Mylan
Better Health for a Better World

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July 26, 2017

Hon. Tom Marino
Chair, Regulatory Reform,
Commercial & Antitrust Law Subcommittee
House Judiciary Committee
U.S. House of Representatives
2138 Rayburn House Office Building
Washington, D.C. 20515

Hon. David Cicilline
Ranking Member, Regulatory Reform,
Commercial & Antitrust Law Subcommittee
House Judiciary Committee
U.S. House of Representatives
2138 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Marino and Ranking Member Cicilline:

Mylan is a leading manufacturer of generic and specialty medications and currently supplies 10% of all generic drugs dispensed in the United States. Mylan provides approximately 22 billion doses of pharmaceutical products in the United States each year at an average price of $0.25 per dose. Mylan currently sells 635 drugs in the United States – mostly generics – and has approximately 240 Abbreviated New Drug Applications (ANDAs) pending with the FDA to gain approval of additional generic medicines. We also have one of the industry's largest portfolios of biosimilars and insulin analogs in development. Our extensive generic portfolio and biosimilars represent the commitment of Mylan and our workforce of more than 35,000 to help provide access to more affordable medicines and create cost savings for our health care system and consumers.

Mylan supports the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (H.R. 2212), which aims to stop the conduct of some brand pharmaceutical manufacturers that have been using Risk Evaluation and Mitigate Strategies (REMS) as a pretext to hinder generic entry and maintain their monopoly power. The CREATES Act is consistent with Mylan's and the generic drug industry's long-standing goal of ensuring that consumers have access to these lower price generic alternatives to branded drugs.

The Food and Drug Administration (FDA) has stated that REMS abuse is "a problem" that "delays the availability of generics."[1] In a court action brought by Mylan challenging a brand firm's REMS abuse conduct, the Federal Trade Commission explained that such abuse "threatens to undermine the careful balance created by the Hatch-Waxman Act and potentially preserve a brand firm's monopoly indefinitely."[2] The FDA agrees, and thus has recently held a public meeting to discuss "The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access."[3]

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[1] Food & Drug Administration (FDA), Dr. Janet Woodcock, Congressional Testimony before House Committee on Oversight & Investigations, March 22, 2017.

[2] Amicus Brief of the Federal Trade Commission, *Mylan Inc. v. Celgene Corp*, 2:14-CV-2094-ES-MAH (D.N.J.) *available at* https://www.wsgr.com/publications/PDFSearch/antitrust-policies-0117.pdf.

[3] Scott Gottlieb, Commissioner of FDA, *Opening Remarks in Public Meeting on Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access* (July 18, 2017), *available at* https://www.fda.gov/NewsEvents/Speeches/ucm567323.htm.

The Hatch-Waxman Act, and the wave of generic approvals it helped to facilitate, is one of the great legislative achievements of the past half-century. Since its approval in 1984, the Hatch-Waxman Act has resulted in the approval and entry of over 10,000 lower cost generic drug products.[4] Generic drugs have been saving American consumers trillions of dollars, increasing from $8-10 billion in 1994 alone[5] to $253 billion in 2016; in fact, from 2007 to 2016 generic drugs saved consumers $1.67 trillion.[6] Mylan is proud of its leading role in delivering generic savings to consumers and taxpayers in the U.S. Over the last decade, Mylan's average share of the generics prescriptions market was 11.2% translating to approximately $187 billion in savings.

The 2016 Generic Drug Savings and Access in the United States Report conducted by IMS reiterates the important role generic companies play in providing patients access to high quality, affordable medicines, with generics representing 89% of prescriptions dispensed in the United States, but only 27% of total drug costs.[7] Generic drugs also generate substantial savings for government payors; for example, the U.S. Department of Health and Human Services found that in 2014 77.5% of Medicare Part D prescriptions were filled with generics but those generics only accounted for 23% of spending.[8]

For years, brand companies' conduct with regard to REMS products has blocked consumer access to important generic products and continues to threaten future savings from generic drugs. This is starkly contrary to Congress's action when it passed the 2007 FDA Amendments Act, which directly addressed this concern by providing that NDA holders cannot use REMS "to block or delay approval of an [ANDA]."[9]

Despite this clear statutory language, certain brand pharmaceutical companies have abused this system and continue to prevent competition by hindering generic and biosimilar drug manufacturers' ability to purchase samples of the Reference Listed Drug (RLD). RLD samples are necessary to conduct bioequivalent testing and ultimately for entry into the market of safe and affordable generic and biosimilar products.[10] Without access to RLD samples, prospective generic applicants *cannot*

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[4] Interview by Tammie Lee Demler with Ralph G. Neas, President and CEO, GPhA (published June 23, 2015), *available at* https://www.uspharmacist.com/article/interview-with-ralph-g-neas-president-and-ceo-gpha.

[5] CONG. BUDGET OFFICE, 105TH CONG., HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (1998) at xi, *available at* https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf.

[6] Association for Accessible Medicine, 2016 Annual Report *available at* http://accessiblemeds.org/wp-content/uploads/2017/02/AAM-Annual-Report-2017.pdf.

