Chemotherapy Shortage: What Patients, Advocates & Survivors Need to Know

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Moderator

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Current GYN-Based Chemotherapy Drugs in Shortage

- Cisplatin 2/10/23 FDA
- Methotrexate 3/13/23 FDA
- Carboplatin 4/28/23 FDA
- Fluorouracil 5/5/23 ASPH
- Docetaxel 5/5/23 ASPH
- Leucovorin 5/17/23 FDA
Currently, a U.S. shortage of carboplatin and cisplatin exists that will likely last several months and possibly longer. Today, SGO released information on how to conserve the drugs and allocate supply to those who will experience significant benefit.

sgo.org/news/drugshort...
The SGO, @GYNCancer and @GOG partners endorsed a recent @NRCOnco Oncology statement to member institutions regarding management of platinum-based therapies on clinical trials during chemotherapy drug shortages.

The SGO/FAC and Gynecologic Oncology Group (GOG) Partners have provided a list of recommendations outlining general principles for institutions who participate in cooperative group or investigator-initiated trials. Please visit sgo.org to review the list of recommendations and more information regarding the platinum drug shortage.

For questions or further guidance, please email sgo@sgo.org.

Amy Park, MD Retweeted
Rnda Nickles Fader, MD @amandanfader - Apr 27
An important statement from @GYNCancer & @SGO.org to our patients with GYN cancers. @ggardnermd, @AngellesSecord and our team stand with you and are working diligently with GYN cancer providers re: clinical recommendations & advocating for solutions to the chemo shortage problem.

† FdnForWomensCancer @GYNCancer - Apr 26
The @ASHPOfficial & @US_FDA recently reported a U.S. shortage of several drugs, including cisplatin, carboplatin & methotrexate. These chemotherapy drugs are used to treat many types of gynecologic cancers, such as those involving the uterus, cervix, ovaries, and fallopian tubes.

Show this thread
SGO/FWC Response: Multi-Pronged Approach

• **Provider Response and Guidance**
  • Rapid drug alternative communiques
  • Webinar series covering multiple topics
  • Connecting providers at local institutions
  • Toolkits for EMR documentation and insurance denial letter templates
  • Advocacy with NCCN, The Hill

• **Patient Communication, Advocacy and Support**
  • Communiques, Educational Webinar
  • Patient Survey for Real-Time Input of Need
  • Patients & Partnership
  • Health Services Research
  • Supportive Services (i.e., Angels for Change)
A MESSAGE TO OUR GYNECOLOGIC CANCER PATIENTS, ADVOCATES, AND COMMUNITY

The American Society of Health-System Pharmacists and Food and Drug Administration (FDA) recently reported a U.S. shortage of several drugs, including cisplatin, carboplatin, and methotrexate. These chemotherapy drugs are used to treat many types of gynecologic cancers, such as those involving the uterus, cervix, ovaries, and fallopian tubes.

The Foundation for Women's Cancer (FWC), alongside the Society of Gynecologic Oncology (SGO), stands steadfastly in support of our patients and the gynecologic cancer community. We recognize these drug shortages as a public health crisis with direct effects on patients, clinical outcomes and historically marginalized rural and urban communities. Addressing this drug shortage is a top priority, and we are working closely with colleagues and fellow advocacy organizations nationally to advocate for patients, minimize harm, and ensure access to equitable treatment.

This work includes discussions with key stakeholders including the FDA, pharmaceutical manufacturers, and collaborating with other oncology medical societies. Additionally, the SGO/FWC is recommending strategies to medical providers to optimize cisplatin, carboplatin, and methotrexate use and
FWC Patient Survey

35 patients in 18 states responded since the survey opened on June 1
FWC Patient Survey

- 27 patients identified as having ovarian cancer
- 4 with endometrial cancer
- 2 with peritoneal cancer
- 1 with vulvar cancer

- 30% have experienced a change and/or delay in treatment due to the drug shortage
As a support group facilitator, it is heartbreaking to listen to the fear and anxiety that the drug shortage causes. This can be a life and death problem.

I anticipate needing more chemotherapy in the fall and I am worried about availability.

Because I am a newly diagnosed case, I am prioritized and only had my cycle changed or medication reduced. However, we believe that it is not fair to doctors to have to make decisions about rationing treatment for patients.

Cancer patients who are trying to fight the good fight should not have to think about whether a backbone drug is available for treatment.

