June 25, 2020

The Honorable Lamar Alexander
Chairman
U.S. Senate Committee on Health, Education, Labor and Pensions (HELP)
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Alexander:

The Association for Accessible Medicines (AAM) is pleased to submit the following comment letter in response to the request for input on the recommendations outlined in the "Preparing for the Next Pandemic" white paper. As the nation's leading trade association for the developers, manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines, AAM and our members are committed to the secure and consistent supply of critical medicines to improve the health of America's patients and as a critical tool in the effort to lower prescription drug costs.

The COVID-19 pandemic reminds us of the incredible value offered by the generics and biosimilars industry, the benefits of a reliable and resilient global supply chain, and the industry's daily commitment to manufacturing safe, effective and high-quality medicines. AAM's members have experienced substantially increased demand for certain medicines that far exceeded historical trends,[1] navigated export restrictions on active pharmaceutical ingredients (API) and finished dose (FD) generic medicines,[2] re-routed the delivery of medicine as air travel was significantly curtailed around the globe,[3] and absorbed much of the increased costs charged for the transportation of medical products to ensure that America's patients are able to access critically needed medicines during the coronavirus pandemic.[4] In response, AAM's member companies have stepped up to meet these challenges.[5]

[1] Ellen Gabler and Michael Keller, "Prescriptions Surged as Trump Praised Drugs in Coronavirus Fight," New York Times, April 25, 2020, Updated May 19, 2020.
[2] Rajesh Roy, "India Again Allows Export of Antimalarial Drug Touted for Coronavirus," Wall Street Journal, April 7, 2020.
[3] Ian Duncan, "Drug Industry Warns That Cuts to Passenger Airline Service Have Put Medical Supplies at Risk," Washington Post, May 2, 2020.
[4] AAM Survey of Biosimilar and Generic Drug Manufacturers, "Pharmaceutical Shipping Costs Spike in Response to Global COVID-19 Pandemic," April 30, 2020.
[5] AAM, "Generics and Biosimilars Industry Supply Chain & Response to COVID-19," April 10, 2020.

The Senate HELP Committee's white paper provides important recommendations on and poses critical questions about how the federal government should prepare for the next pandemic. AAM and its members agree with the Senate HELP Committee's call to action and, as outlined in AAM's "**Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain**," believe there are important steps Congress can and should take to ensure uninterrupted patient access to life-saving medicines now and in the future.

Building upon the existing generic drug supply chain in the U.S., which produces approximately 70 billion doses annually and provides more than 36,000 jobs in nearly 150 manufacturing facilities across the country, AAM's *Blueprint* includes a six-element framework that lays out concrete actions to ensure that U.S. patients and the U.S. health care system have access to a secure and consistent supply of critical medicines.[6]

AAM and its members seek to provide solutions that will enable expanded investment in the manufacturing of medicines domestically.[7] Creating the conditions that support and encourage these investments are critical to ensuring the most critical medicines – those most essential to our country's health and security – are manufactured in the U.S. In order to establish and maintain this environment, AAM's *Blueprint* recommends the following:

- Identify the list of medicines most critical for patient health;
- Provide new grant, tax and other incentives to secure the U.S. supply chain;
- Supply the Strategic National Stockpile, the U.S. Department of Veterans Affairs, and other agencies with essential medicines on a long-term basis;
- Reduce regulatory inefficiencies to streamline the federal approval for U.S.-based facilities to manufacture medicines; and,
- Promote a global, cooperative approach to diversifying the supply chain.

The *Blueprint* includes actionable short-term steps to expedite more U.S.-based production of essential medicines, while putting in place a series of incentives to enhance the security of the U.S. pharmaceutical supply chain. Global coordination across a resilient, high-quality and reliable supply chain is an important element in ensuring the ability to respond to public health challenges and natural disasters. Given modern manufacturing facilities can take 5-7 years and cost up to $1 billion to build, a long-term, consistent commitment from the federal government is critical to harnessing

[6] AAM, "A Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain," April 30, 2020.
[7] Based on a 2016 survey of AAM's member companies.

existing U.S. manufacturing and building an expanded generic manufacturing base in the U.S.

A copy of AAM's *Blueprint* and more detailed responses to the recommendations and questions are enclosed with this cover letter. We look forward to working with the Senate HELP Committee in the months ahead to advance the recommendations outlined in the *Blueprint* and to help prepare the U.S. for future public health emergencies.

