Written Testimony on Hearing:

Examining Chronic Drug Shortages in the United States

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Chairman Smith, Ranking Member Neal, and members of the Committee on Ways and Means, I appreciate the opportunity to submit this written testimony and to appear as a witness at this extremely important hearing on drug shortages, especially in cancer treatment. I frame this written testimony, opening statement, and answers to questions from the perspective of both a medical oncologist and Chief Medical Officer of a large independent community oncology practice.

I implore Congress to take meaningful action to prevent further shortages of vital life-saving cancer drugs and therapies needed to treat this life-threatening disease. These drug shortages, as I will describe in this testimony, seriously interfere with our ability to treat our patients

By way of background, I currently practice as a medical oncologist at Tennessee Oncology, the largest provider of cancer care in the state of Tennessee. Our practice has over 200 providers who practice in 35 clinics in both urban and rural settings across the state. Our mission at Tennessee Oncology is simple: to provide the highest quality, most affordable and comprehensive cancer care close to home, in the communities where our patients live. Last year, we provided care to almost 100,000 patients, and that number continues to grow. Personally, I see patients two days a week in Lebanon, a rural town in Wilson County, TN. I also serve as Chief Medical Officer of our practice. I am extremely proud to say that at Tennessee Oncology we take care of every patient who walks in our doors, regardless of their insurance status or ability to pay.

In addition to my responsibilities at Tennessee Oncology, I serve as an officer and Board member of the Community Oncology Alliance, a non-profit organization dedicated to serving cancer patients in their communities and supporting practices like ours across the country. I am also a member of the American Society of Clinical Oncology.

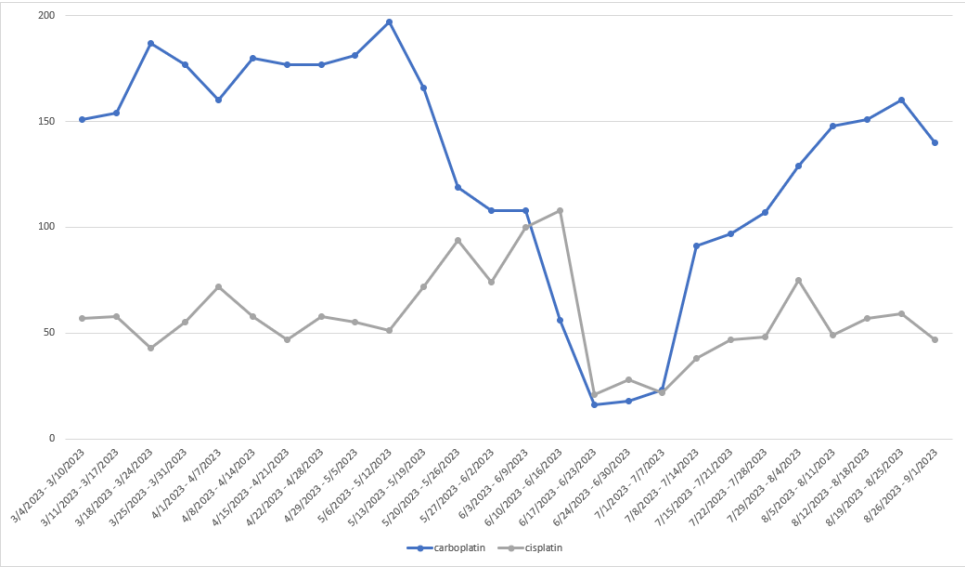
As physicians, we are trained to adhere to evidence-based guidelines based on rigorous scientific and clinical research in order to provide our patients with the best possible treatment, whether it be for a cure to their cancer, whenever possible, or for the preservation of their quality-of-life and to extend their life living with cancer, when a cure is not possible. We develop bonds with our patients during some of the scariest times in their lives. Not to minimize any other physician-patient relationship at all, but the oncologist-patient relationship is a special one that makes this profession more than just a job.

As you may be aware, last year presented a significant challenge for oncologists and our patients due to drug shortages. These shortages were not with new cutting-edge treatments like immunotherapies and other therapies commonly referred to as precision “targeted” therapies, but with generic injectable chemotherapies that have been in use for decades. These generic chemotherapy drugs often serve as the backbone of important cancer treatments for both curative and palliative intent.

