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July 16, 2018

The Honorable Alex M. Azar II, Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW, Room 600E
Washington, DC 20201

RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs [RIN 0991-ZA49]

Dear Secretary Azar:

Thank you for the opportunity to provide comments in response to the Agency's request for information on the *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* ("Blueprint"). Mylan applauds the Administration's keen interest in finding ways to increase generic and biosimilar competition and to end abuses and practices that hinder patient access to these more affordable treatments. As a longstanding leader in generic medicine and a company with one of industry's largest portfolios of biosimilars, Mylan appreciates the opportunity to comment.

In the U.S., Mylan supplies more than 650 products and nearly 10% of all U.S. generic medicines, with an average sales price of 25 cents per dose. In the last two years, Mylan's generic medicines have saved U.S. patients and payors nearly $50 billion according to IQVIA reports for 2016 and 2017. In the last five years, Mylan has launched more generics in the U.S. than any other company and billions of our doses sold here are manufactured in our U.S. manufacturing facilities.

While Mylan has provided comments in coordination with the Association for Accessible Medicine (AAM) and its Biosimilar Council, we offer the following additional comments in response to the Blueprint's specific goals of Increasing Competition and Reducing Patient Out of Pocket Spending. (A one page Appendix is also attached to recap Mylan's five recommendations provided herein).

A. Generics medicine are the proven value based pricing solution in the U.S.

Since the enactment of the Hatch Waxman Act in 1984 which sought to balance both innovation and competition, U.S. generic competition has become the most robust in the world. Today, the U.S. has the world's best generic utilization rate, and American patients and payors have saved more than $1.79 trillion from generics in just the last decade as a result according to IQVIA. Each year, generic drug prices have continued to drop, decreasing overall by 15% annually, while brand prices have increased by 15% per year.[1] According to the 2017 IQVIA Savings Report, the average patient co pay for a generic medicine in the U.S. is just $6, and nearly 95% of all generic prescriptions cost under $20. Generic drug companies supply 90% of all prescriptions dispensed in the U.S. yet those medicines account for only 23% of prescription drug cost, making generic medicines the proven value based drug pricing solution in America. The unprecedented savings and success of generics in the U.S. is the result of a long standing competitive system that is incentivized to expand access to lower cost, high quality generic medicines.

B. There is a concerning trend to move generics from a robust, competition driven system to a rebate driven system

We believe there is an alarming, emerging trend to move generics from a robust, competition-driven system to a rebate-driven one like the U.S. brand market. Currently, branded companies are using rebates to block access to generic and biosimilar versions of some of the costliest medicines in the U.S. This practice threatens future generic and biosimilar savings, particularly for high cost medicines that lack

[1] As affirmed in ASPE Issue Brief 2016, ESI Drug Trends, and IQVIA data.

competition. It also discourages companies from committing the significant investment needed to develop lower cost alternatives and take on costly patent challenges. This trend will perversely, drive already-high drug prices and patients' out of pocket spend even higher, despite the fact that more generics are being approved by the FDA for some of the most expensive medicines that have long lacked competition.

Last year, the top 20 most costly medicines overall in America had sales of $100 billion, and to date, only two of these products have generic or biosimilar competition on the market. Remicade® and Copaxone® collectively had ~$10 billion in 2017 sales. Both have had lower cost biosimilar and generic competition for more than a year but those have only garnered 3% and 15% market share, respectively. Traditionally, generics take 90% of market share as more competition emerges. Additionally, many formularies are not even covering these lower cost alternatives for patients and payors – an almost unheard-of phenomenon, denying patient access to the important, less costly alternatives for such expensive brand medicines.

CMS alone spent $1.4 billion in 2016 on Copaxone, according to the recently released CMS Dashboard. Currently, eight of the top 10 Medicare Part D plans do not even have generic Copaxone on their formularies. This represents a complete reversal of the longstanding approach of incentivizing generic utilization. In the two Part D plans that do cover generics to Copaxone, generics are in the same formulary tier as the brand. These generic alternatives should have saved the overall U.S. healthcare system billions of dollars. However, to date, Multiple Sclerosis patients only have access to these more affordable equivalents to Copaxone just 15% of the time because of formulary and coverage decisions. Patients and payors – the government, healthcare plans and employers – are experiencing this restricted access to more affordable generics because brand companies are using rebates to block generic access.