We could not stay silent. My wife wrote a CaringBridge and public Facebook post about the shortage. We were contacted by our local CBS affiliate to participate in a special report. It is so important to speak out when you see injustice happening especially when it's about profit margins. Here is the link to the news segment.
Amplifying Our Voices

“Patients receiving platinum-based regimen as either standard-of-care or in a clinical trial, should be given equal priorities during the drug shortage.

Leslie Randall, MD
Virginia Commonwealth University Division of Oncology

“We have to be very mindful to advocate for our patients, and also to be mindful of vulnerable populations.

Fernanda Musa, MD, MS
Swedish Cancer Institute
Drug Shortages Near an All-Time High, Leading to Rationing

A worrisome scarcity of cancer drugs has heightened concerns about the troubled generic drug industry. Congress and the White House are seeking ways to address widespread supply problems.
SGO/FWC at Cancer Caucus
June 6, 2023

Dr. Angeles Alvarez-Secord, SGO President
&
Dr. Emily Ko
Dr. Mark Shahin
SGO Health Policy Socio-economic Committee

Congress of the United States
Washington, DC 20515

June 8, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Secretary Becerra and Commissioner Califf:

Thank you for your leadership in addressing ongoing drug shortages and ensuring Americans have access to the medications and devices they need. We especially appreciate the FDA’s recent actions to address current shortages of key oncology drugs. We are writing to you today expressing our concerns with the impact these shortages have on patients, particularly in cancer care. We’d like to request additional information about how the U.S. Food and Drug Administration (FDA) is working to resolve these issues and ways in which Congress can assist in these efforts.

For years, the medical community has experienced shortages of critical drugs that are used to treat a variety of conditions. These shortages are caused by a multitude of factors, including but not limited to quality issues, manufacturer business decisions, disruptions to active pharmaceutical ingredients (APIs) and excipient supplies, natural disasters, and other emergencies that take place in countries that house critical drug manufacturing facilities. In recent years, the United States has experienced shortages in broadly used essential products, as well as to products critical to smaller patient populations.

Within the oncology pharmaceutical supply chain, patients and providers continue to face shortages of potentially curative treatments. A recent survey of U.S. Oncology Pharmacies found that oncology drug shortages occurred frequently in 2020 and led to delays in chemotherapy and changes in treatment or omission, complicated clinical research, and increased risk of medication errors and adverse outcomes. Of the 136 drugs currently in shortage, as reported by the FDA, 15 are oncology drugs. Shortages of these 15 drugs, such as carboplatin and cisplatin, are causing care disruptions across the country. While we cannot quantify the direct impact to patients, estimates show that shortages in cisplatin and fluorouracil could impact 500,000 and 275,000 patients respectively. These drugs are used in the treatment of multiple common cancers, including lung, breast, ovarian, testicular, head and neck cancer, endometrial cancer, and many types of cancers impacting children.

Drug shortages also place children at risk across the United States. Drugs affected by shortage are often critical for treatment, and there are limited or no alternatives. Many childhood cancers
NCCN Releases Statement Addressing Ongoing Chemotherapy Shortages; Shares Survey Results Finding More than 90% of Cancer Centers are Impacted

National Comprehensive Cancer Network’s Department of Policy and Advocacy calls on Federal Government, pharmaceutical industry, providers, and payers to work together on solutions, as 93% of cancer centers surveyed report a shortage of carboplatin and 70% report shortages for cisplatin; two medications that are used in combination to cure many types of cancer.

PLYMOUTH MEETING, PA [June 7, 2023] — The National Comprehensive Cancer Network® (NCCN®)—an alliance of leading academic cancer centers—published survey results today that shed light on just how widespread the current platinum chemotherapy shortage is, and shared a statement calling on the whole oncology community to work together on solutions.

“This is an unacceptable situation. We are hearing from oncologists and pharmacists across the country who have to scramble to find appropriate alternatives for treating their patients with cancer right now,” said Robert W. Carlson, MD, Chief Executive Officer, NCCN. “We were relieved by survey results that show patients are still able to get life-saving care, but it comes at a burden to our overtaxed medical facilities. We need to work together to improve the current situation and prevent it from happening again in the future.”

The statement from NCCN’s Policy and Advocacy department outlines specific steps that can be taken by the Federal Government, pharmaceutical industry, providers, and payers to help mitigate any impacts from the anti-cancer drug shortages. It notes: “The causes and solutions to the recurrent anti-cancer drug shortages that deprive oncology patients of optimal therapy are multiple and fixable. Effective solutions require a whole of oncology effort if they are to be successful.”

