



Podcast Transcript

Impact of the Infant Formula Recall

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Guests

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Transcript

Episode 1 Years in the Making

STEVEN ABRAMS (GUEST):. Babies, because they have decreased immune systems are particularly at risk for infections. There's one really bad infection that can get into the powdered formula, and it's a bacteria called *Cronobacter sakazakii*.

SOUNDBITE OF MUSIC

JANNAH AMIEL (HOST):Hello and welcome to this three-part podcast series about the impact of the infant formula recall on both parents and their babies. In the first two episodes you will hear from Dr. Steven Abrams and in the third episode, the impact on one mother and her son, Mason. Now, let's get started. Dr. Abrams, you're a board-certified pediatrician and professor, right?

ABRAMS: Yes. And I'm also a neonatologist. So clinically, I practice neonatology.

AMIEL: Fantastic. What else can you tell us about yourself? I know there's much more than that. I saw your CV. Come on. Don't be shy.

ABRAMS: Well, I spent my career doing research in infant nutrition, so I both looking at human milk as well as infant formulas, and then I've done a lot of public policy work at the real interest of mine, including being the chair of the Committee on Nutrition that the American Academy of Pediatrics, which is a position I just finished. And right now, I edit a journal, a book actually, called *The Yellow Book*, which is the American Academy of Pediatrics Guidelines for Infant and Childhood Nutrition.

AMIEL: Fantastic. That's excellent. So, I got to be honest, I'm going to open up this conversation. Right. We're going to talk about the core issue around this infant formula shortage. But, honestly and personally, as a nurse, just as a fellow human, this is like frustratingly insane hearing about the shortage and understanding truly the downstream effects of it. So, I would like you to first help frame up exactly what happened. Why are we here? What primarily caused this formula shortage?

ABRAMS: Sure. So beginning with the pandemic in the early 2020, we started to see supply chain issues of all sorts of things, paper towels and the like. And at the same time, we were also seeing some formula shortages. Instead of the shelves being full, they might have been a half full a quarter full. People were having trouble getting formula supplies and getting it into the stores. That got better and 2021 and people kind of forgot about it.

Then the 2021 supply chain issues popped up again. Even if you go to the store now, you see shortages of breakfast cereal and all sorts of things like that. But then we had a big disaster. In February of 2022, one of the largest producers of Formula in the United States, Abbott, which is a factory in Michigan, a place called Sturgis, Michigan.

That factory had a major recall and shutting. And that was just, kind of tips the whole thing over the edge. And in particular that factory made specialized formulas. That's formulas for babies with severe allergies, babies with intestinal diseases, and it supplied those throughout the world. So now we did we not only have a shortage

of regular formula, but then we had this shortage of these specialized Formulas babies have to have to live and grow. So it's all spun out of control. In early 2022.

AMIEL: And the last 48 hours. You know, the funny thing, before we have done it, when I was thinking about this conversation we were going to have, it was in the past tense in my mind. But in the last 48-hours didn't I just see something on the news about a shutdown again, or recall? What, we're here again? Where we at now?

ABRAMS: Yes. So, the factory in Michigan had closed, was reopened about a week and a half ago, June 4th [2022]. And then there's a big storm in Michigan on Monday, and they got some water damage in the factory, and they've closed it down again. So that factory was only going to be making the specialized formula, all the amino acid-based formulas for a while. So it won't affect the main formula production, but it sets those specialized formulas back even farther.

AMIEL: Yeah, and that's a problem. So let's talk a little bit about, let's try to frame up production, right. And regulation. So in the way of supply chain issues, I think we can put that aside for a second. But in the case of the recall where the formula had to be recalled, there was something wrong with that. Right? What's that process look like? Who regulates that and who says, now stop, we're bringing that back?

ABRAMS: So infant formula is the only food in the United States that is regulated by law. So, this law called the Infant Formula Act of 1980. And that law was put in place because in fact formulas were not regulated beforehand. And people actually released the formula with very low amounts of chloride in it and they're trying to limit the salt, and babies are terribly damaged by it. So the FDA regulates all infant formula, and they do that based on this law called the it's the Formula Act of 1980 as amended in 1986. And it's very detailed and it provides not only what should be in formula in terms of the basic components but also the FDA then has all sorts of rules about supervision of the manufacturing, shipping, the importation, how they regulate new formulas on the market. So, the system is virtually entirely controlled by this law, then is executed by the FDA.

AMIEL: OK, how did we come to know then at this point with the recall that something was in fact wrong? There was contamination, there was an issue, how did we get there?

ABRAMS: So how their infant formula is not sterile - you can't sterilize it in a big sterilization system. So liquid formula is sterile before it comes out of the factory. It's run through a sterilizer just like we would sterilize things in a hospital. That can't be done for powder. It would destroy the powder. So, in order to make sure the powder is safe and doesn't have bacteria in it, they rely on all sorts of safety things, cleanliness, wearing caps. It's like a pharmaceutical system of super cleanliness.

Babies, because they have decreased immune systems are particularly at risk for infections. There's one really bad infection that can get into the powdered formula, and it's a bacteria called *Cronobacter sakazakii*. And it used to be called, you may hear it called, *Enterobacteriaceae*. But the current name is *chronobacter*. And *chronobacter* causes severe, severe neurological disease and brain damage, mostly in babies who are either immunocompromised or born prematurely or less than about two months of age, especially under the first month of age.

And sometimes it can live on a countertop. That's why we tell Mom, make sure you're using clean water when they prepare it. And sometimes it can be in the powder formula. So, the factory in Michigan has some cases in which babies who received formula from there, got this bacteria. And when the FDA investigated, they found this bacteria in the factory.

Now, it's a matter of uncertainty whether or not this was a cause and effect. But nonetheless, the FDA had enough concerns that they asked the formula company to take some intervention. The formula company then

made a recall of all the formula that come from that factory and closed the factory down. After three months the FDA and the formula company came to an agreement on reopening it, based on improving that situation. But now we're in a situation where it's closed again.

AMIEL: Yeah, here we are. Were there infants that were affected by that, by the bacteria?

