October 1, 2002

The Honorable Tommy G. Thompson
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Thompson:

Under the Bush Administration, there has been a 70% reduction in FDA enforcement actions against false and misleading drug advertisements, despite the fact that the number of ads submitted to FDA has increased significantly. This precipitous drop in enforcement actions may be a welcome development for the drug industry, but it poses serious dangers to public health. I urge you to direct FDA to reverse course and resume effective enforcement of the provisions of the Federal Food, Drug, and Cosmetic Act that prohibit false and misleading drug advertisements.

Background

In recent years, spending on pharmaceutical advertising and promotion has increased dramatically, almost doubling between 1996 and 2001.[1] This spending has led to increases in drug use and expenditures, as consumers have demanded access to heavily advertised drugs. In fact, a recent study found that half of the $20.8 billion increase in drug spending in 2000 was attributable to increased sales of the 50 drugs most heavily advertised to consumers.[2]

There is an ongoing debate about whether this increase in drug advertising is in the public interest. The pharmaceutical industry and other proponents of increased advertising argue that this advertising helps educate consumers about important health problems, leading to more

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[1]M.B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers*, New England Journal of Medicine, 346 (Feb. 14, 2002); NDC Health, *PharmaTrends: 2001 Year in Review* (2002).

[2]National Institute for Health Care Management Research and Education Foundation, *Prescription Drugs and Mass Media Advertising, 2000* (November 2001).

informed medical decisions. On the other side, doctors and health providers who have concerns about excessive drug advertising argue that it can unnecessarily increase health care costs and jeopardize patient health.

There is no debate, however, about the importance of ensuring that drug advertising is not false or misleading. There is a broad consensus that FDA has a vital role to play in ensuring that drug manufacturers accurately describe the potential benefits and the potential side effects of their products, especially when communicating with the general public.

Under the Federal Food, Drug, and Cosmetic Act and its implementing regulations, drug manufacturers must submit copies of all drug advertisements to FDA at the same time that the manufacturer first disseminates the ad. FDA then reviews the advertisements to determine whether they comply with the Act, which prohibits false or misleading claims by drug manufacturers. If the advertisement is false or misleading, FDA sends the manufacturer a "Notice of Violation" letter, informing the manufacturer of the problem and requesting that the advertisement be stopped. Drug manufacturers typically comply with the Notice of Violation letters, but if they do not, FDA's next step is to send a "Warning" letter demanding that the advertisement be stopped immediately and that the manufacturer conduct a remedial campaign to correct the inaccurate impressions. If the manufacturer still refuses to comply, FDA can seek an injunction against the company.

Until recently, FDA actively sought to fulfill this responsibility. In past years, FDA sent numerous "Notice of Violation" and "Warning" letters to drug manufacturers. In the three-year period between January 1999 and December 2001, FDA sent over 250 of these letters to drug manufacturers. FDA cited serious problems with advertisements such as failing to adequately inform patients and health professionals of potentially lethal side effects or contraindications, making false claims about the effectiveness of the drugs, and promoting drugs for unapproved uses.

The Drop in Enforcement Actions

Starting in December 2001, however, drug advertising enforcement by FDA has dropped precipitously. It appears that FDA is now granting major drug manufacturers virtually a free pass, rarely issuing "Notice of Violation" or "Warning" letters for drug advertising.

Between December 1, 2001 and September 1, 2002, there have been only 19 "Notice of Violation" and "Warning" letters sent to drug manufacturers, an average of only two per month. This represents a reduction in enforcement activity of over 70%.

Enforcement has declined for both direct-to-consumer advertisements and for promotions aimed at doctors. The largest decline in enforcement actions involves the advertisements and

promotions aimed at doctors. Relative to 1999–2001, the number of advertisements and promotions directed at doctors has increased by almost 20% in 2002.[3] But the number of FDA citations for these promotions has declined by almost 80%.

The number of direct-to-consumer advertisements on television and radio being submitted to FDA for review has risen by 75% in 2002 compared to 1999–2001.[4] But despite this 75% growth in the number of ads, FDA enforcement actions have declined by almost 50%.

