Prepared Statement of
The Federal Trade Commission

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I. Introduction

Mr. Chairman, I am Timothy J. Muris, Chairman of the Federal Trade Commission. I am pleased to appear before the Committee today to testify on behalf of the Commission regarding competition in the pharmaceutical industry.[(1)]

Advances in the pharmaceutical industry continue to bring enormous benefits to Americans. Because of pharmaceutical innovations, a growing number of medical conditions often can be treated more effectively with drugs and drug therapy than with alternative means (e.g., surgery). The development of new drugs is risky and costly, however, which has an impact on the prices of prescription drugs. Likewise, the development of generic drugs also can be risky and costly. Expenditures on pharmaceutical products continue to grow. According to the Employee Benefit Research Institute, such expenditures increased 92 percent over the past five years, to $116.9 billion.[(2)] Pharmaceutical expenditures are thus a concern not only to individual consumers, but to government payers, private health plans, and employers as well.

To address the issue of escalating drug expenditures, and to ensure that the benefits of pharmaceutical innovation would be available to the broadest group of healthcare consumers possible, Congress passed the Hatch-Waxman Amendments[(3)] to the Food, Drug and Cosmetic Act ("FDC Act").[(4)] The Hatch-Waxman Amendments were intended to promote robust competition in the pharmaceutical industry and, to a large degree, have succeeded.[(5)] The Congressional Budget Office estimates that, by purchasing generic equivalents of brand name drugs, consumers saved $8-10 billion on retail purchases of prescription drugs in 1994 alone.[(6)] With patents on branded drugs having combined U.S. sales of almost $20 billion set to expire within the next four years,[(7)] these already substantial savings are likely to increase dramatically.

Yet, in spite of this remarkable record of success, the Hatch-Waxman Amendments have also been subject to abuse. Although many drug manufacturers--including both branded companies and generics--have acted in good faith, some have attempted to "game" the system, securing greater profits for themselves without providing a corresponding benefit to consumers. It is these anticompetitive efforts that the Federal Trade Commission has addressed. The nature of that response, both past and present, is the principal subject of this testimony.

Over time, the Commission has developed significant expertise regarding competition in the pharmaceutical industry. The Commission has, for example, brought antitrust enforcement actions affecting both branded and generic drug manufacturers.[(8)] The Commission has also conducted empirical analyses of competition in the pharmaceutical industry, including in-depth studies by the staff of the Bureau of Economics.[(9)] The Commission's efforts have included filing comments with the Food and Drug Administration ("FDA") regarding the competitive aspects of Hatch-Waxman implementation,[(10)] as well as previous testimony before Congress.[(11)] Furthermore, individual

"Paragraph IV certification," asserting that the patent in question is invalid or not infringed.[19]

Filing a Paragraph IV certification potentially has significant regulatory implications, as it is a

provisions can extend the boundaries of the patent monopoly without providing any additional public disclosure or incentive to innovate, and therefore have the potential to run afoul of the principles of antitrust law.[34]

Provisions that restrict the generic's ability to assign or waive its 180-day marketing exclusivity rights. Because a s

purpose of blocking generic competition to its branded drug Tiazac. This is the Commission's first enforcement action to remedy the effects of an allegedly anticompetitive Orange Book listing.

Prior to the events giving rise to the Commission's complaint, Biovail had already triggered a 30-month stay of FDA final approval of Andrx's generic Tiazac product, by commencing an infringement lawsuit against Andrx. Andrx prevailed in the courts, however, so that by February 2001, the stay would have been lifted. According to the Commission's complaint,(53) Biovail, in anticipation of pending competition from Andrx, undertook a series of anticompetitive actions to trigger a new stay and maintain its Tiazac monopoly. Just before the stay was to terminate, Biovail acquired a newly issued patent from a third party and listed it in the Orange Book as claiming Tiazac-- thereby requiring Andrx to re-certify to the FDA under Paragraph IV, and opening the door to Biovail's suit against Andrx for infringement of the new patent and commencement of a second 30-month stay.

According to the Commission's complaint, Biovail knew that the new patent did not claim the form of Tiazac that it had been marketing, and Biovail did not need this new patent to continue marketing Tiazac without infringement risk. In fact, the FDA later learned that Biovail's position was that the newly listed patent covered a new formulation of Tiazac that Biovail had developed only after it acquired and listed the patentaAustt

Two potentially competition-reducing categories of agreements are worth noting. The first involves exclusive distributorship arrangements. A second generic entrant, rather than bringing a competing product to market, might agree to become the exclusive distributor of the first entrant. Such an arrangement would essentially grant the second entrant an agreed-upon share of the market, rather than requiring it to secure that share at the expense of the first entrant through aggressive price competition.

The second involves potential division of market segments. The first entrant might agree to market its product exclusively in one strength, while the second entrant agrees to market its product exclusively in another. Like the exclusive distributorship arrangement, the objective of such an agreement would appear to be less vigorous competition, as the agreement would simply grant each company a reciprocal market segment that would otherwise need to be secured through competition on price and other terms.

As with any antitrust case, the analysis would depend on the actual facts, but, at a minimum, such arrangements would arouse significant interest at the Commission.

IV. Other Commission Efforts to Promote Competition

A. The Commission's 6(b) Study

between branded and generic drug manufacturers--or between generics--may have operated to delay generic drug competition. In addition, the study will provide evidence about branded manufacturers' patent listings in the Orange Book, the timeliness of the listings, and ho

Thank you for this opportunity to share the Commission's views on competition in the pharmaceutical industry. As you can see from this testimony, the Commission has been and will continue to be very active in protecting consumers from anticompetitive practices that inflate drug prices. The Commission looks forward to working closely with the Committee, as it has in the past, to ensure that competition in this critical sector of the economy remains vigorous. In keeping with this objective, the Commission will likewise endeavor to ensure that the careful Hatch-

16. *Id*. at § 355(j)(7)(A).

17. *Id*. at §' 355(j)(2)(A)(iv).

18. *Id*. at § 355(j)(2)(A)(vii).

19. *Id*. at § 355(j)(2)(A)(vii)(IV).

20. *Id*. at § 355(j)(2)(B). Although the patent holder and the NDA filer are often the same person, this is not always the case. The Hatch-Waxman Amendments require that all patents that claim the drug described in an NDA must be listed in the Orange Book. Occasionally, this requires an NDA filer to list a patent that it does not own.

would prejudice parties who may later challenge the listing.