Association for Accessible Medicines
Statement of Chester "Chip" Davis, Jr.
House Energy and Commerce Subcommittee on Health
Hearing on "Lowering the Cost of Prescription Drugs:
Reducing Barriers to Competition"
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Competition is a Proven Solution to Lowering Drug Costs

Chairwoman Eshoo, Ranking Member Burgess, Chairman Pallone, Ranking Member Walden and the members of the Energy and Commerce Health Subcommittee, thank you for the invitation to testify today. I am Chip Davis, President and CEO of the Association for Accessible Medicines (AAM). AAM is the nation's leading trade association for manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines. Our members provide more than 36,700 jobs at nearly 150 facilities and manufacture more than 61 billion doses in the United States every year. AAM's core mission is to improve lives by advancing timely access to affordable generic and biosimilar medications.

I commend you for holding today's legislative hearing on the importance of reducing barriers to competition in order to the lower the cost of prescription drugs. Increasing competition in the prescription drug market – especially with the introduction of more affordable generic and biosimilar medicines – is a proven solution to delivering savings at the pharmacy counter for patients, and this hearing represents an important step toward identifying and advancing meaningful solutions to that end.

Generic medicines play an integral role in health care and enhance patient access to life-saving treatments. The expiration of patents and the introduction of multiple generic manufacturers competing against each other on price results in significant savings for patients and the health care system. Over the last 10 years, generic manufacturers have delivered savings of nearly $1.8 trillion – including $265 billion in 2017 – to patients and the health care system.[1]

Biosimilar medicines represent another critical step forward in reducing high drug prices. Biosimilars are safe, effective and more affordable versions of costly brand biologics. By the year 2025, over 70 percent of drug approvals are expected to be biological products.[2] Experts estimate that FDA-approved biosimilars could save more

[1] AAM, "Generic Drug Access & Savings Report 2018," July 2018.
[2] U.S. Pharmacist, "Biosimilars: Current Approvals and Pipeline Agents," October 2016.

than $54 billion over the next 10 years.[3] In doing so, biosimilars will mean greater access to lifesaving cures for an estimated 1.2 million patients.[4]

However, the sustainability of a competitive generic market and the availability of generic medicines for patients, uninterrupted by shortages, is in jeopardy. Current market realities and anti-competitive tactics, combined with misguided policies, threaten the long-term stability of the generics and biosimilars markets. As we outlined in the February 2018 whitepaper, "Ensuring the Future of Accessible Medicines in the U.S.," generic and biosimilar manufacturers are facing an increasing set of challenges to getting new competitive and more affordable medicines to market and to ensuring patient access to generic medicines on the market continues without interruption.

Today's legislative hearing addresses one of the challenges: the gaming of FDA's safety programs to delay generic and biosimilar entry. However, there are many significant barriers to competition – for example, abuse of the patent system to extend high-priced monopolies, which I will discuss in more detail – and punitive policies – such as the Medicaid Generics Penalty – that impose unpredictable, onerous penalties on generic medicines that undermine patient access to life-saving medicine. Thus, it is critical for Congress to advance policies that increase competition from generic and biosimilar medicines, while avoiding policies that further delay patient access to more affordable treatments, and to also take action to address the very real sustainability challenges faced by generic and biosimilar manufacturers.

Brand-Name Drugs Increase Costs, Generic Medicines Drive Savings

Brand-name drugs comprise only 10 percent of prescriptions filled annually by patients, but now constitute 77 percent of all spending on prescription drugs.[5] Specialty medicines (including brand biologics) are rapidly approaching half of all spending despite being used by fewer than 3 percent of patients.[6] Encouraging competition and patient adoption of more affordable generic and biosimilar medicines is a critical component of lowering patient out-of-pocket spending.

The introduction of generic and biosimilar competition significantly reduces the price of medicine, and patients benefit from greater, more affordable access to FDA-approved drugs. Experience shows prescription drug prices decline by more than half the first-year generics enter the market.[7] Early experience with the nascent biosimilars market in the U.S. also shows that these more affordable alternatives are also providing value and savings to patients, on average priced 40 percent lower than their branded biologic counterparts.[8]

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[3] RAND, "Biosimilars Cost Savings in the United States," October 2017.
[4] The Biosimilars Council, "Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines," August 2017.
[5] Ibid., AAM.
[6] IQVIA, "Medicine Use and Spending in the U.S.," April 2018.
[7] IMS Institute for Healthcare Informatics, "Price Declines after Branded Medicines Lose Exclusivity in the U.S.," January 2016.
[8] AAM analysis of IQVIA WAC Data, December 2018.

