



**Association for Accessible Medicines**  
**Statement of David Gaugh, R.Ph.**  
**House Energy and Commerce Subcommittee on Health**  
**Hearing on “Safeguarding Pharmaceutical Supply Chains in a Global Economy”**  
**October 30, 2019**

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 David Gaugh, Senior Vice President for Sciences and Regulatory Affairs at the Association for Accessible Medicines (AAM).

AAM is the nation’s leading trade association for the 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.<sup>1</sup> AAM’s core mission is to improve the lives of patients by advancing timely access to safe, affordable and high quality generic and biosimilar medications.

**Let me start by making one point clear: patient safety is the number one priority for AAM and its member companies.** Generics and biosimilars are just as safe and effective as their brand-name drug counterparts. Through its rigorous approval process, manufacturing regulations and continuous inspections of manufacturing facilities, the U.S. Food and Drug Administration (FDA) ensures that “medicines at all levels of the supply chain, from active pharmaceutical ingredients (API) to the finished product sold to consumers at the pharmacy counter are safe, effective and high quality.”<sup>2</sup>

As a result of the daily commitment to quality from AAM’s member companies and FDA oversight, the U.S. has one of the safest drug supply chains in the world. Moreover, every administration of both parties and, including as recently as last week from Secretary of Health and Human Services Alex Azar, are publicly on record assuring America’s patients that the FDA would not approve generics if they were not safe and effective treatments.<sup>3</sup>

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<sup>1</sup> AAM, “Generic Drug Access & Savings Report 2017,” June 2017.

<sup>2</sup> Statement from FDA Commissioner Scott Gottlieb, M.D., and Director of FDA’s CDER Janet Woodcock, M.D., “FDA’s continuing efforts to maintain its strong oversight of generic drug quality issues domestically and abroad,” February 2019.

<sup>3</sup> Alaric DeArment, “FDA commissioner praises generic industry’s efforts on quality, shortages, follow-on biologics in GPhA speech,” Drug Store News, February 2013.

Now, it is also important to emphasize that generics and biosimilars are part of the same global pharmaceutical supply chain as the one for brand-name drugs and biologics. And the scrutiny applied to the manufacturers of generic and biosimilar medicines must therefore also be applied to the manufacturers of brand-name pharmaceuticals. As the FDA noted in its testimony, the percentage of API manufacturing facilities – for all pharmaceuticals – located outside of the U.S. is 72 percent, including 13 percent in China. Examining only one part of the pharmaceutical supply chain is akin to diagnosing a heart attack based only on the patient’s complaint of pain in one’s arm without ever examining the patient’s chest. Therefore, we strongly encourage the subcommittee to take a comprehensive and inclusive approach in its examination of the pharmaceutical supply chain.

In examining the pharmaceutical supply chain, one must also consider the underlying economic realities of the generic and biosimilar markets. Prices for generic drugs are plummeting – falling for 34 of the last 38 months – and creating a market in which many drugs are simply and increasingly not economical to manufacture.<sup>4</sup> The biosimilars market is nascent with only nine available products and only one of the 23 FDA-approved biosimilars regularly prescribed.<sup>5</sup> Biosimilar manufacturers are increasingly looking to provide Europe’s patients with access first, rather than the U.S., due to the barriers to competition and a policy environment that inadequately supports their uptake and use domestically.<sup>6</sup>

We understand why the subcommittee would be concerned about recently reported data that paints a distorted picture of a global supply chain that is heavily reliant on China and other countries for API. We are here today in order to help set the record straight and provide more accurate analysis of where generic API and finished dosage form (FDF) facilities are located. In my testimony, I also cover the role of generics and biosimilars in improving patient health, how more affordable treatments enhance patient access, explain FDA’s oversight role and inspections process, and outline our industry’s robust commitment to quality. We would, however, encourage the subcommittee to focus its attention on addressing the very real sustainability challenges facing generic and biosimilar manufacturers given the robust regulatory environment that exists today, and is the result of previous Congressional efforts, to ensure the safety and efficacy of prescription drugs in the U.S.

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<sup>4</sup> Morgan Stanley, October 2019.

<sup>5</sup> FDA, Biosimilar Product Information, September 2019.

<sup>6</sup> Biosimilars Council, “Failure to Launch: Barriers to Biosimilar Market Adoption,” September 2019.