Carboplatin and cisplatin are platinum-based chemotherapies that are frequently used together for systemic treatment, often with the intent to cure. They have been proven to be highly effective across a variety of cancer types, including lung, breast, and prostate cancers, as well as many leukemias and lymphomas. These two treatments are indicated hundreds of times throughout the NCCN Drugs & Biologics Compendium (NCCN Compendium®)—a searchable database of every recommended medication use found in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). They are estimated to be used in the treatment of as many as 500,000 new cancer patients per year.
Today: Move4Her Launch

Dear Elizabeth,

Today, we are thrilled to announce the launch of Move4Her, the Foundation for Women’s Cancers (FWC) largest awareness and fundraising platform to harness the collective power of patients, providers, community members and organizations in support of the mission of the FWC - to eradicate gynecologic cancers!

Every 5 minutes, another patient will be diagnosed with one of the 5 gyn cancers: cervical, ovarian, uterine/endometrial, vaginal, or vulvar cancer. That’s nearly 115,000 diagnoses each year in the United States alone. And more broadly, these cancers affect patients on every continent around the globe.

This year is very special. This is the 50th year of the Society of Gynecologic Oncology (SGO), the premiere medical specialty society dedicated to the prevention and treatment of gynecologic cancers. In celebration of this important milestone, we want to ALL raise a “high 5” to promote awareness, education, and research funding to eradicate the 5 gynecologic cancers. Taking steps to protect your health, connect with others, and build a powerful community will catapult Move4Her to new heights in 2023!

So, how can you get involved?

Build and Empower our Community Together
Research - Education - Awareness
Agenda Today

The Patient Experience
Judy Cacciola

Why Do Drug Shortages Happen?
Roisin O’Cearbhaill, MD

Chemotherapy Options During Shortage
Erin Medlin, MD

SGO/FWC Communications on the Move
Deanna Gerber, MD

SGO/FWC Legislative Policy Efforts
Annie Ellis

What Patients and Advocates Can Do!

Change Solutions and Advocacy
Laura Bray

Discussion – Q&A
All
The Patient Experience

Judy Cacciola
Patient Advocate
Why do Drug Shortages Happen?

Róisín O’Cearbhaill, MD
Memorial Sloan Kettering Cancer Center
Vice-chair, Clinical Practice Committee, SGO
Drug Manufacturing & Delivery involve Multiple Steps
WHY do Drug Shortages Happen?

- Manufacturing or quality problems
- Shipping delays or distribution problems
- A safety issue resulting in a drug recall

Supply Disruption

Drug Shortage

- Drug discontinuations
- Raw materials
- Demand for a drug is greater than the supply available

Adapted from 26-23-3339-Drug-Shortages-EN-05 version B, Canada.ca
Chemotherapy Options In a Shortage (and why these are more than okay!)

Erin Medlin, MD
Colorado Permanente Medical Group
Chair, SGO Communications Committee
“I’m being treated for Stage III Cervical Cancer with cisplatin and radiation, but now it’s on shortage. What now?”

- Consider a different chemo-sensitizing agent
  - Carboplatin (Level II evidence)
  - Capecitabine (Oral Fluourouracil) + Mitomycin IV (Level I evidence)
  - Gemcitabine IV (Level II Evidence)
  - Paclitaxel IV

- What to consider when selecting an agent: toxicity, intensity, ease of administration, and cost

- Very important: timely completion of radiation therapy and brachytherapy
“I’m being treated for recurrent cervical cancer, and platinum is on shortage! Now what?”

- Preferred treatment: cisplatin/carboplatin + paclitaxel + bevacizumab + pembrolizumab
- Alternative treatment: Topotecan + paclitaxel + bevacizumab (+ pembrolizumab) (Level I Evidence)
- Consider substituting oxaliplatin for carboplatin/cisplatin
- Consult NCCN guidelines for alternative regimens
“I was just diagnosed with Gestational Trophoblastic Neoplasia, and methotrexate is on shortage. Help!”

- GTN = Invasive mole, choriocarcinoma, PSTT, and ETT
- Low Risk vs High Risk disease
- Low Risk disease: treated with methotrexate or dactinomycin
  - May consider surgery (hysterectomy) +/- dactinomycin (Level III Evidence)
  - Dilation and curettage if fertility desired (Level II Evidence)
  - Etoposide (Level III Evidence)
  - Fluorouracil (Level III Evidence)
- High Risk disease: EMACO preferred (etoposide, methotrexate, dactinomycin, cyclophosphamide, vincristine)
  - Alternative: FAEV (Vincristine, Dactinomycin, Etoposide, Floxuridine) (Level I Evidence)
  - Consider surgery
- Recurrence: carboplatin/paclitaxel, TP-TE (Paclitaxel, Cisplatin, Etoposide), pembrolizumab, avelumab (Level III Evidence)
“I am being treated for stage III ovarian cancer after a debulking surgery, and carboplatin is on shortage. What else can I get?”