Based on a review of the top 20 highest spend Part D medicines provided in CMS's recent dashboard release, only four products have had generic competition enter the market to date. Of the two Top 20 products that had generic competition emerge in 2017, the average generic utilization rate soon after launch was just 10%. Renvela began with a slow 15% generic conversion at launch and today, even with nine generic competitors 12 months later, the generic market share is only at 55% - far below the historic average of 90% generic utilization. Copaxone 40mg also began with record low generic conversion after launch with just 5% market share. These examples highlight the negative impact that rebates are rapidly having on new to launch generics and biosimilars.

Further, if rebate strategies materially impact generic and biosimilar utilization, many generic and biosimilar companies may fully forgo developing such complex and investment-intensive products in the future, eliminating even the prospect of competition. FDA Commissioner Scott Gottlieb, MD, recently described this precisely in the context of biosimilars but it equally applies to complex generics:

> "I worry that companies are going to pull out and not want to develop biosimilars that cost anywhere between $100-300 million to develop…if they know that they can't penetrate the market… because of the existence of stacked rebates...and a big rebate is paid by to the health plan to keep the biologic in the preferred tier on a formulary…an example of where the structure of the pricing environment frustrates our public health goals." (Atlantic Briefing, 6/2018)

C. In the words of the FDA Commissioner, rebates rig the system against biosimilars and generics

After the FDA approves a product, drug plans decide whether they will cover the medicine for their members by placing the product on their formulary list. Covered medicines that go on the plan's formulary are placed into tiers which determine how much each patient will pay. Generic tiers have the lowest co-pays and coinsurance for patients. Historically, generic medicines have been added to preferred formularies immediately upon FDA approval and placed on favored tiers to encourage maximum generic utilization.

Today, new generic drugs offered at lower prices than the brand are no longer being automatically placed on formularies or generic tiers within them. When brand manufacturers face generic competition, some heavily rebate their product to protect their market share and block generic access often while

maintaining high list prices. Doing so either blocks the generic from even being available to the plan's patients or assures the brand preferred formulary placement over the generic, potentially leaving payors with the bill for a higher price and patients with higher out of pocket costs. The problem is even more concerning in those instances where generic manufacturers have invested tens of millions or in some cases, well over $100 million or more on research and development and legal expenses to bring competition to complex drugs. These medicines are the costliest to make and are protected by multiple patents prompting expensive litigation. Complex and specialty medicines represent the most expensive medicines in the U.S. and most of these still do not have generic competition today.

This dynamic has led FDA Commissioner Gottlieb to call the rebate system "rigged" against biosimilars and noting that "once biosimilar makers see that the system is rigged against them, what's the incentive for a biosimilar maker to pour money into future investments to develop these lower cost alternatives?" (Scott Gottlieb, FDA AHIP 2018).

D. This trend has real consequences for patients and payors like CMS

Just after the Blueprint's release in May, Avalere published a study finding that Part D plans have increasingly moved lower cost generics into higher formulary tiers typically reserved for brand drugs as these have higher out of pocket costs and coinsurance for patients than the traditional generic tiers. The result has been a masking of brand drug price increases. Consequently, Medicare patients are suffering with higher out of pocket costs and generic drugs are no longer being encouraged. From 2011- 2015, Avalere's analysis found that Part D patients paid $6 billion more in out of pocket costs because generics were moved onto less favorable brand formulary tiers even as generic drug prices had decreased or stayed flat during this period. The Avalere study also noted:

> "As plans face pressure to cover new, innovative, and sometimes costly branded medications, they have responded with increased utilization management and creative tier placement strategies to moderate the average cost of covered drugs on each tier. The result of this tiering strategy is that some patients may ultimately pay more out-of-pocket for generic drugs when those drugs are placed on higher tiers."[2]

Additionally, Avalere's study found:

- Part D Plans have increasingly moved lower cost generics to higher formulary tiers even though generic drug prices have either decreased or remained flat.
- Part D plans are adjusting generic tiering as a means of balancing against brand drug price increases which drives up patient cost sharing.
- The number of generic drugs on the lowest formulary tier declined about 53% in Part D plans as generic drugs were shifted to higher priced tiers to mask increased brand prices.