ABRAMS: There were several infants that had the bacteria who were taking formula from that factory. It's in some area of contention whether or not that was a cause and effect, whether or not that's where they got it from. But nonetheless, there were some babies that did get *Chronobacter* and some of them had bad outcomes.

AMIEL: Yeah, I can imagine that. So you mentioned specialty formulas, that being, you know, one of the things that were really affected, right. So something that that really sits the top of mind for me when I hear about this is who is most affected by the formula shortage? So specialty formulas I think about, you know, I'm a nurse myself.

Pediatrics is my clinical specialty. I think about the babies in the NICU, right? I think about those who really do require specialty formula and remembering how wildly important nutrition is to babies and kids in general. And then I think about community. I think about low income. I think about folks that already are experiencing a huge gap in health care and resources. Where are we with them as far as this population?

ABRAMS: We've, you've gotten a lot of the topics that are really at the heart of this. So let me kind of deconstruct that a little bit. First of all, specialty formula. So the most specialty formulas are used for babies who have severe intestinal disease or severe allergies. And the most broken-down protein formulas are called amino acid-based formulas.

The largest supplier in the United States was a factory that closed. There are alternatives around the world than in the United States, but they couldn't fill in the gap. So, there's been a huge crisis for those babies with severe allergies and intestinal disease. Same thing for babies with severe renal disease. And the same thing for babies with very rare inborn errors in metabolism, like in Phenylketonuria.

So those formulas were all made at that factory and all got recalled or shut down. So that was, that was a big problem. So that's one issue. And there's, we'll talk about the importation of formulas was particularly designed to respond to that. That we'll come back to that in a bit. But in terms of the bigger question, you're absolutely right.

This has been an unfair, non-equitable problem in our society. The reality is that in order to find formulas, families are driving for hours, they're searching out formulas, they're buying more expensive formulas than they might have otherwise bought. Unquestionably an equity and social justice kind of a problem. Families who are lower income can't. The other problem is the WIC program. About half of families, including many of our lower income families, get their formula supported from the WIC program.

The WIC program is called the Supplemental Program for Women, Infants and Children, the Special Supplemental Program for Women and Children. And it provides about half the formula used in the United States and for the [inaudible] families. About three quarters of their formula need. That formula works by contract. So, the company that had had the problem and the recall provided a large portion of all of that formula in the WIC program in the whole country, almost half of it. That caused the problem.

So, WIC people did an amazing job. And the WIC program was also dealing with the consequences of the pandemic and trying to deal with getting families signed up on WIC and all that sort of stuff based on the challenges of the pandemic. So, WIC had to reengineer its entire system to allow alternative company formulas.

And the United States Department of Agriculture, the USDA, manages the WIC program, and so they had to give permission.

The WIC program works on a rebate. The company that has the contract basically gives it away to the US government almost for free. OK, but the other companies don't. So, they cost a good bit of money. But we've had to make alternatives and the WIC program normally limits the size of the containers you can buy and all sorts of stuff of that sort. So, all those adjustments have had to be made for lower income families. In some cases, even families for whom it's been a real struggle had to go out there and buy their formula, which is, can be challenging.

AMIEL: Absolutely. You know, this may not be a Dr. Abrams question, but we keep talking about this single factory, right? Not to call out just a single factory, but I keep thinking, why do we have a single factory that produces so much of the formula that we rely on? And if that system fails, we, doesn't sound like we have a great backup.

ABRAMS: Well there are about 20 factories, but some of them are fairly small. And the factory that went down was one of the biggest. These factories are very expensive. There again, they're like pharmaceutical manufacturing factories, and they cost a lot of money. In fact, recently a very small new factory was opened up by a small company that's making kind of a specialty niche formula, a super organic kind of formula. And they claimed when they opened it a few weeks ago, that was the first new factory opened in like 15 years in the United States. So, it's not you can't make these at the same places that you're buying your Cheerios at you know. You're not making those at the same place or level. I mean, again, it's much like making drugs in terms [inaudible] and they're expensive. And then when something happens like a rainstorm that was big, and it caused a leak.

And again, think about sterility. Imagine if you're working at a hospital in an ICU and there's a big leak in the ceiling what that would do to all your sterility. It just so the same thing kind of happened. And that's what causes the problem. Going forward we do need to do something about that. I mean, there's that's a problem.

AMIEL: Yeah, absolutely. What about that? The importing you mentioned, that we're importing formulas or contracting with other companies.

ABRAMS: Sure. So, when it became clear that we were really having severe shortages, you know, shelves were empty. The United States Government has created a system by which they're allowing the importation of formulas. Both from the three largest companies that currently work in the United States, which is Abbot, Reckitt Mead-Johnson and Nestlé Gerber, as well as some new companies that not previously been seen in the United States.

In particular, too, as of today, mid-June, have been allowed permission to enter the United States that were not here before. One from Britain called Kendamil and the other from Australia called Bubs. So those formulas are being flown in, some of them by military craft, some of them by civilian aircraft. And they're begun to reach the United States.

I was just told yesterday that the very first of the English formula, the Kendamil was seen at Target. So, them and the other company have made deals with Wal-Mart, Albertsons, Kroger's, many more, I'm sure, in the process. So they're trying to go after the big name places where available as much as possible. Yeah, broadly, and all what is the society to get these distributed.

So that's a big deal. It'll help, but it's taken some time. They announced the permission to import formula almost a month ago and it's just now getting out to the store shelves.

AMIEL: And what's that mean for us in the United States? So, thinking about our regulations and policies like we know our stuff here and how and what we're looking at and how we manage that, but it's coming from somewhere else. So how do we get those things to sync up?

ABRAMS: The first thing to know is that the formulas are coming in from the United Kingdom and from Australia. Our fabulous formulas are completely safe. The agencies which regulate those in Europe and in Australia are sensational agencies. There's nothing to be concerned about. They're every bit as safe as anything you'd buy in the United States. So we can on the other hand, they do things differently there. So some of the nutrients, are a tiny bit different, they're label differently, and the scoops may be different.

