CONCURRING STATEMENT OF COMMISSIONER J. THOMAS ROSCH ON THE RELEASE OF THE COMMISSION'S INTERIM REPORT ON AUTHORIZED GENERICS

I concur in the bottom-line conclusion of the Commission's Interim Report that the Report cannot properly be read to support a legislative ban on the marketing of Authorized Generics (AGs) during the 180-day exclusivity period (or otherwise) or to suggest that AGs are harmful to consumers. (*See*, Report, Exec. Summ. at 1.) I write separately to correct misimpressions that may arise from various statements and omissions in the Report.

First, Chapter 1 of the Report states that "[g]iven the scope of our preliminary analysis, this chapter makes no attempt to reach any conclusions about the net impact of AGs on consumers or the economy." (*Id.*, Ch. 1 at 1.) But the reason the chapter makes no attempt to reach any such conclusions has nothing to do with the "limited scope" of the chapter. Chapter 1 fails to reach any conclusions about that "net effect" because there is no independent data (or secondary analysis) that supports such conclusions.

Second, as Chapter 1 of the Report admits, the data shows that when AGs enter the market during the 180-day exclusivity period, prices for generic drugs go down. (*See id.*, Ch. 1 at 1, 2, 7-11.) The only remaining question then, so far as consumer welfare is concerned, is whether AG competition affects the *total* output of the particular generic drug at issue (i.e., the *total* quantity of that generic drug – authorized or not – that comes to market). The Report likewise does not reach any conclusion on that point because the data does not allow it. Instead, the Report analyzes the impact of AG competition *on ANDA generics*.[1] In so doing, the Report improperly treats ANDA generics as though they were a separate market from AGs. More specifically, the Report analyzes whether AG competition will reduce *ANDA generics' revenues* during the 180-day period (*id.*, Ch. 1 at 2). However, ANDA generic revenues are a product of (1) the volume of ANDA generic sales, and (2) ANDA generic prices. The introduction of AG price competition – or, for that matter, price competition from another ANDA generic – inevitably will cause a reduction in both ANDA generic volume and prices (and thus the ANDA generic's market share). Indeed, that is what price competition is all about. To my knowledge, no one has ever condemned price competition on the ground that it will reduce another competitor's revenue (at least so long as the prices charged were not below the first competitor's cost). The Report, however, persists in highlighting these effects on competitors (i.e., ANDA generics) notwithstanding the fact that these effects tell us nothing about whether AG competition adversely impacts *consumers or the economy*.[2]

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[1] I use the term "ANDA generics" because sometimes two or more ANDA applicants file on the same day, and each of the multiple filers is entitled to 180 days of marketing exclusivity vis-à-vis other ANDA applicants.

[2] Indeed, although the Report makes no mention of it, consumers may also reap *non-price* benefits from AG competition. AGs, unlike other generics, are *identical* to the brand drug. There is evidence that for some patients the distinction between the brand drug and its "bio-equivalent" (the standard a generic must meet under FDA rules to

Third, as previously stated, the Report repeatedly acknowledges that AG competition causes a reduction in generic drug prices. The only debate is about *how much* those prices go down. To the extent that Chapter 1 estimates the savings that AG competition provides to consumers, the Report understates those effects. The threshold issue in making that determination is whether the best measure of those savings are *retail prices* paid by consumers or *wholesale prices* paid by wholesalers. The Report admits that retail prices do not reflect all of the payments consumers make for prescription drugs. (*Id.*, Ch. 1 at 9.) Notwithstanding that fact, the Report embraces retail prices as the better proxy, and repeatedly finds support for its positions in a study provided by the Generic Pharmaceutical Association ("GPhA") (the "Hollis and Liang" study).[3] (*Id.*, Ch. 1 at 4, 7, 9.) As the Report acknowledges, when wholesale prices are used as the proxy to estimate the effects of AG competition, the discount that AGs provide to consumers increases to 8.1 percent. (*Id.*, Ch. 1 at 11.)

