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FDA ENFORCEMENT ACTIONS AGAINST FALSE AND MISLEADING PRESCRIPTION DRUG ADVERTISEMENTS DECLINED IN 2003

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TABLE OF CONTENTS

Executive Summary i

I Background 1

II. Objective and Methodology 2

III. Findings 3

A. FDA's Enforcement Actions against False and Misleading Drug Advertising Continue to Decline 3

B. Enforcement Delays Appear to Be Increasing 3

C. FDA Actions Have Little Deterrent Effect 4

IV. Conclusion 5

EXECUTIVE SUMMARY

In October 2002, Rep. Henry A. Waxman released a report on FDA regulation of drug advertising under the Bush Administration. The report found that FDA enforcement actions for false and misleading drug advertising dropped significantly in the first two years of the Administration. A GAO report released soon after Rep. Waxman's analysis reached similar conclusions.

In response to these reports, the newly appointed FDA Commissioner, Mark McClellan, pledged more aggressive enforcement of the law in 2003, promising to take stronger enforcement actions and to reduce the delays in responding to false and misleading advertisements.

This report assesses whether FDA has in fact increased enforcement of the prohibition on false and misleading drug advertising, as Commissioner McClellan pledged. It finds the opposite: the number of FDA enforcement actions against false and misleading drug advertising continued to decline in 2003, while enforcement delays increased. The report finds:

- **FDA enforcement of provisions barring false and misleading advertisements continued to decline.** The number of enforcement actions initiated by FDA in response to false and misleading advertisements fell in 2003. In total, the number of enforcement actions initiated by FDA in 2003 was 75% lower than the average number initiated during the last years of the Clinton Administration. In all of 2003, FDA initiated only 24 enforcement actions in response to false and misleading advertisements by drug manufacturers.

- **FDA's responses to false and misleading advertisements were not timely, and delays increased.** When FDA did initiate an enforcement action in 2003, the action was often unduly delayed. In 2003, the average delay between ad placement and FDA action was 177 days — almost six months. This is a significant increase in delay compared to 2002. In one case, FDA did not send a "warning" letter until over one year after the suspect advertisement first appeared. In another case, where FDA found that an ad for the addictive drug Oxycontin "grossly overstate[d] the safety" of the medication, the agency did not send a warning letter until three and a half months after the ad first appeared.

- **The few actions taken by FDA have little deterrent effect.** The enforcement actions that FDA took in 2003 were restricted to sending letters to drug manufacturers warning the manufacturer to cease using an advertisement. Although FDA has the authority to take stronger actions with more deterrent effect, such as bringing a court action seeking an injunction or ultimately a fine against a manufacturer, FDA initiated no such actions in 2003.

BACKGROUND

The Food, Drug and Cosmetic Act prohibits "false and misleading" advertisements for drugs.[1] It also establishes requirements that prescription drug advertisements contain true statements regarding the side effects, effectiveness, and proper or improper uses of the drug.[2] The Food and Drug Administration (FDA) is responsible for enforcing these legal provisions.

Traditionally, FDA has used letters and legal actions to ensure that drug advertisements are not false or misleading. When presented with advertisements or promotions that contain false or misleading claims, FDA's first course of action is to send the manufacturer a "notice of violation" letter, which informs the manufacturer of the problem and requests that the advertisement or promotion be stopped immediately. If the drug manufacturer does not comply, FDA has historically sent a formal "warning" letter to the company, demanding that the advertisement or promotion be stopped immediately and that the manufacturer conduct a remedial campaign to correct the inaccurate impressions. If a manufacturer continues to refuse to comply or has a history of violations, FDA can initiate a court action seeking an injunction, or ultimately fines, against the manufacturer.

During the first two years of the Bush Administration, enforcement of the prohibition on false and misleading drug advertising dropped significantly. In October 2002, a study for Rep. Waxman by the Special Investigations Division found that FDA's enforcement activity declined by 70% between December 1, 2001, and September 1, 2002. The cause of this drop in enforcement actions appeared to be a November 2001 change in agency policy that required FDA's Chief Counsel to approve enforcement actions.[3] Prior to this policy change, career officials at FDA's Division of Drug Marketing, Advertising, and Communications had been responsible for sending "notice of violation" and "warning" letters to drug manufacturers.