So, for example, we tend to scoop in ounces, right? Two ounces a scoop. They don't do ounces in many of these countries. They do milliliters. Now, nurses are used to using milliliters all the time, but families are not. Just as we're used to translating for families in a pediatric setting mls to ounces for their use, we're going to have to do that.

We're also have to make families read the label. It's not always two scoops to an ounce or a scoop to two ounces, which is typical in the United States. Some of them are one to one. So, people have to read the labels. Pediatricians, nurses, dietitians are all going to have to help families understand what a millimeter is, how the label is going to look different. But but they should not be concerned about seeing new brands.

That's a that's a good thing. One other thing. One other thing. They agreed through the importation, a formula made out of goat's milk. We've never had an infant goat milk-based formula. Europe and Australia and other countries have had it for a number of years. Some people feel that babies like goat milk better. I'm not convinced, but, you know, it's an option.

So you may see a cute little picture of a baby goat on a can and they'll say goat's milk-based formula. And this again, these have all been approved by the authorities in the country they come from, and the FDA has looked at the data from those countries and agreed that they're safe to use here in the United States.

AMIEL: OK, well, I like goat cheese, so I'm not mad at that milk option. But let's talk about how they are prioritizing that. If if they are. I'm just curious, if we think about an infant population in here and we think about who is at most risk and we have to prioritize, or we've got to triage, like who gets the formula first, what are we sending first? How do we do that?

ABRAMS: So they then prioritized the importation of some of these amino acid formulas first. Nestlé in Europe had a supply that they shipped over that's reached the United States. So those have been prioritized. That's just such a crisis for those families that can't get those. They're also trying to make some dealings with some of the other specialized formulas the metabolic formulas of that sort.

After that, it's really what they can get. Again, the three companies who primarily operate in the United States, which is Abbott, Reckitt Mead-Johnson and Nestle Gerber have all agreed to increase their imported formulas including importing from countries that they didn't usually import from before. So that meant the FDA had to give them permission to use formula.

So, ones coming in from Singapore, another from Mexico. Again, these are all companies with a tremendous background of producing formulas. So, there's not a safety concern. But they did have to get permission to do that. So, companies themselves are responsible for distribution with some help from the US government, and that's why they're trying to target some of these big stores so that families can shop with all sorts of different stores to find them.

AMIEL: Yeah, one of the things that I saw a note of, and I was telling you this before we recorded, on my shelf right at the grocer, I see all sorts of new milks all the time. Me, I like oatmeal. So I'm always searching for different types of milk. And A2, I see an A2 milk on there. But it's just next to regular milk I would use for cereal, but I'm reading that that is an infant formula brand or something like that. What is that?

ABRAMS: So A2 Milk is milk made from cows who produce a special protein that's a little different from the routine protein called A2 milk. Most cows produce two types of protein. A1, this is the casein, A1 and A2 casein proteins. Cows, if your A2 milk is only A2. There's some limited data, very limited data, that some adults tolerate it better that don't have as much upset stomach etc.

There's no data on infants at all. Nonetheless, some of the formula companies have kind of gone on the bandwagon and are making their milk either from the A2 cows, including one of the companies that's importing. Bubs from Australia uses a lot of A2 milk. I don't think there's any evidence it's any better, but if you see it on the can, it says A2 milk. And like what the heck is A2 and milk, and so on. For for the routine consumer again, there's some people who tolerate. There's a sense that they tolerate A2 milk better, adults and older children. I'm not convinced, but that's yeah, an individualized issue.

SOUNDBITE OF MUSIC

AMIEL: In this episode we heard about the complexity of events that led to the infant formula shortage. Infant formula is the only food that is regulated by law. Because of this, the government, in the form of the FDA, had to intervene to permit imports of infant formula from other countries. Included in those imports are goat-milk based products. Parents may see a goat on the can of formula on their grocer's shelf that was not there before.

Please join us for the next episode in this podcast series when Dr. Abrams talks about how families have been coping with the lack of nutrition for their babies.

This is Jannah Amiel for Elite Learning.

SOUNDBITE OF MUSIC

Episode 2: **Benefits and Hazards**

SOUNDBITE OF MUSIC

JANNAH AMIEL (HOST): Welcome back to the second episode in this podcast series about the impact of the formula recall. I am Jannah Amiel with Elite Learning. In the first episode Dr. Abrams addressed the issues that led to the shortage of formula in the United States; supply chain issues that resulted from the pandemic and the closure of one of the largest factories in the United States that produced specialty formula for at-risk babies. In this episode, we will explore what steps are being taken to help ease the burden of the shortage on parents.

SOUNDBITE OF MUSIC

AMIEL: OK, now on a personal note, my cousin just had a baby and she's.

STEVEN ABRAMS (GUEST): Congratulations.

AMIEL: Thank you. Thank you. We're all wildly excited about it. And one of the things too, that we you know, me personally as a nurse, as, as a just a family member, she's adjusting to becoming a new parent. She's enjoying the new baby and all the things that come with it and also has to think about am I going to be in trouble, right.

For with this issue, am I going to run into a problem. And I don't know that I feel like I'm fully equipped to talk about what she can do. So, for the folks right now that are thinking about alternatives, or they really might be the stuck between a rock and a hard place and trying to figure out what they can give to their babies.

I've read, and seen, and heard a ton of stuff of all the things that you can do, all the alternatives you can feed to an infant. But I imagine that not all of those things are safe. So, can you talk a little bit about that?

ABRAMS: Sure. For new moms who are willing and able to, obviously breastfeeding is best. But we don't want moms who are unable, or have to go back to work, or who for breastfeeding to be successful, to feel that they're anyway harming their infant, they're not. With no guilt whatsoever. So, we do want to focus on making safe formulas available. There are some things where they're clearly not safe.

The single thing that we focused the most on, it's not safe, no matter what you read, is making your own formula at home. I can't emphasize enough that we need to educate families not to make formula at home. There's lots of reasons for that. We've even had reports of babies being hospitalized because of homemade formulas or having cases that the CDC has reported that babies had hypocalcemia and seizures from from these homemade formulas.