Sincerely,

Jeffrey K. Francer
Interim CEO & General Counsel

Enclosed: AAM Comments on "Preparing for the Next Pandemic" White Paper
AAM "Blueprint for Enhancing the Security of the U.S. Supply Chain"

AAM Comments on "Preparing for the Next Pandemic" White Paper

HELP Recommendation 1.1: Congress and the administration should identify and implement public-private manufacturing models to improve and maintain sustainable domestic vaccine manufacturing capacity and capabilities. One approach has been the advanced development manufacturing program.

> **AAM Comments 1.1:** AAM agrees with this recommendation and encourages the federal government to adopt long-term price and volume guaranteed contracts; grants to support construction, alteration, or renovation of facilities; tax deductions and credits to offset the cost of supply chain enhancements; and, streamlined regulatory review of manufacturing sites. These incentives would help create the conditions necessary to support and encourage the pharmaceutical industry to expand its investments and economic footprint throughout the U.S. AAM's "Blueprint to Enhance the Security of the U.S. Supply Chain" provides additional details and recommendations on how to advance this critical public-private partnership.
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> As also noted in Senate HELP Committee's white paper, the current use of advanced manufacturing, including continuous manufacturing, is limited. According to the FDA, eight brand-name drugs are produced with continuous manufacturing. No generic medicines approved by the FDA use continuous manufacturing. There is no doubt that there are potential benefits with continuous manufacturing and additional study will help evaluate whether, and for which products, this emerging technology is appropriate. AAM recommends the incentives mentioned above and recommended in AAM's *Blueprint* be broad in their applicability, targeted to achieve the intended policy goals, and not limited to medicines made only through advanced manufacturing.

HELP Recommendation 1.2: Congress and the administration should continue to support NIH research and its academic partnerships, which have provided key infrastructure to rapidly pivot to COVID-19 research and clinical trials.

> **AAM Comments 1.2:** Over the last four months, clinical guidelines and the standard of care for patients with COVID-19 has evolved as knowledge about the disease has increased. In the months ahead, medical professionals and public health experts will continue to learn how best to treat patients as innovative vaccines are developed and current FDA-approved medicines are tested. Funding for the National Institutes of Health (NIH) and its academic partnerships is critical to evaluating the effectiveness and any potential side effects associated

with potential COVID-19 treatments. In addition to the work NIH and others are doing to develop innovative vaccines and treatments, AAM's members are partnering with health organizations and governments around the world to evaluate the use of currently available generic medicines for the treatment of patients with COVID-19. AAM's members also manufacture prescription drugs, such as dexamethasone,[8] for COVID-19 patients and over-the-counter medicines, for example acetaminophen, used to help treat the symptoms of the illness. NIH funding should be utilized to fully evaluate all potential treatment options for patients with COVID-19.

HELP Recommendation 2.1: Ensure timely communication between health professionals, states, the CDC, and the public, as appropriate, of case data and information regarding how emerging infectious diseases affect populations, including who is at higher risk for severe disease and death, to help inform state and local response and address any potential disproportionate impact on minority populations.

AAM Comments 2.1: AAM agrees with this recommendation. Timely communication is critical in supporting an effective and coordinated response to a public health crisis. In addition, AAM recommends the inclusion of health care distributors and group purchasing organizations (GPOs), among others in the pharmaceutical supply chain, in the lines of communication. As the public health response evolved to COVID-19, demand for certain generic medicines, in certain regions of the U.S., increased far above historical trends. Timely communication with these stakeholders helps ensure the supply of pharmaceuticals keeps pace with demand. As outlined in AAM's "**Generics and Biosimilars Industry Response to COVID-19**" presentation, health care distributors and GPOs purchase medicines in large quantities in order to supply hospitals, physicians and pharmacies with needed prescriptions. Without timely communication and real-time market signals, delays in the production of medicines that could otherwise be mitigated may occur.

HELP Recommendation 3.1: Utilize existing authorities to build public-private partnerships, such as vendor managed inventory contracts with manufacturers and distributors, to create excess medical supplies managed by private sector partners that could be needed for the next pandemic or public health emergency. Additionally, the Strategic National Stockpile could contract with manufacturers to maintain manufacturing capability for certain products, such as N95 masks or other personal protective equipment, to rapidly manufacture supplies needed for a future pandemic.

