

Statement of the American College of Physicians

for the Record of the Public Hearing on
“Consumer-Directed Promotion of Regulated Medical Products”

Department of Health and Human Services
Food and Drug Administration

November 1-2, 2005

The American College of Physicians, the nation's largest medical specialty society representing over 119,000 doctors of internal medicine and medical students, is pleased to provide this statement for the record on the issue of direct-to-consumer (DTC) promotion of prescription drugs. Internists typically provide primary and subspecialty care to large numbers of patients who are Medicare-eligible and have multiple medical problems. It is these patients who are most adversely affected by DTC advertising.

Since 1998, ACP has voiced its opposition to the practice of DTC advertising. DTC advertising of prescription drugs often leaves patients confused and misinformed about medications. It undermines the patient-physician relationship and impedes the practice of medicine by challenging the individual physician's medical judgment. According to one of our members, the current wave of DTC advertising “[puts] patients, not him, in the diagnostic driver's seat.”

Adverse Consequences of DTC Advertising

ACP members continue to complain that more and more patients are presenting them with a list of drugs they would like to try, based on what they see on television, magazines and the Internet, many of which may not be the best choice of therapy for individual patients. Patients arrive at the physician's office already convinced that the products advertised are the answer to their problems. Their conclusions are based on brief ads or commercials that provide insufficient information about the appropriateness of the drug for that patient, the risks and benefits, and comparable and more cost-effective options. Physicians end up spending valuable time fielding requests, clarifying misconceptions, and explaining other, sometimes more effective treatments. Time spent with the patient gets diverted from patient education to negotiation. Then, depending on the patient's insurance plan, the physician usually has to negotiate with the patient what is and is not covered. When a coveted drug is not part of a patient's health plan's formulary, patients may pressure physicians to make a case for medical necessity in hopes of getting the prescription covered—another round of hassle and effort for the physicians. And when a physician withholds something a patient wants, patients often build mistrust in the physician. The result is a subtle but chronic adversarial element in the doctor-patient relationship that takes a substantial emotional toll on physicians.

Surveys have shown that patients ask for a prescription based on an advertisement in up to seven percent of doctor visits — a rate that adds up to millions of requests a year. According to the FDA, 65 percent of physicians believe patients misunderstand the relative risks and benefits of a drug advertised through a DTC ad and 75 percent say the ads lead patients to overestimate the medical value of the drugs. Thirty-eight percent say DTC ads cause patients to question their diagnoses and 28 percent say the ads can lead to doctor-patient tension. The FDA also has reported that although few physicians report excessive pressure to prescribe requested drugs from patients who have seen DTC ads, nearly half report feeling at least a little pressure to prescribe.

The pressure patients impose on physicians is compounded by the fact that physicians are also being ordered by health plans and administrators to hold the line on spiraling prescription costs. Spending on prescription drugs is the fastest growing component of the health care budget and DTC ads are one element – and probably an increasingly important one – in the recent sharp rise in the demand for, expanded use of, and increased spending on prescription drugs. In the four years after the FDA relaxed its guidelines on broadcast drug commercials, the amount spent on DTC ads more than doubled, from \$1.1 billion to \$2.7 billion. By 2003, spending on DTC advertising of prescription drugs totaled \$3.2 billion. At least a fraction of these costs are passed on to the consumer.

In terms of increasing demand and utilization, it is estimated that between 4 percent and 6 percent of the U.S. adult population – 8.5 million to 12.6 million people in 2001 – appear to have received a prescription for a drug as a *direct result* of a DTC ad. In a 2000 analysis of prescription volume and sales of advertised drugs compared to non-advertised drugs, the U.S. Federal Trade Commission (FTC) found that doctors wrote 25 percent more prescriptions for the 50 most heavily DTC-advertised drugs compared to 4.3 percent more scripts for all other drugs combined. Sales of the top 50 most heavily advertised drugs rose an aggregate 32 percent from 1999 to 2000 compared to 13.6 percent for all other drugs combined. Increases in the sales of these 50 most heavily advertised drugs accounted for almost half (47.8 percent) of the overall \$20.8 billion rise in spending on drugs in the retail sector from 1999 to 2000. Although such research proves no direct cause and effect link between DTC ads and increasing drug use and spending, it is highly suggestive.

While DTC advertising may avert underuse of drugs, the practice more often promotes overuse of drugs or use of less cost-effective drugs. A study published this year in the *Journal of the American Medical Association* found that doctors were five times more likely to write prescriptions after patients inquired about a specific antidepressant, Paxil, as compared to patients who did not mention an ad. The study used actresses who pretended to have a mild form of depression, a condition that does not require antidepressants. Another national survey found that when a drug requested by a patient was prescribed, 46 percent of physicians said that it was the most effective drug, while 48 percent said that others were equally effective. Unnecessary spending further weighs down our health system when equally effective alternatives prove to be less expensive. Issues of therapeutic equivalence and cost-effectiveness are particularly important in light of Medicare's new drug benefit. If DTC ads continue to generate a fairly large volume of

inappropriate demand and overutilization, they could end up costing the federal government billions of dollars.

Proponents of DTC advertising claim that it promotes consumer education and stimulates dialogue between physicians and patients. They say that patients are now more willing to discuss symptoms they have seen referred to in advertisements. ACP recognizes the value of consumer education. When evidence exists on appropriateness, effective communication regarding prescription drugs can produce a social good by reducing underuse. The medical community has an obligation to empower consumers by educating them about health conditions and possible treatments. ACP supports the IOM recommendation that patients be offered the opportunity to act more like partners in their care. A healthy patient-physician relationship can lead to better health outcomes through appropriate use of safe and effective medicines that save lives, cure disease, and alleviate pain and suffering.