- A LOT of effort into finding and preserving platinum therapy to those who need it most
- No Carboplatin anywhere nearby:
  - Cisplatin (Level I Evidence)
  - Oxaliplatin + docetaxel + bevacizumab (Level II Evidence)
- Mucinous Cancer?
  - CAPOX (oxaliplatin + capecitabine + bevacizumab) (Level III Evidence)
  - FOLFOX (5-FU + oxaliplatin + bevacizumab) (Level III Evidence)
- Certain types of cancer: May omit chemotherapy
“I just enrolled in a clinical trial with carboplatin, and I heard its on shortage. What is going to happen?”

• What your team is considering
  • Treatment for curative intent or prolonged remission
  • Looking to other institutions
  • Avoiding enrolling new patients
  • Conserving drug: utilization, delaying, omitting, substituting
  • Keeping YOU informed of what is happening
Where to find more information

https://www.sgo.org/chemotherapy-drug-shortage/
What is the SGO Patient Communications and Support Strategy?

Deanna Gerber, MD
New York University Langone-Long Island
April 21, 2023

**SGO STATEMENT: CARBOPLATIN AND CISPLATIN SHORTAGES**

**SGO STATEMENT**
Apr 21, 2023

Currently, a U.S. shortage of carboplatin and cisplatin exists that will likely last several months and possibly longer.

Platinum drug shortages were first reported to the U.S. Food and Drug Administration (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.

Effective immediately, the SGO recommends the following:

1. **Minimize ordering of non-essential platinum.** If an alternative agent with comparable efficacy and safety is available, then cisplatin or carboplatin should not be ordered.

2. **Increase the interval between cycles and reduce the total platinum dose when clinically acceptable to do so.** Where National Comprehensive Cancer Network (NCCN) guidelines state a range for cycle duration, default to the longer end of that range (e.g., if platinum is recommended every 3 to 4 weeks, default to every 4). Where guidelines state a range of dosing, default to the lowest therapeutically appropriate dose.

3. **Consider minimizing or omitting** cisplatin or carboplatin for recurrent platinum-resistant ovarian and other cancers.

4. **Round dose 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 or when prolonged clinical benefit is anticipated.

5. **Consult with your oncology pharmacy to determine your healthcare system’s current supply of these platinum agents and escalate any shortages promptly along the supply chain and to your clinical teams.** We encourage our oncology community to communicate with other local providers regarding drug availability and to consider referrals for select patients if clinically indicated.

6. **If adequate supplies are unavailable, select an alternative, evidence-based regimen and consider a consultation with oncology/hematology colleagues.**

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May 24, 2023

**SGO, FWC, AND GOG-F* COMMUNIQUE: CONSIDERATIONS WHEN TREATING PERSONS WITH OVARIAN, FALLOPIAN TUBE, AND PERITONEAL CANCERS IN THE SETTING OF CISPLATIN AND CARBOPLATIN SHORTAGES**

**JOINT STATEMENT, NEWS ARTICLE, SGO STATEMENT**
May 24, 2023

A platinum drug shortage in the U.S. was first reported to the FDA on February 10th, 2023. Please refer to the SGO Rapid Communiqué dated April 21st, 2023, for details and guidance regarding platinum dosing and sparing strategies. This communication provides guidance for treating patients with ovarian, fallopian tube, and peritoneal cancers in the context of limited drug availability.

Hospital systems or similar organizations are encouraged to facilitate open and frequent communication among multi-specialty teams, including gynecologic, medical and radiation oncologists, pharmacists, infusion managers, advanced practitioners, and patient advocates. In doing so, the goal is to create institution- and population-specific strategies to overcome anticipated treatment challenges.

Importantly, cancer care disparities may emerge or worsen in times of resource scarcity. As treatment recommendations are adjusted during this shortage, identifying patients at risk for experiencing structural barriers to care – and having a plan to mitigate those barriers – must be considered as part of each institution’s strategic plan. Therefore, the allocation of limited-supply drugs must be prioritized in a transparent and data-driven fashion to ensure thoughtful and equitable distribution. Additionally, considerable operational workflow resources must be facilitated by hospital leadership, administrators, pharmacists, and payors to ensure adequate and equitable patient care.