I don't care if you read that your grandma was raised on it, your mom was raised on it, and your 19 cousins were raised on. It's not safe. It's all that they had back 50 years ago. But even if most babies do well on it, significant number of babies won't. Do not make your own formula to matter what you read online. It's not safe. And no matter what you read. The other thing and families just need some education, it's hard for families to sort out what they read online. And sort them out. Now then in terms of alternatives. Now, first of all, right now I think we're in a situation for the most part are not finding any formula, though, is becoming less common.

We're beginning to get over the hump now. That doesn't mean it can't still happen, but we're beginning to get over the hump. And I think by the you know, the end of June, July, we're going to see less cases of absolutely finding no formula. But the first thing is to be very flexible on brands. The overwhelming majority of not severely allergic babies will tolerate most of the formulas that are out there, although they may have a preference for one or the other. But if you're just patient, you know, give them a day or so to get used to it, most of them will do fine on almost any of the routine formulas. Despite what you read, words like sensitive and gentle and pro and all those sorts of things. Those are advertising terms. They don't tell you anything about a formula being better. Don't believe it, OK. Let your baby use what you can find, what you can afford, et cetera. Now, when there's a time when there is no formula at all, through the American Academy of Pediatrics writing in something called Healthy Children.org, which has a lot, which is parents facing website, which is a lot of information, some of that prepared for them.

We did say that for babies over six months, for a few days, for a week, you could use whole cow milk. We don't think that's ideal, but for the older infants, it's OK. As babies get over nine-, ten-months of age, it's a little bit safer. You can use toddler formulas designed for babies over a year, again for short periods of time.

We prefer infant formula throughout the first year of life. But if you absolutely can't find anything, you have an older infant nearing the year of age, you know, a little bit of cow milk, a little bit of toddler formula will give them likely fine. Right now, I think that level of crisis is diminishing.

AMIEL: OK, very good. Are there benefits to some of these alternative formulas, like if we have parents that in one way are kind of forced to try a different type of formula that they weren't using before? Is there a benefit to that? Maybe so. It's not so scary to say you must switch to this, but there's actually some good for that.

ABRAMS: Maybe. Certainly, some babies like one formula or another. But I encourage families not to believe that the most expensive formula on the shelf is the best formula. All the formulas on the shelf, including those ones that don't have a brand name on them purchased from the store, are reviewed by the FDA. They all meet the requirements of the law.

Many of them have lots of really good things in them, like DHA and all that sort of stuff in there. So, find the formula your baby likes but don't feel like, you know, sometimes I hear parents say, Well, I stopped breastfeeding and I really feel like I want to use the very best hormones. I bought the one that was the highest price. Well, that's marketing. That's doing that to that. That's skillful marketing. That's the one that has the highest price tag. You don't need to do that if you want to. More power to you.

AMIEL: But not necessary.

ABRAMS: But it's not necessary. You know, make your own decisions but yeah, there isn't something about one brand, the formula that truly makes it something that this is the formula all babies should have.

AMIEL: OK, that's reassuring. Now, the American Academy of Pediatrics, they released guidelines, right? You spoke a little bit about, I think, cow's milk. That was one of the things that I had read as well. What other recommendations are they making? And I think it's important just to highlight that because one of the things I know that's super important for me as a as a nurse and anyone who's listening in our audience now, who works in health care and maybe is working with families with infants, we want to help.

Right? And it's not that we can just walk to the the the plant and reopen and start to mass produce. But we want to help and we want to guide our patients and we want to guide our community and family. So, talk to me a little bit about guidelines, recommendations about things that I can say to help.

ABRAMS: You know, we want people to be aware of community resources, food banks, WIC. You know, going to friends who might have babies are just almost of the year and saying, hey, can you switch your baby to cow milk a few weeks early? And let me have your formula, you know. I think, I think a lot of our families, especially families for whom being in America is new, Families for whom English is not a language they're comfortable in, can really have trouble.

And families who are financially challenged can have a real trouble manipulating the system. So, understanding that they do have friends out there, whether or not those friends are the nurses that they know, the pediatrician, WIC, food banks, churches and religious organizations, and the like. A lot of these places are in the Internet that's growing. And so, there are resources out there.

But we naturally, those of us who are comfortable in an Internet area, know how to access all these. But many families, especially those who are lower income, are not fluent in English. And that's a real challenge, you know, accessing these resources.

AMIEL: Yeah. So, we can definitely help in that way to guide them or get them connected maybe they don't know what they don't know in that way. You underscored homemade formulas, and I can't tell you how much I have read and seen of recipes to make your own homemade formulas online. And I'm hearing it even in health care circles.

And again, we must underscore how dangerous and unsafe that can be. But can you tell us specifically why someone's listening in right now? I'm thinking to exactly what you said. And I was guilty. I'm thinking about my mom and grandma using things that today is an absolute no no. But back then, we did it because that that was what they had available. But why why is that such a safety concern today?

ABRAMS: We do have to understand that things change. Most of us went to sleep on a stomach years ago. And we learned that that was a huge risk factor for crib death, and moved babies on their back and the instance of SIDs, it went way down. So just because it was good enough for your two generations ago through it again, the isn't isn't the right thing.

And I can tell of cultural practices, some of which you may be familiar with that we've kind of recognize and that not ideal that that may be so. So, we love grandma wisdom but not all grandma wisdom is is is ideal. So first of all, these homemade formulas really don't have the right mix of nutrients in them no matter what. Especially the ones, the worst of the ones, are made out of things like hemp oils and hemp and things, the vegan ones and things that they often lack even most basic amount of minerals that babies need. So, some of the online sites will say, yeah, it has plenty of minerals, but the baby can't absorb, can't use those minerals because they're not in the right form. When we deal with cow milk, even when you add vitamins, these formulas tend to be very low and usable iron. So, the biggest problem with cow milk or even base of cow milk, that's not formula is iron deficiency, which causes severe neurological problems and poor neuro outcomes in small babies cause that's when they really need the iron, in that first year or two years of life. And then of course, as the minerals with the case, I told you, rickets and hypocalcemic seizures reported by the CDC and others. And then there's just plain flat-out growth failure. Babies don't grow on these things. So yeah, most babies survived 50 years ago, but they are not safe.

