American Cancer Society Cancer Action Network (ACS CAN) Statement for the Record
House Energy & Commerce Oversight Hearing on Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains
May 11, 2023

The American Cancer Society Cancer Action Network (ACS CAN) advocates for evidence-based public policies to reduce the cancer burden for everyone. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. By engaging advocates across the country to make their voices heard, ACS CAN influences legislative and regulatory solutions that will end cancer as we know it. We commend the Committee for holding today's hearing and we appreciate the opportunity to provide a statement for the record.

Cancer patients rely on drug therapies to effectively treat their disease. Yet as of early May 2023, there were 15 oncology drugs on the official U.S. Food and Drug Administration (FDA) drug shortage list – including Carboplatin Injection used to treat triple negative breast cancer, ovarian, head, and neck cancers; Fludarabine Phosphate Injection used for treating B-cell chronic lymphatic leukemia; Dacarbazine Injection for treatment of skin cancer; as well as Amifostine Injection; Azacitidine for Injection; Capecitabine Tablets; Cisplatin Injection; Cytarabine Injection; Dexamethasone Sodium Phosphate Injection; Hydrocortisone Sodium Succinate Injection; Leucovorin Calcium Lyophilized Powder for Injection; Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto) Injection; Methotrexate Injection; Pentostatin Injection; and Streptozocin (Zanosar) Sterile Powder; in addition to many products used in cancer care like IV saline solutions.

According to the American Society of Health System Pharmacists, chemotherapy drugs, often without alternatives, are increasingly in short supply and have returned to the list of top-five drug classes affected by shortage.

Shortages of oncology drugs not only exacerbate inequities in health care, and disrupt a patient's treatment schedule but can be directly linked to adverse patient outcomes – including life threatening consequences. Health care providers may intentionally give lower doses to stretch a short supply among

many patients or simply may not be able to provide cancer treatment at all if there are no other reasonable second or third-line drug alternatives to the cancer drug in shortage. Additionally, due to shortages health care providers may be forced into difficult decisions, deciding which cancer patients receive medications and which do not.

Cancer-drug shortages in the U.S. have also caused delays and modifications to clinical trials, threatening progress on new treatments. Cancer drug treatments for the future are determined by the outcomes of clinical trials conducted today. Therefore, drug shortages are negatively impacting cancer patients today – and cancer patients in the future.

We understand that the actual causes of oncology drug shortages are complex and multi-faceted including:

- Manufacturing difficulties including quality compliance that force the shutdown of production lines;
- Failure to accurately project demand for certain drugs;
- Shortages or unavailability of raw materials;
- The small number of companies that have the capacity to produce a drug if one manufacturer ceases production;
- Growth in product use without associated growth in production capacity;
- Tight production schedules that are not readily altered if a manufacturing problem occurs or if demand increases faster than anticipated;
- Business decisions companies make to discontinue manufacturing certain drugs, particularly generic drugs, based on profitability or other business considerations; and
- Limited incentive to invest in low-margin generic drugs.

Congress and pharmaceutical manufacturers must do more to both anticipate potential shortages and help to ensure that patient cancer treatments are not disrupted.

Today's mitigation strategies are largely about encouraging early notification by manufacturers to FDA, who may then be able to work with the manufacturer to limit the public health impact. Without addressing the root causes of shortages, however, this issue will continue to resurface regularly as it has

for the past 12 years. We urge the Committee to look at longer-term solutions that change the fundamental underpinnings of the shortages. In the meantime, we urge the industry to work with medical practitioners to help identify alternatives where possible to ensure that cancer patients' treatments are not delayed.