

# Dire shortages in essential chemotherapy drugs means “people will die” needlessly

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“People will die from this shortage, for sure.” Director of the division of molecular imaging and therapeutics at the University of Alabama, Jonathan McConathy, referring to the drug Pluvicto.

Recently, hospitals across the country have been notified by the Food and Drug Administration (FDA) of severe shortages of critical but commonly used chemotherapy drugs that will persist for the next three to six months. These are creating hopeless situations for possibly hundreds of thousands of patients with either new or recurrent malignancies, while placing the entire edifice of oncologic care into crisis mode.

Jeffrey Pilz, assistant director of Pharmacy, Medication Safety, and Drug Policy at the Ohio State University Wexner Medical Center, noted recently, “Drug shortages are impacting every therapeutic area of practice at this time. In 2023, shortages are reaching record numbers, and unfortunately, our oncology medications are not immune.”

For instance, according to a recent statement issued by the Society of Gynecologic Oncology (SGO) on April 21, 2023, “Currently, a US shortage of carboplatin and cisplatin exists that will likely last several months and possibly longer. Platinum drug [the molecular basis for the two mentioned drugs] shortages were first reported to the FDA on February 10, 2023. The recommendations below address how we can conserve carboplatin and cisplatin and allocate the limited supply to those patients who will experience the most significant benefit.”

These platinum-based agents are front and center of the treatment of women with advanced ovarian and uterine cancer. Both drugs have proven their importance in head-to-head randomized control trials spanning more than three decades.

In their strategy, the SGO issued the following guidance: “Ration doses by rounding doses down to the nearest vial size as a first step to ensure efficient use. If the shortage becomes more critical, consider *reserving* carboplatin and cisplatin for *curative intent treatment*” [my italics-BM]. Medical oncologists at some hospitals have been given this rationing guidance, implying the shortages are quite pronounced.

Besides these, other cancer drugs such as Pluvicto, made by Swiss drugmaker Novartis, for the treatment of advanced prostate cancer, are facing manufacturing delays and will only

“meaningfully” increase by the second half of the year.

Other shortages include methotrexate, fluorouracil, and BCG [Bacillus Calmette-Guerin] that treat a variety of diseases including cancers of the skin, bone, blood or lymphatic, and lungs in all ages. BCG, also known as an anti-tuberculosis vaccine, is effective in the management of bladder cancers. Without these treatment options available to patients, treating physicians may have to turn to less effective options with worse side effects. Some may find their disease progressed beyond hope as they wait to hear from their oncologists.

Drug shortages are not new, but in the last decade, the shortages have been skyrocketing, including for cancer drugs. The American Society of Health Systems Pharmacists has reported that there are over 300 drugs in short supply in the US, which include all classes of drugs. These shortages are also taking longer to mitigate. Moreover, the COVID pandemic has added fuel to the fire.

A Johns Hopkins Medicine report from 2020 noted, “Over the past 10 years, eight of the 10 commonly used drugs in the treatment of acute lymphoblastic leukemia, the most common childhood cancer affecting thousands of children each year in the US, have temporarily been unavailable.”

According to a Senate report released in March by the Committee on Homeland Security and Governmental Affairs, chaired by Michigan Senator Gary Peters, new drug shortages in the US increased by 30 percent from 2021 to 2022. At the end of last year, 295 active drug shortages were reported, a five-year high. Additionally, while shortages on average last about 1.5 years, more than two dozen vital medications have been in scarcity for more than a decade.

In the US, each year, more than one million people are undergoing chemotherapy or radiation across the country. In a report on the estimated number of individuals living with metastatic cancer in the US, more than half are recurrent cancers. For this population of patients, systemic treatment with chemotherapy and other cancer treatment agents is essential to place their disease in remission with the hope it will not recur.

According to a study published in 2019 in the journal *Lancet Oncology*, at a global level, the incidence of cancer is projected to rise to 26 million annual cases by 2040, an increase of over 52 percent in the next two decades. Should evidence-based

guidelines be applied according to a person's cancer diagnosis and stage, the number of patients who would need first-line chemotherapy would increase from 9.8 million to 15 million by 2040.