In particular, I want to focus on two generic injectable chemotherapies: cisplatin, which was first FDA approved in 1978 and carboplatin, which was first FDA approved in 1989. It is true that we have come a long way with cancer treatment since both of these drugs were first approved, with dozens of new FDA approvals in oncology each year[1]. However, these older, now generic drugs still serve as a vital foundation for many important cancer treatment regimens, especially in the curative setting for breast, lung, ovarian, cervical, endometrial, and testicular and bladder cancers, to name just a few. These older but vital generic drugs are not just *options* for treating patients with these diseases, but are often part of the *only* preferred treatment regimen for these cancers.

So how bad was the shortage of these drugs at Tennessee Oncology? Under normal circumstances, when the supply is sufficient to meet demand, we usually administer treatment to approximately 170 patients using carboplatin and 50 patients using cisplatin *per week*. In contrast, as show in **Table 1 (below)**, during mid-June of last year there was a one-two week period where we were only able to treat 16 patients with carboplatin and 21 patients with cisplatin. Described another way, we were **unable to treat 90 percent of patients who required carboplatin and over 50 percent of patients who required cisplatin during that time**. Although the peak of the shortage for our large practice was only several weeks, there was an interval of over 10 days during which we did not receive any shipments of these medications, and without any indication of when the supply would resume. Please keep in mind that we are one of the largest cancer treatment facilities in the country, including both independent practices and large hospital health systems, with significant purchasing power. Just imagine what smaller cancer treatment facilities, particularly those in rural America, must have faced.

Table 1: Doses of carboplatin (blue) and cisplatin (gray) delivered per week at Tennessee Oncology.



[1] New FDA-Approved Oncology Drugs (2021-2022), The ASCO Post, 2022.

How do these shortages impact our patients? The majority of patients whose recommended evidence-based treatments called for the inclusion of carboplatin or cisplatin were unable to receive these medications as part of their treatment for a period of time. Their providers had to ration the use of chemotherapies. Imagine being a patient already dealing with the many difficulties that come with a cancer diagnosis, only to discover that you must also navigate the added obstacle of not receiving the best or only treatment available. Imagine how difficult it was for patients to hear they were not going to receive the optimal treatments.

As oncologists, we suddenly had the near impossible task of determining which patients could receive our very limited allotment of these drugs. The best training in the world and access to all evidence-based guidelines did not prepare us for the moral dilemma we now faced: how to ration our limited supply of these chemotherapies. Was it based on chance at cure? Options for a substitution drug? Number of patients affected? As the Chief Medical Officer, I had to the send the following email to our providers and teams on June 18, 2023:

Please be on the lookout for regular updates on drug shortage treatment recommendations:

- *Current indications where cis/carbo can be used:*
  - *Cisplatin use: we only have enough for **Testicular Cancer** and **Neoadjuvant Bladder**.*
  - *Carboplatin use: we have been completely out but got a small shipment on Friday. For now, due to a lack of good alternatives to platinum agents, we are limiting use to **chemoradiation for curative intent in NSCLC**. As indicated last week, it could take several months to have this fully replete. We will update regularly whenever small shipments come in since recs might change accordingly.*
- *Unfortunately, we do not have enough supply of cis/carbo for any other indications at this time and need to use alternatives instead.*

For patients where there was not an acceptable substitution to the drugs in short supply, they simply did not get the complete evidence-based regimen. For example, two very important and commonly used curative regimens[2,3] in breast cancer require the use of carboplatin.

To share some actual experiences from my practice, last summer I had the privilege of treating a remarkably kind 52-year-old female who was undergoing treatment with a

[2] Schmid P, Cortes J, Pusztai L, et al. Pembrolizumab for early triple-negative breast cancer. NEJM, 2020.
[3] Von Minchwitz G, Procter M, de Azambuja E, et al. Adjuvant pertuzumab and trastuzumab in early HER2-positive breast cancer. NEJM, 2017.

combination of chemotherapy and immunotherapy[4] for aggressive triple-negative breast cancer. Her cancer had metastasized to several lymph nodes but was still potentially curable with this aggressive regimen, of which carboplatin was a critical component. Unfortunately, halfway through her four-month treatment course, we experienced the shortage of carboplatin, resulting in the omission of this drug from her regimen for three consecutive doses. From the outset of her diagnosis, she was overwhelmed with fear, and the news that we could not procure the necessary chemotherapy added to her distress. Her immediate concern was whether this shortage would compromise the efficacy of her treatment, a question for which we unfortunately lack data to provide concrete numbers. Should her cancer recur in the future in an incurable manner, I am troubled by the thought that she might forever question whether the outcome could have been different had she received her complete chemotherapy regimen.