Fourth, the Report states that the revenues of an ANDA generic may "drop substantially with AG entry." (*Id.*, Ch. 1 at 1.) To the extent that that statement implies that an ANDA generic may not be able profitably to meet the price competition offered by an AG, there is nothing in the Report to suggest that the ANDA generic is deserving of protection.[4] To protect an ANDA generic under that scenario, even in a predatory pricing case, one must arguably first determine that the ANDA generic is the most efficient (low cost) producer of the generic drug at issue. There is no data to support that conclusion.[5] To the contrary, so long as the average variable costs (or avoidable costs) of AGs and ANDA generics are used as the basis for cost comparison, it would seem that AGs would almost always, if not always, be the more efficient (low cost) generic

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qualify as a generic) is therapeutically meaningful. As such, a ban on AGs during the 180-day exclusivity period would prevent those patients (and third-party payers, including the Government) from obtaining the reduced prices that AGs afford.

[3] The GPhA is the generics' trade association.

[4] The Report simply says that in some small markets the revenue reduction is likely to change the calculus of the ANDA generic's decision making but it goes on to acknowledge that no analysis has been done that would suggest that "AG entry deters generic entry prior to patent expiration that otherwise would take place." (Report, Exec. Summ. at 2.) Indeed, insofar as the Report's thesis is that AGs deter ANDA generics from competing, that hypothesis is purely speculative – there is no data showing that any generic drugs have not been marketed as a result of potential competition from AGs.

[5] *See, e.g.*, European Commission Communication – Guidance on The Commission's Enforcement Priorities In Applying Article 82 EC Treaty to Abusive Exclusionary Conduct By Dominant Undertakings The Guidance ("Guidance"), *available at* http://ec.europa.eu/competition/antitrust/art82/guidance.pdf (expressly refusing to protect less efficient producers from more efficient, albeit dominant, producers even in cases alleging predatory pricing by the latter); *see also Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962) (noting that Congress enacted the antitrust laws to protect competition, not competitors).

producers since a brand's AG offering is simply an offering of the branded product in generic form.

Fifth, Chapter 2 of the Report is too far afield. No member of Congress has asked the Commission to address the impact of an agreement that provides that an AG will *not* compete. (*Id.*, Exec. Summ. at 1 (reporting request by members of Congress that the Commission address the impact of AG competition).) Chapter 2 nevertheless conflates the debate about the merits of an agreement that an AG will not compete with the debate about the merits of pay-for-delay settlements. That mixes apples and oranges. To the extent that pay-for-delay settlements cause consumers harm, the Report does not (because it cannot) show that AG competition is the cause of that harm. (*See id.*, Exec. Summ. at 1.)

For that matter, the Report does not show that agreements providing that an AG will *not* compete cause any substantial harm. As the Report admits, only 38 out of 152 (or just 25%) (*id.*, Ch. 2 at 1) of the settlements reviewed by the FTC implicated AGs at all. Even that percentage, however, overstates the dimensions of the problem. The only time that an agreement keeping an AG out of the market could be considered to be of significant value to an ANDA generic is when an AG is the *only* potential competitor. The Report supplies no data to show how many settlements involve that situation.

Finally, if pay-for-delay settlements that implicate AGs are a problem, as the Report acknowledges the way to remedy that problem is not to ban AGs from marketing their products during the 180-day exclusivity period (*id.*, Exec. Summ. at 1); it is (at most) to provide that a brand's promises not to manufacture AGs will be presumptively illegal, absent proof adduced by the parties to the agreement to justify their agreement.[6]

[6] This is especially true given the Supreme Court's antipathy towards rules of per se illegality. *See, e.g., Broadcast Music, Inc. v. CBS, Inc.*, 441 U.S. 1 (1979); *Leegin Creative Leather Products, Inc. v. PSKS, Ins.*, 127 S. Ct. 2705 (2007); *see also* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition,* 109 COLUM. L. REV. 629 (May 2009).