And the biggest fear we have is that people will get put on these formulas. Some of them are cheap and money is an issue and they're going to say, well, yeah, my baby made it for a few days on this thing. Let's actually stick with it. And the longer they're on it, the more risks of nutrient deficiencies, growth failure, iron deficiency, anemia and things of that sort. So don't believe what you read all I can do is trust the 60,000 pediatricians, pediatric nurses, dietitians and the like who are telling you the truth.

AMIEL: They might know a thing or two.

ABRAMS: We hope so.

AMIEL: Now. So, for us that are working with patients directly, so working with infants, working with families. Are there things that we should look out for, let's say that if we're concerned that maybe this family is being affected by a formula shortage and that there is a nutritional deficit that exists. How are pediatricians assessing that and helping to manage that? How can a nurse like me be aware and observe for issues and deficiencies?

ABRAMS: With so many things, it starts with a good, non-judgmental history. Tell me how you're feeding your baby. Not you're not using homemade formula are you, kind of thing. Just like so many issues, we learn how to approach families in non-judgmental ways. You know, find out what they're what they're doing, and then of course, you know, the good education comes out physically.

We're focusing on and on growth and not just weight, because you can put a lot of sugar into a baby's feedings. You can give baby sugar water and make them fat, but their head is not growing. The length isn't growing. Make sure we're getting good measurements in the clinic. Of length with a length board done properly, not just, you know, the old tape measure kind of thing, you know. Proper weight and head circumference.

Plot that out on an age-appropriate World Health Organization growth curve, CDC growth curve, properly. So good assessment of the history of the of the anthropometric the growth. In some cases, especially if they've been on something that doesn't sound like it's right for a couple of weeks, you may need to check a hemoglobin or some ferritin or some marker of iron status.

Yeah, and on that clinical history and what they're telling you. We don't normally need to worry too much although we're always worried about infections. We won't routinely evaluate for sepsis or anything like that unless there's a clinical indication. On the other hand, there are still some cases of bacterial infection from contaminated formulas that could exist. So, a baby that's acting like he might be infected needs the same sepsis evaluation that the other baby does.

Infection of a Cronobacter is not federally reportable as a disease. So, we need to make sure if one does hear about the case of the Cronobacter that we remind the caring physicians that that should be directly reported to the FDA and the CDC. Again, you know, we would think, only one state in the country has this as a reportable condition. We're trying to get that law fixed, but it's not reported that by law. So, you know, there I think there's a lot that we can do. And I think supporting parents in appropriate choices, sympathizing with them that, oh, my gosh, I had to drive an hour to find formula. And reassuring them that it is getting better and that will continue to get better if they kind of hang on with us and work through it rather than making a bad health choice.

Yeah, things will get better.

AMIEL: Yeah. And I imagine some of that comes from panic, right? I myself am not in charge of having to feed an infant but I imagine if I was and listening to the news and reading what's out there, that might make me panic a little bit. And then that's I think, where we kind of make bad decisions in that way.

ABRAMS: Right?

AMIEL: So where do we go from from here? We know what the issue is that we've had with our plant. We know that we are importing, we're teaching our community, our families, everybody right the right things to do in this type of scenario. But what happens next year or the year? After that? Are we going to be in this scenario again?

ABRAMS: Well, that's a great question and this worries me a lot and I've written some things about it because it does concern me that our short-term solutions, aren't long term solutions. And let's face it, we tend to think of short-term solutions as a society and then the government and the like. We don't tend to think of long-term solutions.

So they allowances for imported formula and the flying in, flying around, all that sort of stuff only lasts through November of this year. Now, I'm hopeful that the factory will up running full speed, we won't have any trouble in November, but I'm not convinced of that. So, I think that we need to be advocating for a long-term solutions. I think we need to open up the marketplace.

This is a lot more than three companies that are primarily operating. Actually, there's four because the [inaudible] some very small companies. We need to make it importation friendly for some of these companies that are making goat milk formula. If it was safe in 2022, it'll be safe in 2023 to bring these formulas in. So we need to advocate that. We need to look at how the WIC program operates and make sure that they're flexible and able to deal with shortages. We need to hold companies accountable so if they have a problem with manufacture, it's immediately known, and the public is made aware, and the government immediately steps in to provide supplies. So, Congress is looking they are holding hearings that continuing the hold hearings are working on legislation.

But I think we as the public also need to be advocates for our children. As always and pay attention to what's going on in Congress and elsewhere to make sure that the things that are being done are out there to provide a long-term, not just short-term solutions.

AMIEL: Yeah. You know, let me ask you this, because I didn't I didn't ask you before. This sounds novel to me, this shutdown. Right this this issue of formula shortage. But has this ever happened before?

ABRAMS: There have been recalls and there have been factory problems before. But nothing on this scale, nothing like this. The last major recall is about six, seven years ago. And even that wasn't anything on the scale of this recall. So, there have but there have been problems. At this level, and I really think it was the combination of the pandemic and all the challenges related to getting supplies to the formula manufacturers that they could make formula, produce, and ship it out, get it distributed. Combined with this, that sent us off into this panic but we we've had challenges before, but nothing at this magnitude.

AMIEL: Yeah, it's quite, quite large. Now, one final thing, and I had a note about this yesterday and actually came through was a former patient who was asking this question about giving babies water. Right. And I want to make sure that I just took the time to answer this question live. Right? Because, of course, some of this just comes from so much of what we're hearing.

And I get it, we have to collect our information from somewhere and it's difficult to sift through here. But, you know, in the same that same vein of what we can do, someone's maybe thinking, oh, my gosh, I can't feed my baby. But if I fill them up with water, you know, they feel comfortable. They're not whining anymore for food.

ABRAMS: So first of all, I again encourage people to send families to [healthychildren.org](https://www.healthychildren.org). We have articles about all of these things. They're they're written for families, all translated into Spanish and sometimes in the multiple languages for families. So, we're where we're trying to be, you know, inclusive in that in that direction. To specifically answer your question, in general, water is not recommended for babies under six months of age. That in the first six months, babies should only be being breastfed or getting formula. After six months of age, small amounts of water.

