



STATEMENT FOR THE
FOOD AND DRUG ADMINISTRATION
ON
CONSUMER-DIRECTED PROMOTION OF
REGULATED MEDICAL PRODUCTS

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For further information, contact:
Kirsten Sloan/Anna Schwamlein
Federal Affairs Department
(202) 434-3770

Members of the Food and Drug Administration, my name is Lee Hammond and I am a member of AARP's Board of Directors. On behalf of our over 35 million members, thank you for convening this public hearing and for including AARP in your discussions about direct-to-consumer advertising of prescription drugs.

For the past four months, millions of older and disabled Americans have had the opportunity to choose prescription drug coverage as part of their 2006 Medicare benefit options. The new Medicare prescription drug benefit will help many beneficiaries afford their needed medications. However, more needs to be done to ensure that prescription drugs will be made affordable to all Americans, regardless of Medicare eligibility. Controlling direct-to-consumer advertising of prescription drugs has an important role to play in making prescription drugs more affordable for the overall U.S. health care system.

Rising Prescription Drug Costs

Nationally, nine-tenths of older adults report using prescription medicines and, among those using at least one drug, nearly half report using five or more different drugs.¹ Unfortunately, dramatic increases in prescription drug costs have made medicines unaffordable for many Americans. A recent AARP survey showed that, among Americans age 50 and older, one in four said they decided against filling a prescription; cost was reported to be the main deterrent.²

DTC Advertising of Prescription Drugs Can be Beneficial

Direct-to-consumer advertising of prescription drugs can be helpful to consumers to the extent ads provide general information about a specific disease or condition, particularly one that is historically under-diagnosed and/or under-treated (e.g., "help-seeking" advertisements).

Direct-to-consumer advertisements should inform the consumer and provide clear, accurate information. They should also encourage the consumer to have a productive dialogue with their provider about their treatment options, including prescription and non-prescription medicines, and lifestyle changes, if applicable. Appropriate options may or may not include a role for the advertised product.

¹ Safran, D.G., Neuman, P., et al., "Prescription Drug Coverage and Seniors: Findings from a 2003 National Survey," Health Affairs web exclusive, April 19, 2005, <http://www.healthaffairs.org>.

² Prescription Drug Use Among Midlife and Older Americans, AARP, January 2005.

DTC Advertising of Prescription Drugs Can be Harmful

Spending on prescription drugs is one of the fastest components of overall health care spending and we believe that this is due, in part, to the increase in direct to consumer advertising. In recent years, the amount of money spent on direct-to-consumer advertising of prescription drugs has increased rapidly: \$4.1 billion was spent in 2004 vs. \$1.1 billion in 1997 when the FDA first relaxed its guidelines for broadcast advertising. In 2004, the top six prescription products by level of DTC expenditures combined accounted for over \$1 billion.³ In 1999, just 25 top-selling medicines promoted directly to consumers accounted for 40.7 percent of the overall \$17.7 billion increase in retail drug spending from 1998.⁴

Overall health care costs increase when patients are prescribed – often unnecessarily – new, heavily-advertised pharmaceuticals as the first-line therapy, rather than older, equally effective but often less-expensive medications. Ramifications are not purely economic, but may be clinically significant as well, when serious side effects surface only after a new drug is used in large populations. As noted by Michele Spence, the Kaiser Permanente panelist, her research found that for patients who asked their doctor about the type of pain reliever represented by Vioxx – so-called “COX-2s” – after seeing or hearing an advertisement were more likely to be prescribed a COX-2 rather than a non-steroidal anti-inflammatory (NSAID) drug. This was the case regardless of which guideline for clinical appropriateness was used in terms of assessing the patient’s risk of GI bleeding, which is a key clinical factor for deciding between these types of pain relievers.⁵

Prescribers often feel pressured to prescribe the advertised prescription drug, perhaps forfeiting a meaningful dialogue with the patient about other appropriate courses of treatment, including non-drug treatment alternatives.⁶ A recent study in the Journal of American Medical Association found that doctors were five times

³ 11th Annual Report on DTC, MedAd News, June 2005.

⁴ “Prescription Drugs and Mass Media Advertising,” Research Brief, National Institute for Health Care Management, Sept. 2000.

⁵ Spence, M.M., Teleki, S.S., et al., “Direct-to-Consumer Advertising of COX-2 Inhibitors: Effect on Appropriateness of Prescribing,” *Medical Care Research and Review*, Vol. 62, No. 5 (Oct. 2005), pps. 544-559.

