June 5, 2019

Lamar Alexander, Chairman
Senate HELP Committee
428 Dirksen Senate Office Building
Washington, D.C. 20510

Patty Murray, Ranking Member
Senate HELP Committee
154 Russell Senate Office Building
Washington, D.C. 20510

Dear Chairman Alexander and Ranking Member Murray:

On behalf of the Association for Accessible Medicines (AAM) and its member companies, we appreciate the opportunity to offer our views on *The Lower Health Care Costs Act of 2019* ("discussion draft") released on May 23. We share the Committee's goal of lowering the cost of health care and to enhancing patient access to more affordable medicines. Over the last several months, we valued the opportunity to work toward that shared goal and provided a robust set of recommendations to lower out-of-pocket costs for patients.[1] However, we believe that Section 205 of the discussion draft would significantly weaken the only incentive available for generic manufacturers to take on expensive and uncertain challenges to questionable brand-name patents. It is our view that the current version of the proposal would lead to less competition and higher drug prices for America's patients. Without changes to the discussion draft, AAM would be forced to oppose *The Lower Health Care Costs Act.*

For more than 30 years, the Hatch-Waxman Act has provided the only incentive for generic manufacturers to develop more affordable medicines by awarding a 180-day period of exclusivity for first filers that challenge a patent protecting an expensive brand-name drug. By promoting patent challenges, 180-day exclusivity encourages competition and the earlier entry of safe and more affordable generic alternatives. Thus, the 180-day exclusivity provision has been critical to the Hatch-Waxman Act's long track record of success in promoting generic competition.

The proposed changes to the 180-day exclusivity—as set forth in Section 205 of the discussion draft—turn the Hatch-Waxman incentive on its head. Section 205 is overly broad and would fundamentally undermine the ability of generic manufacturers to deliver more affordable medicine to America's patients.

The proposed language could, for example, trigger a loss of exclusivity based on a failure by the FDA to grant final approval by a first applicant within 30 months for any reason *even when the*

[1] AAM, Recommendations to Senate HELP Committee on Lowering Health Care Costs, March 2019.

generic drug applicant is diligently seeking final approval. Thus, first filers could be penalized through no fault of their own due to delays by the FDA. The FDA's statistics confirm that this will occur—its projected median time to final approval is 30 months.[2] Thus, there could be potential triggers and losses of exclusivity for the median of all ANDAs.

As such, the proposed Section 205 injects substantial uncertainty into business decisions. If 180-day exclusivity can be lost due to factors outside of the manufacturer's control, a manufacturer may be less willing to undertake an expensive and time-consuming patent challenge. The net result would be fewer generic drugs introduced into the market and less competition for expensive brand drugs—undermining the potential for patient savings and directly contravening the intent of Hatch-Waxman.

Generic manufacturers should diligently pursue FDA approval under all circumstances and the current market incentives—notably the 180-day exclusivity—provide ample motivation for this to occur. While it is our view that Congress adequately addressed the potential for "parking" as part of the Medicare Modernization Act of 2003, we have provided the Committee with two alternatives that were narrowly and carefully tailored to the FDA's stated concerns. Either of these alternatives would provide the FDA with additional authority to resolve the handful of occurrences it has identified as problematic, while preserving the only incentive available to generic manufacturers to challenge brand-name patents. We are also offering a third alternative that incorporates former FDA Commissioner Scott Gottlieb's suggested revisions to Section 205.[3] Those revisions ensure that generic companies who are actively and diligently pursuing final approval will not be unfairly penalized.

The challenges facing generic and biosimilar manufacturers are significant. In fact, the long-term sustainability of today's generic drug market is in jeopardy. Current market realities and anticompetitive tactics, combined with misguided policies, threaten the long-term stability of the generics and biosimilars markets even as the costs of brand pharmaceuticals continue to rise. In fact, over the last two years, generic manufacturers experienced a net loss of $7.7 billion as a result of price reductions and lower volume. [4] In contrast, spending on protected brand-name drugs increased by $20.8 billion on a net basis due to higher prices and additional volume.[5] *The Lower Health Care Costs Act*, as currently proposed, would only exacerbate this trend by undermining the only incentive for early generic entry and reversing Hatch-Waxman's more than 30-year track record of success.

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[2] FDA, FY2020 Justification of Estimates for Appropriations Committees, March 2019.
[3] Gottlieb, Scott, M.D., "The HELP Committee's Fix For 180-Day Generic Marketing Exclusivity: Does It Solve The Problem?" Health Affairs, May 2019.
[4] IQVIA, Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023, May 2019.
[5] *Ibid.*

Enclosed with this letter please find AAM's detailed comments on the discussion draft. In our comments, we have reiterated our recommendations on steps the Senate HELP Committee could take to increase—*not decrease*—generic and biosimilar competition. Unless *The Lower Health Care Costs Act* is significantly modified, prescription drug prices will increase and America's patients will continue to struggle to afford their medicine.

Sincerely,

Chester "Chip" Davis, Jr.
President and CEO

AAM Comments on Title II – Reducing the Prices of Prescription Drugs

I. Section 201 – Biological Product Patent Transparency

AAM commends the Committee for focusing on increasing patent and exclusivity transparency in the FDA's Purple Book. Greater coordination between the FDA and the Patent and Trademark Office (PTO) is critical to obtaining a more accurate picture of the patent landscape surrounding an originator biologic to ensure timely access to competition.

Section 201 represents a significant step towards making the Purple Book a more valuable resource for manufacturers seeking to develop biosimilar products and improves upon the Purple Book Continuity Act (H.R. 1520) as passed by the House. Section 201 would 1.) require manufacturers to list their patents in the Purple Book; 2.) direct the FDA and the PTO to work in concert to create a publicly available list of manufacturers that do not adhere to this requirement; and 3.) direct the FDA and the PTO to list the patents not disclosed in the Purple Book.

