

March 30, 2001

Secretary
Federal Trade Commission
Room H-159
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

Re: Generic Drug Study – FTC File No. V000014

Dear Sir or Madam:

Our organizations, which represent patients and consumers who depend on prescription drugs as an essential part of their health care, commend the Federal Trade Commission for proposing to investigate the anti-competitive practices of pharmaceutical manufacturers. We urge the FTC to investigate a broad range of anti-competitive practices that brand name manufacturers have used to prevent or delay generic alternatives from reaching the market.

This investigation has come at a crucial time. Brand name drug companies charge more for prescription drugs in this country than in any other industrialized nation. Drug prices are increasing at a faster rate than inflation or overall healthcare costs. Approximately 65 million Americans have no prescription drug coverage, including one-third of the elderly. Millions more Americans have inadequate drug coverage.¹

Generic drugs have saved Americans a significant amount of money, due in large part to the passage of the Drug Price Competition and Patent Restoration Act of 1984 (Hatch-Waxman Act). The Congressional Budget Office (CBO) estimates that brand name drug prices drop by an average of 25% upon the introduction of a generic drug. CBO concluded that Americans saved \$8 to \$10 billion in 1994 alone by purchasing generic drugs.²

The Hatch-Waxman Act represents a careful balancing act. It was designed to increase timely access to generic drugs, while ensuring that drug manufacturers have adequate patent protection to justify substantial investment in research and development.

Although the Hatch-Waxman Act has succeeded in opening the prescription drug market to generic competition, generics now constitute less than 10 percent of the dollar value of all prescription drugs sold in the United States. We believe that this is in part due to the manipulation of the Act by brand name drug companies to extend their lucrative patents beyond what was intended by the law, as has been revealed by previous FTC enforcement action. The manipulation has upset the careful balancing inherent to the Act. We are concerned about a number of anticompetitive tactics used by these manufacturers, including:

- non-competition payments by brand name companies, in which generic firms agree to withhold their drug from the market;

- the listing of and litigation over frivolous patents by brand name firms. Drug manufacturers often record multiple patent claims that have nothing to do with whether a generic alternative is therapeutically equivalent to the brand drug. They then file “nuisance” lawsuits claiming patent violation, which are designed to trigger the law’s automatic delay of the introduction of the generic if patent litigation is ongoing.
- The abuse of “citizen petitions” to delay the introduction of generic drugs. The FDA is required by law to consider each petition individually, which can delay the introduction of a generic alternative for a long time. Brand name drug manufacturers increasingly are filing citizen petitions merely to keep generic competition at bay.

In the wake of the FTC’s settlement with Mylan Laboratories regarding price fixing for two anti-anxiety medications, we also encourage the FTC to evaluate whether the generic drug market is vulnerable to further attempts to corner the market on crucial raw materials.

In the next five years, prescription drugs with annual sales of approximately \$20 billion will be coming off patent.³ Given that generic drugs cost, on average less than one-fifth of what brand name drugs cost under the Medicaid program,⁴ the potential savings to taxpayers, consumers and patients from timely availability of generics drugs is substantial and crucial.

It is for these reasons that we strongly support the FTC’s proposed study of U.S. generic drug competition. Given what is at stake for American consumers, we urge the FTC to vigorously pursue this investigation in a timely manner.

Sincerely,

Alliance for Retired Americans
Center on Disability and Health
Center for Medical Consumers
Communications Workers of America
Consumer Federation
Families USA
Gay Men's Health Crisis
International Union, UAW
National Consumers League
National Senior Citizens Law Center
National Women's Health Network
Public Citizen
Service Employees International Union
U.S. Public Interest Research Group

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¹ Department of Health and Human Services; *Prescription Drug Coverage, Spending, Utilization, and Prices*, Report to the President, April 2000.

² Congressional Budget Office; *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*; July 1998.

³ National Institute for Health Care Management; *Prescription Drugs and Intellectual Property Protection*, August 2000, at 3.

⁴ PRIME Institute; *Prescription Drugs: Demystifying the Industry*, presented at Health Action 2001, January 27, 2001.