OK, but we don't ever want families to do is over-dilute the infant formula at any age. All that's going to do is cause hyponatremia, low sodium, or or just plain growth failure. So babies cannot adapt to having formula over-diluted. So a small amount of water, especially as we go into the summer months for older infants, as they get closer to a year, is fine. There's some guidelines, you know on [healthychildren.org](https://www.healthychildren.org), other places on how much to give, but fairly small amounts. No juice in the first year of life. The AAP came out and I strongly support that. No juice in the first year of life. Solid foods get started about six months of age. You can certainly use that to help fill the baby up. Sometimes you'll start a little bit before six months if the baby seems like they're ready from all the cues that they give. But the general guidance from the World Health Organization is about six months of age. But some families start little bit early on that. Solid foods don't replace formula. They're they're in addition. But water, there's no indication for using water in the first six months, but after that, a small amount of water is generally OK. Any questions call the pediatrician. They handle these questions morning, noon and night, especially nowadays. Again, they're dealing with all the time. So as a family being communication with your health care provider.

AMIEL: Excellent. Excellent. Dr. Abrams, thank you so much for all of this information. This has been fantastic. Is there anything that you want to leave me with, leave our audience with? I hear, [Healthy Children.org](https://www.healthychildren.org) is a fantastic site, parent facing. I've been on there myself. It's super easy to read and understand. Any other resources or just kind of last pearls of wisdom right now in this kind of scary and frustrating time.

ABRAMS: Sure. We're trying to solve a formula shortage by giving families more support. But I don't want us to forget supporting breastfeeding or supporting breastfeeding moms and families, especially those working moms, working families where going back to work six weeks after you give birth and then trying to pump and take care of your baby is challenging. So, I think that this is also a wakeup call to our society. I have no qualms about saying that. That we need to be supportive of breastfeeding moms and families who wish to breastfeed for as long as they want to breastfeed to meet their goals. And we need to make the workplace breastfeeding friendly. We need to make our society public breastfeeding friendly. Every state permits public breastfeeding but try doing it. And, you know, and you're here now.

So we need to take this opportunity to make our society friendly to families, friendly to lower income families, highlight the working families that need this kind of support.

AMIEL: Absolutely. Thank you so much for joining me. You've been a fantastic guest and I'm smarter than I was an hour ago.

ABRAMS: Thank you so much for having me.

AMIEL: Thank you. In this episode we heard Dr. Abrams discuss the shortage and the impact of homemade formulas on babies, some of which have dangerous consequences.

In our next, and final, episode in this series, we will hear from a mother whose son's specialty formula was impacted by the shortage. Please join me.

This is Jannah Amiel for Elite Learning.

SOUNDBITE OF MUSIC

Episode 3: The Lasting Impact

(SOUNDBITE OF MUSIC)

JANNAH AMIEL (HOST): Thank you for joining us for the final episode in this series about the infant formula shortage. In the first two episodes Dr. Abrams, board-certified Pediatrician and neonatologist. He described how the regulation of infant formula is controlled by the FDA, the role of the WIC program, and the factors that impacted the formula shortage. In addition, he discussed the importing of formula from other countries and how we might see formula that is goat-milk based versus cow-milk based. We discussed what A2 milk is and the impact of feeding homemade formula to babies.

In this episode we are joined by Shelly McDonald. Shelly is a nurse, but also a mom to her son Mason. We will hear her story and the impact the formula has had on her and Mason.

SOUNDBITE OF MUSIC

AMIEL: So, Shelly, can you tell us a little bit about yourself?

SHELLY MCDONALD (GUEST): Sure. I am a nurse. I used to do some experience in women's health and dialysis and then moved over into an education role a few years ago. And I am, as of a year ago, a recent first-time mother as well.

AMIEL: Congratulations on that. And new time mother and a nurse. So big bonus, to you. Now, let's talk a little bit about. Yeah, no kidding. Let's talk a little bit about your experience as far as just being a new mom, specifically Mason. Right. So, talk to us a little bit about Mason joining us here and what that experience was like for you.

MCDONALD: So it was a high anxiety, high stress. A lot of struggles to get to this point. It took about five years before we were able to get pregnant with Mason and so very draining experience, but huge blessing once it did happen. And he's my twin, for better or for worse, acts just like me, has my personality, has strawberry red hair that he got from from his father.

But that's that's about it. The rest is all me. So very very happy that he's here and that I get to be with him as much as I do. He did get excited to come early, though, and ended up coming around 37 and a half weeks. So, he was a little bit premature. Not not severely, but a little a little young when he came out. And that did take a toll on things when we were getting started for parenthood.

AMIEL: Yeah, I can imagine that. And then, you know, really, I want to kind of focus in on that for a second, especially as we talk about the impact of the infant formula recall and the shortage that's happened. So, with Mason being born early what complications actually were happening? Did you encounter, did Mason encounter, as we really think about how important formula was to him.

MCDONALD: So, my own medical issues that I had going on, I wasn't able to breastfeed. I, I was going through some cancer treatments at the time and so that was not an option for me. Formula was the only option. And so as soon as he came out, we, we tried bottle. We tried the, the formula that is standard at the hospital, the Similac formula, and he just wouldn't take it. He was very sleepy of course, and we did all of the things to try to stimulate him and make sure that he was able to take formula and it just wasn't working. The first few hours after he was born, and shortly after that, they came in to take him to the nursery just for a well-baby check. Let the doctor see all of the babies that morning.

And after they took him, he never came back to my room. They tried to feed him in the nursery and that was when he was probably about 12-hours old. And the doctor said, OK, we're going to send him to NICU. And that was very difficult. They did a NICU admission, and I didn't get to see him for about eight or nine hours.

So it was it was very hard to know that he wasn't getting what he needed and I couldn't provide him what he needed, and I wasn't going to be with him. So, once we finally got to go see him, they ended up putting an NG tube in, or the tube that goes from the nose down into the stomach, so they could get him some sort of nourishment and calories.