The term “ovarian cancer” includes ovarian, fallopian tube and primary peritoneal cancers.

**General Principles**

1. **For the treatment of epithelial ovarian cancer,** carboplatin-based regimens are the recommended standard of care\(^1\)\(^2\) for patients with
   a. high-grade, early-stage disease
   b. advanced-stage disease
   c. platinum-sensitive recurrence. (Level of Evidence I)

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\*GOG-F: Gynecologic Oncology Group Foundation
Currently, a U.S. shortage of carboplatin and cisplatin exists that will likely last several months and possibly longer. Platinum drug shortages were first reported to the U.S. Food and Drug Administration (FDA) on February 10, 2023.

Below you'll find valuable information including:

- SGO, FWC, and GOG-F Communiques
- Webinars
- SGO Member Community Group
- Media Coverage & Additional Resources
- What You Can Do

https://www.sgo.org/chemotherapy-drug-shortage/
Resources available by cancer type/location

- **SGO, FWC, AND GOG-F COMMUNIQUE: SHORTAGES AND TREATING CERVICAL, VULVAR, AND VAGINAL CANCERS**
- **SGO, FWC, AND GOG-F COMMUNIQUE: CONSIDERATIONS WHEN TREATING GESTATIONAL TROPHOBLASTIC NEOPLASIA IN THE SETTING OF A METHOTREXATE SHORTAGE**
- **SGO, FWC, AND GOG-F COMMUNIQUE: CONSIDERATIONS WHEN TREATING PATIENTS WITH GYNECOLOGIC CANCERS ON CLINICAL TRIALS IN THE SETTING OF CHEMOTHERAPY SHORTAGES**
- **SGO, FWC, AND GOG-F COMMUNIQUE: CONSIDERATIONS WHEN TREATING PERSONS WITH OVARIAN, FALLOPIAN TUBE, AND PERITONEAL CANCERS IN THE SETTING OF CISPLATIN AND CARBOPLATIN SHORTAGES**
We are committed to keeping you informed!

A MESSAGE TO OUR GYNECOLOGIC CANCER PATIENTS, ADVOCATES, AND COMMUNITY

The American Society of Health-System Pharmacists and Food and Drug Administration (FDA) recently reported a U.S. shortage of several drugs, including cisplatin, carboplatin, and methotrexate. These chemotherapy drugs are used to treat many types of gynecologic cancers, such as those involving the uterus, cervix, ovaries, and fallopian tubes.

The Foundation for Women’s Cancer (FWC), alongside the Society of Gynecologic Oncology (SGO), stands steadfastly in support of our patients and the gynecologic cancer community. We recognize these drug shortages as a public health crisis with direct effects on patients, clinical outcomes and historically marginalized rural and urban communities. Addressing this drug shortage is a top priority, and we are working closely with colleagues and fellow advocacy organizations nationally to advocate for patients, minimize harm, and ensure access to equitable treatment.

This work includes discussions with key stakeholders including the FDA, pharmaceutical manufacturers, and collaborating with other oncology medical societies. Additionally, the SGO/FWC is recommending strategies to medical providers to optimize cisplatin, carboplatin, and methotrexate use and acceptable treatment alternatives that may be considered during this shortage. In cases where these drugs must be substituted, other effective treatment options are often available.

The SGO/FWC will continue to advocate for our patients and members until this drug shortage is resolved and to suggest strategies that promote treatment access for all patients with gynecologic cancer. We welcome your insights and/or any questions which may be e-mailed to sgo@sgo.org.
SGO/FWC legislative and policy efforts: How patients and caregivers can get involved from Twitter to Capitol Hill

Annie Ellis
Survivor/Research Advocate
Support SGO/FWC legislative and policy efforts

CHEMOTHERAPY DRUG SHORTAGE: WHAT YOU CAN DO

The Society of Gynecologic Oncology (SGO) and Foundation for Women’s Cancer (FWC) have taken a comprehensive approach to mitigating the chemotherapy shortages and exploring opportunities to prevent drug shortages from occurring in the future.

