

July 6, 2023

The Honorable Cathy McMorris Rodgers  
Chair, House Energy and Commerce Committee  
United States House of Representatives  
2188 Rayburn House Office Building  
20515

The Honorable Mike Crapo  
Ranking Member, Senate Finance Committee  
United States Senate  
239 Dirksen Senate Office Building  
20510

Dear Chair McMorris Rodgers and Ranking Member Crapo,

Thank you for the opportunity to respond to your [June 12 request for information \(RFI\)](#) regarding drug shortages and their impact on patient care. I appreciate your respective committees' focus on this important issue, and I look forward to working with you and your staff on potential policy solutions. In this response, we address questions 1 and 7 to highlight the important experiences of our members in these areas.

The AAMC (Association of American Medical Colleges) is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 157 U.S. medical schools accredited by the [Liaison Committee on Medical Education](#); 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

**Response to question 1.b.: What are the impacts of recent and recurring shortages of generics and other critical medicines on patient care?**

**Drug Shortages Significantly Impact Teaching Hospitals, Health Systems, and the Patients They Serve**

According to data from the American Society of Health-System Pharmacists (ASHP), the United States reported over 300 active drug shortages in the first quarter of 2023.<sup>1</sup> Although drug shortages are an enduring problem, they have increased acutely in recent years; between March 2018 and March 2023, active drug shortages rose by almost 50%.<sup>2</sup> Generic drugs are predominantly impacted by shortages. Based on data from the Food and Drug Administration (FDA), 67 percent of the drugs that went into

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<sup>1</sup> Fox, Erin, "Drug Shortage Statistics," American Society of Health-System Pharmacists, March 31, 2023, accessed June 30, 2023, <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics>.

<sup>2</sup> Ibid.

shortage between 2013 and 2017 were generic products with a median price of \$8.73.<sup>3</sup> Due to manufacturing complexities, injectable drugs are also susceptible to supply chain disruptions and shortages. While the average duration of a drug shortage is 1.5 years (537 days), some can last much longer—over fifteen drugs, most of which are injectable products, have been in shortage for over a decade.<sup>4</sup> These shortages can have devastating consequences for patient care, resulting in treatment delays, a shift towards alternative (and sometimes, less effective) treatment regimens, and in the most extreme cases, care rationing.<sup>5</sup>

Although shortages impact a wide array of drugs, their impact can be felt most acutely in cancer care. ASHP has listed chemotherapy drugs among its top five drug classes impacted by shortages, with 23 chemotherapy drugs identified in short supply as of March 31, 2023.<sup>6</sup> One example of an important chemotherapy drug impacted by recent shortages is carboplatin, which is used to treat breast, ovarian, head and neck, lung, and other types of cancers.<sup>7</sup> A recent survey of 27 cancer centers conducted by the National Comprehensive Cancer Network (NCCN) found that 93 percent of respondents reported that their institution is experiencing a shortage of carboplatin.<sup>8</sup> These shortages have significant consequences for patient care; 36 percent of these institutions reported that they are unable to treat all patients currently receiving a carboplatin-containing regimen according to the intended dose and schedule.<sup>9</sup>

AAMC-member institutions play a crucial role in caring for the nation's cancer patients. Although our members account for just 5 percent of all short-term, non-federal hospitals, they comprise 100% of all National Cancer Institute (NCI)-designated cancer centers.<sup>10</sup> Teaching hospitals and health systems, medical schools, and their affiliated physician faculty play a critical role in the discovery and delivery of cutting-edge therapies and treatments for cancer. Because of this, our members bring an invaluable perspective regarding the impact of drug shortages on cancer patients.

Pediatric oncology drugs are particularly susceptible to shortages, thereby impeding access to care for children and young people. AAMC-member institutions, including 20 standalone children's hospitals and numerous other pediatric facilities, provide life-saving health care services to children impacted by cancer, and have witnessed firsthand the impact of these shortages on patients, caregivers, and families. A 2021 study conducted by U.S. Pharmacopeia, Vizient, and Angels for Change found that pediatric

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<sup>3</sup> Food and Drug Administration (FDA), *2019 Drug Shortages Report*, (Washington, D.C.: FDA, 2020), <https://www.fda.gov/media/131130/download>.

