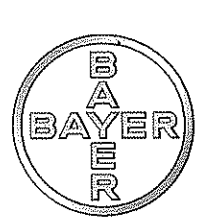
Bayer HealthCare



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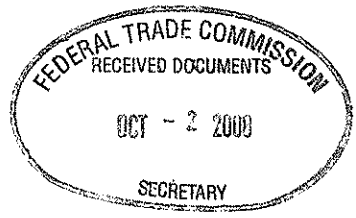

By Hand Delivery

William E. Kovacic, Chairman
Federal Trade Commission
Office of the Secretary, Room H-135 (Annex F)
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Emerging Health Care Competition and Consumer Issues
Comment, Project No. P083901

Bayer HealthCare LLC

Sandra Oliver
VP of Public Policy &
State Government Affairs
555 White Plains Road
Tarrytown, NY 10591
email: sandra.oliver.b@bayer.com

Tel: 914-333-6924
Fax: 914-366-1882

Dear Chairman Kovacic:

Bayer HealthCare LLC ("Bayer") thanks the Federal Trade Commission ("Commission") for this opportunity to offer comments on the first issue raised regarding Emerging Health Care Competition and Consumer Issues—competition provided by developing an abbreviated regulatory approval pathway for follow-on biologics. Although the comment deadline passed earlier this week, we hope that you will kindly consider our remarks nonetheless.

For more than 100 years, Bayer has been a leading innovator company that has developed unique, life saving medicines for the treatment of cancer, hemophilia, multiple sclerosis, infectious disease, women's health, and cardiovascular disease. We understand the complexity involved in the discovery of new medicine and the costs required to bring these medicines from bench to patient through either a traditional small molecule development pathway or by a complex protein manufacturing process. Based on this experience, we present the following comments for your consideration.

As technology has advanced, manufacturers have been able to develop new biologics to treat very specific and often life-threatening diseases that were previously untreatable. New biologics occur because companies like Bayer are appropriately incentivized through patent protections and data exclusivity to complete the long term in vitro and clinical studies required for Food and Drug Administration ("FDA") approval. The development of a biologic is an enormously complicated,

expensive, and long process. If the appropriate incentives are not maintained, innovation will inevitably suffer.

In traditional small molecule drug development, generic products that are chemically identical to the innovator product are allowed to enter the marketplace upon patent expiry of the innovator product as a result of the Hatch-Waxman Act, which created a system that balanced the risks carried by the innovator company in being first to market with the interest in encouraging generic competition. Innovators were rewarded for their research and development through enhanced patent protections and "data exclusivity" provisions, which prevented non-innovator, or generic, companies from using the underlying data from innovators to bring a product to market for a period of time.

As you well know, Hatch-Waxman does not apply to the development of biologics, and there is currently no formal legal or regulatory pathway in the United States to approve a "generic-," "biosimilar," or "follow on-" biologic that claims to be bioequivalent to the innovator product. Importantly, biologics differ from small molecule drugs[1]. In the production of biologics, comparability issues are of greater importance, since even slight changes in the manufacturing process can have dire consequences for patients. Significantly, then, generic biologics raise questions not only about their impact on innovation, but also–even more fundamentally–their risk to patient safety and effectiveness.

For a number of years, federal legislators have considered creating a parallel approval mechanism for biosimilar products. For Bayer, the most important aspects of any such legislation must include the following concerns. Any work by the FTC should also appropriately consider and reflect these important issues.

- ***The need for clear and well-supported guidance for the determination of interchangeability, reflecting convincing levels of scientific evidence that will ensure safety and efficacy.***

  Any legislation must give the Secretary of the U.S. Department of Health and Human Services ("HHS") the authority to establish the necessary quantity and quality of scientific evidence to adequately support the determination that a biosimilar product is "interchangeable" with the innovator product. In the absence of this, safety and efficacy will necessarily be threatened.

[1] Biologics are large molecules produced via a living organism in a complex manufacturing environment.

As an industry, we are just beginning to gain the fundamental insights and understanding needed to distinguish between and among products and their impact on patient health. HHS should develop clear guidance in conjunction with FDA to determine the threshold of data and testing that must be required to make the determination of interchangeability, and to ensure that such a determination does not compromise safety or efficacy.

- ***Twelve years of data exclusivity for the reference product, plus 2 additional years for exclusivity for significant new indications and additional 6 months of pediatric exclusivity.***

  Under some proposed legislation, like the Pathway for Biosimilars Act, H.R. 5629, innovator companies would be afforded fourteen years of data exclusivity post marketing approval, as specified above. We believe that data exclusivity should be afforded these important protections since it is necessary to adequately reward manufacturers for their investment into the critical and enormous research and development needed to demonstrate safety and efficacy of their product. Research and development and the biologic manufacturing process are costly and risky. Innovator manufacturers need significantly longer periods of exclusivity than small molecule product manufacturers to recover these investments. If legislation or action by the FTC does not adequately support the development of innovative biologics, they will not be developed. Policy-makers should carefully consider this important issue in developing their positions.

- ***Creation of critical manufacturing and immunogenicity data by non-innovators.***

  Data exclusivity does not prevent competitor drugs or biologics from entering the market. Data exclusivity only requires biosimilar manufacturers to independently determine the safety and efficacy of their products, rather than rely on data generated by innovator companies and submitted to FDA, at great expense and risk to the innovator. The relevant issues are not limited to encouraging innovation, however. Again, patient safety and efficacy are very much concerns, as well.

  Because of even subtle differences in the manufacturing process that will exist between an innovator and a generic manufacturer, the innovator's data may not accurately reflect the characteristics of the biosimilar product and its manufacturing process. As such, we expect that non-innovator manufacturers must be required to submit independent information regarding manufacturing, at a minimum, to reasonably ensure safety and efficacy.

Similarly, we also expect that non-innovators would be required to submit independent immunogenicity information. Immunogenicity is of special concern for biologics, and at a minimum, HHS should have the authority to require clinical testing for immunogenicity as part of the standard of evidence needed for the Secretary to declare a product to be interchangeable.

- ***Protection of innovator data by developing a pathway to allow innovator companies to exchange information with biosimilar manufacturers.***

  Information submitted by an innovator to FDA for a product's master file is generally subject to protections pursuant to the Uniform Trade Secrets Act and Freedom of Information Act. Such protections should not be disregarded as part of a biosimilar pathway. Any exchange of information should include only the data that a non-innovator has clearly been demonstrated to be necessary to expedite the development of the biosimilar.

* * *

Thank you in advance for your consideration of our initial comments regarding competition provided by developing an abbreviated regulatory approval pathway for follow-on biologics. Bayer appreciates the Commission's efforts to facilitate the implementation of thoughtful legislation that attempts to create a pathway for biosimilars while balancing the need to control costs, maintaining safety protections for patients as well as keeping incentives in place for innovative manufacturers. We anticipate attending the workshops and roundtables this Fall, and we request an opportunity to do so. Based on those discussions, we hope to submit additional comments regarding the impact that the proposals discussion would have on Bayer and the patients whom we serve.

Sincerely,

Sandra S. Oliver
VP, Public Policy & SGA