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Joan Claybrook, President

Public Citizen's Health Research Group's Comments On:

Food and Drug Administration: Attitudinal and Behavioral Effects of Direct-To Consumer Advertising of Prescription Drugs

[Docket No. 98N-0748]

Submitted - September 28, 1998

Since 1972, Public Citizen's Health Research Group has been promoting research-based, system-wide changes in health care policy, as well as advocating for the appropriate prescribing and use of prescription drugs. We testify before Congress and petition the Food and Drug Administration (FDA) on issues such as banning or relabeling of drugs and the misleading advertising of prescription and nonprescription drugs by their manufacturers. Our publications help consumers make informed decisions about the health care they receive and the drugs they are prescribed.

The FDA is soliciting comments on a planned survey to examine consumers' reactions and behaviors that stem from the direct-to-consumer (DTC) advertising of prescription drugs on television and radio and in the print media. The Agency announced its intention to evaluate the effects of DTC advertising in August 1997, when it issued an ill-advised draft guidance allowing drug companies for the first time to produce DTC radio and television commercials promoting prescription drugs.[1] The FDA will use the results of the survey as a source of information to "develop policy on appropriate requirements for disclosure of risk and efficacy information about drugs."

[1]Food and Drug Administration. Guidance for Industry: Consumer-Directed Broadcast Advertisements, August 1997.

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Public Citizen supports a strong research role for the FDA. The Agency can conduct research that the private sector may view as not being in its own best interests. Measuring the impact of DTC advertising on drug prescribing and its economic impact on the health care system are but two examples. Public Citizen is much more confident in the validity and the value of research conducted by an FDA that is open to close public scrutiny by law, in contrast to private sector contracted research, with its inherent conflicts of interest, that can easily blur the boundaries between science and the promotion of corporate self interests.

Public Citizen would like to make two observations concerning DTC prescription drug advertising that we believe are pertinent to the FDA's proposed survey:

1. The public is not protected from deceptive DTC advertising by physician gatekeepers.

2. Drug company censorship has prevented public access to objective prescription drug information for 19 years.

THE PUBLIC IS NOT PROTECTED FROM DECEPTIVE DTC ADVERTISING BY PHYSICIAN GATEKEEPERS

DTC prescription drug advertising is one part of an overall promotional strategy for selling drugs, and the initial thrust of this strategy begins with prescribers. It has been incorrectly assumed that physicians always act as adequate gatekeepers to prevent consumers from receiving inappropriate, or unnecessary, and even dangerous prescription drugs as a result of deceptive advertising. A growing body of research, accumulating since the early 1980s, indicates that some physicians base their prescribing decisions on drug company promotional materials rather than on clinically relevant scientific research. Physicians who are influenced by advertising may, in fact, prescribe inappropriate or dangerous drugs when there are more effective, safer

alternatives available.[2, 3, 4, 5, 6]

Other evidence supporting the position that some physicians are influenced by advertising and thus do not operate effectively as gatekeepers for the public was the prescribing of two new drugs that were recently withdrawn from the market because of serious safety problems; the heart drug mibefradil (Posicor),[7] and bromfenac (Duract),[8] a painkiller. Serious safety problems were known about these drugs before they were cleared for marketing and there were numerous treatment options available to both physicians and patients with drugs in the same classes as mibefradil and bromfenac that were equally or more effective, less expensive, and safer than these drugs. Yet, 200,000 people were prescribed mibefradil and 2.5 million prescriptions were written for bromfenac. Because these were "new" drugs and heavily promoted to physicians, an unknown number of Americans were needlessly killed or injured by mibefradil and bromfenac.

In the case of mibefradil, Hoffman-La Roche, Inc., the drug's manufacturer was cited by the FDA for a medical journal print advertisement that portrayed the safety of the drug in a false and misleading way by saying that mibefradil had an "unparalleled safety profile."[9]

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[2] Avorn J, Chen M, Hartley R. Scientific verses commercial sources of influence on the prescribing behavior of physicians. *American Journal of Medicine* 1982;73: 4-8.

[3] Bowman MA, Pearle DL. Changes in drug prescribing patterns related to commercial company funding of continuing medical education. *Journal of Continuing Education of Health Professionals* 1988;8: 813-820.

