"Examining The Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains"

Energy & Commerce Committee, Oversight & Investigations Subcommittee

Testimony of Laura Bray, Chief Change Maker, Angels for Change

May 11, 2023

My name is Laura Bray. I am founder and Chief Change Maker at Angels for Change. I appreciate the opportunity to testify today and provide the patient voice to these proceedings. Thank you for your leadership and bipartisan work to engage stakeholders to improve the nation's ability to prevent and respond to drug shortages.

Angels for Change is a volunteer-supported organization on a mission to end drug shortages through advocacy, awareness, and a resilient supply chain. As the only non-profit patient advocacy organization mission driven to ending drug shortages, we are passionate about building awareness to create solutions that will provide equal drug access to patients in need. Our focus is to advocate on behalf of and to seek immediate relief for any patient in a life-saving drug shortage, while building relationships with patients and members of the pharmaceutical supply chain with the goal of ending all healthcare crises created by drug shortages.

As of April 2023, there are 301 drugs in shortage—100 more shortages than in April 2018. Within the first quarter of 2023, 47 new drugs went on shortage. Hospitals spend 365 million dollars a year and 8.1 million hospital employee hours navigating drug shortages. 66% of hospital pharmacists report dealing with shortages daily. 55% of hospitals have changed patient treatments because of shortage. And 90% of

oncologists report drug shortages have had a negative impact on patient outcomes. Patients' lives are in the balance. I know. My daughter's life was one of them. Our story starts with a pediatric cancer diagnosis.

I was sitting in a hospital with my daughter Abby, when I first heard the words "we don't have the drug your daughter needs today. It is on shortage." I was sitting in that same hospital a few months earlier when she was diagnosed with Acute Lymphoblastic Leukemia (ALL).

At diagnosis we were told that childhood cancer is a family diagnosis. All members are affected. As the parent, you are now caretaker while your child begins a fight for their life. You can't take it away, you can't kiss it away like a skinned knee. They must take this heartbreaking road. It is your job to support them.

At diagnosis, we were told we were "lucky" ALL (unlike many other pediatric cancers) has a "cure". There is this "miracle" protocol we would follow with a cocktail of drugs given in a very certain timeframe which leads to a hard and multi-year but very successful treatment. The doctors use these success numbers (in the 90%) to help provide assurances and comfort but also to warn parents early that compliance is key. Compliance, in fact, was the single most effective, controllable decision my husband and I could make each day to help our child survive. Then we shared those assurances with our child and used every tool in the parent tool kit to get her to comply.

You root the answers to the tough questions your child asks about treatment in the importance of following the protocol, just like the doctors did for you. When they don't want to take their meds anymore, everyone tells them how important it is. When they can't take the pain of being poked or having their port accessed

again. When they lose their hair. When 17 pills are too many for them to swallow in a 30 minute period. When just walking through the door of a hospital makes them throw up, so you keep plastic hazard bags with you in your bag to catch it. You move forward, always focused on compliance. Doctors, Nurses, Child Life Specialists help as well. We are a team working together to get them to comply, every day, every time. Your child understands the importance, they know it is all for this medicine, for this protocol, for this timing, for survival.

When there is a shortage of their important medicine and you are now forced to pause, miss or remove one of these drugs from protocol, how do you explain this to your child? This is the medicine that they know is killing the "bad cancer guys but also the good hair guys too". They reasonably ask, "wait?! I thought I needed this. What happens now? Will I die without my medicine?" How does a parent answer that question from their very sick child?

I was sitting in a hospital room when my 9-year-old asked me that question. I didn't even know drug shortages existed. But I told her the only thing I could. "We're going to try and find it." I had no experience or power or idea how to but I tried starting with the knowledge I had as a business professor, help from friends and family, and google searches. We successfully found the medicine she needed, but it didn't end there. Abby's protocol was impacted by another drug shortage, followed by another. She had 3 lifesaving, patient-impacting, protocol timing changing shortages in 9 months of treatment. Different drugs and different root causes.