⁶ For example, a 2003 study surveyed patients who saw physicians in Sacramento and patients who saw physicians in Vancouver regarding their exposure to direct-to-consumer (DTC) advertising. The study found that patients who requested advertised drugs were 17 percent times more likely to receive one or more new prescriptions (either for the requested drug or an alternative) than those who did not request an advertised drug. Mintzes, B; Barer, M.L., Kravitz, R.L., Bassett, K., Lexchin, J., et al., “How Does Direct-to-Consumer Advertising Affect Prescribing? A Survey in Primary Care Environments with and without Legal DTCA,” *Canadian Medical Association Journal*, Sept. 2, 2003, Vol. 169, No. 5, p. 405-412.

more likely to write a prescription about a specific drug requested by their patients, compared to those who did not mention a specific drug.⁷

What Needs to be Done

The U.S. health care system can benefit from a more serious investment in research of comparative clinical effectiveness of prescription drugs. Unlike other countries, the U.S. does not require that drugs coming onto the market demonstrate enhanced effectiveness and safety profiles in head-to-head trials with already-marketed drugs in the same therapeutic category. Congress, as part of the Medicare Modernization Act of 2003, authorized \$50 million funding in FY2004 and “such other sums as may be necessary” in subsequent years for comparative effectiveness research. To date, Congress has only appropriated \$30 million for this valuable research, only \$15 million for the past two fiscal years. This amount is \$2 million less than what Merck spent advertising Vioxx in 1999, its first year on the market.⁸

With Medicare footing the bill for many prescription drugs starting in 2006, this is a perfect opportunity for Congress to boost funding for comparative clinical effectiveness studies that would provide scientifically based information on the relative clinical effectiveness of different prescription drugs within a therapeutic class. In some cases, the newer drug may be the best treatment option; in other cases the best treatment option may be an existing brand-name or generic drug. Broad dissemination of the results to both the public and health care professionals may help to reduce the influence of direct-to-consumer advertising.

In 2005, the Pharmaceutical Research and Manufacturers of America (PhRMA) Board of Directors approved voluntary guidelines on direct-to-consumer advertising of prescription drugs. While these guidelines represent a good first step, we would like to see the FDA, working in consultation with other interest groups (including consumers and providers) revise its 1997 “Guidance for Industry: Consumer-Directed Broadcast Advertisements,” rather than relying solely on the pharmaceutical industry to police itself.

AARP believes that the Food and Drug Administration should be empowered with the resources and authority to require FDA review of advertisements – both print and TV – before the advertisement is disseminated to the public. Recently, we have begun to see in some broadcast DTC ads more direct communication of risk information. New research shows that consumer comprehension and recall of risk information in DTC broadcast ads varies depending on whether the drug

⁷ Kravitz, R.L., Epstein, R.M., et al., “Influence of Patients’ Requests for Direct-to-Consumer Advertised Antidepressants,” *Journal of the American Medical Association*, Vol. 293, No. 16, April 27, 2005, pps. 1995-2002.

⁸ National Institute for Health Care Management Research Brief, Sept. 2000.

risks are considered high-severity or low-severity.⁹ We do not yet know if, or how, this will translate into more cautious prescribing for new drugs.

In addition, conveyance of risk information in print DTC ads remains, in most cases, a micro-type reprint of the so-called brief prescribing summary. This is neither useful nor informative for consumers. Indeed, the FDA's own research found that, in 2002, 41 percent of consumers said that they do not usually read any of the brief summary, an increase from the 31 percent who said they did not read them in 1999.¹⁰ However, getting it right is very important. Research suggests a direct relationship between risk statement completeness and consumers' perceptions of drug safety. We support FDA's current research plan to develop more consumer-friendly risk communication strategies for print advertisements.

Conclusion

Direct-to-consumer advertising is just one way to inform consumers about (usually) newly-approved medicines. While AARP will continue to examine how DTC can best educate and inform consumers we will also pursue other ways to promote appropriate and cost-effective prescribing to help consumers make wise choices about their medicines.

⁹ Glinert, L.H., Schommer, J.C., "Television Advertisement Format and the Provision of Risk Information About Prescription Drug Products," *Research in Social and Administrative Pharmacy*, Vol. 1 (2005), pps. 185-210.

¹⁰ "Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results," HHS, FDA, Nov. 19, 2004, p. 24.