[7] "Generic Drug Savings and Access in the United States Report," IMS (2016).

[8] DEP'T OF HEALTH & HUMAN SERV.S, REPORT TO CONGRESS: PRESCRIPTION DRUGS: INNOVATION, SPENDING, AND PATIENT ACCESS (Dec. 7, 2016), *available at* http://apps.who.int/medicinedocs/documents/s23128en/s23128en.pdf.

[9] 21 U.S.C. § 355-1(f)(8).

[10] *See* Scott Gottlieb, *FDA Working to Life Barriers to Generic Drug Competition*, FDA VOICE (June 21, 2017), https://blogs.fda.gov/fdavoice/index.php/2017/06/fda-working-to-lift-barriers-to-generic-drug-competition/ ("To

even file an application with FDA seeking regulatory approval. Thus by withholding or delaying access to the RLD brand manufacturers can extend their monopolies and force consumers, Medicare, and Medicaid to pay higher prices for drugs. As the FDA Commissioner Gottlieb made clear, this conduct constitutes "'gaming' [FDA's] system," and "[t]his sort of gaming is wrong."[11]

REMS abuse has already imposed real and significant costs on American consumers and the healthcare system; indeed, a 2014 study found that REMS abuse cost the U.S. healthcare system $5.4 billion annually.[12] Consumers incur $960 million of this cost, while Medicare and Medicaid bear $1.8 billion and private insurers suffer the remaining $2.4 billion.[13] There is no reason to expect this trend to abate and, if Congress does not act to remedy this issue, certain brand companies will likely become increasingly brazen about REMS abuse.

It is our understanding that some brand firms have argued that their refusal to provide samples to generics is based on their purported safety concerns – this argument is self-serving and contrary to FDA regulation. REMS programs are designed to regulate the commercial sale of certain products to patients to ensure the risks of such products do not outweigh their benefits to patients. For example, REMS programs may include patient education materials, in part, to impress on the patient the importance of following the program's procedures in the absence of constant supervision by doctors.

Unlike the commercial sale of these products to patients directly, generic firms purchase brand samples for bioequivalence testing to support their ANDAs. These trials are conducted under the supervision of trained professionals including medical doctors and are subject to strict regulations and safety precautionary measures. Considering the closely regulated nature of bioequivalence testing, the risk REMS programs are designed to mitigate from occurring is likely substantially lower during testing than when the drug is sold commercially through a REMS program.

In addition, brand firms' safety justifications ignore generic manufacturers' extensive experience with the testing and sale of REMS drugs. Consider Mylan, for example. Mylan is currently an active participant in at least 5 different REMS programs.[14] In fact, in many cases, generic manufacturers are participating in more REMS programs than the brand firms who are claiming that generic companies cannot be trusted to handle a REMS drug.

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perform the studies required to develop a generic alternative to a branded drug, a generic sponsor generally needs 1,500 to 3,000 doses of the originator drug.").

[11] Scott Gottlieb, Commissioner of FDA, *Opening Remarks in Public Meeting on Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access* (July 18, 2017), *available at* https://www.fda.gov/NewsEvents/Speeches/ucm567323.htm.

[12] Alex Brill, *Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry*, at 5 (2014), *available at* http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf.

[13] *Id.*

[14] FDA, Approved Risk Evaluation and Mitigation Strategies (REMS), https://www.accessdata.fda.gov/scripts/cder/rems/ (last accessed July 17, 2017).

Congressional action is necessary to remedy this market-distorting conduct by some brand firms. The CREATES Act is a safe and effective bipartisan solution that would provide generic and biosimilar companies access to the samples they need to bring lower cost alternatives to the marketplace. Unsurprisingly, considering the scope of the problem, support for the CREATES Act is broad and robust. For example, on June 14, 2016, a group of 15 healthcare stakeholders wrote to express concern over REMS abuse as well as their support for the CREATES Act, which they stated "is a common sense solution that will prevent [REMS abuse], and further patient access to safe, effective, and affordable medication."[15] Mylan is pleased to include its name in the long list of organizations that believe the CREATES Act is an effective way to remedy REMS abuse and facilitate the entry of affordable generic products. We applaud those members of Congress in both chambers who have taken lead on this critical issue and urge others to join in to support this legislation.

Thank you for holding a hearing on this important topic and for your consideration of our comments. We urge the committee to mark-up the CREATES Act and move it to the House floor promptly. Should you have any questions, please do not hesitate to contact us by reaching Nimish Shah, Head, Federal Government Relations at nimish.shah@mylan.com or 202-507-5317 to arrange for discussion. We would be happy to meet with you or your staff to further discuss our firsthand experience with this important topic.

Sincerely,

Marcie E. McClintic Coates
Head of Global Policy, Mylan N.V.

[15] Letter to Chairman Grassley, Ranking Member Leahy, Senator Lee, and Senator Klobuchar regarding the CREATES Act (June 14, 2016), *available at* http://www.gphaonline.org/media/cms/CREATES_Act_Group_Letter.pdf.