

Compounding Quality Center of Excellence Virtual Conference

project PROTECT

Laura Bray, MBA

Chief Change Maker



Our Purpose:

Ensuring Access to Life Saving
Drugs

Our Mission:

End drug shortages through
advocacy, awareness, and a
resilient supply.



Angels for Change Believes:

It is a right to have access to life-saving drugs

Doctors, Patients and Science should drive treatment plans, not business decisions

There should not be disparity in treatment because of access decisions

Doctors must have access to the right tools at the time patients need them



Our Story



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



Since our Founding we have:

Advocacy

- Helped 56 patients, mostly children, in life-saving drug shortage
- Advocated on behalf of 10 hospital systems
- Found hundreds of doses of life saving medications
- Supported 3 patients in international searches
- Funded shortage production resulting in +140,000 life-saving treatments in 90 days
- Founding Board Member of the EDSA
- Committee Chair of EDSA
- Launched Advocacy Awards
 - Change Maker of the Year
 - Drug Shortage Guardian



Since our Founding we have:

Awareness

- Hosted 4 National Summits
- 5 lunch and learns
- Built partnerships throughout the supply chain
- Conferences Speaking
- Published White Paper
- Sponsor of Curefest 21 & 22
- Spoke in Washington DC
- Published Case Study
- Funded and Completed Patient Impact Research
- Launched Gala, S2E Shortages and CMCs
- Founded and Operating a non-profit



Haunted by the Need 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?

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?



What is the Root Cause?

Lack of incentives to produce less profitable 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





Enduring Solutions:

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

Source: FDA. “Drug Shortages: Root Causes and Potential Solutions.” Oct. 2019



Build Resiliency 3 Ways



Transparency: Let's really see the situation



Redundancy: Let's have the right plan be for the right situation up stream



Connectivity: Communicating, Collaborating and building tools as a single system instead of members of a system

Connectivity as a Practice

Collaboration:

- is a working practice whereby individuals work together for a common purpose to achieve business benefit.

Cross-functional Collaboration:

- is when a group of people with different functional expertise come together to work on a goal or project



Collaboration strategies to end drug shortages bring



Alignment



Flexibility &



Velocity

Foster Cross Functional Collaboration using the concept of “co-opetition.”



Building Supply in a Short Market

Pilot Project Overview

Angels for Change
August 2022

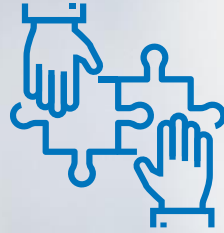


Who is CHA? Children's hospitals are stronger together



Learn

with dozens of events and networking opportunities.



Collaborate

and work together to solve big and small challenges facing pediatrics.



Save

through collective negotiation in supply chain, pharmacy and insurance services.



Benchmark

against peer hospitals to identify opportunities for improvement.



Influence

how policy becomes practice by affecting legislative change for children's health.

To support the supply chain needs of members, CHA provides three types of services ...



COLLABORATE

Practice and policy sharing to achieve best outcomes



COMBINE

Supply contracts leveraged through the GPO to support supply chain sustainability, resilience, and access



COMPARE

Benchmarking to improve care for kids

Maximum benefit achieved when working across all three!

CHA/Vizient drug shortage survey

Goal:

Use comparator analysis to highlight unique impact to pediatric hospitals

38 questions, investigating shortage impacts and mitigation strategies

Sent to over **1500** Vizient Pharmacy Program participants

330 hospitals completed survey in its entirety, **29** of which were CHA “project” hospitals

Number of drug shortages

Percent of hospitals that experienced...	Pediatric hospitals	Other hospital types
Less than 11 drug shortages	0%	15%
More than 20 drug shortages	80%	60%
More than 50 drug shortages	30%	20%