E. Recommendations to increase competition and reduce patient out of pocket spending

Mylan makes the following five recommendations in response to the Administration's Blueprint to help increase generic and biosimilar competition and shift incentives to where they belong – patients:

1. CMS's May 2016 originating guidance should be rescinded

As the Avalere study also noted, "[o]ver time, Part D plans have also placed an increasing number of generic drugs on brand tiers. In response to this trend, as well as plan sponsor feedback, CMS announced a major change to the formulary structure of the Part D program in May 2016, allowing plan sponsors to create a 'non-preferred drug' tier that explicitly includes both brand and generic drugs." This shift in CMS policy by the previous Administration effectively gave Part D plans a license to expand the movement of generics into non-generic tiers, counter to the use of generic tiers designed to encourage generic utilization and reduce patient out of pocket costs. As CMS then noted, the various changes made

[2] Avalere Study, "Generic Drugs in Medicare Part D, Trends in Tier Structure and Placement Study" (May 22, 2018).

were intended “to provide stable payments to plans and make improvements to the program for…the most vulnerable enrollees.” This allowed plan sponsors to incorporate a "non-preferred drug tier” option that allows for a combination of both branded and generic drugs for the first time.

Recommendation: We urge CMS to revisit and rescind its May 2016 guidance and instead encourage maximum utilization for generics and biosimilars through Medicare. Part D plans should be encouraged to place biosimilars and generics on the most favorable and lowest cost sharing tiers relative to the reference brand product to incentivize robust usage of lower cost generics and biosimilars.

2. Part D Issues should be addressed first before moving products from Part B to D

The Blueprint and RFI note that the Administration is considering moving some products from Medicare Part B to Medicare Part D. Today, 16 of the Top 20 medicines by spend in Medicare Part B are biologics.

Recommendation: Given the very limited uptake of biosimilars to date, as well as the current trend described above that is driving generics and biosimilars to a more rebate driven approach in Part D, any movement from Part B to Part D should only be evaluated after first addressing these critical issues in Part D. Additionally, a host of other considerations (several of which are outlined in AAM’s RFI response) would need to be addressed to ensure that companies are incentivized to meet the Administration’s aim of cultivating a vibrant biosimilar market in the U.S.

3. HHS should create incentives and momentum for biosimilar utilization throughout the value chain

Mylan applauds the Administration’s recognition of the importance of a vibrant biosimilar market and HHS’s commitment “to foster and nurture a new, competitive biosimilar drug market.”[3] “Biosimilars not only present opportunities for significant cost savings, they can dramatically expand patient access to therapies. Millions of American patients stand to benefit from increased utilization of lower-cost, high quality biosimilar products.” (Scott Gottlieb, FDA AHIP 2018).

We also applaud the informative educational campaign launched by the FDA to better inform patients and practitioners about biosimilars. We support the Agency’s recognition of the value of increasing biosimilar competition and access for patients to safe, effective, and lower-cost biologic medicines.

Nearly 65% of Medicare Part B drug spending is on biologic medicines. Biosimilar medicines promise competition to these important, but expensive, innovative therapies, resulting in significant new savings for patients and payors alike. This promise can only be realized if the appropriate systemic levers are put in place to develop a robust, sustainable biosimilars market. Currently, incentives are not aligned to encourage use of lower-cost, high quality biosimilar medicines. As of June 2018, only three of the 11 biosimilar medicines approved by the FDA had launched in the US, and all face limited market uptake. Uptake of biosimilars in the US is limited due to a confluence of factors:

- Lack of incentives for biosimilar prescribing, dispensing, formularies and patient acceptance
- Originator gaming preventing biosimilar market access at loss of exclusivity
- Originator tactics around rebating, bundling and casting doubt on biosimilar effectiveness
- High development costs and lack of regulatory certainty/flexibility in a few areas

Recommendation: As further elaborated in the AAM and Biosimilars Council submission to this RFI, there are several steps the Administration can take to realize the full potential of biosimilar competition:

- prioritize efficient development and timely review of applications;
- accelerate the education of physicians, patients and other key stakeholders regarding the safety and effectiveness of FDA-approved biosimilars; and
- advance incentives to ensure further penetration and timely adoption of these lower priced biologic medicines. Incentives could include enhancing physician payments for use of

[3] White House Press Briefing, May 11, 2018.

biosimilars, reducing patient cost-sharing for biosimilars and granting unique, permanent HCPCS codes at biosimilar launch.