<sup>4</sup> United States Senate Committee on Homeland Security and Governmental Affairs, *HSGAC Majority Report: Short Supply: The Health and National Security Risks of Drug Shortages*, (Washington, D.C.: HSGAC, 2023), <https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf>

<sup>5</sup> Fox, Erin, "Drug Shortage Statistics," American Society of Health-System Pharmacists, March 31, 2023, accessed June 30, 2023, <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics>.

<sup>6</sup> Ibid.

<sup>7</sup> Reed, Tina. "Cancer drug shortages highlight supply chain vulnerabilities." *Axios*. June 14, 2023. <https://www.axios.com/2023/06/14/cancer-drug-shortages-supply-chain-vulnerabilities> (Accessed June 30, 2023)

<sup>8</sup> National Comprehensive Cancer Network, NCCN Best Practices Committee Carboplatin and Cisplatin Shortage Survey Results, (Washington, D.C.: NCCN, 2023), [https://www.nccn.org/docs/default-source/oncology-policy-program/NCCN-Drug-Shortage-Survey.pdf?utm\\_campaign=pharmalittle&utm\\_medium=email&hsmi=261813870&hsenc=p2ANqtz--R325mbaVCoHt23zb9zYdLNlJ5O2SU9K9cRIdb\\_ge5XQqr2le1zJuSKNu5UDmj96mYfpHV\\_upSdRE2bpHSYYN\\_uD8yQEw&utm\\_content=261813870&utm\\_source=hs\\_email](https://www.nccn.org/docs/default-source/oncology-policy-program/NCCN-Drug-Shortage-Survey.pdf?utm_campaign=pharmalittle&utm_medium=email&hsmi=261813870&hsenc=p2ANqtz--R325mbaVCoHt23zb9zYdLNlJ5O2SU9K9cRIdb_ge5XQqr2le1zJuSKNu5UDmj96mYfpHV_upSdRE2bpHSYYN_uD8yQEw&utm_content=261813870&utm_source=hs_email).

<sup>9</sup> Ibid.

<sup>10</sup> Association of American Medical Colleges (AAMC), "Health Care," AAMC, accessed June 30, 2023, <https://www.aamc.org/about-us/mission-areas/health-care>.

oncology drugs are more likely to experience shortages because they are disproportionately comprised of lower-priced injectables.<sup>11</sup> Because of the complex processes necessary to manufacture injectables, including lyophilization (a dehydration procedure) and specific storage and handling requirements, these drugs are more expensive to produce and susceptible to supply chain vulnerabilities. These factors, exacerbated by geographic concentrations in the supply chain, make pediatric oncology drugs vulnerable to shortages. Of the 19 pediatric cancer drugs studied by these researchers, 74 percent had experienced a shortage since 2016 (as compared to 18 percent of all drug products).<sup>12</sup>

Taken together, drug shortages can acutely impact AAMC-member institutions and the patients they serve, resulting in serious challenges in access to care, clinical outcomes, and quality.

### **Response to question 7: What role, if any, has growth in the 340B program played in drug shortage trends?**

#### **There is No Reliable Evidence that the 340B Program Contributes to Drug Shortages**

The 340B program allows certain safety-net health care providers, referred to as “covered entities,” to purchase covered outpatient drugs at a discount from manufacturers.<sup>13</sup> Covered entities leverage savings generated through their participation in the program to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services,” in support of congressional intent.<sup>14</sup> AAMC-member 340B hospitals use their savings to care for low-income patients and communities by financing uncompensated care, providing free or discounted medications, and investing in community health programs.<sup>15</sup> It is important to note that the 340B program supports these programs and services at no cost to taxpayers.

Without accurate or reliable evidence to support the claim, some critics of the 340B program have asserted that it contributes to drug shortages by artificially lowering prices.<sup>16</sup> The AAMC strenuously refutes this claim. First, the 340B program accounts for just a small percentage of the total U.S. drug market. According to data from the Health Resources and Services Administration (HRSA), in calendar year 2021, 340B covered entities’ purchases of covered outpatient drugs represented just 7 percent of the total U.S. drug market.<sup>17</sup> Given that the 340B program represents a meager portion of the total drug market, it is dubious that the program has significantly shaped the economic and market forces driving manufacturers’ production decisions, as some would like to claim. Second, as previously noted, the majority of drugs impacted by shortages are generic products. Because generic products are often available for an equivalent or lower price than the 340B ceiling price, 340B pricing does not apply.<sup>18</sup> In

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<sup>11</sup> U.S. Pharmacopeia, Vizient, and Angels for Change, *Quantifying drivers of supply chain resilience in pediatric oncology medications*, (Washington, D.C.: 2021), <https://www.usp.org/sites/default/files/usp/document/supply-chain/pediatric-oncology-drugs-and-supply-chain.pdf>.

