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I. INTRODUCTION

Good morning. It is my pleasure to join you all today.

My comments will reflect my own views, not necessarily those of the Federal Trade Commission or any of my fellow Commissioners. But having said that, I am pleased to report that the Commission as a whole has become increasingly involved in the biosimilars debate. I welcome this opportunityoomBs40 TD4.0400l00 0.0000 598.4400 TD0.0600 Tc0 0.0000 598.4400 TD0..070614ge

[1] Pamela Jones Harbour, Commissioner, Fed. Trade Comm'n, The Competitive Implications of Generic Biologics, Remarks at the Intellectual Property Antitrust Conference of the Sections of Antitrust and Intellectual Property Law, American Bar Association (June 14, 2007), *available at* http://www.ftc.gov/speeches/harbour/070614genbio.pdf.

The Commission has made major progress toward both of my original goals, and will be hosting a workshop on follow-on biologics later this fall. But before I go into details, I'd like to provide a little bit of background regarding the Commission's perspective on the biosimilars debate.

III. THE ROLE OF COMPETITION

Biologics are a huge and growing market. These drugs drastically reduce disabling symptoms, help to manage chronic diseases, and sometimes even save lives. But they come at an extremely high price to consumers. As a result, consumers cannot always afford the best-available treatments for their conditions.

Biologics are expensive, in part, because they cost so much to develop and manufacture. I certainly do not mean to understate the huge investments required by drug companies to develop effective and safe treatments. These companies nee

biologics, in situations where the science supports it. And that's an important caveat. The scientific and patient safety questions are paramount, and they are beyond the Commission's expertise. The FDA is the expert agency on the scientific front. As I have done before,[5] I urge the FDA to take the lead, to objectively determine the circumstances under which safe and effective follow-on biologics are possible. But based on the current state of scientific knowledge, it seems as though, over the last year or so, the discussion has shifted from "whether" to "when" an abbreviated approval process will exist. It seems likely that a law will emerge from Congress at some point.[6] It still remains unclear, however, what form that law will take, and what compromises will be reached along the way.

IV. LETTER TO HOUSE COMMITTEE ON ENERGY AND COMMERCE

As most of you know, in April 2008, the Chairman and Ranking Member of the Subcommittee on Health, House Committee on Energy and Commerce, sent a letter and multiple pages of questions to 35 organizations, to solicit their views on biosimilars and to inform the development of legislation.[7] I was excited – and gratified – that the FTC was included on the list of stakeholders. This outreach from the Hill provided an excellent mechanism for the Commission to share some of its expertise. Thanks to our talented staff, who had been tracking these issues for quite awhile, the Commission was poised to provide some preliminary thoughts.

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[5] Harbour, *supra* note 1.

[6] *See, e.g.*, Pathway for Biosimilars Act, H.R. 5629, 110th Cong. (2008); Biologics Price Competition and Innovation Act of 2007, S. 1695, 110th Cong. (2007); Affordable Biologics for Consumers Act, S. 1505, 110th Cong. (2007); Patient Protection and Innovative Biologic Medicines Act of 2007, H.R. 1956, 110th Cong. (2007); Access to Life-Saving Medicine Act, H.R.1038 and S. 623, 110th Cong. (2007).

[7] Letter from Frank Pallone, Jr., Chairman, & Nathan Deal, Ranking Member, Subcomm. on Health, Comm. on Energy & Commerce, U.S. House of Reps., to 35 groups (including Fed. Trade Comm'n) (Apr. 3, 2008), *available at* http://energycommerce.house.gov/Press_110/110-ltr.040308.list.Biologic%20ltr.pdf.

The Commission submitted a ten-page letter[8] focused primarily on one specific question posed by the Subcommittee: "What lessons can we learn from the Hatch-Waxman Act, and apply towards Congress's discussion about [follow-on biologics]?" Our letter endorsed the concept that an abbreviated approval process for follow-on biologics, with less stringent requirements than those for a new drug approval, would enhance competition, lead to lower prices, and accelerate the pace of innovation. We also noted that, from a competition perspective, an ideal abbreviated approval pathway would create incentives for multiple entrants, and provide a mechanism for automatic substitution, to maximize the benefits of competition.

The basic message of our letter was this: Congress should take care to avoid "unintended consequences" that might severely limit or eliminate the benefits of biosimilars legislation. We highlighted several situations where companies have attempted to "game" the generic drug approval system, securing greater profits for themselves without providing a corresponding benefit to consumers.

We identified three types of unintended consequences that Congress should seek to avoid in legislation governing the approval of generic biologics.

A. Risk of Exclusion Payments

First and foremost, the Commission's letter warned that generic biologics legislation presents a substantial risk of creating a new arena for so-called "exclusion payment" patent settlements, which have become prevalent under Hatch-Waxman.

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[8] Letter from C. Landis Plummer, Acting Secretary, by direction of the Fed. Trade Comm'n, to Frank Pallone, Jr., Chairman, Subcomm. on Health, Comm. on Energy & Commerce, U.S. House of Reps. (May 2, 2008), *available at* http://energycommerce.house.gov/Press_110/110-ltr.050208.respto040308.FTC.pdf.

[9] *See especially* Fed. Trade Comm'n, *Protecting Consumer Access to Generic Drugs: The Benefits of a Legislative Solution to Anticom petitive Patent Settlements in the Pharmaceutical Industry*, Prepared Statement before the

period for the first generic filer can create a "cork in the bottle" that blocks entry by any generic firm, as long as the first filer refrains from entering the market. This creates an incentive for the branded firm to encourage the first filer to delay entry. For this reason, the Commission's letter suggested that if Congress creates any exclusivity period for follow-on biologics, the approval scheme should ensure that branded companies cannot use the exclusivity as a way to prevent generic entry.

But the letter makes a further point. The letter asks Congress to consider whether an exclusivity period for generic biologics is really necessary at all. Under Hatch-Waxman, one of the main rationales for 180-day exclusivity is to provide an incentive for the first generic filer to bear the cost of patent litigation to challenge potentially invalid or narrow patents, knowing that other generic applicants will be able to "free-ride" on the work done by the first generic company. But the economics of entry may be different in the realm of follow-on biologics.

For example, it is unclear how "abbreviated" any abbreviated approval process will be, and how much the costs and time of approval will be reduced for follow-on biologics filers. The rewards that the market provides may be incentive enough for fi

C. "Gaming" of the System

Third, the Commission's letter points out several ways that parties have found to "game" the Hatch-Waxman system to lengthen exclusivity periods and thwart generic entry. For example, until the 2003 reforms to Hatch-Waxman, branded manufacturers could obtain "stacked" 30-month stays delaying FDA approval of generic alternatives by listing additional patents, even if those patents were narrow or weak, or covered only minor aspects of the branded drug. Another strategy branded firms have pursued is to make minor, non-clinically significant changes to a branded product, then "switch" the market to the new version and

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FTC News Release, *FTC Announces Work*

[12] When posted, information will be available on the Commission's website as a link from the "Conferences and Workshops" page at http://www

I have warned before, policymakers should tread carefully, to ensure they fully understand the likely competitive implications and long-term consequences of their decisions.

I am excited that the FTC will continue to play an important role in this policy debate. I hope you will all pay attention to our upcoming workshop and our subsequent report, and as always, we welcome your input.

Thank you.