In comparison, H.R. 1520 only requires patents that are asserted during the patent dance to be listed in the Purple Book. This means that the Purple Book would continue to be of limited value. For first-to-file biosimilar developers, no patents would be required to be listed prior to the initiation of the patent dance with a reference product manufacturer. For subsequent biosimilar developers, the reference product manufacturer may not assert of the patents against the first-to-file biosimilar developer. This leads to additional patents being unlisted and leaves subsequent biosimilar developers in a disadvantage.

Section 201 could be further strengthened with inclusion of an enforcement mechanism as proposed by Senators Collins and Kaine in the Biologic Patent Transparency Act (S. 659). Reference product manufacturers increasingly establish patent thickets to block competition from biosimilar developers. Former FDA Commissioner Scott Gottlieb highlighted these anti-competitive efforts in announcing the agency's Biosimilars Action Plan last year. [1] While the FDA has approved 19 biosimilars to date, only seven are on the market and available to patients due to abuse of the patent system.

To that end, Section 201 should be revised to include the enforcement mechanism (i.e., the estoppel provisions) of the Biologic Patent Transparency Act in order to accelerate patient access to more affordable biosimilars.

II. Section 202 – Orange Book Modernization

[1] Gottlieb, Scott, M.D., Remarks as Prepared for Delivery at the Brookings Institution on the Release of the FDA's Biosimilars Action Plan, July 2018.

AAM appreciates the Committee's work to improve transparency to the patents obtained on brand-name prescription drugs in the Orange Book published by the FDA. In recommendations to the Department of Health and Human Services (HHS) on the *Blueprint to Lower Drug Prices* in July 2018, we recommended that the FDA separately identify formulation changes as different products under the approved brand-name drug and reflect discontinued products in the Orange Book.[2] We also encouraged the FDA to list patent information for brand-name drugs approved prior to 2013 upon request.[3]

Collectively, these improvements to the Orange Book could facilitate more timely generic applications and entry into the market. With improved transparency, generic manufacturers can accurately assess the patents and exclusivities applied to brand-name drugs and determine for which products to prepare applications for approval. Without this information, generic competition is impeded as brand-name drug companies bring lawsuits seeking to stop FDA approval of competitive products due to undisclosed patents.

Section 202 clarifies the information on patents and exclusivities that the FDA must include in the Orange Book. The FDA would also be directed to promptly remove invalid patents due to a Patent Trial and Appeal Board (PTAB) decision or ruling.

Section 202 could be strengthened with the inclusion of drug/device patents in the Orange Book. One study published in 2016 found "unexpired device patent exist for 90 percent of the 49 medicine/device product combinations studied, and were the only sort of unexpired patent for 14 products."[4] The study found that device patents on the drug/device combination products delays competition by a median of 4.7 years (within a range of 1.3 to 15.2 years).[5] Patient access to more affordable drug/device alternatives would be enhanced if these patents were required to be added to the Orange Book.

III. Section 203 – Ensuring Timely Access to Generics

Abuse of the citizen petition process was largely solved by the FDA's October 2018 revised guidance outlining those considerations the FDA would consider when determining whether a citizen petition was submitted with the primary purpose of delaying the approval of an abbreviated new drug application (ANDA).[6] AAM believes the FDA's actions to crack down on abusive or "sham" citizen petitions have been helpful in addressing the problem.

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[2] AAM Comment Letter, HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, July 2018, Page 33.
[3] Ibid., Page 34.
[4] Beall, Reed et al, "Is Patent "Evergreening" Restricting Access to Medicine/Device Combination Products?" DrugPatentWatch, 2016.
[5] Ibid.
[6] "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act" October, 2018.

Congressional action to further address the abuse of citizen petitions should start with codification of the FDA's October 2018 revised guidance on Section 505(q) of the FDCA. Section 203 proceeds in this manner and maintains an appropriate balance where citizen petitions can be used to allow interested stakeholders to notify the FDA of concerns with pending applications while at the same time ensuring that abusive citizen petitions are not used for the primary purpose of delaying approval of these applications. AAM supports Section 203.

IV. Section 204 – Protecting Access to Biological Products

AAM supports the intent of Section 204 as proposed and agrees with the Committee and the FDA that new chemical entity (NCE) exclusivity should not be carried over for products transitioned from regulation under the Food, Drug, and Cosmetic (FD&C) Act to the Public Health Services Act (PHSA).

V. Section 205 – Preventing Blocking of Generic Drugs

As described in the cover letter, AAM opposes Section 205 of the discussion draft. This provision would severely weaken the only incentive available to generic drug manufacturers to challenge patents on brand-name drugs. Without modifications to it as put forth with any of the three alternatives attached here, we would oppose *The Lower Health Care Costs Act*.

A. Summary of Concerns

AAM's concerns with the BLOCKING Act are manifold, including that:

- The BLOCKING Act sets an unreasonable 30-month deadline to obtain ANDA approval. Indeed, FDA's median final ANDA approval time was as high as 41.88 months during one quarter in 2018 and is projected to be 36.75 months in 2019. By setting the final approval date at 30 months—instead of a more reasonable period of 42 months that is consistent with previous amendments to FDC Act—the BLOCKING Act will lead to the forfeiture of 180-day exclusivity eligibility for the median of all ANDAs, and, in particular, for sponsors of complex drug products for which approval within 30 months is highly unlikely. That outcome is wholly inconsistent with the assertion of some that the BLOCKING Act is "narrowly tailored." And it will have a chilling effect on decisions by generic drug manufacturers to challenge patents.
- The BLOCKING Act triggers 180-day exclusivity without notice to a first applicant, and under conditions unknown to a first applicant. FDA does not routinely or timely post tentative approval letters on the Agency's website, making it difficult—if not impossible—to decipher the basis for such approval action. Thus, a first applicant may be unaware that

its exclusivity is running. And that exclusivity cannot be recovered.[7] Procedural protections are necessary to ensure that first applicants are aware of a potential triggering of exclusivity and can take necessary remedial action.