What You Can Do:

1. **Endorse the rapid communications** regarding treatment options to preserve drug supply and alternative chemotherapy drug guidelines if standard-of-care drugs are not available.
2. **Join us for upcoming webinars and round tables** aimed at providing education and support to the cancer community, and share information with your extended networks.
3. **Work together to meet with and inform legislators.** We need legislation for incentives for manufacturers and enhanced supply chain resilience, and to empower the FDA with more options to address drugs shortages. We also must explore the economic relationships between manufacturers and buyers. Click [here](https://foundationforwomenscancer.org/chemotherapy-drug-shortage-what-you-can-do/) to send a pre-written letter to your Members of Congress urging them to take action to mitigate and prevent chemotherapy drug shortages.
4. **Promote our efforts**, alongside the efforts of other cancer organizations like OCRA to **amplify the message**, conduct research on outcomes, and collaborate synergistically.
5. **Join the End Drug Shortages Alliance**, which aims to enhance transparency, redundancy, quality, and production of medications to address supply shortages and improve patients’ access to vital drugs.

Inform legislators

https://www.sgo.org/take-action/

OCRA

https://www.votervoice.net/OCRA/Campaigns/105735/

ASCO Members – ASCO ACT Network

https://asco.quorum.us/campaign/48178/

Sign up for Alerts!
Amplify the message

Share with your support systems and on social media!

Follow SGO and FWC
Twitter: @SGO_org @GYNcancer

#gyncsm
Join End Drug Shortages Alliance

Improve Access. Improve Life.

The End Drug Shortages Alliance is a collaboration of select health system, supply chain, industry and other stakeholders dedicated to solving pharmaceutical supply challenges by increasing transparency.

https://www.enddrugshortages.com/
Change Solutions and Advocacy: Ensuring Access to Life Saving Drugs

Laura Bray
Chief Change Maker
Angels for Change
Angels for Change founded 2019

Our Purpose: Ensuring Access to Life Saving Drugs

Our Mission: End drug shortages through advocacy, awareness, and a resilient supply.
Our Story
My “Why”

We found hope.
“Life-saving treatments exist. Patients must have equal access to the drugs that can save their lives.”
— Laura Bray, Chief Change Maker
Haunted Needing to Know “Why?”

Q: Was this systemic or unique?
Q: How long has this been going on?
Q: Why isn’t the theory of supply and demand working here?
Q: Why isn’t scarcity correcting the issue?
Q: What is being done?
Q: What are the current supply chain mitigation strategies? Early warning triggers?

Big Q: How can this be stopped?
What did I find?

Hundreds of active shortages at any given time
FDA calls the pharmaceutical supply chain “a broken marketplace”?
Hospitals spend 8.1 million work hours & $365 million?
80% of specialty pharmacists affected by at least one drug shortage daily?
After a shortage hospitals order less not more?
Pediatric oncology essential drugs 90% more likely to go into shortage and stay short ~33% longer than adult drugs?
75% of the top 20 pediatric oncology drugs have been on shortage in the last 5 years?
Root Causes?

Lack of incentives to produce less profitable drugs, lack of incentives to buy quality drugs

Market does not recognize and reward manufacturers for “mature quality systems” that focus on continuous improvement and early detection of supply chain issues

Logistical and regulatory challenges make it difficult for the market to recover from a disruption
Theory of Scarcity

Relies on demand pushing on supply to recover. Mitigation moves demand to meet supply, removing scarcity as a tool to increase resiliency.

- Mitigation Asks:
  - How do we use available supply?
  - Who gets available supply?
  - When do they get supply?
  - How do we give available supply?
- Creates disparity through boundaries and rules for use of supply

- Ending asks:
  - How much supply do we have?
  - How much supply do we need?
  - How do we ensure there is enough supply given any situation?
- Creates redundant & resilient supply solutions
Enduring Solutions:

“…Multi-stakeholder effort and rethinking business practices.”

Complex Global Drug Supply Chain

Supplier  Manufacturer  Wholesaler  Pharmacy/Hospital  Patient/Health Care Provider
Who is the Customer?

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Power in the 4 Ps solving this together. This “last mile” of the supply chain we must connect and work together.
Quality, Timing, Economy Connection

- Quality
- Timing
- Economy

- Product Safety
- Resilient supply
- Right place/right time
- Pricing
Path Forward

1) Prediction
2) Partnership; Public/Private/NPO collaborate, align incentives and expertise
3) Additional Supply; both Flexible Gap and Just in Case
4) Inventory Sharing during Scarcity
5) Exit Ramp leaving no patient behind
6) Patient Advocacy; checks and balance
Thank You

Join the race to end drug shortages
Become a Change Maker today!

angelsforchange.org
LauraBray@angelsforchange.org
Q&A