Furthermore, the Administration should carefully consider the impact on the fledgling biosimilars market of proposed changes to Part B, particularly the CAP-like program or transition of medicines from Part B to Part D as noted above, bearing in mind the negative impact that rebate-based formulary management is currently having in Part D, particularly for new generic and biosimilar launches.

4. Adopt a global development approach to spur competition

Increasing the competitiveness of biosimilar medicines is central to reducing the impact of high-priced medicines on US patients. Ensuring that biosimilar medicines are quickly and efficiently developed and FDA-approved is a critical component in spurring competition. While the US has already taken an important step towards increasing efficiency by allowing U.S. biosimilar applicants to use development data comparing the biosimilar candidate with originator reference product licensed by a non-US stringent regulatory authority, such as the European Medicines Agency, this efficiency is not fully realized due to the continued need to conduct multiple bridging studies comparing the non-US-licensed reference product with the US-licensed product. Duplicative bridging studies do not bring any added scientific value and add substantial collective costs to biosimilar development programs. Mylan supports submissions to this RFI from the International Generics and Biosimilars Association (IGBA) and AAM that further elaborate on this topic.

Similarly, complex generics often require clinical endpoint studies to demonstrate their clinical equivalence, or may necessitate bioequivalence studies in patient populations (as opposed to healthy volunteers). This leads to longer and substantially more expensive development processes than those for other generics. The sourcing of the comparator product can also be challenging in some cases.

Recommendation: We urge the Administration to adopt a global development approach for these products, working with other regulators to allow use of one set of data to support approval in multiple countries. This will facilitate access to alternatives to high-priced originator products, when development programs may otherwise be cost prohibitive or infeasible.

5. Patent abuses, at home and abroad through trade policy, should be stopped

a) Abuse of the patent system

Promoting innovation and increased competition for biologics and generics is crucial to lowering drug prices and reducing out-of-pocket costs to patients in the US. Despite attempts to close loopholes allowing brand companies to “game” FDA rules to thwart generic and biosimilar competition, such gamesmanship is still common with originator companies creating patent thickets around old products with non-innovative modifications.

Although patents claiming these minor modifications may later be successfully challenged in both federal court and at the Patent Trial and Appeal Board, the time and expense spent by generic and biosimilar companies to combat these weak patents are a deterrent to both ANDA and biosimilar filings and the launch of products, ultimately to the detriment of patients paying for brand prices long after the original patent term has expired.

Recommendation: As outlined further in the response from AAM, Mylan encourages the Administration to continue maintaining a strong Inter Partes Review (IPR) process at the USPTO. The utilization of the IPR system combats invalid patents granted in part due to the limited time examiners have to review references and assess the validity of an application. We recommend the implementation of a more arduous patent examination regime and opposing pending legislation which would undermine the bipartisan goals of the America Invents Act by eliminating IPRs in the pharmaceutical sector. Loopholes should be closed which would allow brand companies to opt out of the IPR system, and legislation that would allow for timely appeals of IPR determinations in the Federal Courts should be supported.

b) Trade policy should balance competition and innovation

Mylan strongly believes that U.S. trade policy provisions should balance both innovation and competition. History has shown measures in trade agreements that overly promote innovation without adequate balance and advancement of competition can reduce or delay patient access to affordable generic alternatives For example, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), part of the Uruguay Round of GATT (General Agreement on Tariffs and Trade), set the global standard for the protection of IP rights nearly 30 years ago. The implementation of this new standard, which among other things extended patent terms from 17 years from the date of granting of a patent to a minimum term of 20 years from the date of filing of the patent, had a profound impact on the U.S. generic pharmaceutical industry, consumers and health care expenditures. In the case of Mylan, we had to delay the launch of generic drugs that were in the pipeline and about to enter the market, which also had a direct and immediate impact in lost savings for U.S. patients. This provision alone continues to affect every single drug that has associated patents.