- The BLOCKING Act could cause at-risk launches, exposing generic drug manufacturers to massive damage awards if the validity of a patent is upheld. The BLOCKING Act would trigger a first generic applicant's 180-day exclusivity upon the tentative approval of a subsequent application. This will occur in most cases, forcing a first applicant to launch at-risk during the course of patent infringement litigation or in violation of a pro-competitive settlement, subjecting that manufacturer to massive damages, or losing exclusivity in its entirety. Thus, the BLOCKING Act will eliminate the incentive for most—if not all—generic drugs that would otherwise be eligible.
- The BLOCKING Act could significantly upset company and market expectations. Given the significant change in 180-day exclusivity that the BLOCKING Act represents, it should only be applied to ANDAs submitted to FDA after the date of enactment of the bill, thereby following suit with other amendments to the Hatch-Waxman Act. Otherwise, it will be retroactively applied to existing ANDAs that were submitted under a different framework and with wholly different expectations.
- The BLOCKING Act is based on a prevarication. The BLOCKING Act appears to be based on the faulty assumption that the harsh penalty of losing 180-day exclusivity will bring more generics to the market earlier by removing a barrier to the approval of subsequent generics. That's simply not true. There is no reason to believe that subsequent applicants will launch their products any more quickly than first applicants if the BLOCKING Act is passed. But there is significant reason to believe that fewer generic drug manufacturers will challenge patents given the destruction of the 180-day exclusivity incentive, thereby delaying generic competition.

AAM is not alone in its criticism and concerns with the BLOCKING act. Indeed, former FDA Commissioner, Dr. Scott Gottlieb, recently commented that "[a]ny provision should protect generic companies from forfeiting the exclusivity if they're actively seeking final approval."[8] The BLOCKING Act includes no such protections.

B. Overview of 180-Day Exclusivity

Congress created the 180-day exclusivity for first generics as part of the 1984 Hatch-Waxman Amendments and as part of a broader compromise between brand-name pharmaceutical companies and generic drug manufacturers. The 180-day exclusivity is the only Hatch-Waxman

[7] FDA, Draft Guidance for Industry – 180-Day Exclusivity: Questions and Answers, at 12 (Jan. 2017), available at https://www.fda.gov/media/102650/download (recognizing that "the 180-day period runs without interruption" once triggered).

[8] Scott Gottlieb, M.D., The HELP Committee's Fix For 180-Day Generic Marketing Exclusivity: Does It Solve The Problem? Health Affairs Blog (May 30, 2019), available at https://www.healthaffairs.org/do/10.1377/hblog20190529.223594/full/.

incentive for companies to challenge a patent and bring a generic drug to market earlier than patent expiry. And it has been a resounding success – 90 percent of all prescriptions dispensed in the U.S. are for generic drugs, and patients have saved $2 trillion over the last decade, including $293 billion in 2018, as a result of the availability of low-cost generics.[9]

In a misguided attempt to get after an allegedly narrow problem, Section 205 would risk upending the benefits experienced under the Hatch-Waxman framework by reducing competition in the prescription drug market and causing patients to pay the high cost of brand-name drugs for longer. Section 205 is overly broad in its applicability and would lead to a number of unintended consequences in situations where generic manufacturers are clearly and diligently pursuing approval yet lose the 180-day exclusivity incentive due to no fault of their own.

First, the 180-day exclusivity does not act as a barrier to generic competition and it is a misconception that generic drug manufacturers are intentionally "parking" applications in order to impede other competitors from obtaining approval and entering the market. Moreover, generic competition around products entitled to 180-day exclusivity often experience more overall competition than compared to products where there is no incentive.

Second, Congress and the FDA have already adequately solved for this problem as part of the Medicare Modernization Act of 2003. Instances when a generic manufacturer has been eligible for 180-day exclusivity but has been unable to obtain final approval of a marketing application because of deficiencies in that application are limited. And when they do occur, the FDA's current statutory and regulatory authorities allow the agency to conclude that 180-day exclusivity will not be awarded to a first applicant that does not diligently pursue approval. Notably, FDA's regulations state: "If FDA concludes that a first applicant is not actively pursuing approval of its ANDA, FDA may immediately approve an ANDA(s) of a subsequent applicant(s) if the ANDA(s) is otherwise eligible for approval."[10] Moreover, the "forfeiture" provisions enacted in the 2003 Medicare Modernization Act empowered the FDA to determine that eligibility for 180-day exclusivity has been lost on the basis of an FDA determination that a generic drug application does not meet the statutory and regulatory approval requirements because of deficiencies in the application.[11]

C. Overview of the BLOCKING Act

In spite of this clear authority, however, the Administration included a legislative proposal in its Fiscal Year 2019 and 2020 budget request to "ensure[] that first-to-file generic applicants who have been awarded a 180-day exclusivity period do not unreasonably and indefinitely block subsequent generics from entering the market beyond the exclusivity period."[12] According to the budget

[9] AAM, 2019 Access and Savings Report: The Case for Competition, May 2019.
[10] 21 C.F.R. § 314.107(c)(3).
[11] FDCA § 505(j)(5)(D)(i)(II).
[12] HHS, FY19 Budget Proposal, February 2018, and FY20 Budget Proposal, March 2019.

proposals, "when a first-to-file generic application is not yet approved due to deficiencies, FDA would be able to tentatively approve a subsequent generic application, which would start the 180-day exclusivity clock, rather than waiting an indefinite period for the first-to-file applicant to fix the deficiencies in its application."[13]

While Section 205 of the discussion draft was derived from the Administration's budget proposal, the legislation's scope is broader than the stated problem. Section 205 moves beyond simply addressing deficient applications that potentially block generic competition and undermines altogether the 180-day incentive for first generics with a parallel structure to the MMA reforms.

Section 205 would trigger a first applicant's 180-day exclusivity if four conditions are met:

1. the tentative approval of a subsequent applicant's ANDA on the basis of a first applicant's eligibility for 180-day exclusivity;
2. the passage of 30 months after the submission of any first applicant's ANDA;
3. the termination of a 30-month patent litigation stay with respect to any first applicant; and,
4. the lack of FDA approval of a first applicant's ANDA as of the date each of the three prior conditions is met.

While seemingly simply, these conditions are immensely complex to implement in practice and would almost certainly lead to costly and time-consuming litigation.

