



December 8, 2017

Maureen Ohlhausen  
Acting Chairman  
Federal Trade Commission  
600 Pennsylvania Avenue, NW  
Washington, D.C. 20580

Scott Gottlieb, MD  
Commissioner  
U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

***BY ELECTRONIC DELIVERY***

**RE: Federal Trade Commission Workshop on "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics"**

Dear Acting Chairman Ohlhausen and Commissioner Gottlieb,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide written comments in response to the Federal Trade Commission's (FTC's or the Commission's) November 8, 2017, workshop titled "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics." BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. Our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, including productivity and quality of life, but also have reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

We commend both the FTC and the Food and Drug Administration (FDA or the Administration) on convening a diverse group of stakeholders to examine competitive issues in pharmaceutical markets and supply chains. Competition is the cornerstone of thriving and innovative markets. In enacting the current Hatch-Waxman framework more than three decades ago, Congress struck a careful balance between encouraging the development of innovative medicines that treat patients in need and creating a pathway for generic medicines to enter the market. Although no system is perfect, we believe this framework has served its intended purpose by supporting a robust generic marketplace and sending the right signals to innovators that promote the development of new medicines. Today, nearly 90 percent of prescriptions in the United States are for generic medicines. And in FY 2017, the FDA approved a record 763 new generic drugs.<sup>1</sup>

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<sup>1</sup><https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm584749.htm>

In its assessment of ongoing debates around prescription drug pricing and the competitive nature of these markets, the FTC and FDA have questioned what actions could be taken to correct perceived deficiencies in the current system. This type of monitoring and oversight is critical to well-functioning markets. But before the agencies embark on a wholly new regulatory approach in this space, we encourage both the FTC and FDA to monitor activities currently under way that are designed to speed generic entry and promote efficiencies through market-based mechanisms.

For example, under the leadership of Commissioner Gottlieb, the FDA has been engaged on a number of work streams to correct incongruences in the generic drug development process. Earlier this year the Commissioner announced FDA's Drug Competition Action Plan – a multi-pronged approach by the Administration to implement policies that ensure patients have robust access to the latest advances in medicine. Recent efforts under this action plan include draft guidance to abbreviated new drug application applicants to help streamline the approval process for manufacturers developing complex generic drugs.<sup>2</sup> Additionally, the FDA has published a list of off-patent, off-exclusivity drugs that do not currently have a generic competitor with instructions and considerations for manufacturers who may wish to pursue approval of a generic version.<sup>3</sup> These are just the first in a series of efforts by the FDA to “identify gaps in the science and develop more tools, methods, and efficient alternatives to clinical endpoint testing” to ease choke points in the generic drug development process.

We believe these efforts will have a significant impact on the signals and incentives for generic drug manufacturers. Before considering any additional regulatory action to promote competitive markets, we encourage both the FTC and FDA to allow the effects of these new efforts to work their way through the drug development process so that all stakeholders can fully understand their impact. Only after they are fully implemented should the agencies consider whether additional action, if any, is needed.

BIO appreciates the opportunity to provide written comment on the issues discussed during the FTC's workshop. Please feel free to contact me at (202) 962-9200 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Sincerely,

/s/

Crystal Kuntz  
Vice President  
Healthcare Policy and Research

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<sup>2</sup><https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM578366.pdf>

<sup>3</sup><https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/UCM564441.pdf>