## **Generics and Biosimilars Are Integral to Patient Health**

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 result in significant savings for patients and the health care system. Over the last 10 years, generic manufacturers have delivered savings of nearly \$2 trillion – including \$293 billion in 2018 – to patients and the health care system.<sup>7</sup>

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.<sup>8</sup> Experts estimate that FDA-approved biosimilars could save more than \$54 billion over the next 10 years.<sup>9</sup> In doing so, biosimilars will mean greater access to lifesaving cures for an estimated 1.2 million patients.<sup>10</sup>

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.<sup>11</sup> Early experience with the nascent biosimilars market in the U.S. 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.<sup>12</sup>

However, these savings are only possible because of the commitment from AAM's members to quality, safety and efficacy throughout the pharmaceutical drug supply chain.

## **FDA's Oversight of the Pharmaceutical Supply Chain**

The FDA ensures all pharmaceuticals meet the same high-quality standards regardless of where brand-name drugs, biologics, generics and biosimilars are manufactured. All pharmaceuticals, whether generic or brand, must be manufactured in accordance with

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<sup>7</sup> AAM, "The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report," September 2019.

<sup>8</sup> U.S. Pharmacist, "Biosimilars: Current Approvals and Pipeline Agents," October 2016.

<sup>9</sup> RAND, "Biosimilars Cost Savings in the United States," October 2017.

<sup>10</sup> The Biosimilars Council, "Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines," August 2017.

<sup>11</sup> IMS Institute for Healthcare Informatics, "Price Declines after Branded Medicines Lose Exclusivity in the U.S.," January 2016.

<sup>12</sup> AAM analysis of IQVIA WAC Data, December 2018.

rigorous regulatory standards that require high levels of diligence and accompanying documentation.<sup>13</sup> FDA and other governmental requirements cover each of the following areas:

- Acquisition of raw materials and drug packaging components, including auditing the manufacturers and suppliers of critical ingredients;<sup>14</sup>
- Testing of active ingredients using qualified equipment and validated methods;<sup>15</sup>
- Constructing and maintaining manufacturing equipment and facilities that have been constructed and maintained to provide sanitary conditions and to protect against contamination;<sup>16</sup>
- Appropriate and documented training of manufacturing personnel;<sup>17</sup>
- Validation of manufacturing processes to ensure that they consistently produce safe, effective and uniform medicine;<sup>18</sup>
- Thorough contemporaneous documentation of each manufacturing step, with oversight by an employee other than the operator for critical manufacturing steps;<sup>19</sup>
- Taking samples of prescription drugs during the manufacturing process at predetermined intervals, and testing the samples for potency and, where appropriate, sterility;<sup>20</sup>
- Maintaining rigid controls over labels placed on drug containers, to ensure the correct labels are placed on every package;<sup>21</sup>
- Thorough testing of prescription drugs before packaging to ensure that they are free of microbial contamination or other defects, and that they meet tight specifications for uniformity, potency and lack of impurities;<sup>22</sup>
- Retention of samples of all manufactured batches of prescription drugs;<sup>23</sup>
- Routine stability testing to ensure that prescription drugs, including biologics, will remain safe and effective for the duration of their shelf lives;<sup>24</sup>

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<sup>13</sup> 21 Code of Federal Regulations Parts 210, 211, 600-680; Inspection of Biological Drug Products, FDA Compliance Program Guidance Manual, Chapter – 45 Biological Drug Products, Section 7345.848.

<sup>14</sup> 21 CFR §211.182.

<sup>15</sup> 21 CFR §211.84.

<sup>16</sup> 21 CFR §211.42, §211.56 (facilities), §211.65, §211.67 (equipment).

<sup>17</sup> 21 CFR §211.25.

<sup>18</sup> 21 CFR §211.100.

<sup>19</sup> Ibid., 21 CFR §211.101(c), §211.180(a), §211.186, §211.188(b).

<sup>20</sup> 21 CFR §211.110.

<sup>21</sup> 21 CFR §211.122, §211.125, §211.130, §211.134.

<sup>22</sup> 21 CFR §211.113, §211.165, §211.194.

<sup>23</sup> 21 CFR §211.170(b).

<sup>24</sup> 21 CFR §211.165.

