

**Testimony to the Members of the**  
**Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism**  
**U. S. Senate Committee on Commerce, Science, and Transportation**

**presented by**

**Mark Cloutier, MPP MPH**  
**Policy Director, RxHealthValue**

**July 24, 2001**

**Mr. Chairman, Members of the Subcommittee, I am Mark Cloutier, Policy Director of RxHealthValue, a national coalition of consumer groups, labor unions, provider groups, business groups and employers, insurers and health plans, pharmacy benefits management organizations, and academic researchers committed to improving Americans' access to health-improving prescription drugs. (Our membership list is appended below.) As you can understand, a deliberative body comprised of nearly 30 organizations will rarely arrive at full consensus regarding any issue. Remarkably, our membership has achieved consensus regarding the recommendations I am offering regarding Direct-to-Consumer (DTC) advertising of prescription drugs to consumers and patients. Safety is at stake. I believe the fact of these consensus recommendations indicates the fundamental importance of this issue for the members of RxHealthValue. It is our belief that this form of advertising affects the health and safety of American patients and consumers.**

**The tremendous increase in the extent of DTC advertising of prescription drugs since the FDA removed the requirement for the "brief summary" of risk information in 1997<sup>1</sup> is well documented<sup>2</sup>. It is almost impossible to open a general news magazine, view a prime time television program or listen to the radio and not see or hear advertising for prescription drugs. Given that the prescribing physician is the decision-maker regarding the use of these medications, it is all the more startling that so many resources are expended by drug manufacturers to affect the attitudes of consumers and patients. Although there is little**

---

<sup>1</sup>Draft Guidance for Industry: Consumer Directed Broadcast Advertisements: Availability. Federal Register 1997; 62:43171.

<sup>2</sup>Findlay, Stephen. Prescription Drugs and Mass Media Advertising. NIHCM, Sept. 2000.

evidence<sup>3</sup> currently available regarding whether consumer and patient attitudes affect physician choice in prescribing, no stakeholders in the health system and health economy have suggested that the impact of such advertising is insubstantial. Given the FDA's expressed interest in assessing the effects of DTC advertising, we expect more direct evidence of impact will be available in the near term future.

While we await the results of planned and pending studies on the effects of DTC advertising on the attitudes, behaviors and medical outcomes of consumers and patients, RxHealthValue members are concerned that risk information in particular is not adequately or effectively conveyed in DTC advertising. One of our member organizations, AARP, recently conducted a survey of members to assess the impact of DTC advertising<sup>4</sup> finding that the majority of those surveyed could not recall ever seeing risk information in the ads. This poses a serious safety risk to consumers and patients. In our first public recommendations to the FDA, presented one year ago at the National Press Club, RxHealthValue emphasized the fundamental importance of protecting the safety of patients and consumers who are confronted by DTC advertising<sup>5</sup>

Thus, RxHealthValue recommends that the Congress direct the FDA:

- To convene a task force of key stakeholders, including the pharmaceutical manufacturers who advertise prescription drugs, as well as consumer groups, patient organizations, provider groups, payers and relevant experts, to develop and test standards for information disclosure in DTC advertising.
- To more carefully define the concrete meaning of "fair balance" in disclosing benefits and risks of advertised medications to include disclosure of

---

<sup>3</sup>Bero, Lisa A. & Lipton, Shira. Methods for Studying the Effects of Direct-to-Consumer Pharmaceutical Advertising on Health Outcomes and Health Services Utilization. (Paper to be presented at ASPE Conference on Methods to Assess Effects of DTC Advertising, May 30, 2001).

<sup>4</sup>Foley, Lisa A. & Gross, David J. Are Consumers Well Informed About Prescription Drugs? The Impact of Printed Direct-to-Consumer Advertising. AARO: Public Policy Institute, April 2000.

<sup>5</sup>Policy Recommendations. RxHealthValue May 10, 2000.

**other appropriate therapies in addition to alternative medications.**

- **To further define "fair balance" to mean that full disclosure of risks and side effects be given equal print and air time as the description of benefits in the same communication.**

**RxHealthValue recommends that the Congress direct that the appropriate agencies of the Federal Government conduct on-going research to evaluate the effects of DTC advertising on the health of American consumers and patients. It is a given that many Americans appreciate the increased awareness of diseases and conditions and potential therapies which DTC advertising makes possible. It is also true that such advertising can obscure potential hazards of the pharmaceutical advertised and neglect the relative value of other forms of therapy. Only thorough, independent research can demonstrate the differential impact of such advertising upon the health choices of American patients and physicians.**

**In conclusion, the members of RxHealthValue applaud the Subcommittee for beginning the investigation of the effects of this increasingly pervasive influence on the therapeutic choices of American consumers and patients. We pledge our assistance in implementing any of the recommendations we have offered and thank the Subcommittee for this opportunity to comment.**