[8] Harper, Matthew, "Major study finds common steroid reduces deaths among patients with severe Covid-19," STAT, June 16, 2020.

AAM Comments 3.1: AAM agrees with this recommendation and supports leveraging the Strategic National Stockpile (SNS) to help in the ongoing response to COVID-19 and in preparation for future public health emergencies. The Department of Health and Human Services (HHS) could enter into purchase agreements with manufacturers for generic medicines to supply SNS. HHS could take possession of such purchases or pay manufacturers an inventory management fee to produce and maintain the specified quantity on behalf of the SNS. AAM recommends that specific volume and price levels be negotiated on a company-by-company basis. Multiple suppliers in the market helps ensure, whenever possible, that no one company supplies the entire market (this protects against supply disruptions). AAM also recommends that HHS pursue a similar approach for all federal agencies that procure medicines through the Federal Supply Schedule. Guaranteed volume and price agreements are critical to encouraging U.S.-based generic manufacturing and to ensuring the sustainability of the market. AAM's "Blueprint to Enhance the Security of the U.S. Supply Chain" provides additional details and recommendations.

HELP Recommendation 3.3: Require appropriate levels of personal protective equipment and ancillary medical supplies to be stockpiled and replenished, both at the federal and state level. Additionally, stockpiled supplies and countermeasures should more frequently and consistently utilize the shelf-life extension program to extend the life of a product in reserve or better identify the expiration of such products and plan to use those products before expiration.

AAM Comments 3.3: AAM supports this recommendation and, as noted in the comments to 3.2, believes a public-private partnership between HHS and generic manufacturers could be implemented to ensure the appropriate management and maintenance of essential medicines.

HELP Recommendation 3.5: Moving forward, state and health system stockpiles must be developed and maintained, with some federal support, to ensure the United States is ready for the next public health emergency. The federal Strategic National Stockpile must also be replenished and expanded to include certain supplies we now know are needed to respond to a pandemic and maintained with more oversight and accountability.

AAM Comments 3.5: AAM supports one national stockpile and, as noted in the comments to 3.2, believes a public-private partnership between HHS and generic

manufacturers could be implemented to ensure the appropriate management and maintenance of essential medicines.

HELP Recommendation 4.1: Get Americans back to their routine health care safely, and develop better plans for the future so that doctors and hospitals can continue to provide health care services and outpatient treatment during a pandemic.

AAM Comments 4.1: AAM agrees with this recommendation. While COVID-19 is presenting the global health community with new challenges and has tested the pharmaceutical supply chain, AAM's members responded, working around-the-clock to continue to meet the health care needs of America's patients. AAM will continue to work with its member companies, government regulators to help ensure a steady supply of generic and biosimilar medicines during this public health emergency. With generic medicines accounting for 90% of all prescriptions filled, AAM's member companies understand the vital role our industry plays in making sure patients can continue to access essential medicines. This includes medicines used in the treatment and care of COVID-19 patients, as well as those for patients with non-COVID-related health care needs.

AAM Responses to HELP Questions

Section 1: Tests, Treatments, and Vaccines – Accelerate Research and Development

1. What incentives can the federal government offer to the private sector to encourage development of more medical countermeasures with no commercial market?

AAM Response to Question 1. AAM recommends the federal government adopt long-term price and volume guaranteed contracts; provide grants to support the construction, alteration, or renovation of facilities; enact tax deductions and credits to offset the cost of supply chain enhancements; and streamline the regulatory review of manufacturing sites. These incentives, outlined in more detail in AAM's *Blueprint*, are essential to the creation of a redundant and resilient supply chain, and helps ensure the steady supply of generic medicines.

As AAM has noted previously and in other venues, the underlying economic realities of the generic and biosimilar markets threaten sustainable patient access to medicines. Prices for generic drugs are plummeting – falling for 40 of the last 45 months – and creating a market

in which many drugs are simply and increasingly not economical to produce.[9] For biosimilars, the market is still developing with 17 of the 27 FDA-approved biosimilars launched with only a handful regularly prescribed.[10] 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.[11] Congress should also take action to address the sustainability challenges evident in the generic and biosimilar markets, and avoid enacting policies that would have the unintended impact of limiting or restricting patient access to essential medicines.