- Release of each batch of prescription drugs for distribution only upon review of all batch records and testing data by a quality unit that is independent of manufacturing personnel;<sup>25</sup>
- Continuous oversight by management and regular audits by an independent quality unit of the manufacturer or outside consultants;<sup>26</sup>
- Rigorous documentation of every step in the storage and distribution of manufactured prescription drugs;<sup>27</sup> and,
- Prompt reporting to FDA and thorough investigation of any complaints about distributed medicines, or any reports that the prescription drugs may have failed to remain safe and effective.<sup>28</sup>

When the FDA finds any deviation from the strict standards of production, the FDA can take swift action. Potential actions include: pressuring manufacturers to recall products; issuing public Warning Letters; imposing import alerts and barring the admission into the U.S. of violative API or FDF; seizing violative medicines; seeking court orders suspending distribution of drug products until the FDA approves resumption of operations; and pursuing criminal prosecution of individuals and companies when necessary.<sup>29</sup> The FDA does not hesitate to exercise these powers, taking action not only when prescription drugs are determined to be defective, but when the FDA believes that the system of manufacturing is insufficient to guarantee that all prescription drugs are safe, effective and uniform.

The Generic Drug User Fee Amendments (GDUFA) of 2012 and its reauthorization in 2017 included a \$4 billion commitment from the generic drug industry.<sup>30</sup> One of the reasons the generic drug industry supported the user fee program for generic drugs was the imbalance between the frequency of inspections for domestic manufacturers and foreign manufacturers, especially those located in China and India. Statistics at the time showed that large generic manufacturers located in the U.S. could expect to be inspected by the FDA once every two to three years. In contrast, major suppliers of prescription drugs based in China and India were inspected, on average, less than once every 10 years.

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<sup>25</sup> 21 CFR §211.22, §211.142, §211.167, §211.192.

<sup>26</sup> 21 CFR §211.180(e), (f).

<sup>27</sup> 21 CFR §211.150(b), §211.196; Drug Supply Chain Security Act, Title II of the Drug Quality and Security Act of 2013.

<sup>28</sup> 21 CFR §211.198.

<sup>29</sup> FDA Public Databases on Drug Recalls, Warning Letters, and Import Alerts; Ned Sharpless, M.D., "Expanding Criminal Enforcement Operations Globally to Protect Public Health," FDA, October 2019.

<sup>30</sup> FDA, Five-Year Financial Plan for the Generic Drug User Fee Amendments, 2018.

GDUFA has significantly increased and continues to augment the funding of FDA's generic drug review and inspection programs. GDUFA substantially increased FDA's review capacity and the frequency of inspections. The FDA hired nearly 1,200 employees to strengthen oversight under GDUFA implementation and 338 additional employees were added as a result of GDUFA II.<sup>31</sup>

Indeed, GDUFA fees and the foreign drug manufacturer inspections by the FDA that the fees enable have dramatically changed where FDA has focused its inspection and enforcement efforts. Until 2012, the majority of FDA Warning Letters relating to manufacturing violations issued to mainstream drug manufacturers were based on inspections at facilities located in the U.S. In 2011, for instance, 45 percent of FDA Warning Letters for drug manufacturing violations were based on inspections of facilities outside of the U.S. More recent data, for 2016, shows 98 percent of FDA Warning Letters were issued to facilities located outside of the U.S.<sup>32</sup> The increase in enforcement actions against drug manufacturing facilities located outside of the U.S. is directly attributable to an increase in the number of FDA inspections. However, it is important to remember that most manufacturers that are inspected are found to be fully compliant with the regulations.<sup>33</sup>

The FDA utilizes a risk-based inspection strategy, established under the GDUFA I Commitment Letter, to maintain a robust inspections footprint around the world. The FDA has established offices in China and India and uses GDUFA funding to support those offices. The FDA's global inspection efforts are prioritized and focused on facilities in a way to prevent, uncover and combat data integrity issues and manufacturing problems. Using a risk-based site selection surveillance inspection model, the FDA prioritizes domestic and foreign inspections based on multiple factors carefully selected to appropriately target the agency's resources.

In fiscal year 2017, the FDA conducted 935 inspections of generic drug manufacturing facilities in the U.S. and around the world.<sup>34</sup> This includes 547 international inspections and 388 domestic inspections. Moreover, the level of inspections increased between fiscal year 2013 and fiscal year 2017 (five years) from a total of 721 inspections. As former FDA Commissioner Scott Gottlieb, M.D., noted at the time, "We expect these trends to continue due to resources from GDUFA II."<sup>35</sup>

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<sup>31</sup> Kathleen Uhl, Director of Office for Generic Drugs, Presentation: Director's Update, February 2016.

