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**U.S. Senators Release GAO Report on Direct-to-Consumer  
Prescription Drug Advertising**

**Washington, DC** – U.S. Senators Herb Kohl (D-WI), Majority Leader Bill Frist, (R-TN), and Chuck Grassley (R-IA) today released a General Accountability Office (GAO) report examining the impact of direct-to-consumer (DTC) advertising of prescription drugs on overall health care spending. The study also looked at the Food and Drug Administration’s (FDA) role in monitoring ads and taking steps to remove inappropriate or deceptive ads.

In brief, the GAO found:

- 1.) Drug company spending on DTC advertising increased twice as fast as spending on promotion to physicians or on the research and development of new drugs.
- 2.) Increases in DTC advertising have contributed to overall increases in spending on both the advertised drugs and other drugs treating the same condition.
- 3.) The FDA reviews only a very small portion of the DTC materials it receives and cannot ensure that it is identifying the materials it considers to be highest priority.
- 4.) Since 2002, FDA’s process for issuing regulatory letters to companies with inappropriate or deceptive ads has taken longer and the agency has issued fewer letters per year. Because of this lengthy process, the effectiveness of FDA regulatory letters in stopping the dissemination of violative DTC materials has been limited.

“I appreciate the GAO’s work in producing this comprehensive report,” Frist said. “Americans are besieged today with advertising for prescription medications. Therefore, it is necessary for Congress to fully review the advertising practices of the pharmaceutical industry and federal regulatory practices to ensure patients are getting safe and effective prescription drug treatment. I will continue to work with my colleagues in both Congress and Medicine to address the issues raised in the report.”

“Transparency and access to information are key elements to improving the drug safety work of the Food and Drug Administration. Those fundamentals are the policy basis for my legislation to require drug makers to submit advertising plans to the FDA

before ad campaigns are launched,” Grassley said. “This new GAO report underscores the need for the FDA to be able to handle the information it already receives about direct-to-consumer advertising, and documents the impact of this advertising.”

Sen. Kohl said, “Americans are bombarded by DTC ads everyday, yet this report makes it clear that the FDA’s effort to police those ads is inadequate. It is unacceptable that the FDA lacks a review process to regulate DTC ads of prescription drugs, particularly at a time when spending on drug advertising is increasing at such a rapid rate. As the incoming chair of the Appropriations panel that oversees FDA’s budget, I will be pressing the agency to establish a system and protect the health of consumers through proper review and regulation of drug advertising.”

*Full text of the report attached.*