

Testimony of Sidney M. Wolfe, MD
Director, Public Citizen's Health Research Group
Senate Commerce Committee
Subcommittee on Consumer Affairs
Hearing on Direct-to-Consumer (DTC) Advertising
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Because of the strong First Amendment in the U.S constitution, there is no way that DTC prescription drug advertising could ever be banned in this country. Having said that, however, there is an urgent need for more fine-tuned, better-staffed and much tougher government regulation of its content. There is little doubt that false and misleading advertising to patients and physicians can result in prescriptions being written for drugs that are more dangerous and/or less effective than perceived by either the doctor or the patient. This can then lead to a subsequent toll of deaths and injuries that would not have occurred had safer, more effective drugs been prescribed.

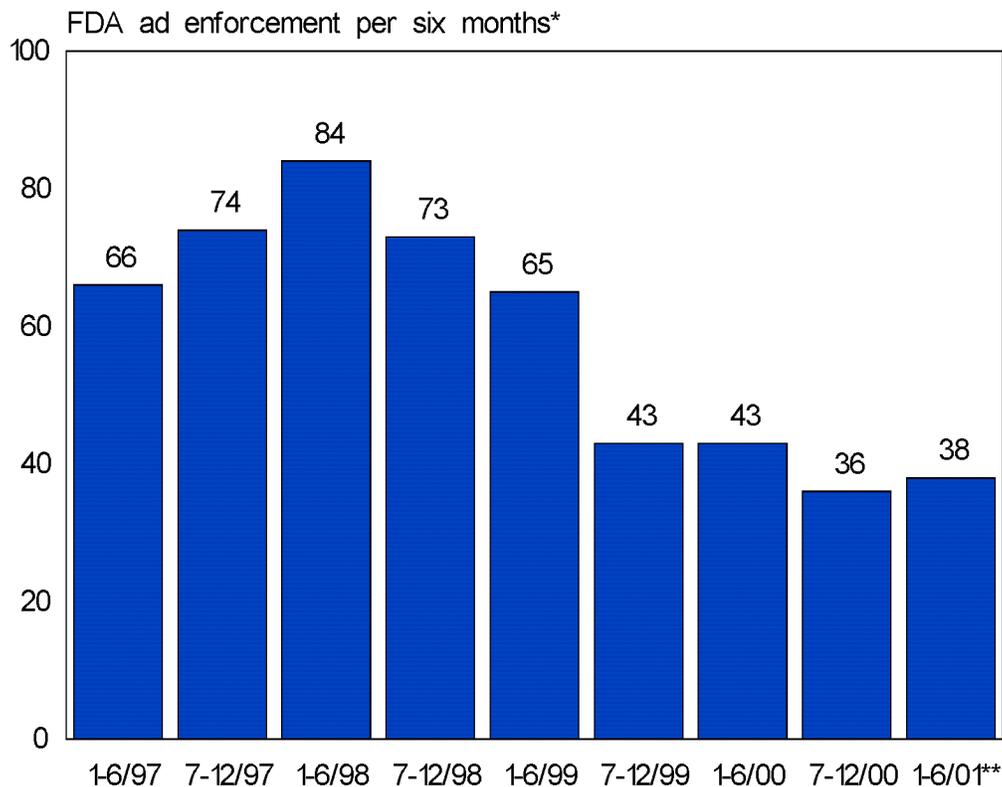
The more than 500 prescription drug advertisements that have been found by the FDA to violate federal laws and regulations from 1997 through the present include approximately 90 DTC ads. These numbers would be significantly larger if FDA's DDMAC (Division of Drug Marketing Advertising and Communication) had more staff to investigate the rapidly expanding area of DTC drug promotion. Such advertising has more than tripled in dollar volume from \$791 million in 1996 to \$2.5 billion in 2000. But the number of FDA staff assigned to reviewing and investigating all of prescription drug advertising, during the same interval, has only increased from 11 in 1996 to 14 at present. I have been informed that there is, or will shortly be, an increase in DDMAC staff to monitor such advertising and it comes none too soon. Even this may well not be adequate.

As seen in the table on the next page, there has been a sharp and steady decrease during the last three years in the number of FDA warning letters and notices of violation of FDA laws and regulations to drug companies concerning prescription drug advertising. From a peak of 84 such enforcement actions during the first six months of 1998, the number has fallen steadily to 36 FDA actions during the last six months of 2000 and an estimated 38 actions during the first six months of 2001.