And we started working with him, and he ended up in the NICU for a week. But we worked with him on trying to get him to learn how to take a bottle. It's funny now with how much he eats, looking back and saying, we were just trying to get him to take just a small, tiny amount, any amount, and these little goals that we had set day in and day out.

And he started to take it. He started to thrive. We were very blessed with being able to watch him meet all these milestones. And after about a week in the NICU, he was sent home. But we still struggled at that point. We used the formula that the physicians had gotten him on, the Similac Sensitive. We used that and kept him on it, and we noticed things that were really painful, were uncomfortable to him. He had excessive gas, he had constipation, he had bad reflux. He would spit up terribly. There were some instances of vomiting. And so we started the journey of formula hopping which is very time consuming. Because you can't try one thing one day and try one the next day because it's still in their system and you have to know which one's actually working which ones not. And it took months, and it took about nine different formulas.

And of course, my special little guy that we waited so long on, ended up on one of the most costly, most hard to find formulas. So much so that I ordered it from the supplier directly and I would get a few canisters at a time, make sure that we had some on hand.

And it finally it finally helped him. But we went through so many, some that even cause projectile vomiting. And it's very interesting to know that he struggled with so many different types because people assume you just give a baby formula and they go and they take it. And he had so many issues from the beginning that that was not our journey.

It really was trial and error until we found something that he could tolerate, something that he would take, that he wouldn't spit out or that he wouldn't try and get away from, and that he enjoyed drinking. But also, that didn't cause all of these other issues that we were saying.

AMIEL: Yeah, and then this is just to frame it up. This is before the shortage, the conversation. Now this is before shortage, right? This is before the recall. This is just you, new mom and Mason trying to figure out what works best for him. Now, you mentioned having to order it directly from the manufacturer. You mentioned about pricing. Talk a little bit about that because you're right in what you said, you're right.

There is this like misconception that we can just give babies whatever milk product is available, but it's not quite like that. Now, I feel like you're in a different position in the sense that you're a nurse, right? So, you might have more knowledge and more access in that type of way, but you're still a human being and a new mom who's trying to do the best thing for the baby.

So how how much did that impact you just even from a financial standpoint, even from just making sure you have enough? What was that experience like for you?

MCDONALD: So I'm very blessed that I still was able to work and do all of that through entering motherhood. And so I knew what it would cost once we moved over to this formula. But that was by far, that was more expensive than diapers and wipes. That was the most expensive part. And I didn't have the option of breastfeeding and I didn't want him to be in pain or uncomfortable with all of the others that we tried.

So this was the only option. And the good thing about having to buy it from the supplier was that they gave you a small discount to do so, but it definitely was something that every month it's thinking about, OK, if I'm going to order this much, this is how much it's going to cost. This is what we're going to see on the bills and make sure that we had that at the forefront of our minds. It is always something that I tried to prepare for and tried to make sure that I was ordering it, that I was keeping up with it, and that we had some in the pantry ready to go because I knew this was his only option. This was the only thing that was going to work for him.

Even when we started seeing that he was getting older, transitioning to solid foods, he was a little bit slower to do that, too. He didn't take to it right away. He didn't want a whole lot of solid foods. Very, very picky. Like a lot of babies are. And so we still needed that formula. As he's continued to grow, that was where he was getting his calories. So, we had to be very cognizant about how long it was going to take to ship it and get it to us.

And we got in the routine. And all of this with the shortage kind of threw a wrench into those plans. And our routine is no longer the norm.

AMIEL: Yeah. Let's fast forward to that point. So, we've been talking about pre-shortage, right? And now thinking about now the recall, the shortage happening in May, since on this very special formula that he needs now. Now what would you do then?

MCDONALD: Panicked.

AMIEL: Fair. Fair.

MCDONALD: And I thought maybe it would be like some of the other shortages we've seen in the supply chain where people were freaking out for no reason. And I also thought in my head, well, I order it straight from the supplier. This is a special one. It's more costly if they don't need it, they're not going to buy this formula.

And I was very wrong. I ordered another supply, our normal amount of supply, and the next time I thought, well, maybe I should go ahead and stock up on one more. Maybe this is something that's about to impact us. He wasn't, I think, but maybe nine, nine or ten-months at that point. We still had a few months of definitely needing to keep him nourished through this.

And I looked and the supplier was sold out. And I looked on Amazon, I looked on Walmart's website, I looked on all of these other places that you might be able to get something shipped to you. And it just wasn't there. It, the supply chain had taken it away. They weren't making that one. Or what they did have was, was already bought out.

So I panicked and I think a lot of it might be owed to nursing background or mother's intuition and started trying to figure out what's plan B. What can we do instead of? I know he still needs this. We tried sipping a little bit on whole milk and maybe thinking about transitioning to that a little early, and he just wouldn't take that either. He didn't have the taste for it. It was going to take longer to transition into that than what we had timewise. So, we spoke to the pediatrician, and I said, I did find a toddler formula. It's not an infant one. I know it's different with the calories and what's in it, but this is what I found. Can I use this instead? It's supposed to be somewhat equivalent to the one that he's been on that he's tolerated well. And he said, try it. That's that's completely fine. So, I did I bought a can or two of it. We tried it. We slowly moved him over to it, mixing it with what he was originally on, and he did OK with it.

He had a little bit more gassiness, a little bit more fussiness. But overall, it wasn't nearly the experience like what we had right after he was born, trying to find a formula that works. And I thought, OK, good, we'll just continue with this formula. And sure enough, I guess that caught on, and that one was off the shelf.

AMIEL: Oh, no. No, no. Oh, no. So, and then what? So now you're like, OK, so now we're in [plan] C.

MCDONALD: Yeah. So, I was able to find a few more cans online that I got shipped to me. And around that time we just said, we're going to have to do something with milk. And we were very lucky that this happened when he was a little bit older and his his body was ready for milk and he could make that transition because there were lots of friends of mine that are not as far along in that process of the first year.

MCDONALD: And they're doing what they can. They're doing the best they can, transitioning very early to regular milk, which hopefully the babies are tolerating. But we started mixing it and rationing it a little bit and making sure that we didn't just shock his system with 'here's milk', take this, and that's it. So, we started mixing it in with the formula. We did have checking the stores and the websites regularly to see if there was any more in stock that I could swipe up and get and moving him over into more of a whole milk traditional type of drink. As we tried to get off the formula a little bit, sooner than what we had planned.

