



AMERICAN COLLEGE OF PHYSICIANS  
INTERNAL MEDICINE | Doctors for Adults

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February 18, 2004

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Rm. 1061  
Rockville, MD 20852

RE: Docket No. 2004D-0042

Dear Division of Dockets Management:

The American College of Physicians (ACP), representing more than 115,000 internal medicine physicians and medical students, appreciates the opportunity to comment on the *Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions*, as published by the Food and Drug Administration (FDA) at 69 Fed. Reg. 6,308 (February 10, 2004). The three guidances referred to in our comments are: "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements" (Brief Summary Guidance), "Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms" (Disease Awareness Guidance), and "Consumer-Directed Broadcast Advertising of Restricted Devices" (Device Broadcast Advertising Guidance). Although the College continues to maintain that the promotion of commercial products does not constitute appropriate patient education about therapeutics, ACP recognizes that drug advertising targeted to consumers is here to stay, and therefore, supports strong regulations and strict guidelines to make such advertising as honest and useful as possible.

ACP has long- advocated that the FDA require that all direct to consumer advertisements provide patients with complete and non-confusing information. At the same time, the College favors a forum in which physicians and pharmaceutical representatives can work together to create advertisements that inform patients with clear information and that will facilitate discussion of treatment options between patients and physicians. We therefore applaud the FDA for continuing to study consumer reactions to drug advertisements and reevaluate regulations in an effort to ensure that advertisements continue to represent clear and credible communication. We also commend the FDA for recognizing that the language and format chosen to present risk information can affect consumer understanding.

In terms of the Brief Summary Guidance, ACP supports increased patient education and commends the FDA's goal of increasing consumer understanding of the key risks of a product. However, ACP does not agree with the way FDA has proposed meeting this goal. The College's "Ethics Manual" states that advertising by physicians and health care institutions is unethical "when it contains statements that are unsubstantiated, false, deceptive, or misleading, including statements that mislead by omitting necessary information." This principle can be applied to health care advertising more broadly. While omitting less serious, infrequent risks from patient labeling may increase the readability of this information by making more important risks stand out more clearly, ACP does not equate less information with increased consumer comprehension. By concentrating on the most common or important side effects, as proposed by the FDA,

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consumers would essentially receive less information. Critical information, such as drug interaction warnings, may be omitted.

Should this proposal move forward, at the very least ACP requests that advertisements contain a "Highlights" section that sets forth in a concise manner the information that is most important to safe and effective use, including information on the most common and the most serious risks associated with the product. ACP also requests that advertisements include a statement reminding consumers that the information presented is not comprehensive and providing a toll-free telephone number or website address where consumers can obtain additional information if they wish.

Physicians have a duty to balance beneficence-- acting in the best interests of patients and the public health--and respect for autonomy-- protecting and fostering the patient's free, uncoerced choices and adhering to the rules of truth-telling and disclosure. As a result, ACP believes that only those advertisements that fully disclose the potential benefits and harms of the advertised product and ensure consumers' informed choice of all available options can be considered in the best interest of the potential patient.

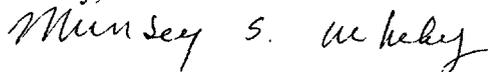
In terms of the Disease Awareness Guidance and the Device Broadcast Advertising Guidance, ACP commends the FDA for taking steps to promote consumer health awareness and to regulate unregulated areas, such as device advertisements, to ensure consumers are receiving accurate information. ACP encourages drug and device manufacturers to develop disease awareness communications, particularly for diseases and health conditions of particular public health importance. ACP also supports strengthened FDA regulations to ensure that consumers receive complete and non-confusing information.

We also appreciate FDA's honesty in admitting that there is much to be learned before the agency can develop final guidance on how best to inform patients about the drugs being promoted. ACP encourages the FDA to continue to evaluate ways to ensure that consumers receive accurate, complete, truthful and non-confusing information and to continue studying consumer reactions to various formats of advertising.

Although significant progress has been made in recent years on the issue of drug advertisements, and these latest proposals are a step forward, there is still room for more improvement. Problems arise when physicians end up spending time correcting misconceptions that are abundant in drug information. Consumer information should not compromise the patient-physician relationship.

ACP appreciates the opportunity to share our views with you. We look forward to working with the FDA and the Administration to explore ways to ensure that consumers are presented with complete and comprehensible health care information. If you have any questions regarding our comments, please do not hesitate to contact Rachel Groman, Health Policy Associate, Policy Analysis and Research at 202-261-4546 or [rachelg@apconline.org](mailto:rachelg@apconline.org).

Sincerely,



Munsey S. Wheby, MD, FACP  
President