May 6, 2008

Chairman Bart Stupak
Ranking Member John Shimkus
Subcommittee on Oversight and Investigations
Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Cc: Chairman John Dingell
Ranking Member Joe Barton
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Stupak and Ranking Member Shimkus:

Consumers Union, the independent non-profit publisher of *Consumer Reports*, appreciates your decision to hold an investigatory hearing on Direct-to-Consumer (DTC) advertising for pharmaceuticals and devices. DTC advertising has been shown to not only drive up health care costs, but also result in needless suffering by improperly characterizing a drug's benefits, risks and target patients. DTC advertising is increasingly used as a marketing tool to boost a drug's market share. According to a 2006 GAO report, spending on DTC advertising increased by roughly 300% from 1997 to 2005, while spending on promotion to physicians increased by 86% and spending on pharmaceutical research and development increased by 103%.

Consumers Union urges the Committee to consider legislation that would: 1) require a three year moratorium on advertising of new drugs approved by the FDA, 2) provide adequate funding for FDA review and enforcement of false or misleading ads, and 3) require all TV drug ads to list the MedWatch toll-free number and website to report serious adverse events. In addition, we would urge the Subcommittee to look into the industry's use of cable TV infomercials, internet ads, and the funding of patient advocacy groups and patient information websites to promote their products.

First, new drugs' risks cannot be fully understood until they are used by a large number of people, which does not occur until after a new drug comes on the market. Before new drugs are released onto the market, the clinical trials required for FDA approval have enrolled from a few hundred to a few thousand patients. The timely approval of new

drugs is important, but many adverse events or side effects do not become statistically significant or apparent until the drugs are used in larger samples of the population. The first few years a drug is on the market is the time period most likely to reveal previously unrecognized risks and side effects of a new drug. Unfortunately, this time period also sees some of the heaviest marketing of new drugs, as manufacturers seek to maximize name recognition and use of their drug before market exclusivity for the drug runs out. Consumers Union believes a three-year moratorium on DTC advertising is an important and rational step to take to: 1) allow doctors to get used to using a new drug and evaluate it in their patients before patients start requesting it based on ads, 2) permit further safety evaluations and adverse event surveillance of new drugs, and 3) minimize any inappropriate overuse.

Second, the FDA needs more resources for reviewing DTC ads and taking enforcement action when advertisements are unlawfully misleading, deceptive or unbalanced. Often, FDA does not issue a warning letter until months after a deceptive or misleading ad has been widely aired. Recent ad campaigns for the widely prescribed cholesterol-lowering drugs Vytorin and Lipitor are cases in point. In light of recent research indicating problems with respect to their safety or effectiveness, we have been particularly disturbed by ads for Zetia, Vytorin, Avandia, Procrit/Epogen, Boniva, Advair, Chantix and Aricept. Each of these drugs made the 2007 "Top 20" list of highest DTC advertising budgets. We would be pleased to provide the Subcommittee with our specific concerns about these drugs.

Delays in FDA enforcement result in windfalls for violating companies. Although ads for Lipitor featuring non-practicing physician Dr. Jarvis stated that the drug was superior to generic alternatives (a claim without substantial evidence), the ad ran for months before it was pulled off the air, misleading consumers and helping to continue Lipitor's reign as the top-selling prescription drug in the U.S. A *Consumer Reports* National Research Center survey recently showed that Dr. Jarvik was a very effective and believable spokesman while the ads were running. Of the 978 people shown the ad, sixty-five percent said the ad conveyed that leading doctors prefer Lipitor. More than one-quarter (29 percent) got the impression from the ad that Dr. Jarvik sees patients regularly. Forty-one percent said the ad conveyed that Lipitor is better than generic alternatives. FDA now has authority under the FDA Amendments Act (FDAAA) to require prereview of television ads. FDA should be encouraged to provide meaningful prereview for a fair balance of benefit and risk information and should take prompt action against ads already on air that do not meet this standard.

Third, FDA has been slow to study whether the MedWatch toll-free number and website to report serious adverse event should be included in TV drug ads, as FDAAA requires for print ads. Consumers Union has filed a petition asking the FDA to require that this information be included in TV ads so consumers can easily report serious adverse events. Including Medwatch information in TV drug ads is a common-sense way to improve post-marketing surveillance of serious adverse drug events. Drug companies argue that consumers are informed enough to use DTC ads to assist in making medical decisions; it

would be a gross inconsistency to then claim that consumers are not informed enough to decide if a drug was influential in an adverse event they have experienced.

A national poll by the *Consumer Reports* National Research Center found that among consumers who have ever taken a prescription drug, one in six (16 percent) had experienced a serious drug side effect at some time in their life, but only 35 percent of consumers polled were aware that serious side effects can be reported to the FDA. Yet Americans were very familiar with drug advertising. Eight in 10 (81 percent) said they had seen or heard an advertisement for prescription drugs within the past 30 days. Among them, virtually all – 98 percent – viewed an ad on television. When asked if they think prescription drug advertising should include information to report an adverse drug reaction to the FDA, 87 percent of consumers said TV ads should contain this information.

Currently, DTC ads provide a disservice to patients by skewing risk and benefit information of new drugs. Patients place enormous reliance on the accuracy of the data their doctors use to balance the risks and benefits of medications. When drug companies elect to advertise their products directly to consumers, companies have an obligation to accurately characterize the drug's risks and benefits for the consumer as well. Ads for drugs that have recently entered the market are unlikely to contain balanced information about a product's true benefits and risks. If FDA does not facilitate consumer reporting of serious adverse events, then FDA, physicians and patients will not have complete information with which to fairly evaluate drug risks. Without adequate resources for FDA enforcement, many ads will continue to contain false or misleading information.

Thank you again for your efforts on this very important issue.

Sincerely,

Steve Findlay
Consumers Union

Shannon Baker-Branstetter
Consumers Union