This complexity and uncertainty introduced by Section 205 makes eligibility for the 180-day incentive unpredictable for generic drug manufacturers. Without the historical precedent of the 180-day exclusivity, the resounding success of Hatch-Waxman that has led to greater—and earlier—market competition would be undermined. Generic manufacturers would be far less likely to take on the risks associated with developing high-quality, low-cost generic drugs and challenging brand-name patent thickets as a result of Section 205.

Section 205 allows for several circumstances to trigger the 180-day exclusivity period for reasons beyond the generic manufacturer's control and unrelated to application deficiencies. For instance, under the discussion draft, a first applicant seeking final approval could lose exclusivity in the following examples:

- Citizen petitions directed to a first applicant's formulation that causes a delay in the FDA's approval a first applicant's marketing application;

- The FDA's failure to timely inspect or re-inspect a generic drug manufacturing facility;

- An FDA decision to change or review the requirements for approval of a drug; and,

[13] Ibid.

- A first applicant's decision to challenge later-expiring rather than earlier-expiring patents covering a brand-name drug.

While there are many steps Congress could take to increase competition and enhance patient access to more affordable FDA-approved generic drugs and biosimilars, Section 205 would do the opposite. It would delay generic drug competition and lead to higher health care costs for patients and taxpayers.

Attached to these comments please find three proposed alternatives to Section 205. We would gladly meet with the Committee again to discuss these alternatives and find a solution that avoids the unintended consequences of Section 205 as currently proposed.

VI. Section 206 – Education on Biological Products

AAM commends the Committee for its work on Section 206. This provision would direct the FDA to close the education gap and address misinformation about biosimilars for both patients and providers.

Misinformation and a lack of basic understanding about the safety and efficacy of lower-cost biosimilars threaten patient access to these life-saving therapies and cost U.S. billions in lost savings. Some brand manufacturers have taken advantage of this unfamiliarity with blatant misinformation campaigns that sow seeds of doubt with stakeholders. However, as the gold standard of global regulatory authorities, FDA-approval of a product means that a developer has demonstrated to the agency's satisfaction that the product is safe and effective. Rebutting misinformation about biosimilars will encourage adoption, reduce patient out-of-pocket costs, and increase patient access.

VII. Section 207 – Biological Product Innovation

Section 207 would exclude biologic medicines from the requirement that all medicines marketed in the United States adhere to quality standards established by the United States Pharmacopeia (USP). We believe that the USP standards have been and should remain a foundational element in the framework ensuring that the medicine supply in the United States is the safest in the world. Therefore, we are concerned that the proposal would not accelerate the development of biosimilars and therefore urge the Committee to eliminate this section.

Public quality standards are essential for ensuring the quality of medicines for patients and the practitioners who prescribe, dispense, and administer them. USP's public quality standards are established by independent scientific experts from government, academia, industry, and the healthcare practitioner and patient communities. USP standards also go through a transparent and open public comment process. The USP standards provide manufacturers with key attributes

of a quality medicine, as well as tests, methods, and other information that support the development and manufacturing of medicines, and therefore contribute to a more efficient and reliable medicine supply.

As you may recall, Congress previously considered this proposal during consideration of the 21st Century Cures Act. However, it was ultimately rejected after robust engagement from numerous stakeholders. We encourage the Committee to do so again.

VIII. Section 209 – Streamlining the Transition of Biological Products

There is increasing attention on patient *inaccessibility* to insulin, a biologic medicine relied upon by more than 7.5 million Americans every day. [14] The FDA announced steps to encourage biosimilars, more-affordable versions of brand insulin, beginning in March 2020. [15] Former FDA Commissioner Scott Gottlieb has called the agency's efforts "a watershed moment for insulin products."[16] However, FDA's own actions as well as a variety of market factors have led to significant barriers to the development and approval of "generic" or biosimilar alternatives. These result in today's public health crisis, highlighted by members of Congress on both sides of the aisle, as patients struggle to afford a medicine that was discovered more than 100 years ago.[17]

Congress sought to address the issue by establishing an abbreviated pathway for lower-cost biosimilar and interchangeable biological products. The Biologics Price Competition and Innovation Act (BPCIA) included a provision that would "transition" certain protein products, including insulin, after March 23, 2020, to be regulated as biologics under the Public Health Service Act (PHSA). However, FDA's final guidance on the implementation of this provision is at odds with congressional intent and puts efficient development of more-affordable insulin alternatives at risk.[18] Specifically:

- FDA is creating a "regulatory dead zone" by refusing to approve any pending "follow-on" insulin applications after March 23, 2020, and instead requiring them to be re-submitted under the new pathway if they are not able to gain approval prior to that date.
- FDA will require doubled user fees for those "follow-on" applications that were pending and not approved prior to March 23, 2020 and were forced to be resubmitted. FDA is not requiring this of brand-name drug applications.

[14] Congressional Letter to the FDA. "Durbin, Cramer, Cassidy, Smith To FDA: Price Of Insulin Is Unacceptable". Available: https://bit.ly/2C8sKR7.
[15] FDA Press Release. "Statement from FDA Commissioner Scott Gottlieb, M.D., on new actions advancing the agency's biosimilars policy framework." Available: https://bit.ly/2Ggr38N.
[16] *Ibid.*
[17] Congressional Diabetes Caucus Report. "Insulin: A lifesaving drug too often out of reach." Available: https://bit.ly/2QcViOu.
[18] Congressional Letter to the FDA. "Durbin, Cramer, Cassidy, Smith To FDA: Price Of Insulin Is Unacceptable". Available: https://bit.ly/2C8sKR7.

These issues may cause generic developers to delay their current development programs of "follow-on" or "generic" insulin until after March 2020 to submit applications under the biosimilar pathway. Moreover, FDA guidance related to the naming of biosimilar and interchangeable biologics will have a particularly burdensome effect on the post-March 2020 biosimilar insulin market.