<sup>32</sup> Independent review of FDA's public database of Warning Letters.

<sup>33</sup> FDA, "Facts about the Current Good Manufacturing Practices (CGMPs)," June 2018.

<sup>34</sup> FDA, FY2017 Performance Report to Congress for GDUFA, May 2018.

<sup>35</sup> Scott Gottlieb, Tweet on FY2013-17 Inspectional Data, January 2019.

AAM and its members remain committed to ensuring the FDA continues to have the resources to perform thorough inspections of facilities that manufacture all medicines approved in the U.S. We are pleased that the number of FDA's foreign inspections continue to rise, in no small part based on funding provided by AAM's member companies through GDUFA and the Biosimilars User Fee Act (BsUFA).

### **Our Industry's Commitment to Quality and Patient Safety**

As noted, patient safety is the number one priority for AAM and its member companies. AAM's members adhere to a code of business ethics and the "Safety of Medicines" is its first principle.<sup>36</sup> Every AAM member company pledges to "conform to high standards of quality, safety and efficacy as determined by regulatory authorities in each economy in which they operate."<sup>37</sup> This commitment to quality, safety and efficacy applies regardless of where medicines are manufactured.

Patients should know and be confident in the quality of the generic medicines prescribed and picked up at the pharmacy. Generics and biosimilars are just as safe and effective as their brand-name drug counterparts. Independent research consistently demonstrates the clinical equivalence of generic medicines compared to the brand-name drug.<sup>38</sup>

Patients can trust the safety and effectiveness of generic medicines. And it is important that patients take their medicines as prescribed by their physicians. As Secretary Azar recently stated:

"Every single drug I take is a generic. They are exact copies. They wouldn't get approved by the FDA if they weren't."<sup>39</sup>

While it is not always possible to combat all of the misinformation that exists, we encourage lawmakers to avoid, to the extent possible, repeating and sometimes promoting inaccurate information on quality because of the adverse consequences for patients who may think it is unsafe to take their prescribed medicines. As FDA has emphasized, not taking one's medicine as prescribed by a doctor or as instructed by a pharmacist, due to unsubstantiated claims on quality, could have the undesired effect of exacerbating a patient's illness or disease, and lead to worse health outcomes.

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<sup>36</sup> AAM, Code of Business Ethics, March 2018.

<sup>37</sup> Ibid.

<sup>38</sup> FDA, Generic Drugs: Questions & Answers, June 2018.

<sup>39</sup> Sec. Azar, Interview on Fox & Friends, October 2019.

Moreover, and as described previously, the FDA provides regulatory oversight of the manufacturing of generic and biosimilar medicines. Manufacturing facilities located overseas, as well as in the U.S., are routinely inspected by the FDA to ensure the medicines are of the highest quality for patients. A standardized, transparent and dynamic system is in place and is working for doctors, pharmacists and patients.

### *Quality is Standard*

Exacting standards ensure the reliability of the medicines we take. These standards make it possible for us to trust that a pill dispensed from a pharmacy in Oregon in the spring will match, in every way that matters, a pill picked up at a drug store counter the following winter in Miami.

Dr. Jeremy Greene, professor of medicine and the history of medicine at Johns Hopkins University and author of *Generic: The Unbranding of Modern Medicine*, explained in a recent interview with United States Pharmacopeia (USP):

“There’s a mutual interest among manufacturers, whether they are brands or generics, for establishing and disseminating a public standard that helps us determine if a drug is what it says it is.”<sup>40</sup>

The various stakeholders – health care professionals, industry, and government – that keep our drug supply safe agree upon the standards, and USP publishes the standards and the methods that manufacturers and regulators can employ to demonstrate that medicines are what they should be. These standards apply to a drug’s molecular structure, and to the amount of active and inactive ingredients it contains to ensure a drug’s efficacy and safety.

USP strives for comprehensive standards, which is no small task. According to its latest annual report, more than 3,700 reference standards and more than 6,700 documentary standards have been issued.<sup>41</sup> USP’s collaborative work with the FDA to set drug quality standards for nearly 80 years has made drugs marketed in the U.S. the gold standard worldwide for safety and quality.

