Federal Trade Commission

FOLLOW-ON BIOLOGIC DRUG COMPETITION:

A REPORT BY THE FEDERAL TRADE COMMISSION

Commissioner Pamela Jones Harbour

Remarks as prepared for delivery[1] to the
Health Industry Forum
"Federal Strategies for Promoting Affordable Biologics:
Enhancing Market Competition"

Washington, DC
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[1]Remarks were delivered by Tara Isa Koslov, Attorney Advisor to Commissioner Harbour.

[2]FEDERAL TRADE COMMISSION, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION: A FEDERAL TRADE COMMISSION REPORT (June 2009) [hereinafter FOB REPORT], *available at* http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf; *see also* FTC News Release, *FTC Releases Report on "Follow-on Biol*

II. THE COMMISSION'S INVOLVEMENT IN THE FOB DEBATE

But before I launch into the report, and by way of background, I want to share a brief overview of the Commission's involvement in the FOB debate, leading up to the issuance of this report.

I first spoke publicly about biosimilars in June 2007.[4] (I believe I was the first person from the FTC to do so.₱.00o 0.0 0bm1Hr (the b0 0.0000 cm1.00000 0.000 o(.)Tj4800 0.0000 TD(om)Tj-1cm)Tj0.0000

[4]Pamela Jones Harbour, Commissioner, Federal Trade Commission, 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.

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

[6]Letter from C. Landis Plummer, Acting Secretary, by direction of the Federal Trade Commission, to Frank Pallone, Jr., Chairman, Subcommittee on Health, Committee on Energy & Commerce, U.S. House of Representatives (May 2, 2008), *available at* http://energycommerce.house.gov/Press_110/110-ltr.050208.respto040308.FTC.pdf.

[7]FTC News Release, *FTC Announces Workshop and Roundtable on Emerging Health Care Competition and Consumer Protection Issues* (Aug. 27, 2008); Fed. Trade Comm'n, Public Workshops and Roundtables: Emerging Health Care Competition and Consumer Issues, Notice of Public Workshops and Roundtables and O

As we all know, one way to reduce the costs of biologics would be to authorize the Food and Drug Administration ("FDA") to permit follow-on biologics, or FOBs, to enter the market once a biologic drug's patents expire. Currently, an FOB applicant must replicate all of the tests to generate a complete set of data about a biologic drug's safety and efficacy, even where some of the prior knowledge about the pioneer biologic would also be relevant to the FOB. There is no statutory or regulatory pathway to allow abbreviated FOB entry without the FOB applicant having to duplicate the existing knowledge. This duplication represents an inefficient use of limited research and development ("R&D") resources.

Also, as the FDA has explained, repeating all of the clinical trials raises ethical concerns associated with unnecessary human testing. Of course, these ethics issues are far beyond the scope of the Commission's competition concerns, so I mention them only in passing. But I must admit, as a government official charged with protecting the public interest, I cannot help but think about the human costs of subjecting very sick patients to unnecessary double-blind studies, where some patients inevitably will receive placebos, even when we know for a fact that these patients are being denied safe and effective treatments.

Elements of the Hatch-Waxman Act provide a model for reducing FOB entry costs and addressing ethical concerns. Hatch-Waxman – which applies to small-molecule generic drugs – does not require generic applicants to duplicate the clinical testing of branded drugs that already have been proven safe and effective. By reducing R&D costs, Hatch-Waxman enables generic firms to enter the market with lower-cost versions of branded drugs.

Hatch-Waxman has successfully reduced drug prices, broadened access, and hastened the pace of innovation. But in other important respects, the Hatch-Waxman model is not a perfect template for FOB legislation. According to the FDA, there are key scientific differences between biologic and small-molecule drug products. Most notably, under Hatch-Waxman, in asking the FDA to rely on existing safety and efficacy data, the generic applicant must show that its product is "bioequivalent" to the branded drug product. This has at least three important implications.

- First, a bioequivalence showing is much less expensive to achieve, compared to the full clinical testing required for approval of a pioneer branded drug product.

- Second, if the generic drug is deemed bioequivalent to the branded drug, it usually can be safely substituted for the branded drug, and will be as effective as the branded drug. This means that the branded and generic can, in theory, compete head-to-head in the marketplace.

- Third, because such substitution is possible, many states have laws that allow pharmacists to *automatically* substitute a generic for a branded drug

In the interest of time, let me briefly summarize the four major reasons why FOB

As a result of all of these factors, the Commission's report predicts that FOB markets are likely to develop with the following characteristics.

- FOB entry is likely to occur only in biologic drug markets with more than $250 million in annual sales.

- Only two or three FOB manufacturers are likely to attempt entry in competition with a particular pioneer drug product.

- These FOB entrants likely will not offer price discounts larger than 10 to 30 percent off the pioneer product's price. Although this discount is not as steep as with small-molecule generic drugs, it does represent millions of dollars in consumer savings for these very expensive products.

- Pioneer manufacturers are expected to respond by offering competitive discounts to maintain their market share. This price competition likely will increase consumer access and further expand the market.

- Without automatic substitution, FOB market share acquisition will be slowed. Pioneer manufacturers likely will retain 70 to 90 percent of their market share. This means that a pioneer firm will continue to reap subst

drugs. Prices also enable firms to receive accurate market signals about the value of developing particular biologic drugs.

Currently, pioneer drug manufacturers race against other firms to bring products to market, in both pharmaceuticals and biologics. This competition benefits consumers by accelerating the pace of innovation, and also through eventual price competition. Given that FOB competition is likely to resemble competition by another brand, FOB competition is likely to promote the same consumer benefits, without the need for any additional incentives.

VII. IMPLICATIONS FOR FOB SYSTEM DESIGN

These findings have several implications for the design of an abbreviated approval system for FOBs. In the interest of time, I will briefly summarize what I view as the three key implications. I strongly encourage you to review the report itself for many more details.

A. Pioneers Do Not Need Additional Incentives to Innovate

First, pioneer manufacturers are unlikely to need additional incentives to continue to

patent infringement damages. But looking at the cost and complexity of bringing FOBs to market, it is likely that only well-funded firms will seek FOB entry, which will mitigate concerns about the enforceability of patent infringement judgments.

Special procedures are unlikely to succeed in raising and resolving all pertinent patent issues prior to FDA approval, especially given that pioneer biologics are covered by more and varied patents than small-molecule drugs. Special procedures also may create competit

[9]Henry Grabowski, *Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition*, 7 NATURE REVIEWS DRUG DISCOVERY 479 (June 2008). Subsequent calculations and adjustments to the Nature model include: Henry Grabowski *et al.*, *Updating Prior Analyses and Responding to Critiques*, DUKE UNIV. DEPT. ECON. WORKING PAPER, No. 2008-10 (Dec. 22, 2008); Matrix Global Advisors Comment (12/22/08); Alex Brill, *Proper Duration of Data Exclusivity for Generic Biologics: A Critique*, MATRIX GLOBAL ADVISORS, LLC, WHITE PAPER (2008).

IX. CONCLUSION

A couple of months ago, when staff first previewed the direction the report would be taking, one staffer joked with me: if each of the different constituencies will strongly disagree with something in the report, we are probably doing something right. Depending on the tone of your questions, we will see how that theory plays out.

I do thank you again for this opportunity to summarize the Commission's report, and I look forward to the panel discussion.