Focused on Pediatric Essential Drug Shortages

	Essential Drug	Pediatric Essential Drug
Impact	Broad patient population	Disproportionate impact to children
Recognition of Shortage	Better monitoring and recognition due to impact scale	May not be listed on national shortage list due to limited facilities/patients
Mitigation response	Many players working to develop alternatives	Slow or no response due to limited players
Manufacturer ROI	High ability to recoup investment and turn profit	Small market Limited return without drastic price increase
Readily available alternative(s)	Usually more	Often none, due to formulation or limited pediatric product market

Refining our focus

- Pediatric essential drug (per PDSP criteria)
- Disproportionate use in pediatrics
- Protection status from GPO, supplier, distributor
- Number of manufacturers in space
- History of shortage





Safety | Transparency | Availability | Quality

August 2022

- STAQ is high-cost relative to normal channel (our volume is driven only where the products cannot be otherwise purchased)
- CHA and Angels For Change step in to “de-risk” project as it is expected to be short-term
- STAQ and CHA monitoring supply to await return to normal (and removal of product from 506E list) and STAQ stops production
- But for the partnership, this would not have worked to solve a crucial shortage.

Current Active Partners & GPO's:



Board Members

- Joe Bagan (Chair); Jeff Hval; Mark Spiecker (Secretary)
- Dan Seff (Managing Partner CBIZ MHM Audit, Tax and Business Advisory, Treasurer)
- Jerrod Milton (SVP Operations at Children's Hospital Colorado)
- Scott Hawig (CFO Froedtert Health)
- Chet Kaczor (VP Operations and Chief Pharmacy Officer, Nationwide Children's Hospital)
- Abram Gordon (VP Innovation and Exec Director of Proton Therapy Center, Cincinnati Children's Hospital)
- Carol Lewis (Vice President University of North Carolina Health Ventures)

Drug Development Timeline

New Product Implementation Timeline

Activity		Expected Duration	Pre-requisites	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7
1	Develop Master Formulation Records	1 month	None	█						
2	Identify API and Excipients	1 month	1	█						
3	Verify Compendial Drug Product Analytical Test Methods	1 month	1,2	█						
4	Perform Supplier Audits and Source API and excipients	1 month	2	█						
5	Order API and excipients and Test to USP specifications (per cGMP requirements)	1 month	4	█						
6	Develop Master Batch and Fill Records	1 month	1,2		█					
7	Method Suitability, Endotoxin, and CCIT Validation	1 month	6		█					
8	Media Fills	1 month	1,2,3,4,5,6			█				
9	Compound Stability Batches	0.5 months	1,2,3,4,5,6,7,8				█			
10	Stability Testing (90 day BUD)	3 months	9				█	█	█	
11	Commercial Production	0.5 months	10							█

Break Even Business Case Example

	Stand Alone	With AFC
Pre – Production Activities (2 Drugs Simultaneously)	\$200,000	\$100,000
Average Sales Price Per Syringe	\$20	\$20
Average Net Margin	20%	20%
Net Profit Per Syringe	\$4	\$4
# Syringes Needed for Breakeven	50,000	25,000
Batch Size	850	850
Batches Per Week	2	2
Production Days to Break-even	59	29
Production Weeks to Break-even	29	15

*Ignores cost of capital & assumes facility is built, operating and expansion/construction is not needed to add the production.

- September 2021 – Children’s Hospital Association, CHCO & CHOC raise concerns on availability of Pediatric Electrolytes
- December 2021 - Children’s Hospital Association & Vizient share electrolyte shortage concerns. STAQ starts preliminary development work. Some Pediatric Hospitals report turning away patients and concern for health of neonates and infants in their care.
- December 2021 - STAQ Board Members request STAQ look into production of specific Electrolytes
- February 2022 – Angels for Change, CHA & STAQ meet and development grant funding plan for KCl & 23.4% NaCl
- March 2022 – 23.4% NaCl & KCl go on stability / Shortage goes critical
- April 2022 – Product Launch
- July 2022 – 90 day Pilot Complete / Providing supply where normal channels are not working