I was haunted by this experience and I had a lot of questions. I wanted to know 'why'? Why was this the state of our pharmaceutical supply chain? Was this a systemic crisis? It seemed unlikely that one patient could have been hit by three market failures if it wasn't. Why wasn't the theory of scarcity fixing this? Who was working to fix this? What has been done? Why wasn't that enough? And of course, the biggest question: How can this be stopped? It was such a cruel place to put a family already in crisis. It wasn't enough that my 9-year-old daughter had to consider her mortality when she was diagnosed with cancer, she had to then consider it again just because enough supply wasn't being made of the medicines we told her would save her.

As I searched for answers, I was surprised how easy it was to find them. All of the answers were shocking to me. There was almost 20 years of research into this problem and many calls to action. This more than 2-decade crisis was in fact systemic. The key drivers of drug shortages: low price, manufacturing complexity, greater geographic concentration of production, and previous quality issues have been identified. If there is two decades of shortage research why wasn't this resolved? Why did my child and our family have to go through this? Our patients deserve a supply chain that is resilient enough that it can recover from any situation. Why is it not recovering? Why wasn't patient harm enough to cause action? Why didn't the previous research result in ending drug shortages? If we have known it was an issue for over 20 years, why hasn't this been fixed?

I concluded that Scarcity and Market Economics were broken partly because during a time of shortage, our system mitigates the crisis by lowering demand to meet available supply. This happens differently depending on the individual hospital's available supply. A hospital with no supply isn't treating any patient, but a hospital down the road had enough to treat all patients. Mitigation asks what should we do with available

supply? In life-saving medicine this means who is going to get this medicine and who will not. Economics relies on demand forces, usually the customer, pushing back on supply during a time of shortage. Instead, after a shortage demand for the drug decreases! How could that be? Certainly, patients didn't disappear. The answer may lie with the complexity of the customer in this marketplace. Who is the customer here? Is it the hospitals, who order medicines? Is it the pharmacists, who deliver the medicines? Is it the doctors, who prescribe the medicines? Is it the insurance companies, who pay for the medicines? Or is it the patient, who receives the medicine?

I began my work under the hypothesis that maybe this crisis had endured because the patient voice, the true customer, was not part of the supply chain dialogue. No patient would sit in a room and make mitigation strategies to not supply themselves. They would be asking, how could we end this? How do we get more supply? The same questions I was asking. I began to search for the non-profit that was working on this to share my story and offer to help. I found there was not a single patient advocacy organization mission-driven to tackle drug shortages. Certainly, the absence of patient voice is a missing part of this crisis.

I knew that no patient should have to hear the words, "we don't have the medicine to treat you" and no doctor should have to say them. I thought maybe I could share my knowledge with other patients. And at the very least no patient or parent will have to go through a drug shortage search alone or start a search from google like I did. With help from family and friends, we created a website and a facebook page and launched Angels for Change in the fall of 2019. Our purpose: Ensure Access. Our mission: End Drug shortages through Advocacy, Awareness and a Resilient Supply Chain. At founding we became the only patient advocacy organization in the United States mission-driven to end drug shortages. Almost immediately,

patients began to call.

Each time a patient called we navigated the supply chain to find medicine that was in the wrong place and get it to the patient and hospital in need. Each time I met new members in the supply chain. Subject Matter Experts who spent their life's work trying to build a more resilient supply chain. I would call and they would be ready to help in the most miraculous ways. After the supply chain helped with a shortage, I went back to the members who helped me to thank them and ask questions – basically a post action report. First, I made sure they knew the importance of the work they did with us and the life they saved. Bringing the patient back through the supply chain to create deeper meaning and patient connection in what could seem like a 9-5 business job instead of important healthcare. Then I asked questions: Why, from your point of view, did this shortage happen? What do you think will keep it from happening again? Is there anything you and I can do today, in our control, to make this patient or disease or medicine more resilient? And my favorite: if you had a magic wand how would you end drug shortages?