Unfortunately, the ability of biosimilars to fulfill their potential is threatened by market abuses by brand-name drug companies and misguided policies that block access to lower-cost medicines. Seventeen biosimilars are now approved in the U.S., yet only seven are on the market and available to patients.[9] In comparison, more than 50 biosimilars are available to patients in Europe.

It is sobering to consider what America's patients would face if there were no FDA-approved generic or biosimilar medicines to provide reliable access to affordable treatments. Generics not only deliver the most medicine at the lowest cost and the greatest savings. Generic medicines also cushion the significant impact dealt to patients and the health care system by high brand-name drug prices every day. Put another way, the availability of low-cost generics offsets the impact of high brand-name drug prices.

CREATES/FAST Generics End the Abuse of FDA's Safety Rules

For these reasons, AAM greatly appreciates the leadership of Chairman Pallone, Congressman Welch, Congressman McKinley and their bipartisan cosponsors on the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019 (H.R. 965/ S. 340) and the Fair Access for Safe and Timely (FAST) Generics Act of 2019 (H.R. 985). The CREATES and FAST Generics Acts lower the cost of prescription drugs for patients through increased competition and by stopping the abuse of FDA's safety programs and non-FDA mandated closed distribution systems. With the support of more than 90 organizations, these bipartisan, market-based solutions will reduce spending on prescription drugs by an estimated $13.4 billion each year.[10] **AAM strongly supports the CREATES and FAST Generics Acts.** Congress should immediately pass the CREATES and FAST Generics Acts and enact these solutions into law.

Generic and biosimilar manufacturers face significant challenges obtaining the samples needed for generic or biosimilar development. This is a result of the misuse of FDA's rules designed to ensure the safety of medicines by certain brand-name drug companies focused on delaying or prevent competition. Abuse of FDA-mandated safety programs occurs when brand-name drug companies, using a Risk Evaluation and Mitigation System (REMS) or their own voluntary "safety" program as an excuse, refuse to sell brand-name doses to generic and biosimilar manufacturers at fair market value. These doses are necessary for generic and biosimilar manufacturers to conduct bioequivalence testing. Without the ability to purchase samples, generic and biosimilar manufacturers are unable to seek FDA approval and deliver more affordable, alternative medicines to patients.

In addition, brand-name drug companies establish non-FDA mandated closed distribution systems. These arrangements often restrict the ability of generic and

[9] FDA, FDA-Approved Biosimilar Products, January 2019.
[10] Brill, Alex, "Unrealized Savings from the Misuse of REMS and Non-REMS Barriers," September 2018.

biosimilar manufacturers to purchase brand-name doses and this serves as another obstacle to competition. FDA has noted that closed distribution systems lack transparency and a clear benefit to patients.

Generic and biosimilar manufacturers are also challenged by brand-name drug companies' refusal to negotiate in good faith on the creation and implementation of a single-shared REMS system (SSRS). Current law stipulates that a generic medicine must utilize a single-shared system along with the brand-name drug unless FDA waives this requirement for one of the reasons set forth in the statute.

AAM and its member companies believe that patients and providers benefit from a shared system. In fact, the creation of a single-shared REMS system should be relatively straightforward and simple; however, brand-name drug companies regularly use a variety of tactics to delay and extend negotiations. This refusal to engage in good faith negotiations can delay the approval of the generic product and force consumers to pay more to fill their prescriptions.

Last year, and updated recently, the FDA published a list of over 170 instances where access to samples has been at issue.[11] The FDA's list covers 55 unique medicines. Brand-name drug companies with the highest number of products and inquiries are: Celgene (recently acquired by Bristol-Myers Squib) with three products (Pomalyst®, Revlimid®, and Thalomid®) with 31 complaints; Actelion Pharmaceuticals (a subsidiary of Johnson & Johnson) with four products (Opsumit®, Tracleer®, Veletri®, and Zavesca®) with 26 complaints; and, Gilead with two products (Letairis® and Truvada®) with 11 complaints.[12] While FDA's leadership in shining a light on this abusive practice is welcome, the data is alarming: the number of inquiries and the products they cover is an indication that the practice continues to grow.

The CREATES and FAST Generics Acts would end these abuses and facilitate patient access to new, more affordable FDA-approved generic and biosimilar medicines. Under the CREATES and FAST Generics Acts, the FDA's current processes, oversight and approval process would be maintained; patient safety would be further enhanced by codifying the FDA's current guidance on the safe handling of samples into law; and, comparable protections for safety systems, as determined by the FDA, would be in place.