### *Transparency Enhances Quality*

All of the links along the supply chain have an obligation to be open and transparent about issues related to safety and quality. This is how the system secures the

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<sup>40</sup> Jeremy Greene, “Similarity and difference in the world of drugs,” USP, accessed October 2019.

<sup>41</sup> USP Annual Report, “USP by the numbers: Fiscal year 2019,” accessed October 2019.



accountability necessary to earn and retain the trust of the medical profession and, ultimately, the patients.

The FDA has a robust around-the-clock program for inspecting pharmaceutical manufacturing facilities worldwide. The Office of Regulatory Affairs (ORA) conducts assessments, inspections, research and surveillance of pharmaceutical manufacturing facilities. AAM's member company manufacturing facilities, all over the world, must be ready for FDA inspection whenever they are operating, 365 days a year. Our member companies have established interlocking processes and procedures to ensure the quality and integrity of the medicines manufactured in these facilities.

Generic manufacturers not only readily comply with inspections audits; they also fund this oversight through GDUFA, which supports FDA staffing and best practices in protecting public health and accelerating innovation. These fees total nearly \$500 million annually.<sup>42</sup> Foreign as well as domestic companies identify and register all facilities involved in the manufacturing of generics and their active ingredients. BsUFA operates on similar principles.

Reports from the public, health care professionals and the industry of potentially defective drug products help the FDA identify sites for inspection or investigation. Most companies that are inspected are found to be fully compliant with the regulations.<sup>43</sup> In addition, Post-marketing Surveillance Programs are in place to identify adverse reactions that did not appear during the drug approval process.

Critics may point to product recalls to draw attention to issues in the supply chain, but we believe the rarity of these events demonstrates the system's effectiveness. Indeed, recalls are occasionally required not when a flaw or defect is identified in a medicine, but rather when the FDA believes that there is inadequate assurance of adequate quality systems at a plant because manufacturing does not strictly comply with the rigorous regulatory requirements. I would also note that while 90 percent of prescriptions filled in the U.S. are generic medicines, generic drugs account for only 56 percent of any prescription drug recalls.<sup>44</sup> Brand products on the other hand account for only 10 percent of prescriptions filled, but 44 percent of the total recalls.<sup>45</sup>

When an issue is discovered, the proper mechanisms are activated, and industry works with the FDA to appropriately address it. In the unlikely event that flawed medication does reach a patient, we should take comfort that all medicines can be traced to the

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<sup>42</sup> FDA, "GDUFA II Fee Structure Summary," accessed October 2019.

<sup>43</sup> FDA, "Facts about the Current Good Manufacturing Practices (CGMPs)," June 2018.

<sup>44</sup> FDA database, "Recalls, Market Withdrawals, and Safety Alerts," 2011-18.

<sup>45</sup> Ibid.

manufacturer. The manufacturer of the product immediately notifies stakeholders in the supply chain, and then pharmacists or physicians reach out to notify patients and to determine alternative prescription options. Obviously, these recalls are widely publicized; transparency contributes to quality.

### *The Global Supply Chain is Dynamic*

The FDA and the industry are constantly adapting to manufacturing innovations. Current Good Manufacturing Practice (cGMP) regulations address methods, facilities and controls used in manufacturing, processing and packaging. The globalization of the supply chain, which is a fact of life for brand, generic and biosimilar drugs, is often mentioned as a matter of concern, but in fact, the record bolsters confidence in the system. While it is true that so-called fake drugs circulate in developing nations through mail-order and online pharmacies, U.S. regulations, guidance and legislation are in place to minimize the possibility that they could reach America's patients.<sup>46</sup> Further, the only additional method of preventing counterfeit or unapproved medications from reaching the U.S. market would be to rigorously examine and test all incoming parcels and packages that could contain medications – a measure that AAM would support. Only a tiny fraction of incoming parcels and packages are currently examined.

These factors ensure patients can take their medications with confidence. Michael Kopcha, director of the OPQ in the FDA's Center for Drug Evaluation and Research (CDER), may have put it best when he said:

"The quality of our drug supply is better than ever before. There is no difference in the quality of drugs based only on where they are made."<sup>47</sup>

### **Setting the Record Straight on the Global Production of Generics**

We understand why the subcommittee would be concerned about recently reported data that paint a distorted picture of a global supply chain that is heavily reliant on China and other countries for API. Let me take a moment to provide the subcommittee with more accurate analysis of the global location of where generic finished product manufacturing facilities and API facilities are located.