AMIEL: Yeah. You know, I want to underscore two things as you're saying this. So, one I think, you know, thinking about our audience and everyone who's listening and even us right now, we're both in the health care field, right? And we know enough to say we know it's super important for infants and babies as they're growing to get the right nutrition right.

They need that for healthy growth and development. And that seems to have been the focus. Now, when we talk about the formula recall in the formula shortage, we're very focused on the infant. Very focused on making

sure that we're taking care of their needs. That's a priority. But as I'm sitting here talking to you, and I'm thinking about even some of my friends and family members that are first time moms right now, there's also a whole entire component that we don't really talk about. You are a first-time mother really going through a real thing of trying to find food for your baby.

And so that in and of itself also is part of the downstream effects. I think in my opinion, when we talk about the formula shortage, yes, it will directly impact the infant who requires this this nutrient, this formula. But what about what about you? What about Shelly, who's running around trying to figure out how to do this? Personally, did that weigh heavy on you? Did that feel at times like, I don't know what's going to happen. I'm not sure if I'm doing the right thing? Like what was that experience for you? Because I can imagine and I'll just say I'm not a mom, but I have a dog. And if I can't find dog food, I'm already up to here.

So, what is that? You know, what is that for someone who really is taking care of of another life? How is that for you?

MCDONALD: It's stressful for a baby that young. You can't force them to eat it. You can't say, well, then go to bed hungry. You can't do that with them. And so it's stressful. You feel like a failure. You feel like you did something wrong even though you had no impact on the supply chain. You had no impact on this happening.

And all of the shortages that we're experiencing going through, it's very hard to read on social media. Well, why didn't you just breastfeed, or you should have done that, or saying well, why don't you breastfeed now? Well, that's not how that works. But there's a lot of individuals that aren't taking it to consideration those other factors where someone wasn't able to breastfeed, which in my case was very real and saying that that's the default, that's the backup plan.

That's what you should have done from the beginning. Well, that makes me feel like I failed as a mother if I'm struggling to find what my son needs. It's it's very anxiety producing it feels like everyone is judging the fact that I was one that did formula over breastfeeding and makes it seem like that is always the answer to this.

It's definitely a problem that is more widespread and there's a lot of different factors that go into it. It is not that simplistic. But it does hurt to see those things. And I know on some of the Facebook groups and things like that that I'm in, moms were trying to trade for formula or does anyone have this particular brand because their baby is in the same boat of not being able to tolerate some types of formula. So if you have this one, I'll trade you if I have one that you need, I found this one in the store. Does anyone need it? I'll trade you if you have the one that my son or daughter can tolerate and we're all doing the best that we can. We're all trying to make it work. We're thinking outside of the box. Adjusting as moms and and as dads and you know, trying to find something that will get us through whatever this timeframe is until things are straightened out and we can access what we need for our children again.

AMIEL: Absolutely. Were there things that you found that were particularly helpful for you, even if it was through, you know, the profession, through nursing or through groups or communities that you belonged to that you felt like was a good support for you and really helped kind of guide you to where you needed to be.

MCDONALD: My pediatrician is wonderful. He's very knowledgeable and he understood what Mason's needs were and has been with them since the beginning. And so, he knew we tried all of these things and he knew what to suggest. And then I think there's a lot of mom support groups that I've turned to just because of the journey that we were on to even get to having Mason.

And then the the ups and downs right after he was born and the NICU visits. So, I'm in a lot of support groups, and even though they may not be where I'm at locally and they may not have been able to say, this store just

got a shipment in, is there any care that you need? They helped a lot with that stress and anxiety factor. They helped calm me down and reassure me that this isn't something that I caused. This isn't something that I can do anything about, that we're all in the same boat, we're doing the best that we can. And so having that support and that realistic look at what things we're doing to try and make this work in the meantime was a huge help even if it wasn't directing me to resources and just constantly checking the apps and the websites of the stores that I have locally and the ones online.

Did they get a shipment and is it here yet? Making sure that I'm kind of following why this is happening? And is it ramped up again or are things being produced again? Are we, is this the long-term thing or are we just expecting a couple more weeks before we have it in stock? And what we need. So, it may not fully help me get what I need, but it helps me understand when things might calm down enough and when I can expect to start seeing things on the shelves again and being able to access that a little bit more readily.

AMIEL: Yeah, the anticipation probably helps little bit more than not knowing at all. Yeah. And how is Mason today? How is Mason right now?

MCDONALD: He is. He's wonderful. He finally figured out how to eat real food and now he won't stop eating real food.

AMIEL: Yeah. Me neither. Me neither, Mason.

MCDONALD: Me too.

But he's thriving. He's growing. He's actually 80th percentile for his weight, so he is keeping up with what he needs to. And coming from this little NICU baby that came too early, he is just amazing. He's a little terror sometimes, and I absolutely adore, and love him. But we are still transitioning off the bottle with the little bit of a formula that I have found, but he's doing a lot better drinking the milk, too, and making that transition over since he's old enough now.

But he is definitely doing better with actually having real food, which is which is a blessing during the middle of all of this.

AMIEL: That's fantastic. Shelly, thank you so much for joining me. Thank you for sharing your story, for sharing Mason's story with us during this time. And, you know, it really is important, this conversation. You know, there's a lot of though we're speaking to our audience right now, right? We think about all the health care professionals listening in but like yourself, these are also parents, right?

AMIEL: These are also people that might be experiencing something really similar to what we're talking about. So, thank you for sharing that.

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AMIEL: Thank you for joining us in this third and final episode of this podcast series about the infant formula shortage. In the first two episodes we heard from Dr. Abrams about the cause of the shortage and the role healthcare professionals. In this episode Shelly shared Mason's journey with formula and his special nutritional needs in his first year of life and the impact it had on her as a first-time mom.

This is Jannah Amiel for Elite Learning.

SOUNDBITE OF MUSIC