[4] Lexchin J. The medical profession and the pharmaceutical industry: an unhealthy alliance. *International Journal of Health Services* 1988;18: 603-616.

[5] Orlowski JP, Wateska, L. The effects of pharmaceutical firm enticements on physician prescribing patterns. *Chest* 1992;102: 270-273.

[6] Siegel D, Lopez J. Trends in antihypertensive drug use in the United States: Do the JNC V recommendations affect prescribing? *Journal of the American Medical Association* 1997;278: 1745-1748.

[7] U.S. Department of Health and Human Services, Food and Drug Administration. FDA Talk Paper: Roche Laboratories Announces Withdrawal of Posicor From the Market, June 8, 1998.

[8] U.S. Department of Health and Human Services, Food and Drug Administration. FDA Talk Paper: Wyeth-Ayerst Laboratories Announces the Withdrawal of Duract From the Market, June 22, 1998.

[9] Letter to Rudolph W. Lucek, Group Director, Drug Regulatory Affairs, Hoffmann-La Roche Inc., regarding the false and misleading promotion of Posicor from Janet Norden, MSN, RN, Regulatory Review Officer, Food and Drug Administration, Division of Drug Marketing, Advertising and Communications dated September 5, 1997.

Coupled with this growing evidence that physician prescribing decisions can be influenced by advertising and surveys that have shown that almost half of direct-to-physician[10] and DTC[11] print prescription drug advertising is misleading, the drug industry's strategy clearly is to: FIRST DUPE THE GATEKEEPER THEN DELUDE THE PATIENT.

An example of duping the gatekeeper and then deluding the patient is the misleading promotion of the nonsteroidal anti-inflammatory drug (NSAID) nabumetone (Relafen), used for arthritis, by SmithKline Beecham Pharmaceuticals to both physicians and consumers.

Nabumetone was first marketed in Ireland in 1985, and was launched in the U.S. in 1992. SmithKline Beecham began claiming that nabumetone caused less gastrointestinal (GI) toxicity, the most common serious adverse effect of NSAIDs, than other drugs in its class.[12] The Clinical Trials Section of nabumetone's FDA approved professional product labeling indicates that nabumetone is no better than aspirin or naproxen (Naprosyn) in the treatment of osteo- or rheumatoid arthritis. Nabumetone's labeling also carries the same GI toxicity class warning as other NSAIDs, and does not indicate any GI safety superiority over other members of the NSAID family of drugs. Nabumetone is also much more expensive than generic naproxen.

SmithKline Beecham began running DTC print ads in *Arthritis Today* magazine, a publication of the Arthritis Foundation, in 1995.[13] Some of these ads read, referring to NSAID GI toxicity, that: "Relafen, however, has been found to have a low potential for such ulcers," implying that nabumetone had less GI toxicity than other NSAIDs. In 1995, SmithKline Beecham committed $11 million to promote nabumetone directly to consumers,[14] and by 1996 nabumetone jumped from the 44th to the 42nd most frequently sold drug in the U.S. with 7.5 million prescriptions being dispensed.[15] In 1997, the FDA's Division of Drug Marketing, Advertising and Communications found that SmithKline Beecham had been conducting a false and misleading promotional campaign aimed at physicians claiming that nabumetone was safer than other

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[10] Wilkes MS, Doblin BH, Shapiro MF. Pharmaceutical advertisements in leading medical journals: experts' assessments. *Annals of Internal Medicine* 1992;116: 912-919.

[11] Drug advertising — Is this good medicine? *Consumer Reports* June 1996: 62-63.

[12] Nabumetone - a new NSAID. *The Medical Letter on Drugs and Therapeutics* 1992;34: 38-40.

[13] Memorandum from Terry Early, The Arthritis Foundation dated June 19, 1998.

[14] Conlan MF. In-your-face pharmacy. *Drug Topics*, July 8, 1996: 92 - 98.

[15] The top 200 drugs. *American Druggist* 1997;214: 30-37.

NSAIDs.[16]

False and misleading advertising was used by SmithKline Beecham to promote nabumetone directly to physicians and consumers. Sales of the drug increased even through equally, or more effective, less expensive, older NSAIDs were available with better understood safety profiles.