Thus, AAM appreciates and supports the Committee's focus on addressing the "regulatory dead-zone" pertaining to the transition of certain protein products. Directing the FDA to "carry-over" pending applications for products effected by the transition from the FDCA to the PHSA will ensure that more affordable, competitive alternatives to brand-name medicines affected by the transition can get to market without having to be resubmitted. AAM commends the Committee's efforts for including Section 209 to help remedy this issue. The provision would ensure efficient review of products currently under development through the 505(b)(2) pathway.

AAM Comments on Title III – Improving Transparency in Healthcare

I. Section 306 – Health Plan Oversight of Pharmacy Benefit Manager Services

AAM commends the Committee for its work on Section 306 and supports efforts to increase transparency in the health care system. Generic and biosimilar medicines, despite having lower list and net prices, face increasing hurdles to formulary placement and patient access because of opaque anti-competitive exclusionary rebate contracting practices by manufacturers of high-priced brand drugs. These tactics are intended to stifle competition and maintain market monopolies for branded products, and lead to higher costs for patients and the federal government.

As the Committee considers possible changes, AAM encourages the Committee to ensure that the discussion draft continue to shine a light on these practices by providing transparency when a lower priced generic or biosimilar is excluded from formulary or placed on formulary at a disadvantage vis-a-vis the brand-name reference product.

AAM Comments – Additional Proposals Under Discussion

I. The Prescription Drug Rebate Reform Act (S. 1384)

The Committee also indicated the Prescription Drug Rebate Reform Act (S. 1384) is under consideration. The legislation would require a payer or pharmacy benefit manager (PBM) to set a patient's copay or coinsurance for a prescription drug as a set amount or percentage of the "net price" of the drug, which reflects the cost of a drug to a plan or PBM after rebates or discounts provided by a manufacturer. Payers and PBMs often set patient copays or coinsurance on a

product's "list price," or Wholesale Acquisition Cost (WAC), before rebates or discounts. To that end, increases in list price directly impact a patient's ability to afford their medicines and can cause increased patient abandonment and lower adherence.[19] The legislation, as introduced, would likely significantly reduce out-of-pocket costs for patients and provide savings to the health care system.

However, we note that as drafted, the bill would not prevent exclusionary brand rebate schemes used by brand-name drug manufacturers to block generic and biosimilars from inclusion on plan formularies.

If the Prescription Drug Rebate Reform Act is included, we recommend the Committee ensure that health plans and PBMs encourage the use of lower-cost therapeutically equivalent generics and biosimilars to increase pharmaceutical competition and reduce patient out-of-pocket costs. Congress could do so by requiring brand-name and generic or biosimilar medicines to be on respective brand and generic tiers with cost-sharing encouraging use of the lower-priced generic or biosimilar, requiring plans to automatically include generic and biosimilar medicines on generic formulary tiers immediately after launch, and creating a dedicated, more favorable specialty tier with lower beneficiary cost-sharing for generics and biosimilars. These are integral components to ensuring patient access to the lowest-cost available option and achieving the goal of the Prescription Drug Rebate Reform Act.

The Fair Accountability and Innovative Research (FAIR) Drug Pricing Act (S. 1391)

The Committee also indicated possible consideration of the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act (S. 1391). As the Committee examines the affordability challenges of high-priced prescription drugs, it is essential to recognize the differences between the brand-name and generic drug markets and how the different pharmaceutical supply chains operate. Not only is the Food and Drug Administration's (FDA) approval process different for generics and brand-name drugs, but their respective markets and the path by which they reach patients diverge significantly, with important policy implications. These markets vary significantly in many ways – not least in price – leading to different outcomes for patients, differences in the amount of spending funded by taxpayers, and differences in what consumers pay for health care coverage.

For this reason, requiring advance notification of price increases for generic drugs raises the potential for abusive purchasing and stockpiling by middlemen who could then resell product for profit.

Moreover, independent research and data demonstrate one undeniable conclusion: Brand-name drug prices continue to rise, while generic drug prices continue to fall. Brand-name drugs comprise only 10 percent of prescriptions filled annually by patients, but now constitute 78 percent of all

[19] Forbes, "Rebates And Drug Costs: What The New Proposal Would Mean," February 28, 2019.

spending on prescription drugs.[20] In contrast, the amount spent on generic medicines has declined for 33 of the past 35 months.[21] In fact, every month but one in this time period generic sales declined at least 5 percent.

S. 1391 takes steps to recognize some differences between the brand-name drug market and the generic drug market. We applaud its application only to medicines with a WAC of $100 or more for a 30-day supply (or course of treatment). This roughly focuses on medicines costing $3 or more per day. It is critical that policymakers focus on the driver of drug cost challenges – namely the shift to more complex products with higher list prices.

However, because percentages are relative to the initial price, using percentage increases as the basis for additional reporting requirements neglects this principle of focusing on true cost drivers. Because small price increases on low-cost medicines can result in significant percentage increases, while large price increases on high-cost medicines result in relatively minor percentage increases, the provision would likely direct a disproportionate share of scrutiny on generic drugs with small (real) cost increases while exempting higher-priced brand drugs with large (real) cost increases.

For example, if the price of the branded product Humira is raised 22 percent, as it was between 2014 and 2015, the total cost for Medicare (excluding volume growth) would be $270 million, or about $124 million per 10 percent increase.[22] However, raising the price of phenazopyridine HCl by 121 percent would cost Medicare $4 million, or $383,000 per 10 percent increase. Rather than focusing on products with high percentage increases, the legislation should focus on those products driving overall spending in Medicare and other health programs.

In fact, just this week, researchers published a study in JAMA in which they found that the median price increase for top-selling brand drugs was 9.5% - less than the threshold established in the legislation.[23] Annual price increases of less than 10 percent on brand-name drugs and the cumulative impact of such price increases translates into hundreds, if not thousands, of dollars in higher prescription drug spending. AARP found 94 percent (133 of 142) of brand-name drugs more than doubled in price between 2005 and 2017.[24] And the Office of Inspector General at the Department of Health and Human Services (HHS) found that "reimbursement for brand-name drugs in Part D still increased 62 percent from 2011 to 2015" after accounting for rebates.[25]

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[20] IQVIA Institute for Human Data Science. (May 2019). *Medicine Use and Spending in the U.S.*

[21] Morgan Stanley. (May 30, 2019). *Spec/Gx Trends in Pictures North America*.