Nevertheless, ACP continues to hold that DTC advertising *does not* constitute appropriate patient education. Instead, it results in patients attempting to influence their own treatment regimens based on what they see in the media, rather than by what may be the best medical treatment option for them.

Drug Manufacturers' Contributions to Improving Patient Care

The College's objections to DTC advertising do not imply that the pharmaceutical industry does not play an essential role in improving patient care. Quite the contrary: the College strongly believes that the pharmaceutical industry makes invaluable contributions to the field of medicine as it continues to develop new life-saving therapies and provide financial support to public education programs that educate patients on how to manage their own health. Internists would not be able to provide patients with the benefits of life-saving therapies without the availability of the thousands of medications that are available because of the pharmaceutical industry's investment in research and development. The ability of the industry to continue to develop new therapies is essential for continuous improvements in patient care to occur.

The College also believes that there is an appropriate role for pharmaceutical companies to provide financial support for public education programs that do not promote a particular drug product. The drug industry spends millions of dollars to support the efforts of non-profit charitable organizations, including ACP, to educate the public through unrestricted educational grants that do not promote a specific product. As an example, ACP and the ACP Foundation recently received a multimillion-dollar unrestricted educational grant from Novo Nordisk to create and disseminate educational tools and information for physicians, patients, and other members of the health care team to raise awareness and teach best practices in diabetes care. This partnership illustrates that the medical and pharmaceutical professions share the goals of high quality care--including the promotion of evidence-based medicine for care of all chronic diseases, identification of the gaps between current practice and acceptable standards of care, and recognition of physicians that demonstrably improve care of their patients.

The College acknowledges the need for the pharmaceutical industry to market its products, but believes that such marketing should be directed at increasing awareness among clinicians about new medication therapies (including advertisements directed to clinicians that provide balanced and accurate information about the medication's approved uses, relative effectiveness, and risks) rather than directly marketing to a patient population that lacks the training and skills to make an informed judgment about the effectiveness of new drug products.

The College appreciates that the Pharmaceutical Research and Manufacturing Association (PhRMA) has begun to take steps to address concerns about DTC advertising by issuing voluntary guidelines to regulate the industry's use of DTC ads. We believe, however, that voluntary guidelines are not a substitute for an effective regulatory approach to DTC advertising. Further, we believe that the industry should continue to consider additional actions to limit the potential adverse consequences of DTC advertising while Congress and the FDA continue to work on creating a more effective regulatory structure. We note, for instance, that some companies have gone beyond the PhRMA guidelines by voluntarily agreeing to delay advertising of new drugs to consumers until they have been on the market long enough for their safety and effectiveness to be tested.

Improving Regulatory Oversight of DTC Advertising

ACP would prefer to see Congress ban DTC advertising. In the absence of a prohibition on DTC advertising, however, the College calls on Congress, the FDA, and the industry itself to take actions to minimize the deleterious effects of DTC advertising. ACP supports the following recommendations:

- Federal regulations and guidelines must be strengthened to make drug advertising as honest and useful as possible. The FDA must impose serious limits on the pharmaceutical industry to ensure that consumers receive complete and non-confusing information. While ACP appreciates recent efforts by the FDA to assure that drug ads reflect "truthful, balanced, and accurately communicated" information about drugs, including the recent creation of an independent Drug Safety Oversight Board to oversee the management of drug safety issues, the current system still lacks a sufficient process with which to review the pharmaceutical industry and the products it markets directly to the public. For example, the retrospective regulatory process used by FDA is much too lenient, allowing drug companies to transmit advertising messages directly to the public before the FDA has had a chance to check the appropriateness of the information. ACP favors mandatory pre-release screening of all pharmaceutical advertising to ensure clarity and truthfulness.
- Although DTC advertising may increase public awareness about untreated conditions, ACP feels this information could be conveyed to patients in more effective ways. For instance, marketing should be directed at providing clinicians with accurate information on new drug products, rather than overwhelming consumers with confusing and often misinterpreted information. Physicians and

- pharmaceutical companies must continue to work jointly to create effective consumer advertising and educational initiatives. The pharmaceutical industry has a duty to meet with physicians to provide new information about drugs and warn physicians about the questions they will be receiving from their patients, due to an advertising campaign that is about to be launched. At the same time, ACP and other medical societies have a duty to work with the pharmaceutical industry to develop medically appropriate information that can be provided to consumers.
- Finally, the federal government must continue to fund studies to further define and measure the impact of DTC ads. While direct-to-consumer advertising has become commonplace, the practice still raises many questions. Can consumers understand advertised medical information and apply it to their own conditions? Can advertising be considered a form of education? Does the "information" presented in ads change patient expectations of the medical encounter and treatment for the better or for the worse? Does it appropriately influence the prescribing habits of physicians?

ACP is pleased that the FDA has decided to address the serious problems associated with DTC drug advertising. In addition to patient misperceptions, DTC advertising results in inefficient use of valuable physician time, challenges a physician's professional authority, inflates the cost of drugs, and can ultimately compromise patient access to life-saving treatments. ACP asks that the FDA consider recommending that the use of DTC ads be prohibited. At the very least, ACP calls on the federal government to expeditiously strengthen regulations governing these ads. Thank you for considering the views of ACP.