Legitimately, the question can be asked did the physicians that prescribed mibefradil, bromfenac, or nabumetone act as adequate gatekeepers to prevent consumers from receiving inappropriate or dangerous drugs? We think not.

DRUG COMPANY CENSORSHIP HAS PREVENTED THE PUBLIC ACCESS TO OBJECTIVE PRESCRIPTION DRUG INFORMATION FOR 19 YEARS

Overarching the potentially serious public health issues surrounding DTC prescription drug advertising is the fact that consumers do not have access to objective information that places the risks and benefits of prescription drugs in a context that can be used to make informed decisions about drug treatments. Drug companies have prevented the FDA from mandating the distribution of useful drug information, in the form of "patient package inserts," written specifically for consumers since 1979.[17] Now, the only written drug information readily available to prescription drug consumers are unregulated patient information leaflets (PILs) distributed by pharmacists that are produced by commercial information vendors. In some cases, these PILs have been found to be dangerously misleading by omitting vital risk information or containing risk information that is out of date.[18]

Without the protection of objective drug information consumers are naked in the pharmaceutical marketplace, subject to the misleading influence of billions of dollars worth of slick advertising, that promotes new drugs, that may be less safe and effective and more expensive than older drugs or non-drug treatments. The drug industry's assertions that 60 second TV commercials "empower" or "educate" consumers, while blocking the distribution of useful consumer drug information for 19 years, is conspicuously immoral.

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[16] Letter to Howard Pien, President, North American, SmithKline Beecham Pharmaceuticals from Minnie Baylor-Henry, R.Ph., J.D., Director, Division of Drug Marketing, Advertising, and Communications, dated March 13, 1998.

[17] *Federal Register* of July 6, 1979 (44 FR 40016).

[18] Public Citizen's Health Research Group. Citizen's Petition to Stop the Distribution of Dangerously Misleading Prescription Drug Information to the Public, filed with the FDA on June 9, 1998.

Public Citizen believes that the FDA's proposed survey will provide interesting baseline data on the effect of DTC advertising on the relationship between consumers and their health care providers. Surveys such as those conducted by Prevention Magazine and Time, Inc., have measured public opinion toward DTC advertising. However, unless those surveyed were exposed to objective, comparative information about the risks and benefits of the drugs being promoted, to gauge the completeness and accuracy of the information contained in a particular DTC ad, the survey can only measure the obvious, that consumers believe that some information about prescription drugs is good, even though it may be false or misleading, and is better than no information at all. Such a result only serves the interests of those who benefit from DTC advertising, ad agencies and drug companies.

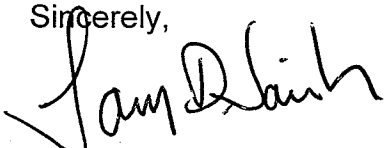
Public Citizen believes that two research questions should be addressed by the FDA. Briefly these are : (1) do consumers opinions about the risks and benefits of prescription drugs, as communicated in DTC ads, change when consumers are presented with objective comparative risk and benefit information about the drugs that are being promoted; and (2) does DTC prescription drug advertising stimulate the sales of drugs that are less effective, more expensive, and with potentially greater risks over older drugs already on the market?

The first question could be addressed by a randomized controlled study. The study group would receive a DTC prescription drug ad, and be asked to evaluate the risk and benefit information content of the ad using a questionnaire. The comparison group would receive the same DTC ad plus objective comparative risk and benefit information about the drug appearing in the ad, and be asked to complete the same questionnaire assessing the risk and benefit information content of the ad. Such a study would provide an insight into the issues of whether current DTC ads fairly balance the risk and benefit information of prescription drugs in the opinion of consumers.

The start of a DTC advertising campaign linked with prescription sales data would address the second question. DTC advertising that stimulates the sales of new drugs in highly competitive classes over older, less expensive drugs with better understood safety profiles in the same classes would suggest that DTC advertising does stimulate the sales of inappropriate or unnecessary drugs. This assumption can be made when there is no comparative efficacy information documenting the therapeutic superiority or safety of new drugs being directly advertised to consumers over older drugs in the same class.

Public Citizen appreciates the opportunity to comment on this topic that is of vital interest to the health of American prescription drug consumers.

Sincerely,



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