

CASE STUDY

Tampa, FL

JULY 2022

A NEW APPROACH TO MITIGATE DRUG SHORTAGES

90-DAY PILOT PROGRAM PROVIDES PEDIATRIC HOSPITALS
WITH OVER 140,000 ESSENTIAL MEDICINE TREATMENTS

PREPARED BY

Angels for Change

Ending drug shortages through Advocacy, Awareness and a Resilient Supply Chain



OVERVIEW

Shortages of essential and life-saving drugs have become commonplace at virtually every hospital in the country and disproportionately affect children, who often require personalized compounded medicines. Despite Herculean efforts by hospitals, pharmacists, physicians and purchasers, these shortages can disrupt and delay patient treatment plans, require therapeutic substitutions and increase the risk of medication errors.

This problem has become so pervasive that, during the 2018 annual meeting, the American Medical Association declared that drug shortages were **“an urgent public health crisis.”**

In a 2019 report on the root causes and potential solutions for drug shortages, a U.S. Food and Drug Administration (FDA)-led task force stated that:

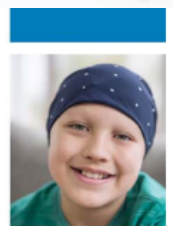
“Economic forces are the root causes of drug shortages (and) enduring solutions will require multi-stakeholder efforts and rethinking of business practices throughout the healthcare system.”

This case study documents a multi-stakeholder 90-day pilot program that demonstrates how such an approach can build supply chain resiliency and end patient level drug shortages.

Drug Shortages:

Root Causes and Potential Solutions

2019



More than 55% of hospitals reported they had changed patient care or delayed therapy because of drug shortages.

Drug Shortages: Root Causes and Potential Solutions, 2019 FDA Report



PROGRAM GOALS

- Demonstrate that a model built on a collaborative, risk-sharing partnership could improve supply chain resiliency and help hospitals avoid shortages of essential medicines.
- Mitigate the financial risk and stimulate consistent production for two sterile-injectable concentrated electrolytes – potassium chloride and 23.4% sodium chloride– for Children's Hospital Association (CHA) hospitals in the pilot program. These essential medicines -- which premature newborns and young babies rely on to survive and thrive –are often vulnerable to drug shortages.
- Prove that this model could alleviate the patient impact of pediatric essential medication shortages with speed, efficiency, flexibility, and scalability while increasing capacity (net new medicines), readiness to supply and marketplace opportunity.
- Lay the groundwork to expand and scale other programs to help mitigate shortages of essential medications.



“Non-profits have administered grants to support the marketplace in times of national disasters and emergencies, but not in drug shortages. We believe drug shortages are a national health crisis and this pilot shows proof of concept that innovative public/private partnerships will help address this crisis.”

-Laura Bray
Angels for Change

KEY PARTICIPANTS

Angels for Change

A non-profit organization dedicated to ending persistent drug shortages throughout our healthcare system. Laura Bray, its founder and Chief Change Maker, started the organization in 2019 after her daughter Abby faced several life-threatening drug shortages while being treated for acute lymphoblastic leukemia (ALL), the most common childhood cancer. As a business professor, Laura soon realized that collaborative partnerships focused on ensuring supply chain “readiness” would be needed to address the systemic problems caused by market forces that superseded patients’ needs.



Angels
for
Change

Children's Hospital Association

The national voice for more than 220 children’s hospitals in the United States. CHA was a founding member of the End Drug Shortages Alliance, a group of diverse stakeholders (along with Angels for Change and STAQ Pharma) taking aim at this urgent problem. Terri Lyle Wilson, CHA’s director of pharmacy, Supply Chain Services, was a driving force in developing, guiding and executing the pilot program.



CHILDREN'S
HOSPITAL
ASSOCIATION

STAQ Pharma

A 503B Outsourcing Facility that produces pre-filled syringes of sterile compounded medications in a cGMP facility for pediatric and adult hospitals. Mark Spiecker, the president of STAQ Pharma, has worked closely with Children’s Hospital Association and Angels for Change for several years to find innovative ways to help hospitals mitigate and/or prevent drug shortages.