In addition, a limited legal pathway is made available only in instances when the FDA has ensured the appropriate safeguards are in place and a brand-name drug company continues to unjustifiably deny the purchase of samples.[13] If the doses are available for purchase, there is no opportunity for a generic manufacturer to bring a claim. Further, brand-name drug companies are provided with an affirmative defense for which one only needs to show that the doses are available for purchase on market-based terms and that no restrictions are in place that would prevent sale of the brand-name doses.

[11] FDA, "Reference Listed Drug (RLD) Access Inquiries," Published May 2018, Updated February 2019.
[12] AAM analysis of FDA's RLD Access Inquiries List, March 2019.
[13] Kirkland & Ellis, "The CREATES Act (S. 974/H.R. 2212) – Legal Analysis of Criticisms," March 2018.

Abuse of the Patent System Delays Generic and Biosimilar Competition

Perhaps the greatest barrier to increased prescription drug competition occurs due to abuses of the U.S. patent system, and AAM applauds Chairman Pallone's recent remarks at the launch of the Coalition Against Patent Abuse (CAPA). While AAM's member companies strongly support innovation, they are finding it increasingly challenging to deliver new, more affordable generic, and especially biosimilar, medicines to patients due to patent abuse.[14]

In my testimony to this Subcommittee in December 2017, I explained how abuse of the patent system to prolong a brand-name drug's monopoly – a practice commonly referred to as "evergreening" – is increasingly being used as a delay tactic. These anti-competitive practices run counter to Congress's stated goal of bringing lower cost generic and biosimilar alternatives to market at the earliest possible date certain.[15] The problem, unfortunately, has only gotten worse since then and, without action to curtail these practices, patients will continue to pay monopoly prices for brand-name drugs and biologics.

Recent research demonstrates the extent of the problem and the increased costs borne by patients. Increasingly, brand-name drug companies are building patent "estates" around their 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.[16] 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. [17]

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.[18] 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.[19] The price of Humira increased 144 percent since 2012.[20]

[14] AAM, "Ensuring the Future of Accessible Medicines in the U.S. – Ensuring Competition for America's Patients," February 2018.
[15] AAM, Statement of Chester "Chip" Davis, Jr. to the Energy and Commerce Health Subcommittee, Hearing on "Examining the Drug Supply Chain," December 2017.
[16] Feldman, Robin, "May Your Drug Price Be Evergreen," December 2018.
[17] Ibid.
[18] I-MAK, "Overpatented, Overpriced," August 2018.
[19] Ibid.
[20] Ibid.

- 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.[21] The price of Revlimid increased 79 percent since 2012.[22]

- Diabetes patients who rely on the insulin treatment, Lantus®, may not see a generic alternative for 37 years due to the 49 patents issued.[23] The price of Lantus increased 114 percent since 2012.[24]

In these instances, branded 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.

Improving Patent Transparency in the Orange and Purple Books

AAM appreciates the Subcommittee's work to improve transparency to the patents obtained on brand-name prescription drugs in the Orange and Purple Books 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.[25] We also encouraged the FDA to list patent information for brand-name drugs approved prior to 2013 upon request.[26] In addition, the FDA should update the Purple Book to provide clarity around the exclusivity periods (unexpired and pending) for brand-name biologics, include interchangeability guidance, and improve its functionality by making it a searchable, electronic database.[27]

Collectively, these improvements to the Orange and Purple Books could facilitate more timely generic and biosimilar applications and entry into the market. With improved transparency, generic and biosimilar 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 and biosimilar competition is impeded as brand-name drug companies bring lawsuits seeking to stop FDA approval of competitive products due to undisclosed patents.

[21] Ibid.
[22] Ibid.
[23] Ibid.
[24] Ibid.
[25] AAM Comment Letter, HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, July 2018 (page 33).
[26] Ibid (page 34).
[27] Ibid (pages 28-29).

The Orange Book Transparency Act of 2019 (H.R. 1503) and the Purple Book Continuity Act of 2019 (H.R. 1520) include steps to improve patent transparency and disclosure. The Orange Book Transparency Act directs the FDA to include information on patents related to the drug, drug substance, drug product, and method of use. Unexpired exclusivities shall also be specified. FDA would also be directed to promptly remove invalid patents due to a Patent Trial and Appeal Board (PTAB) or court decision. The Purple Book Continuity Act directs the FDA to ensure the Purple Book includes the name, date of licensing, and type of bioequivalence study to be publicly listed and updated monthly. In addition, patent information would be listed if provided by a brand-name drug company to a biosimilar (351(k)) applicant.