Another way to view the decline in enforcement activity is to consider the number of enforcement actions compared to the number of complaints received by FDA regarding false or misleading advertisements. There has been no significant change in the number of complaints received by FDA, but there has been a large decline in the number of enforcement actions initiated by FDA per complaint received. According to FDA data, between 1999 and 2001, FDA received a total of 715 complaints from health care professionals, consumers, and drug companies regarding the promotion of prescription drugs.[5] During these years, the agency sent a total of 253 "Notice of Violation" or "Warning" letters — one letter for every 2.8 complaints. In the first six months of 2002, FDA received a total of 111 complaints, but issued only eight "Notice of Violation" or "Warning" letters — one letter for every 13.5 complaints.

In the rare instances when FDA does initiate enforcement actions, these actions are often not timely. For example, in August 2002 the FDA sent TAP Pharmaceuticals, the manufacturer of Prevacid, a "Warning" letter because of concerns about a false and misleading television advertisement for the drug. This letter was sent five months after the ad was submitted to FDA. Similarly, in May 2002 FDA issued a "Warning" letter in response to a false and misleading radio advertisement for the flu medication Tamiflu. This letter was sent after the end of the flu season, two and a half months after the advertisement was first submitted to FDA.

This delay in enforcement has serious consequences. Prior to 2002, enforcement letters in response to direct-to-consumer advertisements were typically sent within a month of submission. For example, in 2000 the average time between the submission of direct-to-consumer broadcast ads and a response by FDA in the form of a "Warning" or "Notice of Violation" letter was 19 days.[6] The result of the delays under the new policy is that millions of

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[3]FDA, *Number of Promotional Pieces Received by DDMAC* (Sept. 20, 2002).

[4]FDA, *DTC Broadcast (TV/Radio) Ads Submitted to DDMAC* (September 2002).

[5]FDA, *Number of Complaints About Promotions Received by DDMAC* (Sept. 20, 2002).

[6]E-mail communication from FDA to Minority Staff, Committee on Government Reform (Sept. 26, 2002).

consumers are exposed to false or misleading advertisements for months before the advertisements are finally withdrawn.

The November 2001 Change in Policy

The dramatic decline in enforcement actions for prescription drug advertising and promotion dates to November 2001. At this time, under the guidance of new appointees to FDA, the procedures used by FDA to cite manufacturers for false and misleading advertisements were changed. My staff has obtained a copy of these new procedures, entitled "Procedures for Clearing FDA Warning Letters and Untitled Letters."[7]

Under the new policy, all "Notice of Violation" and "Warning" letters must be reviewed by FDA's Office of Chief Counsel and are to be sent only if approved by the Chief Counsel. Specifically, the policy provides that the Chief Counsel will "review all Warning Letters and Untitled Letters prior to their issuance, for legal sufficiency and consistency with Agency policy."[8] Prior to the adoption of this policy, the vast majority of these letters were sent directly by the FDA Division of Drug Marketing, Advertising, and Communications (DDMAC), the FDA office responsible for advertising enforcement, without review by the Office of Chief Counsel. And if enforcement letters were sent to the Office of Chief Counsel prior to their issuance, they were reviewed in an expeditious fashion.

The new policy received little attention when it was issued. Some FDA observers, however, predicted a significant change in FDA enforcement actions. For example, one former FDA enforcement official said that the policy could "gut the operation" by adding months of delay.[9] Dr. Sidney Wolfe of the consumer group Public Citizen predicted that the policy would have "a chilling effect on the issuance of future Warning Letters."[10]

The concerns about the new policy were exacerbated by the appointment of Daniel Troy as the new FDA Chief Counsel by President Bush in August 2001. Prior to his appointment, Mr. Troy had represented plaintiffs in industry-supported cases that challenged FDA's authority to

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[7]FDA, *Procedures for Clearing FDA Warning Letters and Untitled Letters* (December 2001). "Untitled letters" is another name for "Notice of Violation" letters.