Then after each conversation, I added the knowledge back into my process. The patients and their families stuck in a drug shortage are our WHY. They drive our purpose. But it is the people who make up the supply chain that have stepped up and done the amazing, collaborative, patient focused work with us at Angels for Change. Members who answer my calls and are called to action for one patient or one hospital. I don't have supplies, I don't make medicine, I don't purchase medicine, I don't distribute medicine, I don't regulate medicine. I connect the patients who rely on these stakeholders and make sure we aren't leaving one behind because of a broken marketplace.

I am extremely proud of this advocacy work. Yet, more must be done. Each time I am called, we are jumping into a reactive situation. It is a completely manual process and there are no economies of scale. There is very little access to see into the supply chain and very few guarantees to give patients. Most importantly, in this work a patient or hospital has already been disrupted by a supply chain that is not redundant enough to recover. The goal should be to completely eradicate the hospital level shortage conversations; the ones the Doctors are having with patients and the ones patients are having with me. To accomplish that goal, we must start higher into the supply chain, and it can't be done per patient, hospital, shortage drug or disease. We must build resiliency together, sustainably, by design.

I define resilient as a supply chain's ability to recover after disruption. For the pharmaceutical supply chain this means recovery without patient impact. At Angels for Change, we work to bolster 3 key values to build a more resilient pharmaceutical supply chain.

Transparency: We must clearly see the situation. There are gaps in information and this supply chain is deeply fragmented. We cannot problem-solve together until we can see the entire situation.

Redundancy: We must build a more redundant supply chain. Redundancy is not one solution. It is multiple safeguards working together to protect all patients from supply chain disruption.

Connectivity: We must act as a collaborative system of health to solve this crisis. We must build connectivity tools to support collaboration. This will help the entire supply chain engage, guard and react together both proactively and during disruption.

Building this into our supply chain is possible. There is already work in progress to support these key resiliency values. Look to the important work being done at the End Drug Shortages Alliance as an example. We will need the resolve, sense of urgency and support of all stakeholders to accomplish this goal.

Pathway to Preventing Shortages

I would like to share a pathway forward to build a more resilient supply chain, based on our success through Angels for Change. While navigating the supply chain for patients, physicians, hospitals, and pharmacists hundreds of times in the last four years, I have come to the following layered solutions to remove the patient and hospital impact of shortages and create a more resilient supply chain. In 2019, the FDA *Drug Shortage: Root Problems and Possible Solutions* report said the marketplace "does not recognize incentives and motives" and that "enduring solutions would require multi-stakeholder involvement and rethinking business practices." Here is how Angels for Change would do that:

Step 1: Align Incentives and Motives through Partnerships. Use models already used to incent behavior in the orphan drugs and food supply chains. This must include public, private, and non-profit engagement. See the attached[1] Angels for Change Project Protect case study.

Step 2: Prediction and Forecasting must be employed. This will require transparency to identify the medicines most vulnerable to shortage and classification for the reason for shortage (different causes need

[1]https://static1.squarespace.com/static/5d67c8df2b3916000122fdf7/t/62db04ac2c9cfd6b88397807/1658520751564/Case-Study_-New-Approach-to-Mitigate-Shortages.pdf

different partnership incentives to resolve). There is already work being done in this space we do not have to start from scratch.

Step 3: We must be ready to supply patients. This requires increasing supply and designing a platform to share medications within the supply chain during disruptions.

The current "Failure to supply" stick-based incentive program is not incentivizing the right market behaviors. It is reactive, not proactive. We need to incentivize and measure a risk management plan that is proactive and redundant based on the supply chain being ready to supply to patients, especially for low-margin essential medicines. High-margin medicines and pharma products are already placing the needed ready-to-supply redundancies in place because losing a single sale has very real Profit & Loss consequences. The cost of not supplying is high enough to build these practices in. That is why they are typically not short. But the generic manufacturing market relies on razor thin margins. Building redundancies do not have the same Profit and Loss consequences. So we will need to incentivize this important quality and access work.

