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Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

RE: Docket No. 95N-0227
"Direct-to-Consumer Promotion"

Sirs:

It is our pleasure to provide comments regarding the important issue of direct-to-consumer promotion of prescription drugs. The American College of Clinical Pharmacy (ACCP) is a national professional and scientific society of clinical pharmacists dedicated to optimal drug therapy outcomes in the pharmaceutical care of patients.

If properly performed and regulated, certain forms of direct-to-consumer promotion could help educate patients about prescription drugs and their appropriate roles in disease prevention and treatment. Such ads can open an avenue for communication between the patient and their pharmacist or physician. The patient may feel more of a partner in their drug therapy regimen. Direct-to-consumer ads may also provide much needed education about important public health problems.

However, these educational benefits are not without risk. At least one market research study of which we are aware apparently found that, if asked by a patient for a particular drug by name, 99% of physicians say they will at least consider prescribing it and 17% say they are likely to prescribe it (*Drug Topics*, August 7, 1995, page 22). FDA's own studies have found that the promotional aspects of direct-to-consumer ads were recalled by consumers much better than was information about the potential risks of drug therapy (*FDA Consumer* 1987; 37-38). We are concerned that unregulated direct-to-consumer advertising may promote the concept that there is a "pill for every ill," lead to an increased use of unnecessary prescription medications, and inappropriately de-emphasize the importance of life-style modification in the management of many chronic illnesses.

We offer the following considerations and recommendations:

- I. At the present time there are no regulations that pertain specifically to consumer-directed promotion of prescription drugs. ACCP believes that FDA should develop guidelines in this area.
- ii. We understand that pharmaceutical manufacturers are currently asked to voluntarily submit proposed direct-to-consumer promotional materials to FDA for review prior to release. If it can be done without introducing an inappropriate delay in the manufacturer's ability to implement their advertising campaign, we suggest that such prior review become mandatory. It could be easily argued that direct-to-consumer advertising should be scrutinized even more closely than that to health professionals. Health professionals are in a much better position to understand and evaluate advertising information. Misrepresentation of information to the general public would have very wide reaching ramifications and would be much more difficult to correct. If a timely, responsive prior review process cannot be established, then FDA should consider some system of significant sanctions against companies that repeatedly violate the agency's eventual guidelines in this area.
- iii. All forms of direct-to-consumer promotions should conclude by advising patients to seek additional information from their pharmacist or physician.
- iv. "Help-seeking" promotional materials, including infomercials, can serve an important public health service. ACCP believes that help-seeking ads should continue, and further, that FDA should allow such ads even "if the only available treatment for a condition is a specific prescription drug product." We understand that in such cases materials focusing on the condition would, by implication, promote the product. However, as long as such help-seeking ads do not include direct "linkages" to the prescription drug, their public health benefits remain uncompromised. In the specific case of infomercials, a statement that the program was paid for by the respective pharmaceutical manufacturer should be required when the show begins, ends, and every time it is interrupted.
- v. ACCP is opposed to any form of "reminder" promotional materials directed to consumers. These promotional efforts have no educational value and do not provide any public health benefit.
- vi. Provided that they are accompanied by adequate written disclosure of side effects and contraindications, ACCP is not opposed to product-claim advertisements to consumers using the print media. However, FDA should rethink the way in which such written disclosure is provided to consumers. ACCP believes that the current procedure of essentially reprinting the package insert is completely ineffective in providing real patient education. Its length and style of presentation are intimidating, and most patients cannot comprehend the information presented. Rather than essentially reprinting the package insert, we believe that acceptable disclosure and more effective education could occur if the *USP-DI* patient education monograph were reprinted.

- vii. Because it is impossible to provide effective disclosure of side effects and contraindications, ACCP is opposed to any form of product-claim advertisements to consumers using the broadcast media, including infomercials. Scrolling approved labeling or similar information on the television screen is useless because it cannot be read effectively and because the patient is left with no permanent copy. Providing a toll-free telephone number would be equally ineffective because it requires the patient to take an additional step and creates a barrier to information provision.
- viii. Materials distributed by independent third parties, such as disease-specific foundations, should be subject to the same regulations as other print or broadcast media promotions. Additionally, the role of the sponsoring pharmaceutical company in developing or supporting the promotional materials should be stated explicitly.
- ix. Direct-to-consumer promotions should not contain implicit or explicit comparative claims between other prescription or nonprescription drugs.
- x. Direct-to-consumer promotion of controlled substances should not be allowed.
- xi. For the present time, ACCP recommends that direct-to-consumer promotions via the Internet be limited to help-seeking ads and that product claim promotions not be allowed. After FDA gains additional experience with regulation of standard print-based media, consideration could be given to allowing product claim ads to be distributed via the World Wide Web.

In summary, the American College of Clinical Pharmacy believes that all reasonable means should be used to better educate patients about their drug therapy. To the extent that it can help in this educational effort, ACCP supports certain forms of regulated direct-to-consumer promotion of prescription drugs. When properly done, such promotions can alert consumers to newly available treatments, encourage people to seek medical advice for conditions that otherwise might go untreated, enhance patient communication with their pharmacist or physician, and encourage healthy life styles. The potential risks of direct-to-consumer advertisements should not be minimized, and we encourage FDA to develop effective, reasonable guidelines in this area.

Again, thank you for this opportunity to comment.

Sincerely,



Robert M. Elenbaas, Pharm.D., FCCP
Executive Director