AAM supports the Orange Book Transparency Act and the Purple Book Continuity Act, and recommends additional transparency and disclosure requirements consistent with our comment letter to HHS be included.

Preserving the Ability to Challenge Patents and Increase Patient Access to Generics and Biosimilars

Challenging potentially non-innovative patents is an expensive endeavor without any guarantee of success. Some have estimated litigation expenses on the order of $1 million per patent. When one considers the patent thickets established around the top-selling brand-name drugs as described earlier, it is fair to question whether patients will in a timely manner be able to benefit from competition from more affordable, FDA-approved generics and biosimilars.

Seemingly impenetrable thickets of patents cannot be overcome by generic or biosimilar manufacturers in a single patent litigation. For example, Humira® – one of the most expensive drugs in America – is now protected by a thicket of more than 100 patents, with the potential for that thicket to grow to over 200 patents.[28] The expiration of the last patent on file is 2034.

Despite the deterrent effect of patent thickets, a patent challenge is increasingly the only way a generic or biosimilar manufacturer can begin the process of bringing a competitive generic product to patients. However, in order to do so, there are two critical elements to achieving successful generic entry – the right of two private parties to reach a settlement providing for competition earlier than the expiration of the last patent and the 180-day exclusivity period provided to the first filer generic manufacturer that is able to successfully challenge a patent and reach the market.

Patent Settlements Expedite Patient Access to Generics

Patent litigation settlements can produce numerous additional pro-competitive benefits that benefit patients. For example, one study has found that settlements lead to generic

[28] Ibid., I-MAK.

entry, on average, 81 months (6.75 years) *prior to* patent expiry.[29] That early entry has created enormous value for consumers – one generic manufacturer estimated in 2009 that its settlements had removed 138 years of monopoly protection through early generic entry.[30] In addition to these direct, bottom-line benefits, settlements also avoid additional expensive, burdensome litigation costs.[31]

Settlements also provide generic and biosimilar companies with essential pro-competitive benefits that could not be achieved through expensive, years-long litigations. In addition to patent monopolies, drug products are subject to regulatory exclusivities that prevent the FDA from approving generic drug applications. Thus, even if a generic manufacturer believes it can invalidate the brand-name drug's patents, it may still be blocked from launching its product through a regulatory exclusivity. That barrier to entry is almost always addressed in a settlement agreement via a regulatory waiver – a waiver that cannot be achieved via litigation or by other means. Without such a waiver, generics cannot get approval to launch their products before the expiration of regulatory exclusivities.

Patients benefit from generic competition when a pro-competitive patent litigation settlement is achieved. Unfortunately, so-called "pay-for-delay" patent settlement legislation would overturn the Supreme Court's 2013 decision in *Federal Trade Commission (FTC) v Actavis* and outlaw pro-competitive settlements that benefit patients. Given the benefits of pro-competitive settlements, we recommend the "pay-for-delay" proposals be modified to preserve the ability of brand-name and generic companies to continue to settle their disputes, consistent with the *Actavis* decision and provide for substantial consumer cost-savings through timely generic entry.

180-Day Exclusivity Encourages Competition, First Generics for Patients

For more than 30 years, the Hatch-Waxman Act has provided the only incentive for generic manufacturers to be the first to market 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 earlier entry of safe and effective generic alternatives that are less expensive than the brand. Thus, the 180-day exclusivity provision has been critical to the Hatch-Waxman Act's track record of success in promoting generic competition.

Weakening the 180-day period of exclusivity for first generics will ensure that more non-innovative brand-name drug patents remain in place, delaying the availability of generic medicines for patients. As a result, patients will pay high brand-name drug prices for longer without competition from more affordable FDA-approved generic medicine.

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[29] Patent Docs, "IMS Study Shows Pro-Competitive Effects of Reverse Payment Settlement Agreements in ANDA Litigation," July 2013.
[30] Teva, Statement in Response to Federal Trade Commission Claims on Patent Settlements, June 2009.
[31] *Ohio Willow Wood Co. v. Thermo-Ply, Inc.*, 629 F.3d 1374, 1376–77 (Fed. Cir. 2011) and Herman, Note, "The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation," 2011.

Moreover, no evidence has been provided to date to justify any changes to the 180-day exclusivity for first generics. Concerns about the potential for "parking" of applications were adequately addressed by Congress as part of the Medicare Modernization Act of 2003. FDA's current statutory and regulatory authority allow the agency to conclude that 180-day exclusivity will not be awarded to a first applicant that does not diligently pursue approval. Specifically, current FDA 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."[32] Hence, both Congress and FDA have already solved for alleged "parking" of generic exclusivity.