[22] Democratic Staff Report: Committee on Oversight and Government Reform, U.S. House of Representatives. "Skyrocketing Drug Prices: Year One of the Trump Administration." March 2018. Available at: https://bit.ly/2IWSpgi. Accessed: July 5, 2018.

[23] Wineinger NE, Zhang Y, Topol EJ. Trends in Prices of Popular Brand-Name Prescription Drugs in the United States. JAMA Network Open. 2010.

[24] AARP, "Trends in Retail Prices of Brand Name Prescription Drugs," September 2018.

[25] HHS OIG, "Increases in Reimbursement for Brand-Name Drugs in Part D," June 2018.

In contrast, nine out of every 10 prescriptions filled in the U.S. are for generic drugs and spending on generic drugs accounted for only 22 percent of total prescription drug spending.[26] Continued growth in the use of generic drugs and declining generic drug prices led to savings of $293 billion in 2018.[27] Moreover, in recent years, the Assistant Secretary for Planning and Evaluation (ASPE) at HHS and the Government Accountability Office (GAO) examined trends in the prices of generic drugs. Due to the relatively low-cost of generic medicines, minor price changes can result in significant percentage increases. GAO, for example, cited the price of hydrocortisone increasing from $0.16 per tablet in 2012 to $0.41 per tablet in 2013 – an increase of 160 percent.[28] Correspondingly, the HHS ASPE report concluded, "Our review of the evidence strongly supports the conclusion that generic drug prices are not an important part of the drug cost problem facing the nation."[29]

Therefore, if the Committee considers inclusion of the FAIR Act, we encourage it to adopt price and increase thresholds tailored to the differences of the generic and brand markets.

AAM Comments – Additional Proposals for Consideration

In addition to the aforementioned recommendations to strengthen the discussion draft, we encourage the Committee to include additional, more impactful policies to meaningful reduce prescription drug costs and enhance access for America's patients. AAM provided a robust set of recommendations to the Committee on March 1 and, as noted above, appreciates the inclusion of several of these policies. There are many other steps – within the Committee's jurisdiction and related to the FDA – that could also be included as the Committee moves forward with its process.

Biosimilars Labeling

We also encourage the Committee to expand its efforts to speed biosimilar competition by addressing one of the greatest barriers to biosimilar market entry: the complex patent "thickets" created by brand companies. These include patents claiming methods of using the products as described in their labeling – labeling which biosimilar companies must copy for their own products. This challenge can be significant, as brand companies are obtaining patents at an extraordinary rate. Humira®, the best-selling drug in the U.S., currently has nearly 250 patent applications.

One-way biosimilar companies navigate these patent thickets is to "carve-out" patented indications or uses from their labeling, even though the FDA has approved the biosimilar for those indications, gaining approval with "skinny labeling" that only includes uses for which there are no patent issues.

[26] AAM, "Generic Drug Access & Savings Report," May 2019.
[27] AAM, "Generic Drug Access & Savings Report," May 2019.
[28] GAO, "Generic Drugs Under Medicare," August 2016.
[29] ASPE Issue Brief "Understanding Recent Trends in Generic Drug Prices," January 2016.

As additional patents are addressed through litigation or settlement, the companies can add these uses back into their labeling. This process is critical for the success of biosimilars, as each carved-out use limits the potential market and savings for consumers.

However, there is not an established process for adding uses back into the labeling of biosimilars once patent issues have been addressed. The FDA currently treats such applications as "Supplements with Clinical Data" under the Biosimilar User Fee Act, reviewing them on a 10-month clock, despite the agency having already reviewed and approved the biosimilar for those indications. This is inappropriate. It severely undermines the ability of biosimilar companies to bring their products to market, costing consumers millions of dollars and hurting the industry for years to come.

In January 2019, former Commissioner Gottlieb said that FDA was "going to be putting out policy this year to explain how to carve back in indications … We're working on defining an efficient way to do that."[30]

We ask Congress to encourage the FDA to follow through on its commitment and reduce the review time for these specific type of supplements to no longer than 90 days. This policy will go a long way toward creating a healthy biosimilars market, improving consumer choice, and saving the healthcare system billions of dollars.

We have attached draft legislation for your consideration.

Suitability Petitions

AAM is concerned that the FDA is failing to achieve required statutory deadlines regarding processing timelines for suitability petitions. Under section 505(j)(2)(C) of the FDCA, the FDA is required to decide whether to grant or deny a suitability petition "within ninety days of the date the petition is submitted." Similarly, FDA regulation states that "no later than 90 days after the date a petition…is submitted, FDA will approve or disapprove the petition."[31] Further this target of 90 days was reinforced by commitments made by the Agency as part of the Generic Drug User Fee Amendments of 2017 (GDUFA II).

However, the agency has not met these timelines, with the result that America's patients are suffering from a delay in access to affordable medicines. The agency's own data show that out of 135 suitability petitions received since 2013 only 25 were processed.[32] The remaining 110 remain in a 'pending' status, and the average age of these pending petitions is over 3 years – a far cry from the 90 days stipulated in statute.

[30] Gottlieb, Scott, M.D., Keynote Address to the J.P. Morgan Healthcare Conference, January 9, 2019.
[31] 21 CFR 314.93(e)
[32] FDA, "OGD Suitability Tracking Report," August 2015.

For added context, two of the pending petitions are for drugs that are in shortage with no product on the market because the innovator has discontinued the drug. Sodium chloride 23.4% is regularly used as a diluent for intravenous infusions, and cysteine hydrochloride injection 5% provides amino acid therapy to newborn infants. The cited change for these two products in the petition is regarding the volume of product provided and it raises no new questions of safety or efficacy. In addition, 20 suitability petitions are for drugs that have no generic competition, and six of these are on FDA's priority list of drugs that are off-patent and have no exclusivity. These drugs are for indications such as Type 2 diabetes, cancer, heart disease, and broad-spectrum antibiotics. While these petitions remain pending, patients are left without a safe and affordable generic option.