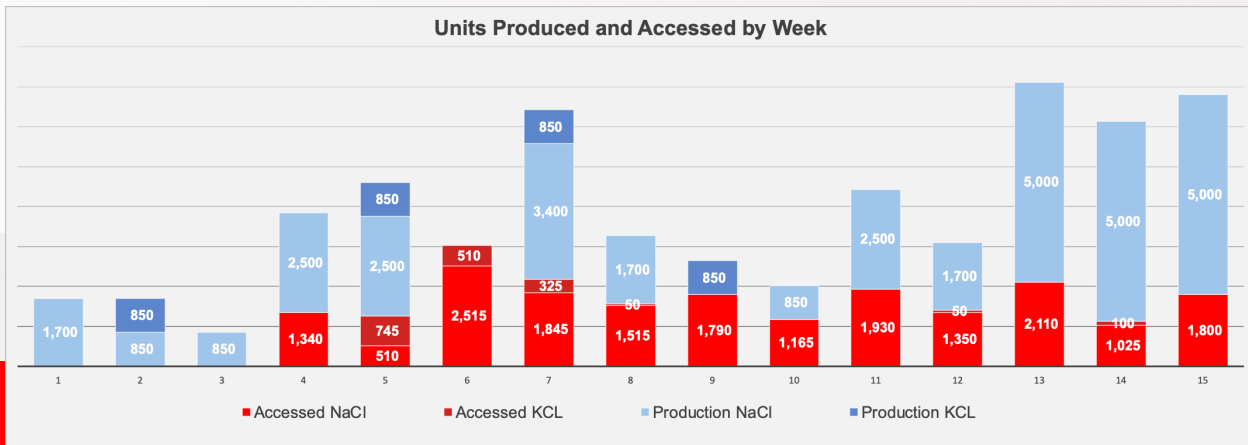
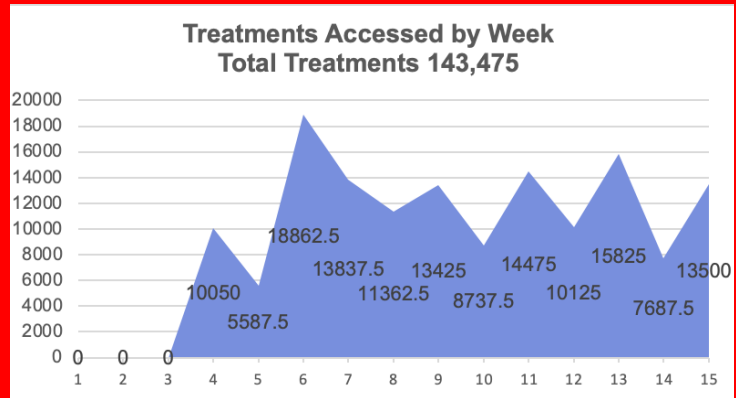
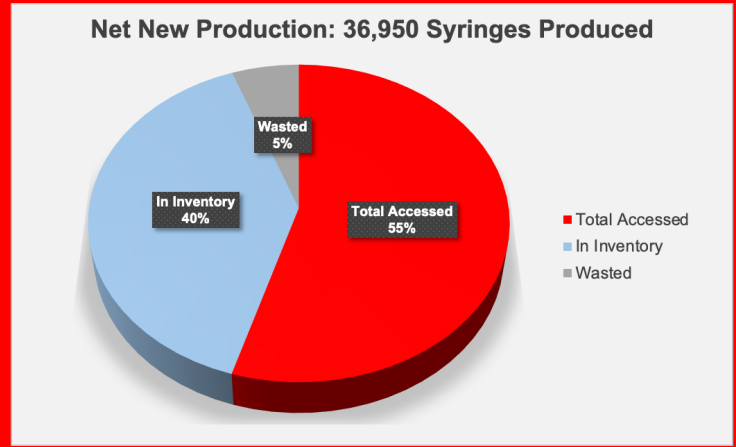


OUTCOMES & BENEFITS

The program showed that this public-private partnership was a fast, effective way to mitigate drug shortages. Within 90 days, STAQ Pharma manufactured **36,950** net new essential medicine units, distributed **20,675** units of the concentrated electrolytes and hospitals used these drugs to administer more than **140,000** life-saving essential treatments.