<sup>12</sup> Ibid, 2.

<sup>13</sup> Health Resources and Services Administration (HRSA), “340B Drug Pricing Program,” accessed June 30, 2023, <https://www.hrsa.gov/opa>.

<sup>14</sup> 102<sup>nd</sup> Congress, Second Session, H.R. Rept. No. 102-384(II), (1992).

<sup>15</sup> Association of American Medical Colleges (AAMC), “Securing Our Safety-Net: The 340B Drug Pricing Program,” accessed June 30, 2023, <https://www.aamc.org/media/66471/download?attachment>.

<sup>16</sup> “Rx Drug Shortages: Regulation Can Be Deadly”, Health Affairs Blog, June 8, 2011. DOI: 10.1377/hblog20110608.011632

<sup>17</sup> U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), *Fiscal Year 2023 Justification of Estimates for Appropriations Committees*, (Rockville, MD.: HRSA, 2022), <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2023.pdf>.

<sup>18</sup> “Setting The Record Straight On Drug Shortages”, Health Affairs Blog, June 21, 2011. DOI: 10.1377/hblog20110621.011872.

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the market for brand-name pharmaceutical drugs, the discount available to 340B covered entities depends, in part, on the “best price” available for that drug. However, as some stakeholders have pointed out, generic drugs are not subject to this “best price” adjustment, which means that non-340B hospitals can often purchase these drugs for less than 340B covered entities (which is not the case for brand-name drugs).<sup>19</sup> Because the 340B program encompasses a small portion of the drug market and generally does not apply to those drugs most acutely impacted by shortages, it is inaccurate to assert that the program is causing shortages. Rather, for over thirty years, the program has been instrumental in ensuring that historically under-resourced patients and communities have access to life-saving medications.

Numerous industry groups, policymakers, governmental bodies, and academics have studied the root causes of current drug shortages. These groups point to vulnerabilities in the pharmaceutical supply chain, including just-in-time manufacturing practices and the geographic concentration of source materials, as contributing to widespread shortages. Other stakeholders cite economic factors, such as the lack of financial incentives for drug manufacturers to enter and remain in the generic market. Based on the AAMC’s review of these studies and reports, very few stakeholder groups have identified the 340B program as contributing to drug shortages. In fact, the foremost trade organization representing brand-name pharmaceutical manufacturers, Pharmaceutical Research and Manufacturers of America (PhRMA), does not identify the program as one of the main causes of drug shortages. Rather, PhRMA cites, “shifts in clinical practices; wholesaler and pharmacy inventory practices; raw material shortages; changes in hospital and pharmacy contractual relationships with suppliers and wholesalers; natural disasters; public health emergencies and manufacturing issues” as the primary reasons for drug shortages.<sup>20</sup>

Again, the AAMC appreciates your efforts to better understand and address the pervasive drug shortages facing our health system and their impact on patients. We look forward to working with you and your staff on potential solutions. Please contact me, Len Marquez ([lmarquez@aamc.org](mailto:lmarquez@aamc.org)), Senior Director of Government Relations and Legislative Advocacy, or Sinead Hunt, Legislative Analyst ([sihunt@aamc.org](mailto:sihunt@aamc.org)) if you have any questions or concerns.

Sincerely,



Danielle P. Turnipseed, JD, MHSA, MPP  
Chief Public Policy Officer  
Association of American Medical Colleges

CC: David J. Skorton, MD  
President and CEO  
Association of American Medical Colleges

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<sup>19</sup> Ibid.

<sup>20</sup> Pharmaceutical Research and Manufacturers of America, "Understanding Prescription Drug Shortages," PhRMA, access July 2, 2023, <https://phrma.org/en/policy-issues/drug-shortages-supply-chain>.