AAM recognizes that the agency balances many responsibilities and that it has chosen to allocate its resources in directions other than addressing the backlog of suitability petitions. As a result, AAM proposes that Congress reinforce the requirement that the agency meet these timelines by focusing first on suitability petitions dealing with different dosage forms or strengths. These two categories of suitability petitions make up the bulk of the pending petitions and do not require extensive work on the agency's part.

Our proposed language would streamline the agency's review process for suitability petitions by allowing sponsors to include suitability petitions related to changes in dosage forms or strengths with the abbreviated new drug application (ANDA). Under current procedures, the agency will not accept a proposed new dosage form or strength unless it has previously approved a suitability petition for that new dosage form or strength. Due to the agency's delay in approving suitability petitions this has had a chilling effect on the submission of new ANDAs. In fact, our members report that they have resorted to the 505(b)(2) route to work around this delay, although this route may cost them over $1,000,000 in additional costs. We look forward to working with the Committee to address this problem.

We have attached draft legislation for your consideration.

Patent Abuse

Perhaps the greatest barrier to increased prescription drug competition occurs due to abuses of the U.S. patent system. While AAM's member companies strongly support innovation, they are finding it increasingly challenging to deliver new, more affordable generic and biosimilar medicines to patients due to patent abuse.[33]

Recent research demonstrates the extent of the problem and the increased costs borne by patients. Increasingly, brand-name drug companies are building patent "thickets" around their

[33] AAM, "Ensuring the Future of Accessible Medicines in the U.S. – Ensuring Competition for America's Patients," February 2018.

drugs, not just for the original innovative research, but for much smaller changes that may not be deserving of decades-long monopolies. At least 78 percent of the new patents in the FDA's Orange Book are associated with *existing* drugs on the market.[34] Moreover, of the roughly 100 best-selling drugs, more than 70 percent obtained a patent that extended the monopoly period beyond the duration of the initially-granted patent. [35]

Moreover, a recent report from I-MAK examined the top 12 brand-name drugs on the market and found that a total of 848 patents (71 per drug) shield these medicines from generic and biosimilar competition for an average of 38 years.[36] A few examples from the report demonstrate how patent thickets are established on these blockbuster drugs:

- The world's top-selling brand-name drug, Humira®, treats arthritis and other chronic conditions. On the market since 2002, 132 patents block competition for up to 39 years.[37] The price of Humira increased 144 percent since 2012.[38]

- One of the most prescribed cancer treatments, Revlimid®, was approved by the FDA in 2005. The patent thicket consists of 96 patents providing potentially 40 years without competition.[39] The price of Revlimid increased 79 percent since 2012.[40]

- Diabetes patients who rely on the insulin treatment, Lantus®, may not see a generic alternative for 37 years due to the 49 patents issued.[41] The price of Lantus increased 114 percent since 2012.[42]

In these instances, brand-name biologic manufacturers are attempting to accumulate patents not because they are innovative, but rather to increase litigation and development costs for potential would-be generic and biosimilar competitors.

Addressing abuse of the patent system must be front-and-center if Congress is effectively going to reduce drug prices for patients.

AAM thus encourages the Committee to consider several policies that would allow for expeditious challenge of brand-name drug patent thickets. For example, we recommend:

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[34] Feldman, Robin, "May Your Drug Price Be Evergreen," December 2018.
[35] Ibid.
[36] I-MAK, "Overpatented, Overpriced," August 2018.
[37] Ibid.
[38] Ibid.
[39] Ibid.
[40] Ibid.
[41] Ibid.
[42] Ibid.

- *Providing a Date Certain for Generic and Biosimilar Entry.* Congress rewards brand-name drug companies with a set period for monopoly protection, and upon expiration of that time period, competition should begin. Congress could take steps to kick-start biosimilar competition by, for example, ensuring that patents do not impede competition beyond the 12-year term of market exclusivity.

- *Accelerate the Biosimilar "Patent Dance."* Congress could allow for the initiation of patent litigation at the point when a biosimilar developer has a Type III development meeting with the FDA. This would accelerate the timeline and permit biosimilars to be marketed sooner, speeding their cost-savings to patients.

- *Harmonize Hatch-Waxman with Inter-Partes Review (IPR).* A 30-month stay on the FDA's approval of a generic drug application is imposed under Hatch-Waxman and only dissolved when a court decision finds the asserted Orange Book patents are invalid or not infringed. Congress could update Hatch-Waxman to reflect the current market realities by not allowing a patent that has been held invalid in an IPR to be the basis for a 30-month stay on FDA approval.

We will gladly work with the Committee and its members on these solutions, as well as other policy ideas we have put forth, to address the high price of patent abuse – a price that is ultimately borne by patients who are without alternatives when there is no FDA-approved, more affordable generic or biosimilar medicine on the market and competition is delayed for decades.

Attachments:
- Alternatives to Section 205
- Legislative Proposal on Biosimilars Labeling
- Legislative Proposal on Suitability Petition

Proposed Alternatives to Sec. 205

Alternative I:

This proposal codifies FDA's existing authority and deems an application "withdrawn"—and exclusivity forfeited—if a sponsor is not actively seeking approval or is on the application integrity policy.

Section 505 of the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. § 355) is amended by inserting the following in sub-section (j)(5)(D)(i)(II):

(D) Forfeiture of 180-day exclusivity period.—

(i) Definition of forfeiture event.—In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:
. . . .

(II) Withdrawal of application.—

(A) The first applicant withdraws the application*;* or
(B) *T*he Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4), *including if:*

(1) The sponsor is not actively pursuing approval of its ANDA; or
(2) The sponsor is identified on the Application Integrity Policy list described in 56 Reg. 46191 at the time the subsequent applicant containing a certification described in paragraph (2)(A)(vii)(IV) could be granted final approval but for the 180-day exclusivity.
(C) The Secretary may, after opportunity for public comment, issue guidance describing the factors taken into consideration under subparagraph (B).

