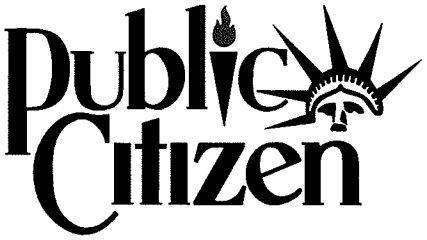

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Joan Claybrook, President

Public Citizen's Health Research Group Comments on the Food and Drug Administration's Draft Guidance for Industry:

Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs)

[Docket No. 97D-0525]

Submitted - April 8, 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. The Health Research Group testifies before Congress and petitions the Food and Drug Administration (FDA) on issues such as banning or relabeling of drugs and the misleading advertising of prescription and non-prescription drugs by their manufacturers. Our publications help consumers make informed decisions about the health care they receive and the drugs they are prescribed.

Our comments will focus on prescription drug promotion to health care professionals and to the public.

Promotion and advertising of prescription drugs, whether done directly by manufacturers or by healthcare organizations and pharmacy benefit management companies (PBMs) for manufacturers, clearly falls under the authority of the Food and Drug Administration (FDA). Rather than issuing this draft guidance for industry and asking for comment the FDA should be vigorously enforcing existing law and regulations relating to the promotion and advertising of prescription drugs.

THE PUBLIC HEALTH RISK OF DRUG ADVERTISING

Public Citizen concurs with the FDA, as the agency stated in this draft guidance, that drug companies' promotional activities may create a public health risk. When physicians and consumers are persuaded to use new drugs with unproven health benefits the quality of healthcare is lowered when the use of older drugs that have been shown in rigorous clinical trials to improve health outcomes are declining.

Ralph Nader, Founder
1600 20th Street NW • Washington, DC 20009-1001 • (202) 588-1000

For example, in the drug treatment of high blood pressure, recent research has linked drug advertising with the increasing use of newer antihypertensive drugs, drugs without conclusive evidence of a health benefit, and the declining use of older drugs that have a well documented benefit of reducing the risk of heart attack and stroke when used to treat hypertension.[1]

NEW SCHEMES — THE SAME RISKS

Fierce competition in the drug industry has resulted in manufacturers creating new schemes to sell more drugs by influencing the decisions of both health professionals and consumers. A recent report by the Office of Inspector General was concerned that PBMs, either owned by or in partnership with drug companies, have used drug formularies, drug use review programs, so called educational interventions to health professionals and patients, and cost-effectiveness research as new platforms for drug promotion and advertising.[2]

A recent series of articles appearing in *The Washington Post* described another scheme for promoting prescription drugs directly to consumers.[3] Drug companies in an arrangement with CVS Corporation and Giant Food Incorporated, two large Washington DC area drug chains, used confidential prescription drug information and Elensys, a Woburn MA marketing firm, to directly target consumers with drug ads. In some instances these drug chains sent letters to consumers urging them to ask their doctors to change to another drug. Other letters were claimed to be "refill reminders" done as a public service by the drug chain, but were nothing more than ads paid for by drug companies to influence consumers to stay on a drug even when safer or more effective alternatives were available. The only beneficiaries of these activities were the drug companies that paid for the mailings and the pharmacies, not the public.

LEVELING THE INFORMATION PLAYING FIELD FOR CONSUMERS

In this draft guidance, the FDA is concerned in maintaining "a level playing field" for the drug industry with respect to the regulation of their promotional activities. The agency should pay more attention to leveling the information playing field for prescription drug consumers by first doing something it should have done years ago, proposing direct-to-consumer (DTC) prescription drug advertising regulations. Because of pressure from the industry through professional trade groups such as the American Medical Association, the American Pharmaceutical Association, and the American Society of Health-System Pharmacists, consumers have been prevented from having access to high quality objective information about the risks and benefits of prescription drugs written in non-technical language.

To level the information playing field for consumers, the FDA must require the following box warning on all drug company sponsored materials intended for distribution to consumers. This would include, but not be limited to print ads or so-called educational materials intended for consumers, and prescription refill reminders paid for

by drug companies.

THESE MATERIALS ARE A PAID ADVERTISEMENT BY THE MANUFACTURER. OTHER DRUGS OR NON-DRUG TREATMENTS MAY BE SAFER OR MORE EFFECTIVE FOR THE CONDITION FOR WHICH YOU ARE BEING TREATED. DISCUSS THESE OTHER OPTIONS WITH YOUR PHYSICIAN.

CONCLUSION

Drug companies only inform the public about their products in a manner that is in their own economic interest. This information is not intended to educate consumers about the safe and effective use of drugs, but only to sell more drugs. All activities such as those described above are intended to increase drug sales, whether done directly by a drug's manufacturer or in partnership with a healthcare organization, a PBM, a pharmacy, or other third parties, are nothing but advertising and fall under existing FDA authority.

Sincerely,

Larry D. Sasich, Pharm.D., M.P.H., FASHP
Research Analyst,
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.
Director,
Public Citizen's Health Research Group

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