Recommendation: To further advance competition, trade policy should 1) encourage trade and export provisions that will enhance the ability of generic and biosimilar manufacturers to access markets globally, and 2) spur greater generic and biosimilar competition to drive even greater prescription drug savings to U.S. patients and taxpayers. To achieve the goals of the Administration in promoting greater competition in the U.S. pharmaceutical market as a means of addressing high drug costs, it will be critical to ensure that any trade agreements the U.S. is involved with do not further increase and broaden protections for originator pharmaceutical companies to the detriment of timely access to generic and biosimilar medicine.

F. Conclusion

Mylan looks forward to working with all stakeholders to best address the challenges outlined herein to preserve the competition driven approach that has made the U.S. generics market the world's gold standard for generic savings and access. With one of the industry's most robust generic and biosimilar portfolios, we are committed to ensuring a sustainable and vibrant market here in the U.S.

Without sufficient incentives to encourage generic and biosimilar competition everyone loses – patients, payors, and the entire healthcare system. Ultimately, the delicate balance that the U.S. has worked so hard to achieve between innovation and competition will be lost. These measures are crucial for ensuring that affordable medicines are available for patients and companies are not discouraged to make the significant investment needed to bring complex generics and biosimilars to market in the U.S. We also urge the Administration to focus heavily on these measures which can also help address the economic root cause of shortages. We are encouraged by FDA's recent announcement of a new Drug Shortages Task Force to evaluate reimbursement policies from CMS and other payors that may make it difficult to develop and manufacture certain drugs profitably.

Thank you again for the opportunity to comment on the Blueprint and for HHS's leadership in advancing many measures to date to encourage more generics and biosimilar competition both within FDA and CMS and through this Blueprint.

Respectfully submitted,

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(Appendix: Mylan's Five Recommendations to HHS's Blueprint)

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Appendix

Five Recommendations in response to HHS's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Mylan makes the following five recommendations in response to the Administration's Blueprint to help increase generic and biosimilar competition and shift incentives to where they belong – patients:

1. **Rescind CMS's May 2016 guidance and discourage the growing influence of rebates to block generic and biosimilar competition.** We urge CMS to revisit and rescind its May 2016 Call Letter guidance that gave rise to the movement of more generic medicines into brand formulary tiers, causing Part D patients to pay $6 billion more in out of pocket expenses according to a recent study. Originator companies are also alarmingly using rebates to block or limit new generic and biosimilar competition, which increases patient and payor costs and discourages companies from making the heavy investment needed to develop these complex medicines. All facets of Medicare policy should encourage maximum utilization for generics and biosimilars with favored formulary tiers through a competition driven system, not a rebate driven system.

2. **Address disincentives in Part D for generics and biosimilars first before considering Part B movement to Part D.** Any consideration to move products from Part B to Part D must first address the negative impact rebate-based formulary management is currently having in Part D, particularly for complex generics and biosimilars which offer the greatest savings potential to the U.S. healthcare system.

3. **HHS should create incentives and momentum for biosimilar utilization throughout the value chain.** To help foster a vibrant market, HHS should further prioritize efficient development and timely review of applications; accelerate the education of physicians, patients and other key stakeholders regarding the safety and effectiveness of FDA-approved biosimilars; and advance incentives (ie, enhancing physician payments for use of biosimilars, reducing patient cost-sharing for biosimilars and granting unique, permanent HCPCS codes at biosimilar launch) to ensure further penetration and timely adoption of these lower priced biologic medicines.

4. **Adopt a global development approach to spur competition.** We urge the Administration to adopt a global development approach for generics and biosimilars, working with other regulators to allow use of one set of data to support approval in multiple countries. This will facilitate access to alternatives to high-priced originator products, when development programs may otherwise be cost prohibitive or infeasible.

5. **Patent abuses, at home and abroad through trade policy, should be stopped.** A strong Inter Partes Review (IPR) process at the USPTO should be maintained to combat invalid patents. A more arduous patent examination regime should be implemented and legislation that undermines the bipartisan goals of the America Invents Act by eliminating IPRs in the pharmaceutical sector should be opposed. Loopholes should be closed which would allow brand companies to opt out of the IPR system, and legislation that would allow for timely appeals of IPR determinations in the Federal Courts should be supported. Trade policy should seek to spur greater generic and biosimilar competition and not further increase protections for originator pharmaceutical companies to the detriment of timely patient access to generic and biosimilar medicine.