The Special Investigations Division analysis was followed by a report by GAO in October 2002. GAO found similar flaws in FDA's enforcement of drug advertising, criticizing FDA for its inability to respond to false and misleading advertisements in a timely fashion. GAO also criticized FDA for its inability to

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1 Federal Food, Drug, and Cosmetic Act, § 502(a).

2 Federal Food, Drug, and Cosmetic Act, § 502(r).

3 Letter from Rep. Henry A. Waxman to Tommy G. Thompson (Oct. 1, 2002).

deter manufacturers from repeatedly running false and misleading advertisements.[4]

In response to these concerns, FDA Commissioner Mark McClellan, who was appointed by President Bush in November 2002, promised to strengthen FDA enforcement efforts. In a letter to Rep. Waxman, Commissioner McClellan stated that the agency had moved "towards a risk-based enforcement strategy designed to achieve effective deterrence through use of warning and untitled letters that are more clearly designed to serve as a basis for further enforcement actions."[5] This letter stated that "firms that commit repeated violations will face a much stronger basis for further enforcement actions."[6] The letter also stated that the FDA Office of the Chief Counsel would establish a goal of completing reviews of regulatory letters within 15 days.[7]

In August 2003, FDA promised to develop new guidance to assist manufacturers in complying with provisions barring false and misleading advertising.[8] According to Commissioner McClellan, the guidance was being developed because "I don't want to just play whack-a-mole with ads. To deter misleading ads in the first place, to provide a clear basis for enforcement activities, and to help make sure patients get an accurate picture of risks and benefits of a drug, we need positive, clear guidance" on what is acceptable in prescription drug advertisements.[9]

OBJECTIVE AND METHODOLOGY

Rep. Henry A. Waxman, the ranking member of the House Committee on Government Reform, requested this report to evaluate whether FDA improved its response to false and misleading drug advertisements in 2003, as Commisioner McClellan pledged. The analysis in this report is based on publicly available information on enforcement actions taken by FDA against false and misleading advertisements, as well as additional information obtained from FDA. This report

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4 GAO, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations* (Oct. 2002) (GAO-03-177).

5 Letter from Mark B. McClellan to Rep. Henry A. Waxman (Mar. 31, 2003).

6 *Id.*

7 *Id.*

8 *New Guidance for DTC Ads Expected by Year's End*, Wall Street Journal (Aug. 29, 2003).

9 FDA Commissioner Mark B. McClellan, *Meeting New Threats With Toughened Enforcement Standards*, Speech at the National Press Club (Aug. 8, 2003).

contains the first analysis of FDA enforcement of drug advertising regulations in 2003.

FINDINGS

FDA's Enforcement Actions against False and Misleading Drug Advertising Continue to Decline

After declining dramatically in 2002, FDA enforcement activities involving prescription drug advertising declined even further in 2003. In 2002, FDA sent drug manufacturers 27 letters in response to false and misleading advertisements, an average of 2.25 per month. But in 2003, FDA sent only 24 such letters to drug manufacturers, an average of only 2.0 per month. This represents an additional decline of almost 15%.

In 1999 and 2000, the last two years of the Clinton administration, FDA sent an average of 95 enforcement letters per year to drug manufacturers for false and misleading advertisements. The number of enforcement letters sent by the Bush Administration in 2003 is 75% below the average level of the last two years of the Clinton Administration.

The continuing decline in FDA enforcement actions cannot be explained by either a decline in the number of drug advertisements or a decline in the number of complaints about drug advertisements received by FDA. Overall, FDA reviewed a monthly average of over 3,200 drug promotional pieces in 2003, an increase of 6% over 2002.[10] Moreover, there was no decline in the number of complaints about false and misleading advertisements submitted to FDA.[11] In 2002, FDA cited one advertisement for every seven complaints submitted to the agency. But in 2003, the citation rate declined to one citation for every eight complaints submitted to FDA.

