http://finance.senate.gov

<u>MEMORANDUM</u>

TO: Reporters and Editors FR: Jill Kozeny, 202/224-1308

RE: PhRMA announcement

on direct-to-consumer advertising

DA: August 2, 2005

Sen. Chuck Grassley today issued a statement about the pharmaceutical industry's newly unveiled guiding principles on direct-to-consumer advertising.

In April, Sen. Grassley introduced legislation with Sen. Dodd to set up a new drug safety office within the Food and Drug Administration and require drug makers to submit ads to the FDA for review in advance of ad placement. Their legislation would also require new disclosures in ads for higher risk or newer drugs. The legislation is pending in the Senate.

Since 2004, Grassley has conducted extensive oversight of the FDA and put pressure on the drug safety agency to respond in a more timely and forthcoming way when new information about drug risks is available. In addition to the post-market review legislation, Sens. Grassley and Dodd introduced a bill to establish a mandatory clinical trials registry for drug manufacturers.

Here is a comment from Sen. Grassley about the announcement made today by the pharmaceutical industry.

"This announcement acknowledges the need for greater transparency when it comes to drug safety, but it doesn't deliver a single guarantee for consumers. The Food and Drug Administration needs to stop dragging its feet and start exercising its authority to closely monitor the marketing of pharmaceuticals. In addition to a dramatically stepped up effort by the FDA, we need an updated law that requires drug makers to submit their ads to the FDA for review. It doesn't make sense to rely on drug companies to police themselves."