[8]*Id.*

[9]*FDA Chief Counsel to Screen All Warning Letters*, FDA Webview (Dec. 5, 2001).

[10]*Id.*

regulate advertising.[11] Moreover, Mr. Troy publicly urged judicial intervention to "rein in" FDA's "overzealous" restrictions on drug advertising.[12]

It now appears that the November 2001 policy has had the "chilling effect" on FDA enforcement that was predicted last year.

The Views of Independent Experts

Independent experts consulted by my staff have voiced serious concerns about the sharp decline in FDA enforcement actions. These experts did not believe that the decline could be attributed to an improvement in the veracity of drug company advertisements. According to Dr. Michael Wilkes, Vice Dean of Medical Education at the University of California at Davis School of Medicine:

> Despite the fact that the number of [direct-to-consumer] drug ads continues to rise, there is no evidence of an improvement in the quality or accuracy of the ads. Further, there is absolutely no evidence that the public's health or their understanding of their health has improved as a result of these promotional messages.[13]

According to Barbara Mintzes of the University of British Columbia:

> I have not seen any evidence of an increase in quality and overall veracity of pharmaceutical advertisements in the last year. The violations cited by FDA thus far are similar qualitatively to other violations during the previous few years, and involve presentations of misleading and inaccurate information, promotion of unapproved indications, etc.[14]

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[11] *Washington Legal Found. v. Friedman,* 13 F. Supp. 2d 51 (D.D.C. 1998); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001).

[12] Daniel E. Troy, *FDA Censorship Could Cost Lives*, Wall Street Journal (July 23, 1999).

[13] E-mail communication from Dr. Michael Wilkes to Minority Staff, Committee on Government Reform (Sep. 23, 2002).

[14] Letter from Barbara Mintzes, University of British Columbia, to Rep. Henry A. Waxman (Sept. 20, 2002).

In fact, Ms. Mintzes cited several recent examples of advertisements of questionable legality for popular drugs, including Viagra and Sarafem, that have not been subject to FDA action.[15]

Dr. Richard Kravitz of the University of California at Davis also indicated that he did not believe that "the steep decline in FDA letters . . . is due to an improvement in the quality of either DTC or physician-directed advertising.[16] Other experts have expressed similar views to my staff.

Conclusion

A pattern of FDA actions that benefit regulated industries but jeopardize public health is emerging. In March of this year, FDA announced an initiative to suspend regulations relating to pediatric testing of prescription drugs.[17] This proposal, which would have halted FDA's authority to require that drug manufacturers test their products to determine if they are safe and effective for children, was abandoned only after sustained congressional and public pressure. More recently, FDA has developed plans to essentially deregulate colored contact lenses, a move that would end manufacturing standards and professional oversight and would seriously endanger children's health.[18] FDA has even initiated a review of its legal authority to consider whether it should further weaken the agency's ability to prevent false and misleading advertisements for drugs and medical devices.[19]

The failure of FDA to initiate enforcement actions involving drug advertising is part of this unfortunate pattern. It is a development that benefits the powerful pharmaceutical industry at the expense of consumers. It will lead to wasted drug expenditures if consumers insist on being prescribed drugs that are unnecessary or if doctors are influenced by false or misleading ad campaigns. Even worse, patient health will be jeopardized when vital information about side effects or contraindications is not disseminated by drug manufacturers.

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[15] *Id.*

[16] Letter from Dr. Richard Kravitz, University of California at Davis, to Rep. Henry A. Waxman (Sep. 18, 2002).

[17] *FDA to Suspend a Rule on Child Drug Testing: Agency Says Patent Plan Meets Safety Goal,* Washington Post (Mar. 19, 2002).

[18] *Health Concerns Tinge Use of Cosmetic Lenses*, Los Angeles Times (Aug. 26, 2002).

[19] *Looser Lips for Food and Drug Companies?* Wall Street Journal (Sep. 17, 2002).

I urge you to intervene personally to ensure that FDA resumes effective enforcement of the federal prohibition on false and misleading drug advertisements.

Sincerely,

Henry A. Waxman
Ranking Minority Member