it is identifying and reviewing the highest-priority DTC materials.” In comments it submitted to GAO’s draft report, FDA disagreed with GAO’s conclusion and defended the efficacy of its review process.

**Volume of DTC-Related Regulatory Letters Issued by FDA**

In 2002, FDA required all draft regulatory letters – including warning letters – to be reviewed by the Office of the Chief Counsel (OCC). GAO’s report states that this change (1) slowed FDA’s review process, and (2) led FDA to issue fewer regulatory letters to manufacturers publishing violative DTC advertising. The time it takes FDA to draft and issue a regulatory letter has increased significantly from an average of two weeks between 1997 and 2001 to as much as 19 months between 2002 and 2005. Moreover, FDA issued almost half as many regulatory letters per year between 2002 and 2005 as it did between 1997 and 2001. In its defense, FDA advised GAO that the regulatory letters it does issue are typically for drugs that “are the most likely to negatively impact consumers.”

**Effectiveness of FDA Regulatory Letters**

Finally, the GAO report addresses the effectiveness of FDA regulatory letters at stopping or at least limiting false and misleading DTC advertising from reaching the public. GAO concludes that “FDA regulatory letters have been in their effectiveness at halting the dissemination of false and misleading DTC advertising materials.” On average, FDA did not issue regulatory letters until eight months after a manufacturer first disseminated a false or misleading DTC advertisement. GAO explains that the manufacturer or distributor had already removed the violative DTC materials by the time FDA’s regulatory letter reached them. GAO reports that even when regulatory letters reached manufacturers in time, manufacturers and distributors took five months or more on average to take corrective action. GAO further states that FDA regulatory letters do not stop drug companies from later disseminating false or misleading DTC advertising for the exact same drug. FDA did not agree with GAO’s criticism of the effectiveness of FDA regulatory letters.

**GAO Recommendations**

GAO recommends that FDA take the following actions to improve its oversight of DTC advertising: (1) develop and document criteria for determining which DTC materials to review; (2) apply those criteria consistently to all DTC materials; and (3) keep track of the material it has received. GAO’s recommendations are not binding on FDA and FDA has already indicated its disagreement with much of the GAO report. FDA believes that it is doing the best job it can given its limited resources. The process by which FDA reviews DTC advertising will not change, therefore, absent Congressional action. GAO’s report will likely help shape Congressional debate on this issue.

What GAO’s report does not acknowledge is the initiative that the pharmaceutical industry has taken to self-regulate DTC advertising. In July 2005, Pharmaceutical Research and Manufacturers of America (PhRMA) announced voluntary Guiding Principles on Direct to Consumer Advertisements of Prescription Medicines. That guidance established 15 principles that drug manufacturers should follow in issuing DTC advertisements.

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