Mylan

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Regarding LD 1280

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Introduction

My name is Marcie McClintic Coates and I am Head of Global Policy at Mylan N.V. Prior to my current role, I have held the positions of Head of Global Regulatory Affairs, Vice President and Chief of Staff, and Global Regulatory Counsel during my 10 years with Mylan. I am here to express my support for LD 1280.

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 U.S. – mostly generics – and has approximately 240 Abbreviated New Drug Applications ("ANDAs") pending with the U.S. Food and Drug Administration ("FDA") to gain approval of additional generic medicines. We also have one of the largest portfolios of biosimilars in development. Our extensive generic portfolio and biosimilars represent the commitment of Mylan and our employees to ensure consumers have access to more affordable options when filling their prescriptions. LD 1280 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.

LD 1280 will provide Maine, and its citizens, access to generic versions of many important drugs at substantial savings. This legislation is aimed at addressing brand manufacturers' refusal to sell drug samples to generic manufacturers under the guise of Risk Evaluation and Mitigation Strategies ("REMS")

programs. Such programs were created by FDA to ensure safety for drugs with significant safety concerns by imposing risk mitigating measures to ensure that the drugs' benefits outweigh its risks. But, brand firms have taken advantage of such safety considerations as a pretext for not providing generics with samples of these products. Without access to brand samples, a generic manufacturer cannot conduct bioequivalence testing, and thus cannot even file an ANDA with the FDA, the application required to get approval of a generic drug product. Brands have used pre-textual safety concerns based on REMS to justify their conduct despite the fact that REMS only governs the commercial sale of a drug and does not apply to the sale of pharmaceutical product to generic companies for the purposes of bioequivalence testing. Such conduct clearly runs contrary to the Hatch-Waxman Act of 1984, which created the ANDA process to facilitate the availability of lower-cost generic drugs and has been extremely successful since its adoption. However, some manufacturers have found a way to use REMS to thwart this key goal, avoid generic competition, and maintain high prices to the detriment of consumers, taxpayers, governments and the healthcare system.

LD 1280 addresses these abuses, and thus, facilitates the entry of low-cost generic alternatives to the benefit of Maine and its consumers. This legislation will help Maine consumers gain access to lower cost generic versions of many important drugs.

REMS Abuse Harms Consumers

As part of the 2007 FDA Amendments Act ("FDAAA"), Congress required the development of REMS for certain drugs to ensure that the benefits of those drugs outweighed their risk to patients. Since FDAAA's passage, the application of REMS to branded products has grown significantly; indeed, a 2014 study concluded that "[n]early 40% of new FDA approvals are subject to REMS."[1] While REMS programs are an important tool that helps to facilitate the availability of life-saving medication, some manufacturers

[1] Alex Brill, "Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Entry," Matrix Global Advisors (July 2014) *available at* http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf.

have been using them as a justification to hamper generic competition and undermine the Hatch-Waxman Act.

The Hatch-Waxman Act has facilitated the approval and entry of over 10,000 lower cost generic drug products since 1984.[2] Generic drugs have been saving American consumers trillions of dollars, increasing from $8-10 billion in 1994 alone[3] to $227 billion in 2015; and from 2006 to 2015 generic drugs have saved consumers $1.46 trillion.[4] In Maine, generic drugs have generated savings of nearly $1 billion to Maine patients and taxpayers just in 2015 alone (through savings of $139 million in Medicaid spending, $293.2 million in Medicare Part D, $30.8 million in cash pay, and $491.7 million in commercial insurance spending).[5] Generics have also generated substantial savings for government payors. The 2016 Generic Drug Savings and Access in the United States Report from 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 U.S., but only 27% of total drug costs.[6] Additionally, 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.[7]

Under Hatch-Waxman, in order to demonstrate bioequivalence and file an ANDA, a generic manufacturer needs access to samples of the brand drug to conduct testing to demonstrate sameness with the brand drug. Generally, a generic can obtain samples through its normal wholesale and product

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[2] 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.

[3] 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.

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

[5] *Id.* at 16.

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

[7] 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.

purchasing partners, but this pathway has not been available in many circumstances for drug products subject to REMS or restricted distribution systems. In those circumstances, the generic manufacturer must seek to procure samples for bioequivalence testing directly from the brand firm, and brand firms have declined to sell Mylan and other generics samples for bioequivalence testing under the guise of their REMS programs and purported safety concerns.

Without access to samples, there is simply no way for a generic to conduct bioequivalence testing, file an ANDA, or receive FDA approval. Thus, if generics cannot access brand samples, there is no way for consumers to benefit from lower priced generic alternatives. The lack of generic competition results in a disincentive for brand firms to lower their prices to meet competition as well as the absence of more affordable generic alternatives. Correspondingly, consumers lose out on the generic savings they would normally have under the Hatch-Waxman regime. In fact, the absence of more affordable generic drugs means that some consumers are forced to forego some drug treatment regimens.[8]

LD 1280 Will Help Remedy REMS Abuse

Brand manufacturers have been able to abuse the REMS program by refusing to allow generic manufacturers to obtain samples in the manner described above because the federal statute establishing the REMS regime lacks any effective enforcement mechanism. FDAAA states: "No [brand manufacturer of a REMS product] shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an [ANDA]."[9] However, the Act fails to provide an enforcement mechanism in the event that brand manufacturers violate this prohibition. In light of this, the FDA has recognized that

[8] *See, e.g.*, "New Pills Gain in Cancer Fight, Till Cost Gets in the Way," Health & Medicine, February 26, 2012, *available at* http://pilotonline.com/news/local/health/new-pills-gain-in-cancer-fight-till-cost-gets-in/article_c5d65355-0445-5696-9a82-32995e3dae4a.html.