For the last year (mid-2000 through mid-2001) the total number of DDMAC advertising enforcement actions—74—was less than one-half (47%) of the 158 enforcement actions taken three years ago (mid-1997 through mid-1998). There is no evidence of an advertising/pharmaceutical industry epiphany, resulting in fewer illegal advertisements for prescription drugs. Therefore, the only plausible explanation for this dangerous decrease is that the police force---DDMAC--- has not been strong enough in numbers of investigators along with a lack of adequate pro-enforcement leadership from the top officials in FDA. That this latter explanation,

inadequate enforcement, is correct will be seen when the FDA, with the urging and support of your committee, begins to increase the number of actions taken against these violative ads. Until then, Americans--both physicians and patients---will be harmed by prescribing decisions about which drugs to use based on all-too-frequently false and misleading information from advertisements which are much less likely to be stopped because of poorer enforcement by the FDA.

Decreased FDA Enforcement of Prescription Drug Advertising 1997 through mid-2001



*FDA notice of violation/warning letters by date of letter ** extrapolated from data thru mid-June

In addition to more staff, there is a dire need for DTC-specific regulations since, other than the late 1990's guidance concerning TV advertising---which is a guidance not a regulation---there are no regulations specifically written for DTC advertising. The FDA has been using the regulations promulgated after the 1962 Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act that were clearly intended for prescription drug advertising directed at health professionals such as doctors and pharmacists. We have been urging the agency since the mid-1980s to propose and finalize such consumer specific DTC regulations that would make it

easier to evaluate the ads in the context of patient, not health professional, comprehension. Beyond more staff and DTC-specific regulations there is a need for much more enforcement power. At present, the FDA is limited to a Notice of Violation or Warning Letter to companies found to violate the law or regulations. Theoretically, in the face of multiple warnings to the same company, criminal prosecution is a possible tool. This latter power has only been used a handful of times in the past 35 years. To our knowledge, criminal prosecution has never been used in the context of DTC advertising, despite, for example, a series of 11 illegal ads for Claritin (8 DTC), 14 illegal ads for Flonase/Flovent (8 DTC). (Flonase and Flovent are the same drug in two versions, one used for allergy, the other for asthma). There have also been five illegal ads for Celebrex (1 DTC).

The ability to assess drug companies large civil monetary penalties for advertising violations might actually serve as a deterrent for companies who now just stop the violative ad, when requested by the FDA, then create and massively disseminate a new one shortly thereafter. The FDA currently lacks the authority to impose any civil penalties for drug advertising or, in fact, for any other illegal drug industry activity concerning prescription drugs. It is long overdue that the Congress give the FDA this authority.

A search of the peer-reviewed, published medical studies concerning DTC advertising yields findings that, for the most part, are also quite worrisome:

- In one study, researchers found that consumers rated the safety and appeal of drugs described with an incomplete risk statement significantly more positively than those whose risks were described more completely.¹ (This has significant implications since so many DTC ads understate the safety of drugs.)
- Another study found that consumer beliefs that there was prior scrutiny of DTC ads by the FDA and that they were held to higher standards than other ads were generally wrong. A substantial proportion believed that only the safest and most effective drugs could be advertised DTC and that the FDA required prior review of ads. DTC ads led one-fifth of people to request a prescription.²
- A study on the educational content of DTC ads found that while many ads provided information about the name and symptoms of the disease for which the drug was being promoted, few educated the patients about the success rate of the drug, how long you had to use the drug, alternative treatments including behavioral changes which could improve their health, or misconceptions about the disease. The authors concluded that the ads

¹ J Health Commun 2000 Oct-Dec;5:349-69.

² J Gen Int Med 1999;14:651-7.

provided only a minimal amount of educational information.³

- One study asked patients what they would do if a doctor refused to prescribe a drug that the patient wanted as a result of a DTC ad. One-fourth of patients said they would seek a prescription elsewhere and 15% said they would consider terminating their relationship with their physician. The patients with these attitudes were ones who had a more favorable evaluation of DTC advertising and who possessed more faith in the current government regulation of DTC drug ads.⁴

In summary, FDA resources and specific regulatory authority to monitor the accuracy of drug safety and effectiveness portrayed in DTC ads are dangerously inadequate and many patients' perceptions of the ads and their subsequent response to the "information" therein is similarly dangerous. The present situation concerning DTC advertising is unacceptable and it is our hope that your committee will initiate actions to remedy these serious problems.

³ J Fam Pract 2000;49:1092-8.

⁴ J Fam Pract 1999;48:446-52.