We conducted analysis of data publicly available on the FDA's website.<sup>48</sup> These data are provided pursuant to GDUFA II self-reporting and provide information on the FDF

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<sup>46</sup> Fight the Fakes, "US FDA Gives Tips on Spotting Fake Medicines," June 2014.

<sup>47</sup> Michael Kopcha, "CDER Conversation: Assuring Drug Quality Around the Globe," FDA, May 2019.

<sup>48</sup> FDA, Generic Drug Facilities, Sites and Organization Lists, FY2020, October 2019.

facilities and API facilities of generic manufacturers for the last eight years. Our analysis of these data for FY2020 found:

*API Facilities*

- 31 percent of the generic API facilities are located in India and 17 percent in China.
- Overall, 13 percent of generic API facilities are located in the U.S. and 87 percent are located outside of the U.S.

*FDF Facilities*

- 24.5 percent of the generic FDF facilities are located in India and 8.5 percent in China.
- Overall, 40 percent of the generic FDF facilities are located in the U.S. and 60 percent are located outside of the U.S.

Considering this analysis of FDA's data, it is important to accurately depict – and not overstate – where generic API and FDF facilities are located.

Moreover, these data are only applicable to one part of the pharmaceutical market – generic drugs – and do not reflect where brand-name drugs are manufactured or the overall API source. For members of the subcommittee to have a complete picture of the global manufacturing of prescription drugs, we strongly encourage the subcommittee to examine all sectors.

**Conclusion**

In closing, patients can and should trust in the safety and effectiveness of generic medicines. The FDA ensures all pharmaceuticals meet the same high-quality standards regardless of where medicines are manufactured. Globalization of the supply chain – a market reality for brand-name drug companies and generic and biosimilar manufacturers – is often mentioned as a matter of concern, but the record should in fact bolster confidence in the system. The U.S. has one of the safest drug supply chains in the world. And this is the result of the daily commitment to quality from AAM's member companies and FDA oversight.

Given the robust regulatory environment that is in place today to ensure the safety and efficacy of prescription drugs in the U.S., we encourage the subcommittee to focus its attention on addressing the very real sustainability challenges facing generic and biosimilar manufacturers. The U.S. health care system and America's patients – as evidenced by the fact that 90 percent of all medicine prescribed annually is now generic

– depends on AAM’s members for the continued delivery of high quality, affordable generics and biosimilars. Without a reliable and stable generics and biosimilars industry, and the billions in savings provided annually as a result of patient access to these medicines, the benefits of increased patient adherence, improved health outcomes, and significantly lower health care costs are all at risk.

The first step is to do no harm and to avoid policies that further exacerbate the sustainability of the generic and biosimilar markets. This includes:

- **Fixing the Medicaid Generics Penalty.** The Medicaid Generics Penalty threatens the viability of low-cost generics which are now subject to additional rebates even when the generic drug price does not increase. These unpredictable, onerous penalties on often low-margin medicines create significant risk for manufacturers.
- **Reconsidering Changes to the 180-Day Exclusivity Period for First Generics.** The BLOCKING Act (H.R. 938) erodes the one incentive generic manufacturers have to challenge brand-name drug patents.<sup>49</sup> Enactment of the BLOCKING Act, without changes, would reduce competition from more affordable generics and lead patients to paying the high-cost of brand-name drugs for longer.
- **Revisiting Limits on Patent Settlement Agreements.** The Protecting Consumer Access to Generic Drugs Act (H.R. 1499) creates a presumption that patent settlement agreements are anti-competitive and should be amended to enshrine the Supreme Court’s *Actavis* decision into law and preserve current FTC practice.<sup>50</sup>

While well-intentioned, each of these policies if advanced by Congress would only reduce patient access to more affordable generics and biosimilars.

Thank you for the opportunity to testify. I would be glad to answer any questions.

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<sup>49</sup> Chip Davis, AAM Testimony to the House Energy and Commerce Subcommittee on Health, March 2019.

<sup>50</sup> AAM Letter to the House Judiciary Committee on Patent Settlements, April 2019.