[9] 21 U.S.C. § 355-1(f)(8).

REMS abuse is a problem that it "struggle[s] with a lot and that the companies struggle with and it has delayed availability of generics."[10]

LD 1280 will help remedy REMS abuse by creating an enforcement mechanism when brand companies refuse to provide drug samples to generics for the purpose of bioequivalence testing. Specifically, the statute will enable the Maine Attorney General to seek injunctive relief, *i.e.* a court order that the brand manufacturer make available to generic manufacturers the REMS product "at fair market price and without any restriction that delays access." In addition, the enforcement mechanism will facilitate generic access to samples when brand manufacturers self-impose restricted distribution programs and refuse to provide samples to the generic manufacturers even when they are under no REMS obligations. In short, LD 1280 will make it possible for generic manufacturers to obtain samples when faced with brand firms' roadblocks under the guise of REMS, which in turn will provide more affordable generic alternatives for Maine patients and payors.

LD 1280 Will Benefit Maine Consumers

This legislation will help Maine consumers and allow them to fill their prescriptions with lower cost drugs. By creating an avenue for generic manufacturers to obtain samples of REMS drugs for bioequivalence testing, this legislation will facilitate availability of generic alternatives for those branded products, which, in turn, will provide Maine consumers access to lower priced drugs. As noted above, 89% of prescriptions were filled with generic drugs in 2016, yet those drugs only accounted for 27% of total drug spending.[11] Maine consumers are currently being deprived of these savings for many REMS drugs because certain brands are misusing the REMS framework to block generic competition. This legislation will address this consumer harm and could save Maine and its residents millions of dollars a year.

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[10] *Examining FDA's Generic Drug and Biosimilar User Fee Programs: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 15th Cong., Preliminary Transcript at 35-36 (2017) (statement of Janet Woodcock M.D., Director, FDA CDER), *available at* http://docs.house.gov/meetings/IF/IF14/20170302/105631/HHRG-115-IF14-Transcript-20170302.pdf.

[11] Association for Accessible Medicine, 2016 Annual Report *supra* note 4.

The Brands' Safety Concerns are Pre-Textual

Brand manufacturers have argued that their refusal to supply samples to generics is based on reasonable safety concerns. But this argument is divorced from reality. REMS programs are designed to regulate the commercial sale of certain products to ensure their risks do not outweigh their benefits to patients. For example, REMS programs generally include patient education components, 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 trials used to support their ANDAs. These trials are conducted under the supervision of trained professionals and medical doctors and are subject to extensive regulations and safety precautions. Considering the closely regulated nature of bioequivalence testing and other clinical trials, the probability of an adverse event is likely substantially lower in bioequivalence testing than when the drug is sold commercially through a REMS program.

In addition, brand firms' safety justifications ignore generic manufacturers' extensive experience with REMS drugs, as well as other drugs with serious side effect profiles. Consider Mylan, for example. Mylan is currently an active participant in at least 5 different REMS programs,[12] and has extensive experience in implementing others in the past. In fact, in many cases, generic manufacturers are participating in more REMS programs than the brand who is claiming generic companies cannot be trusted to handle a REMS drug.

In reality, brand manufacturers that utilize REMS and restricted distribution systems to block or delay generic competition are more concerned about erosion of their market share to generics. When generics enter the market, the brand immediately loses substantial market share as consumers switch to lower cost alternatives. While consumers benefit from the generic's lower price, the brand faces increased competition and decreased market share. However, if the brand can use its REMS program as an excuse to

[12] FDA, Approved Risk Evaluation and Mitigation Strategies (REMS), https://www.accessdata.fda.gov/scripts/cder/rems/ (last accessed May 2, 2017).

withhold samples from generic firms, they can effectively insulate their product from competition. For example, Mylan has been blocked from conducting bioequivalence studies as some brand companies have used REMS as a pretext to delay generic competition by refusing the sale of products. In this situation, as explained above, Maine consumers lose the ability to fill their prescriptions with low cost generic alternatives because brand manufacturers were able to take advantage of the loopholes in a system designed to increase the availability of drugs to consumers.

Conclusion

I would like to thank Senator Jackson for presenting this bill, as well as his co-sponsors, Representatives Gattine, Lawrence, and Mastraccio, and Senators Bellows, Carson, Saviello, and Vitelli for their leadership on this issue and for fighting so that Maine's citizens have access to affordable medication. I also want to acknowledge the efforts on this important issue of Senator Susan Collins at the federal level. Recently, the U.S. House and Senate introduced the CREATES Act to combat anticompetitive practices that block entry of lower-cost generic drugs of which Senator Collins was an original co-sponsor. Maine's citizens should be proud that their legislators are working to ensure that they are protected from the regulatory games played by certain brand manufacturers. REMS abuse is a very serious problem that causes consumers to pay more to fill their prescriptions because competition has been blocked. This legislation is an effective solution to this problem and I encourage every member to vote for it.

I am happy to answer any questions you might have.