Enforcement Delays Appear to Be Increasing

Both the Special Investigations Division and GAO found in their October 2002 reports that FDA delays in responding to false and misleading advertisements were excessive. GAO, for example, found that for "warning" letters issued

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[10] Through August 31, 2003, FDA had reviewed 25,990 drug promotions, or 3,249 per month. On an annual basis, this is equivalent to 36,717 drug promotion reviews. Electronic mail from FDA to Government Reform Committee, Minority Staff (Sept. 25, 2003).

[11] *Id.*

between March and July 2002, the average delay between the ad placement and the FDA letter was 41 days.[12]

For this report, the Special Investigations Division obtained the initial date of placement for 14 of the 24 advertisements that were cited by FDA in 2003. In these cases, the average delay between ad placement and FDA citation was 166 days — over five months. For direct-to-consumer advertisements, the average delay in response was 177 days, almost six months.

In one case, a "warning" letter in response to a misleading direct-to-consumer advertisement for the cancer drug Taxotere was sent more than one year after the first appearance of the ad. In this case, Aventis, the manufacturer of the drug, began running the direct-to-consumer advertisements in October 2002. It was not until November 2003, however, that FDA issued a "warning" letter citing Adventis for making misleading effectiveness claims and omitting or minimizing important risk information.

In the case of Xeloda, a drug used to treat breast cancer, FDA waited over seven months before citing the manufacturer, Hoffman-LaRoche, for failing to present risk information regarding "serious, potentially life-threatening risks." In two other cases, involving false and misleading promotions for the drugs Nutropin and Quixin, the FDA citations did not arrive until at least ten months after the promotional activity was started.

FDA even delayed its response when the drug involved was the addictive painkiller Oxycontin. In January 2003, FDA cited Purdue Pharma, the manufacturer of Oxycontin, for advertisements that "grossly overstate the safety profile of Oxycontin" by failing to include information on "the potentially fatal risks associated with the use of Oxycontin and the abuse liability of Oxycontin." This warning letter came three and a half months after the ads initially ran.

The Oxycontin delay stands in stark contrast to the actions of the Clinton Administration. In May 2000, the Clinton Administration cited Purdue Pharma was cited for advertisements that overstated the effectiveness of the drug, and presented a misleading safety profile. This citation came only one week after the ads initially ran.

FDA Actions Have Little Deterrent Effect

When FDA took enforcement actions in 2003, the actions had little deterrent effect. Although FDA has the authority to bring judicial enforcement actions to obtain fines or court injunctions against drug manufacturers, FDA initiated no

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[12] GAO, *supra* note 4.

such court actions in 2003. Instead, the only enforcement actions taken by FDA in 2003 were to send letters to drug manufacturers. Of the 24 enforcement letters the agency sent in 2003, 18 were "notice of violation" letters, the lowest level of agency response, and six were "warning" letters.

In his letter to Rep. Waxman, FDA Commissioner McClellan promised that "firms that commit repeated violations" would face enhanced enforcement actions.[13] This has not occurred. Even manufacturers who were repeatedly cited for false and misleading advertisements faced no judicial actions in 2003. Novartis was cited four times for false and misleading advertisements between November 2002 and April 2003. Pfizer was cited for four false and misleading advertisements in 2002 and for two additional false and misleading advertisements in 2003. GlaxoSmithKline, Berlex, and Hoffman-LaRoche were also cited in both 2002 and 2003. FDA did not, however, institute any legal action against these manufacturers in 2003 beyond sending them either a "notice of violation" or a "warning" letter.

Other promises by FDA officials regarding enforcement have also not been fulfilled. In August 2003, FDA said that the agency would soon publish new guidance for drug manufacturers to ensure that standards for advertisements were clear and unambiguous.[14] This guidance has not yet been published.

CONCLUSION

Despite pledges by FDA that the agency would take a more aggressive approach to enforcing the prohibition on false and misleading drug advertising, FDA drug enforcement activities continued to decline in 2003. FDA enforcement activities involving false and misleading drug advertising dropped by 75% in 2003 compared to levels at the end of the Clinton Administration. Delays in response time also increased significantly in 2003.

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[13] Letter from Mark B. McClellan, *supra* note 5.

[14] *New Guidance for DTC Ads Expected by Year's End*, *supra* note 8; FDA Commissioner Mark McClellan, *supra* note 9.