UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

To: Don Clark, Secretary
From: Alyssa O'Connor
Date: May 23, 2013
Re: Proposed Changes to the HSR Rules: Comments to be Placed on the Public Record

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On April 18, 2013, Chairwoman Edith Ramirez and FTC staff met with counsel for the Pharmaceutical Research and Manufacturers of America ("PhRMA") to discuss proposed amendments to the Hart-Scott-Rodino ("HSR") premerger notification rules that address patent licensing transactions in the pharmaceutical industry.[1]

During the meeting, PhRMA counsel provided an overview of the organization's legal and policy concerns with the Notice of Proposed Rulemaking ("NPRM"). Counsel argued that the HSR Act is a law of general application that permits statutory exceptions but not affirmative targeting of a specific industry. Counsel stated the HSR Act's legislative history reinforces this assessment of the Act's scope. Counsel also asserted that the NPRM does not comply with Section 553 of the Administrative Procedure Act because the NPRM (1) does not include a reasonable explanation or factual basis of harm for why the transactions in question are anticompetitive; and (2) inappropriately discriminates against the pharmaceutical industry without justification or explanation.

PhRMA's counsel also raised policy concerns with the NPRM. First, counsel argued that the Commission should not enact what PhRMA views as discriminatory antitrust policy when the agency promotes nondiscrimination internationally. Next, counsel again asserted the NPRM lacks a factual record. Counsel mentioned that there was no investigation or study justifying the NPRM's proposed changes and opined that the agency's statement of subject matter expertise is an inadequate substitute. Third, counsel returned to the legislative history of the HSR Act and argued that different HSR rules for different industries are inconsistent and confusing. Finally, counsel expressed the view that the rulemaking proceedings were not transparent. Given their concerns, PhRMA counsel requested that the Commission refrain from adopting the proposed changes.

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[1] In attendance were James M. Spears, Executive Vice President & General Counsel, PhRMA; Melissa Kimmel, Assistant General Counsel, PhRMA; and James Rill and Stephen Weissman of Baker Botts, LLP (outside counsel to PhRMA). In addition to Chairwoman Ramirez, Lisa Kimmel, Attorney Advisor, and Alyssa O'Connor, Honors Paralegal, participated on behalf of the FTC.