Sixty-seven percent of these patients reside in low or middle-income countries, which means that the shortages presently being faced in the US are amplified in these regions who do not have the resources to compete for these life-saving treatments. Researcher Brooke Wilson at the University of New South Wales, lead author of the *Lancet* study on the global cancer outcomes, told *Cancer World* magazine, "The rising cancer burden and the increasing demands for chemotherapy globally will be major health crises during the next 20 years. The gap between available service provision and demand is substantial, especially in low-income and middle-income countries."

She added, "Strategic investments to expand capacity for chemotherapy delivery globally are urgently needed." And when the issue of capacity is raised, this also implies a legion of physicians, nurses, technicians in almost every discipline of health care that includes laboratory, radiographic, pathology, surgical, patient care, infectious diseases, and the assortment of equipment and well-stocked pharmaceuticals to tend to urgent health needs.

These raise the present questions of the shortage in chemotherapy to a socioeconomic and, therefore, a political level. What are the mechanisms in place to ensure the world's population, when faced with such a devastating diagnosis as cancer, can be provided with evidence-based treatment that should be available to all as a democratic and social right?

As the report notes, by 2040, 53 percent of the 26 million cancer cases will need chemotherapy. By then there will be around 2.5 million lung cancers, 1.9 million breast cancers, and 1.7 million colorectal cancers; the report warns "the greatest absolute increases in new cases will occur for these three types of cancer (around 900k cases of lung cancer, 620k of colorectal and 500k breast cancer requiring chemotherapy annually)."

A study published in the *British Medical Journal* in November 2020, in the midst of the raging COVID pandemic, found that delaying chemotherapy by even one month meant the risk of dying increased by six to 13 percent. And the longer the delay in providing treatment, whether it was surgery, radiation or chemotherapy, the higher grew the risk of dying.

The authors concluded, "Taken as a whole, these results suggest there is an urgent need to consider how we organize our cancer services. The prevailing paradigm has been around access to new treatments to improve outcomes, but from a system level, gains in survival might be achieved by prioritizing efforts to minimize the time from cancer diagnosis to initiation of treatment from weeks to days."

With regards to the March 2023 Senate report and shortage of active drugs, Senator Peters states, "Drug shortages are not a new problem. They are caused by a number of factors, including economic drivers, insufficient supply chain visibility,

and a continued US over-reliance on both foreign and geographically concentrated sources for medications and their raw materials." And over the last two decades much of the manufacturing has shifted to China, and even more so to India, in line with economic diktats to decrease production costs.

Revenue from oncology drugs for 2023 has been estimated at over \$200 billion and is expected to rise by nearly 70 percent over the next four to five years. The shortages being felt are mainly affecting older generic drug products, which account for 90 percent of all the drugs sold in the US. According to the FDA, of the drugs that went into shortage between 2013 and 2017, two-thirds were generic, with a median price of \$8.73 per dose, and first approved for use more than 35 years ago.

In short, delays in manufacturing have more to do with the narrow profit margins that do not incentivize the markets to produce them in sufficient quantities to forestall critical drug shortages. As Dr. Vimala Raghavendran, senior director of the pharmaceutical supply chain center at US Pharmacopeia, testified, "Manufacturers only receive pennies per dose for some of these drugs."

As an FDA report to Congress noted in 2020 and reiterated in the Senate report by Peters, "With few incentives to enter or remain in the market for a narrow but critical set of generic drugs, manufacturers of these products often decide to leave the market, and few if any others decide to enter, which can lead to shortages and have lingering effects on a product's availability over time."

Although the report attempts to couch the crisis of drug shortages in the oft-used rhetoric of national security risk, warning that the US is overly reliant on "foreign and geographically concentrated sources for critical drugs," the driving force is, in final analysis, the crisis of capitalist production based on profit, and the ossified nation-state system.

The grotesquely wealthy, with an entourage of physicians at their beck and call, will never feel the horror of being told that life-saving treatments are not available for them or their families. The chaos of capitalist markets only means that the financial aristocracy cannot even conceive of spending even "a few pennies" for the life-saving medicines required by the working class, when a planned socialist economy could ensure that access to evidenced-based health care is made possible for all.



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