We must increase the number of suppliers in the market for vulnerable drugs, encourage "just in case" supply for those vulnerable drugs, have gap active pharmaceutical ingredient (API) supply on shore with 503B compounding facilities ready to turn on fill finish when needed creating flexible on shore gap supply. This must be done sustainably, in partnership, focused on equal patient access.

The last line of defense to be ready to supply is an inventory sharing network. This is a way to make sure we can get supply sitting on the self to the right place at the right time while the supply chain recovers and

catches up. Angels for Change is currently doing this one patient, one hospital at a time. We must build a transparent, trusted, connected platform to ensure equal access during a time of shortage. This supply chain gap was apparent during COVID 19. We should learn from the successful ways stakeholders connected scarce supply through the supply chain during the pandemic and move that work forward to support all pharmaceutical shortage events.

Step 4: Collaboration. Authorizations during the COVID-19 pandemic allowed for unprecedented collaboration and the marketplace stepped up. We want that same opportunity during a drug shortage crisis. Incentives, Urgency and Collaboration were engaged, and the supply chain reacted, recovered and innovated for the greater good.

Step 5: Patient advocacy available to help navigate any patients or medicines that fall through the cracks, convene and micro-source if needed. This is the final check and balance for the supply chain. Patients and hospitals deserve a last line of defense.

Step 6: An Entrance and Exit Ramp for Generic Manufacturers. Many supply disruptions can be traced back to manufacturers leaving the marketplace due to sustainability issues or changes in product focus. We must allow for these changes in the market for there to be an efficient marketplace, but they must be done with a longer lead time while incentivizing new market entrants. Patient treatments can not be impacted when the market changes.

These steps used together will lead to a redundant supply chain, one that can recover during a disruption and remove the impact of shortages from patients and hospitals.

Shortages of essential medicines are significant public health threats that affect everyone from individual patients to large health systems. Congress has a real opportunity to address these issues. Enacting the above recommendations would increase transparency and reporting, bolster the pharmaceutical supply chain, increase domestic production, and offer a last line of defense for individual patients. This would create a new domestic ecosystem of essential medicines and strengthen our national health security.

No patient should be faced with harm up to death because of a drug shortage and our beloved physicians must have the tools to save patients where and when they need them every time for every patient.

When we were founded, I gave myself the title Chief Change Maker. Change isn't passive; its active. Ending drug shortages will take purposeful effort from all of us, together. No one can do this alone, but together we can build a resilient supply chain that leaves no patient behind. We must commit to and deliver that change. Our patients and healthcare workers deserve and expect it. We cannot sit on 20 more years of research to come back to discuss this crisis again. Another child should not have to ask their parent, "will I die if I don't get this medicine?"

We are at an inflection point. We can do this together. It will take all of us.

Thank you,

Laura Bray
Chief Change Maker
Angels for Change

Summary

Angels for Change is the only non-profit patient advocacy organization mission driven to ending drug shortages. Our focus is to advocate on behalf of and to seek immediate relief for any patient in a life-saving drug shortage, while building relationships with patients and members of the pharmaceutical supply chain with the goal of ending all healthcare crises created by drug shortages.

At Angels for Change, we work to bolster 3 key values to build a more resilient pharmaceutical supply chain. Transparency: We must clearly see the situation. We cannot problem-solve together until we can see the entire situation. Redundancy: Redundancy is multiple safeguards working together to protect all patients from supply chain disruption. Connectivity: We must build connectivity tools to support collaboration to help the entire supply chain engage, guard and react together both proactively and during disruption.

A pathway forward to build a more resilient supply chain should include the following layers:

Step 1: Align Incentives and Motives through Partnerships.

Step 2: Prediction and Forecasting must be employed.

Step 3: Increasing supply through sharing medications within the supply chain during disruptions.

Step 4: Empowering collaboration in the marketplace during a drug shortage crisis.

Step 5: Utilize micro-sourcing to navigate patients or medicines that fall through the cracks.

Step 6: Establish an Entrance and Exit Ramp for Generic Manufacturers with longer lead time.

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