By providing hospitals with readily available medicines, the program:

- Enabled hospitals to treat tens of thousands of patients without delay or substitution.
- Allowed clinical teams to focus on care rather than searching for drugs in short supply or having to initiate complex and time-intensive mitigation practices.
- Provided medications as part of a nutritional care plan to babies in Neonatal Intensive Care Units (NICUs) who had to be fed intravenously at a time when their nutritional needs are higher than at any point in their lives.



“Angels for Change made this project possible by mitigating the financial risks of product development. Our employees found it really rewarding to know that their work each day was having a have a profound impact on more than 140,000 of the nation’s most vulnerable patients.”

-Mark Spiecker, President, STAQ Pharma

PROGRAM DETAILS



- Angels for Change contributed a grant of \$100,000 to cover about half of STAQ's expenses for formulation development, stability testing, initial manufacturing, and launch of the drug products, which is typically a 6-9 month, \$200,000 process.
- To expedite availability, the program featured shortened drug stability dates from the typical 90 – 180 days to as low as 42 days. This helped alleviate hospitals' concerns that products might not be available, which led to improved efficiencies in the ordering process while reassuring hospitals that they no longer had to keep extra drugs on hand in case of an emergency shortage.
- Hospitals in the program made a commitment to purchase three-week supplies of the medicines, allowing STAQ to develop a weekly delivery cadence with the hospitals and mitigating the risk that product would go unsold. It also allows for STAQ to stop production more quickly once commercially available product is back on market.
- STAQ was able to expand production and extend this program eligibility to additional hospitals outside of those included in the original pilot, including those that primarily care for adults.
- Shortages of 23.4% sodium chloride and potassium chloride occurred about six months after STAQ began product development, which enabled it to meet hospitals' pressing needs months sooner than what would have been possible without the pilot. For many hospitals, STAQ Pharma was the only source available to supply these drugs during this shortage.
- STAQ will cease production and distribution when normal supply returns to the market. The terms of the Angels for Change grant ensures that it will be ready to supply these two essential medicines during times of shortage through 2024.

“ Providing pharmaceutical care to children is a complex proposition that becomes even more challenging when not all therapeutic options are available. This program was a huge relief for our clinical staff.

Jerrold Milton, Chief Clinical Officer,
Children's Hospital of Colorado

ANGELS FOR CHANGE

WHAT IS NEXT?



The success of this pilot program points the way to developing practical solutions for the systemic problems that cause these shortages. Supporting 503B Outsourcing Facilities to be prepared to produce vulnerable essential drugs before shortages occur. Building partnerships between 503B Outsourcing Facilities, manufacturers, hospitals, not-for-profit organizations and others committed to stabilizing access to essential medications is a road map toward attaining true readiness to supply for all essential medications.

Angels for Change will expand the ideas tested during this pilot into a full program launching in the third quarter of 2022. Introducing project PROTECT: predict, partner, prepare. PROTECT is a proactive readiness program designed to build flexibility and resiliency in the supply of essential medicine vulnerable to drug shortage and work into end the damaging impact of drug shortages on patients, clinicians and many others in our healthcare system.

Another major step forward is Angel of Change's SummitONE, a forum where key healthcare supply chain decision-makers focus on creating programs to improve supply chain resiliency. The active involvement and support of all supply chain stakeholders will go a long way to resolving this public health crisis. The project team members of this pilot will speak and host a Question-and-Answer session at SummitONE on July 29th, 2022 followed by breakout sessions for industry input and feedback facilitated by McKinsey and Company.

"I am very proud of the work this project team accomplished in just a few months. It is amazing what can be accomplished when we work together. One thought keeps running through my mind, 'what would the last 90 days have looked like for patients, physicians, and pharmacists without the proactive work done in the pilot?' We can and we must do more!"

Laura Bray, Angels for Change, Chief Change Maker



To learn more about project PROTECT, go to angelsforchange.org
Join the Change Maker movement today!



CONTACT US

LAURA BRAY CHIEF CHANGE MAKER

LAURABRAY@ANGELSFORCHANGE.ORG

Cell: 352.200.0021 Office: 813.501.7742
2408 Fountain Grass Drive
Valrico FL 33594

www.angelsforchange.org

We founded Angels For Change after my own daughter's life-saving drug shortage while fighting leukemia. The feeling of hopelessness when she asked me, "Am I going die without my medicine?" is what drives our efforts everyday. We must fix the supply chain for today's therapies and tomorrow's cures.

Laura Bray, Angels for Change Founder