By clarifying that eligibility for exclusivity is forfeited when a sponsor is not actively seeking final approval, this alternative would address "parking" without otherwise diluting 180-day exclusivity. Such an approach could also avoid inconsistencies—and potential unpredictable outcomes—by modifying and clarifying the existing forfeiture provisions in the MMA rather than creating a new framework. Notably, this proposal expressly adopts former FDA Commissioner Scott Gottlieb's suggested revisions on active pursuit of final approval—provisions not included in Sec. 205.

Alternative II:

Sec. 205 could also be modified to ensure that it is consistent with FDA's own median approval times and is narrowly tailored to address the purported problems giving rise to the legislation. Additionally, given the fundamental changes that are being made to 180-day

exclusivity, this proposal makes clear that these provisions should only apply to ANDAs filed after the date of enactment of the legislation.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Bringing Low-cost Options and Competition while Keeping Incentives for New Generics Act of 2019" or the "BLOCKING Act of 2019".

SEC. 2. CHANGE CONDITIONS OF FIRST GENERIC EXCLUSIVITY TO SPUR ACCESS AND COMPETITION.

Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amended—

(1) in subclause (I), by striking "180 days after" and all that follows through the period at the end and inserting the following: "180 days after the earlier of—

"(aa) the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant; or

"(bb) the applicable date specified in subclause (III)."; and

(2) by adding at the end the following new subclause:

"(III) APPLICABLE DATE.—The applicable date specified in this subclause, with respect to an application for a drug described in subclause (I), is the date on which both of the following conditions are first met:

"(aa) All first applicants have failed to obtain final approval within 42 months of submission because such application(s) do not meet the requirements for approval under paragraph (4)(A).

"(bb) A subsequent applicant has tentative approval that could be converted to final approval but for the eligibility of a first applicant for 180-day exclusivity under this clause.

"Before determining that the conditions under this subparagraph (III) have been met, the Secretary shall notify all first applicants of its preliminary determination and offer all first applicants at least ten days to comment on the preliminary determination. If the Secretary subsequently determines that the conditions have been met, the Secretary shall notify all first applicants of the determination, providing a full rationale for the determination, at least five days before implementing the determination. The Secretary's determination that the conditions of this subparagraph (III) have been met is final agency action subject to the Administrative Procedure Act, and irreparable injury to first applicants is presumed.

SEC. 3. EFFECTIVE DATE. The provisions of Section 2 apply only to abbreviated new drug applications first submitted to FDA on or after the date of enactment of this Act.

Alternative III:

SEC. 2. CHANGE CONDITIONS OF FIRST GENERIC EXCLUSIVITY TO SPUR ACCESS AND COMPETITION.

Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amended—

(1) in subsection (I) by striking "180 days after the date" and inserting "180 days after the earlier of the following:

"(aa) "The date"; and

(2) by adding at the end the following:

"(bb) The date on which all of the following conditions are first met:

"(AA) An application for the drug submitted by an applicant other than a first applicant could receive approval, if no first applicant were eligible for 180-day exclusivity under this clause.

"(BB) Thirty months have passed since the date of submission of an application for the drug by at least one first applicant.

"(CC) Approval of an application for the drug submitted by at least one first applicant is not precluded under clause (iii).

"(DD) No application for the drug submitted by any first applicant is approved at the time the conditions under items (AA), (BB), and (CC) are all met, regardless of whether such an application is subsequently approved.

(3) by adding in subsection (II) the following, and renumbering current (II) as (III):

"(II) EXCEPTION.—The date in paragraph (I)(bb) shall not apply if any first applicant is actively pursuing final approval of its application.

Proposed Biosimilar Carve-Out/Carve-In Legislation

(a) Section 351(k)(5) of the Public Health Service Act (42 U.S.C. § 262) is amended by inserting after subparagraph (C) the following –

"(D) **Action on Certain Supplements**. –

(i) The Secretary shall review and act on an original supplement described in clause (iii) no later than 3 months after receipt of the original supplement.

(ii) The Secretary shall review and act on a resubmitted supplement described in clause (iv) no later than 1 months after receipt of the resubmitted supplement.

(iii) An original supplement described in this clause is a supplement to an application under this subsection that seeks to add an indication or other condition of use for which the reference product is licensed based primarily upon data and information previously submitted in such application (including any amendments thereto).

(iv) A resubmitted supplement described in this clause is a complete response to an action letter for an original supplement to an application under this subsection that seeks to add an indication or other condition of use for which the reference product is licensed based primarily upon data and information previously submitted in such application (including any amendments thereto).

(v) A major amendment to an original or resubmitted supplement may extend the action dates set forth in clauses (i) and (ii) by 2 months.

(vi) The actions dates set forth in this subparagraph shall supersede any performance goals established under the Biosimilar User Fee Act, as amended from time to time, as set forth in the letters from the Secretary to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, and as further set forth in the Congressional Record.

SEC. 1. SUBMISSION OF PETITION FOR SUITABILITY DETERMINATION.

Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(C)) is amended to read as follows—

"(C) SUBMISSION FOR SUITABILITY DETERMINATION. —

"(i) A person may submit an abbreviated application for a new drug that has a different dosage form or strength from that of a listed drug.

"(ii) The Secretary shall approve or disapprove the submission of such an abbreviated application during the course of its determination whether to receive the application pursuant to section 314.101 of title 21, Code of Federal Regulations (or any successor regulations).

"(iii) The Secretary shall approve the submission of such an abbreviated application, provided the application is otherwise determined to be eligible to be received, unless the Secretary finds—

"(I) that clinical investigations must be conducted to show the safety and effectiveness of the drug or of any of its dosage form or strength which differ from the listed drug; or

"(iv) If the Secretary disapproves the submission of an abbreviated application under this subsection and considers the application not to have been received within the meaning of section 505(j)(5)(A), then the Secretary shall refund 75 percent of any fee paid, pursuant to section 744B(a)(3)(D)(i) (21 U.S.C § 379j-42(a)(3)(D)(i))."

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