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BY HAND DELIVERY & REGULAR MAIL

Honorable Joshua D. Wright
Commissioner
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: HSR IP Rulemaking Project No. P989316 – Response to Commissioner Wright's Request for Information About Costs

Dear Commissioner Wright:

Thank you for meeting with us recently regarding the above-referenced Notice of Proposed Rulemaking, which singles out the pharmaceutical industry for increased burdens under the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act"). As we explained both at the meeting and in our earlier written comments, the principal objections of our client, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), to the proposed rulemaking are that the HSR Act does not authorize the FTC to increase the Act's coverage and burden to only a single industry to the exclusion of all others, nor does the proposed rulemaking comply with the Administrative Procedures Act ("APA"). During our meeting, we raised the additional concern that the proposed rulemaking, if adopted, would inflict a number of substantial and unnecessary costs on the pharmaceutical industry, especially when viewed against the absence of any articulated and demonstrated need for the proposed rule. You asked us to provide you with additional information about these projected costs.

Since the meeting, we have undertaken to further quantify the costs based on information from PhRMA members as well as on a review of our firm's own experience in preparing and filing HSR forms, particularly for pharmaceutical companies. The costs that businesses face when required to file HSR forms with the FTC and DoJ include filing fees, costs associated with collection of information and documents necessary for completion of the HSR form (including attachments such as so-called "Item 4(c)" and "Item 4(d)" documents), and costs associated with responding to requests by the agency for additional information.

- **Filing Fees**: As summarized in our earlier comments, the current HSR filing fee per transaction ranges from $45,000 to $280,000, depending on the value of the transaction. Based upon the Commission's estimate of an annual increase of 30 HSR reportable

transactions as a result of the proposed rulemaking,[1] companies subject to the proposed HSR rule amendments each year would be forced to expend between $ 1,350,000 to $ 8,400,000 in increased filing fees alone.

- **Costs Associated with Preparation of HSR Forms, Including Document Collection and Review.** Based on information we obtained in responding to your question, we estimate that, on average, the costs associated with preparation of the HSR forms, including collection and review of so-called Item 4 documents, amount to $40,000 - $60,000 in legal fees and direct costs for each party to the transaction. This amount does not include the substantial costs incurred as a result of management time and effort involved in document collection and review, which are difficult to quantify but can be a significant burden and distraction for companies.

  The $40,000 - $60,000 per party, per transaction estimate can be lower (≈ $15,000 - $20,000) in straightforward transactions; *e.g.*, where the number of Item 4 custodians and potential documents is very small and where license valuation for HSR purposes is not an issue. But those situations are relatively rare. In our experience and based upon feedback from PhRMA members, the significant costs associated with the preparation and submission of HSR forms in the pharmaceutical industry is a function of various factors. These factors include the number of individuals frequently considered "officers" for purposes of Item 4; the often large, multi-function teams that are involved in investigating, assessing, negotiating and approving licensing transactions; the difficulty of determining fair market valuation for HSR purposes based upon the often uncertain nature of future milestone payments, royalty streams, and other financial elements typical of pharmaceutical licensing transactions; and the thoroughness and care expended by pharmaceutical companies to search for, review, and collect Item 4(c) and Item 4(d) documentation.

- **Responding to Additional Information Requests.** It is common for the Commission staff reviewing a proposed HSR filing to ask for additional information and materials from parties before the end of the initial 30-day waiting period. Such requests can range widely based on, among other factors, staff's familiarity with the businesses or business segments of the transacting parties. Similarly, costs associated with responding to staff's inquiries can vary significantly based upon the scope and extent of the information requested, as well as whether such information is readily available. While it is difficult to quantify an average cost figure, it is not uncommon in our experience for filing parties to expend many thousands of dollars responding to requests for information during the 30-day waiting period after the forms are filed.

  Furthermore, when an antitrust agency issues a Request for Additional Information (a "Second Request") pursuant to 15 U.S.C. 18a(e), the costs associated with an HSR filing increase exponentially. According to estimates compiled by the Antitrust Section of the

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[1] *See* PhRMA Comments, dated October 25, 2012, at 2-3 n. 3 (citing Notice of Proposed Rulemaking, 77 FED. REG. 50,060).

American Bar Association in 2006, compliance with a Second Request on average costs about $5 million per transaction and up to $20 million in very complex cases.[2] According to a recent HSR Annual Report, in FY 2011 the agencies issued Second Requests in 8% of HSR-reportable transactions involving the chemical, including pharmaceutical, manufacturing industries.[3] While the Notice of Proposed Rulemaking provides no basis to conclude that any of the pharmaceutical licensing transactions at issue would raise competitive concerns so as to trigger a Second Request, simply applying this 8% to the 30 additional HSR-reportable transactions estimated by the FTC yields between 2 and 3 additional Second Requests. An additional two to three Second Requests per year would result in approximately $10 million to $15 million in increased annual costs to businesses, on average.

Moreover, the above costs do not account for the potential distortion to the marketplace that would result from the proposed rulemaking. The proposed rule not only would incent companies to structure their transactions less efficiently to avoid licensing transactions that might most effectively allocate the investment, risk, and shared benefits of development and commercialization of intellectual property. As we mentioned during our meeting, it also proposes to impose added regulatory cost and delay on early stage pharmaceutical research and development so as to further discourage the already diminishing funding of such projects. *See* "*Vital Signs: The Crisis in Investment in the U.S. Medical Innovation and the Imperative of FDA Reform*," NVCA and MedIC, Oct. 2011, http://www.nvca.org/vital_signs_data_slides.pdf .

We hope this responds to your request for additional information. Please do not hesitate to contact us if you have any questions or would like additional information. Thank you your consideration.

Sincerely,

Stephen Weissman

cc: Chairwoman Edith Ramirez
Commissioner Judith Brill ✓
Commissioner Maureen K. Ohlhausen
James F. Rill
James M. Spears
Melissa B. Kimmel

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[2] Comments of the Section of Antitrust Law, ABA, in Response to the Antitrust Modernization Commission's Request for Public Comment Regarding the HSR Second Request Process (2006), at 4.

[3] *See* Hart-Scott-Rodino Annual Report, Fiscal Year 2011, at 6 *available at* http://www.ftc.gov/os/2012/06/2011hsrreport.pdf.