Testimony of

Julie R. Gralow, MD, FACP, FASCO

Chief Medical Officer and Executive Vice President

Association for Clinical Oncology

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Examining Chronic Drug Shortages in the United States

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Chairman Smith, Ranking Member Neal, and members of the Committee, it is my pleasure to appear before you to discuss the ongoing drug shortage crisis facing patients today. I am Dr. Julie Gralow, Chief Medical Officer, and Executive Vice President for the Association for Clinical Oncology (ASCO). I am Professor (emeritus), Medical Oncology and Global Health, at the University of Washington School of Medicine. Previously, I was the Jill Bennett Endowed Professor of Breast Cancer at the University of Washington School of Medicine, Professor in the Clinical Research Division of the Fred Hutchinson Cancer Research Center, as well as Director of Breast Medical Oncology at the Seattle Cancer Care Alliance.

ASCO is a leading professional organization representing nearly 50,000 oncology professionals, including physicians, researchers, and other healthcare providers dedicated to improving cancer care. ASCO appreciates the Committee's dedication to addressing drug shortages.

Every day we hear from oncologists around the country about the challenges cancer patients and their providers are facing, amid some of the worst oncology drug shortages to date. This crisis is forcing providers to make impossible choices, including having to decide which patients receive lifesaving and life-prolonging oncology drugs on schedule and in the established doses or whether we're left to use sub-optimal alternatives, reduce doses, delay treatments, and in the worst situations, are unable to provide any of the necessary therapies.

An oncologist in Texas shared that a patient's metastatic breast cancer was responding to a commonly used oncology drug, carboplatin, in combination with immunotherapy. After four cycles, her cancer was under control. She stopped receiving carboplatin because of the shortage, but continued immunotherapy and unfortunately, her cancer has progressed.

Another oncologist in California sent a patient with bladder cancer to an academic center to participate in a clinical trial because that was the only way to guarantee they would have access to cisplatin, another drug in shortage. Clinical trials assess whether an experimental treatment *is better*

than the traditional standard of care. In this case, though, the oncologist saw clinical trial enrollment as the only way to achieve *at least* the standard-of-care that his office could not provide.

An oncologist in Puerto Rico could not treat a head and neck cancer patient with the preferred regimen because the practice was projected to run out of the required drug during the treatment cycle. The physician and patient were forced to select an alternative. As you can imagine, this places a tremendous emotional toll on patients and their families.

These are the deeply troubling choices that my colleagues frequently face amid the drug shortage crisis, emotionally taxing the entire health care team. The oncology care team is compelled to deviate from recommended practice guidelines, either by working with unconventional and unproven treatments or by determining the allocation of scarce resources. When physicians are forced to opt for the non-standard of care, the already burdensome process of acquiring prior authorization from payers becomes even more intrusive, creating additional obstacles for patients in accessing necessary care. Further, the staff time and expense of managing shortages – looking for supply, allocating limited drugs, changing treatment plans, counseling patients and their families – is a tremendous cost to the system. As we consider these solutions, we also recognize concerns around increased costs to the health care system. We will pay a greater long-term cost in the form of delayed or denied care if we do not address the underlying economic forces driving these shortages of generic drugs. While 90 percent of prescriptions were filled in 2022 with generic or biosimilar medicines, they accounted for less than 18 percent of total prescription drug spending[1]; furthermore, at least one analysis showed that over half of the drugs actively in shortage were some of the very cheapest on the market. In addition to the cost to patients' health, hospitals have seen an increase in costs – an estimated $230 million a year – in additional costs to purchase alternatives and to manage the shortages and $360 million a year in labor to

[1] https://accessiblemeds.org/resources/blog/2022-savings-report#:~:text=91%25%3A%20Portion%20of%20U.S.,country%27s%20spending%20on%20prescription%20drugs.

handle the shortages[2]. These staggering numbers only include hospitals, not other settings of care such as private practice or other community settings. To avert future shortages, the United States (U.S.) must establish a more resilient pharmaceutical supply chain, especially for generic drugs. Most oncology drugs in shortage are generic sterile injectables that sell for anywhere from $1 to $8 per dose, leaving these drugs with slim profit margins, sometimes to the point of production costs exceeding the selling price[3] often driving U.S. manufacturers out of the market or looking to manufacture outside the U.S. to keep costs down. Many of these drugs do not have alternatives. There are few manufacturers of these sterile injectables, and the ones that remain in the market face significant costs to remain in business. The leading cause of drug shortages is manufacturing quality issues, which are largely driven by economic factors. Often, any disruptions from quality issues leave the manufacturer unable to ramp up production for several months and at significant expense. When one manufacturer experiences quality issues, it has an impact on the entire supply chain. Some manufacturers decide to leave the market completely, while others take weeks or months to make expensive repairs, or they shift production to other more profitable drugs. Even if another manufacturer is willing to enter the market to help shore up supply, that too can take weeks or months to get Food and Drug Administration (FDA) approval and get production up and running, due to the complexity of sterile production requirements.

Fundamentally, current drug payment policies compound quality issues. Purchasers have limited information – typically only price data – and do not have access to quality or supply information. This creates adverse market incentives for manufacturers to prioritize cost-cutting over quality improvements

[2] https://www.aha.org/news/headline/2019-06-27-survey-drug-shortages-cost-hospitals-360m-annually#:~:text=Hospitals%20spend%20close%20to%20%24360,this%20week%20by%20Vizient%20Inc. https://www.acpjournals.org/doi/abs/10.7326/M18-1137?journalCode=aim

[3] https://accessiblemeds.org/resources/blog/2022-savings-report#:~:text=91%25%3A%20Portion%20of%20U.S.,country%27s%20spending%20on%20prescription%20drugs

or capital investments. These are particularly challenging for oncology drugs in shortage, as generic manufacturers often operate on a slim or negative profit margin compared to brand drugs.

Approximately half of newly diagnosed cancer patients are over 65 years old, which makes Medicare the largest single payer of cancer care in the country.[4] As such, there are three areas where Congress can take immediate action: payment, manufacturing, and quality. In the area of payment, Congress could explore alternative payment methodologies that would provide relief from artificially low generic reimbursement rates, thereby encouraging a more reliable supply of drugs. Payment reforms should factor in quality and reliability of supply. With respect to manufacturing, Congress could encourage the adoption of advanced technology, for example, continuous manufacturing for critical drugs and active pharmaceutical ingredients (APIs). There could also be incentives such as tax credits or government contracts to increase manufacturing in the U.S. Finally, in the important area of quality, Congress could consider stronger requirements for risk management plans and incentives for purchasers to contract with manufacturers who demonstrate quality and the ability to provide reliable supply. These are only a few recommendations that have been proposed. Most are not new, and they are on a long list of suggestions made by stakeholders over the past decade. The shortage of critical cancer drugs is an urgent crisis. We must act. Cancer patients, and their families, deserve to know that they will get the care they need without delay, and for as long as they need it. Providers should not have to make these heartbreaking choices about patient care. ASCO stands ready to collaborate with you to advance comprehensive solutions that ensure individuals with cancer receive the lifesaving and life-prolonging treatments they require.

[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7318119/