Even for patients without curable cancers, these drug shortages had a profound impact. For example, one of my colleagues was treating a 61-year-old female in Chattanooga who had incurable lung cancer with the goal to control her cancer as effectively as possibly, thereby enhancing her quality of life and prolonging her lifespan to the greatest extent possible. Unfortunately, following the depletion of our carboplatin supply – a key component of her therapeutic regimen – her condition deteriorated rapidly, and she quickly died. Whether she could have lived an additional several months or longer to spend cherished time with family, we will never know. And as my colleague said, *"The family still believes this was the main reason which led to her cancer progressing and ultimately her death. This will probably be on their minds every time they think about her."*

Thankfully, as I have stated previously, I practice at a large oncology group that additionally has many ties to other community and academic oncology practices. The 200 oncology providers in Tennessee Oncology were able to email and call each other asking *"How would you treat this cancer given we have no drug available?"* We were able to lean on each other as a team going through this together and ask each other for help. In addition, we have analytics to help us monitor drug inventory and are large enough to absorb any financial burden of "overstocking" as much as possible once we see supply of a certain drug starting to decrease. And despite these benefits of being large, we still faced huge challenges during this time that negatively impacted our patients.

With that said, I cannot even imagine what it would have been like to be part of a mid-size or even smaller physician group, especially in rural America where a provider may not have colleagues to discuss cases with or the resources to manage complicated drug inventory. I can only think that their situations were even worse than ours – for the oncologists, their staff, and most importantly their patients.

To put the complexity of inventory management into perspective, at Tennessee Oncology we purchase and deliver over 200 unique drug formations each year to our patients. To add

[4] Schmid P, Cortes J, Pusztai L, et al. Pembrolizumab for early triple-negative breast cancer. NEJM, 2020.

to this complexity, the influx of biosimilars has made it such that in some situations, a parent drug like trastuzumab now has 5 different biosimilars. This would potentially be manageable if we could select one preferred biosimilar to use for all appropriate patients. However, we are often forced to carry every single biosimilar since each payer often requires a specific biosimilar based on their own economics. Balancing the plethora of drugs needed to deliver high quality care plus the payer mandates that require their own preferred biosimilar is nearly impossible!

Thus, with the number of drugs we must inventory, it is virtually impossible to have enough drug in inventory to avert a shortage. Furthermore, if cancer treatment practices and hospitals were to inventory large quantities of drugs prone to shortages this could actually amplify shortages and worsen disparities in care (those with supply versus those without).

While the shortages of carboplatin and cisplatin have now improved, we continue to face risks of shortages with similar older generic chemotherapies. This includes methotrexate, which is a common part of treatment regimens for hematologic malignancies. For example, at Tennessee Oncology I know of several patients who had treatments delayed for the cure of CNS lymphoma. We will never know the impact these delays had on their outcomes. Additionally, we have also been close to facing a crisis with vinblastine, part of the treatment regimen[5] for highly curable Hodgkin's Lymphoma.

I am not here to tell you with absolute certainty that these shortages have led to increased patient deaths. However, I can state unequivocally that there were too many patients – in fact, hundreds just at Tennessee Oncology– that were unable to get the optimal cancer treatments they needed and should have received. The clinical and psychologic consequences from these drug shortages are all too real and need to be addressed.

My goal in this testimony as an oncologist is to share this story on behalf of my patients, as well as the thousands of cancer patients around the country and their oncologists who care for them. I am not an economist or policy maker, and therefore ask for your guidance and help solving this problem. However, if you ask my view on what is causing these shortages and how to fix them, it is clear that manufacturers have decreasing financial incentives to make these very inexpensive but critical generic injectable drugs, thereby jeopardizing the stability of their supply chains. While we are all concerned about the financial toxicity patients face with increasingly expensive cancer drugs and other therapies, we must also be equally concerned about the challenges patients face when they cannot get access to less expensive mainstay generic drugs.

[5] Canellos GP, Anderson JR, Propert KJ, et al. Chemotherapy for advanced Hodgkin's Disease with MOPP, ABVD, or MOPP alternating with ABVD. NEJM, 1992.

The Community Oncology Alliance, with which I am affiliated, has identified probable causes for these shortages and proposed several detailed, targeted solutions. I call the Ways & Means Committee's attention to the following documents:

- Witness testimony to the Energy & Commerce Committee on Drug Shortages
- Response to Energy & Commerce RFI on Drug Shortages
- Comments to the Senate Finance Committee that Ranking Member Crapo Submitted for the Record

I appreciate the opportunity to provide this testimony.

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