For these reasons, **AAM opposes the Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act (H.R. 938), the Protecting Consumer Access to Generic Drugs Act (H.R. 1499), and the Fair Access for Safe and Timely (FAIR) Generics Act (H.R. 1506) as introduced.** Unfortunately, these proposals, as drafted, would have the unintended impact of *reducing* generic and biosimilar competition in the prescription drug market and thus lead to patients paying the high-cost of brand-name drugs for longer.

We are ready and willing to work with the Subcommittee to increase competition and enhance patient access to more affordable FDA-approved generics and biosimilars. AAM supports and encourages the Energy and Commerce Committee to consider several policies that would allow for expeditious challenge of brand-name drug patent thickets. For example, we recommend:

- *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.

[32] 21 C.F.R. § 314.107(c)(3).

We will gladly work with the Subcommittee 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.

Conclusion

Independent research and data demonstrate one undeniable conclusion: Brand-name drug prices continue to rise, while generic drug prices continue to fall. With brand-name drugs accounting for 77 percent of total spending on prescription drugs in 2017, the high cost of many prescriptions is often out of reach for patients.[33] Higher spending on prescription drugs impacts everyone – directly in the form of higher premiums and out-of-pocket costs and as taxpayers to cover the costs of Medicare, Medicaid, and other federal health care programs. Prescription drugs now account for $0.23 out of every premium dollar and the average co-pay for brand-name drugs was $40.30 in 2017.[34] [35]

In contrast, the amount spent on generic medicines has declined for the last 30 consecutive months.[36] Nine out of every 10 prescriptions filled in the U.S. are for generic drugs and spending on generic drugs accounted for only 23 percent of total prescription drug spending.[37]

Savings from generic and biosimilar medicines, however, often go unrealized. HHS found "incompletely aligned incentives for generic substitution leave significant savings uncaptured."[38] Seniors and the Medicare Part D program would have saved $3 billion in 2016 if generics had been dispensed rather the brand-name drug.[39] Last year, the FDA reported that patients could have saved "more than $4.5 billion in 2017" if they had the ability to purchase FDA-approved biosimilars.[40]

Moreover, new analysis from Avalere shows generic drugs are increasingly being placed on higher formulary tiers for seniors with Medicare Part D coverage. From 2011 to 2019, the number of generic drugs on Tier 1 (Preferred Generic) has declined from 71 percent to 14 percent.[41] Generic drugs are now placed on Tier 3 (Preferred Brand) 18 percent of the time and Tier 4 (Non-Preferred Drug) 25 percent of the time.[42] As a result, patients are shouldering more of the out-of-pocket costs for the same drugs at

[33] Ibid.
[34] America's Health Insurance Plans (AHIP), "Where Does Your Health Care Dollar Go?," May 2018.
[35] Ibid., AAM.
[36] Morgan Stanley, Monthly YOY Generic Prescription Drug Sales, January 2019.
[37] Ibid., AAM.
[38] HHS, "Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D," January 2018.
[39] Ibid.
[40] FDA, Remarks from FDA Commissioner Scott Gottlieb, M.D., FDA's Biosimilars Action Plan, September 2018.
[41] Avalere, "Effect of Potential Policy Change to Part D Generic Tiers on Patient Cost Sharing and Part D Plan Costs," February 2019.
[42] Ibid.

the same price. Avalere found “patient cost-sharing would have been $15.7 billion lower” over the last four years if generic medicines were placed only on generic formulary tiers.[43]

The Centers of Medicare and Medicaid Services (CMS) – with the support of Congress – could take immediate action to lower the out-of-pocket costs for seniors with Medicare coverage by adopting the “Generics on Generic Tiers” proposal for 2020. If finalized, Avalere estimates seniors would save $4 billion a year in prescription drug costs.[44]

Efforts to ensure patients are able to fully realize the savings available from generic and biosimilar medicines on the market today combined with Congressional action to advance policies that increase competition is the ultimate equation to achieving the shared goal of enhancing patient access to more affordable generic and biosimilar medicines.

AAM greatly appreciates the attention and work of the Energy and Commerce Committee and the Health Subcommittee to address many of the barriers to competition that are delaying or altogether preventing patient access to more affordable medicines. We look forward to continuing to work with you to advance the CREATES/FAST Generics Acts, curtail the undeniable abuse of the patent system, increase transparency of patents in the Orange and Purple Books, and preserve the ability of generic and biosimilar manufacturers to challenge patent thickets. Thank you for considering our views.

[43] Ibid.
[44] Ibid.