2. Should the federal government create government-owned-contractor-operated facilities to solve supply chain and manufacturing challenges?

AAM Response to Question 2. With approximately 70 billion doses currently produced in the U.S. by generic manufacturers each year, AAM believes the most efficient and effective approach would be to build on and expand the capacity that exists today. Modern manufacturing facilities can take 5-7 years and cost up to $1 billion to build, and the quantity of medical equipment and supplies likely to be needed for future public health emergencies, government-owned-contractor-operated facilities would be slow to establish, costly to build and maintain, and may not result in an improved public health response. AAM's "Blueprint to Enhance the Security of the U.S. Supply Chain" provides recommendations on how to advance a public-private partnership with generic manufacturers to ensure uninterrupted patient access to essential medicines.

5. How can the United States build manufacturing systems that can rapidly respond to new threats, whether naturally occurring or manmade?

AAM Response to Question 5. Given the U.S. cannot produce all the medicines needed for its health care system and its patient population, HHS should be given the authority to identify the most critical medicines for U.S. investment and to engage with the pharmaceutical industry to identify specific incentives necessary to maintain, leverage existing capacity, and attract investments that can cost as much as $1 billion and

[9] Morgan Stanley, April 2020.
[10] Biosimilars Council, "FDA Biosimilars Approvals," April 2020.
[11] Biosimilars Council, "Failure to Launch: Barriers to Biosimilar Market Adoption," September 2019.

take 5-7 years to build. AAM released a six-element framework that lays out concrete actions to ensure that U.S. patients and the U.S. health care system have access to a secure and consistent supply of critical medicines.

AAM's *Blueprint* recommends: identifying the list of medicines most critical for patient health; providing new grant and tax incentives to secure the U.S. supply chain; supplying the SNS, the U.S. Department of Veterans Affairs, and other agencies with essential medicines on a long-term basis; reducing regulatory inefficiencies to streamline the federal approval for U.S.-based facilities to manufacture medicines; and, promoting a global, cooperative approach to diversifying the supply chain. A copy of the *Blueprint* is enclosed with these comments.

8. How can the United States better leverage public-private partnerships, industry, and academic institutions?

AAM Response to Question 8. AAM recommends Congressional and administrative action to create the conditions to support and encourage the pharmaceutical industry to expand its investments and economic footprint domestically. In order to do so, a renewed public-private partnership between the federal government and generic manufacturers is necessary. As outlined in the *Blueprint*, AAM encourages the federal government to adopt long-term price and volume guaranteed contracts; grants to support construction, alteration, or renovation of facilities; tax deductions and credits to offset the cost of supply chain enhancements; and streamlined regulatory review of manufacturing sites. AAM's *Blueprint* provides additional details and recommendations on how to advance this critical public-private partnership.

Section 3: Stockpiles, Distribution, and Surges – Rebuild and Maintain State and Federal Stockpiles and Improve Medical Supply Surge Capacity and Distribution

1. How can the Strategic National Stockpile be better managed and how can Congress increase oversight and accountability?

2. How can states and hospitals improve their ability to maintain a reserve of supplies in the future to ensure the Strategic National Stockpile is the backup and not the first source of supplies during emergencies?

5. Could states and hospital systems establish their own vendor managed inventory programs with manufacturers and distributors? Should the federal government or states contribute to such hospital stockpiles?

AAM Response to Questions 1, 2, and 5. AAM supports leveraging the SNS to help in the ongoing response to COVID-19 and in preparation for future public health emergencies. HHS could enter into purchase agreements with manufacturers for generic medicines to supply SNS. HHS could take possession of such purchases or pay manufacturers an inventory management fee to produce and maintain the specified quantity on behalf of the SNS. AAM recommends that specific volume and price levels would be negotiated on a company-by-company basis. Multiple suppliers in the market helps ensure, whenever possible, that no one company supplies the entire market (this protects against supply disruptions). AAM also recommends that HHS pursue a similar approach for all federal agencies that procure medicines through the Federal Supply Schedule. Guaranteed volume and price agreements are critical to encouraging U.S.-based generic manufacturing and to ensuring the sustainability of the market. AAM's "Blueprint to Enhance the Security of the U.S. Supply Chain" provides additional details and recommendations.