MINORITY STAFF
COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES
FEBRUARY 2005

The Decline in FDA Enforcement Efforts

FDA is responsible for enforcing the federal laws that ensure the safety of food and drugs and prohibit false and misleading advertisements. In recent years, however, FDA enforcement of these provisions has declined significantly. These declines coincide with the tenure of Dr. Lester Crawford, who was appointed as Acting Commissioner of the FDA in February 2002.[1]

Drug Advertising. The Federal Food, Drug and Cosmetic Act prohibits prescription drug manufacturers from promoting their products in a false and misleading fashion. Beginning in December 2001, however, there has been a marked decline in enforcement actions taken against drug manufacturers for illegally promoting their products. FDA data show:

- **FDA enforcement against false and misleading advertisements has declined in the last three years.** In the three-year period from January 1999 through December 2001, FDA sent over 250 Notice of Violation or Warning letters to manufacturers regarding false or misleading advertisements. In the following three years, from 2002 through 2004, FDA sent only 75 such letters. This represents a decline of 70%. Figure 1.

- **The enforcement declines occurred despite dramatic increases in prescription drug advertising.** The significant drop in advertising enforcement activities cannot be explained by a drop in drug advertising or in complaints to FDA. Overall industry promotional spending increased from $15.7 billion in 2000 to $25.3 billion in 2003, a 61% increase. There also has been no change in advertising complaints that could explain the drop in enforcement actions. FDA received 187 complaints regarding prescription drug advertising in 2003, compared to 212 in 2001.

- **In the rare cases where FDA took action against drug manufacturers in recent years, there were long delays.** When FDA did take enforcement action in 2003, the average delay between the placement of a false and misleading advertisement and the FDA action was 177 days.[2] In one case, FDA action did not take place until over one

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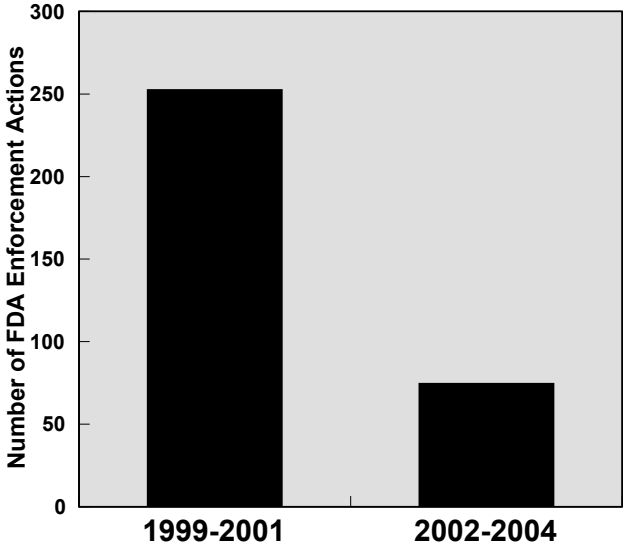
1 Dr. Lester Crawford has served at FDA for the last three years. From February 2002 through November 2002, he was Acting Commissioner. From November 2002 to February 2004, he was Deputy Commissioner. In February 2004, President Bush again named him Acting Commissioner.

2 House Committee on Government Reform, Minority Staff, *FDA Enforcement Actions against False and Misleading Drug Advertisements Declined in 2003* (Jan. 2004).

Figure 1: FDA Enforcment Against False and Misleading Advertising Has Declined in Recent Years



year after the false advertisement was submitted to FDA. In another case, where FDA found that an ad for the highly 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. In contrast, in earlier years, FDA routinely sent letters within days or weeks of the submission of the false or misleading advertisement.

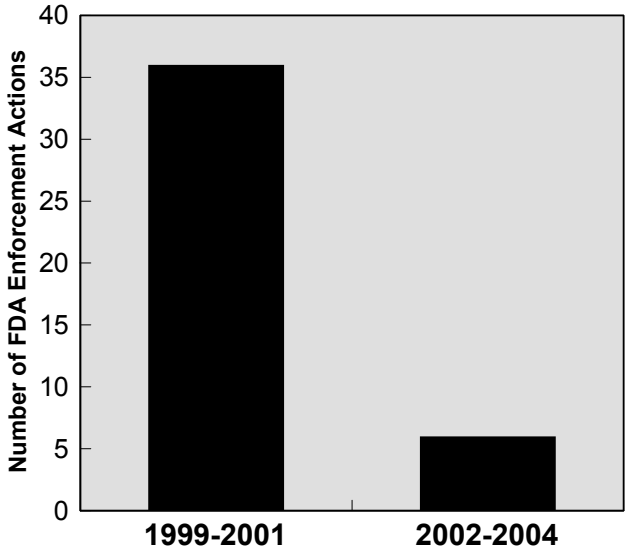
- **These problems continued throughout 2004.** Analysis of 2004 data shows that enforcement actions have remained at low levels, with FDA sending only 24 Notice of Violation or Warning letters to manufacturers. Enforcement delays also remained long, averaging over four months.

Biologic Drug and Vaccine Manufacturing. FDA is responsible for ensuring that drug manufacturers produce biologic drugs and vaccines using FDA-approved manufacturing standards. Beginning in January 2002, however, there was a marked decline in enforcement actions taken against manufacturers for violating these standards.

FDA data show that enforcement of FDA standards governing the manufacturing of biologic drugs and vaccines has declined dramatically since January 2002. Between January 1999 and December 2001, FDA took 36 official enforcement actions against biological drug and

vaccine manufacturers. During the next three years, from 2002 through 2004, the agency has taken only six enforcement actions. This represents a decline of over 80%.[3] Figure 2.

Figure 2: FDA Enforcement of Biologic and Vaccine Manufacturing Standards Has Declined in Recent Years



[3] *See* Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, Warning Letters (2004) (online at http://www.fda.gov/cber/efoi/warning.htm).