A Hard Look Podcast: Audio Transcript – The Infant Formula Shortage

Opening Theme 0:08

Welcome to a hard look, the Administrative Law Review podcast from the Washington College of Law. We'll discuss how administrative law impacts your daily life from regulatory actions by agencies and the litigation over them to the balance of power among branches of the government. This is a hard look.

Alexander Naum (Host) 0:40

Hello, and welcome to a hard look. We are recording on a pretty stormy summer day in our nation's capitol. So you may hear some thunder periodically, but don't be alarmed. We are safely indoors. My name is Alexander Nam. And I'm ALR Senior Technology editor and curator of this podcast. Joining me and hosting today's episode is ALR as technology editor.

Eva Bogdewic (Co-Host) 1:01

Hey guys, it's Eva here.

Alexander Naum (Host) 1:03

We are so excited for today's episode. So let's begin. Beginning in September 2021. The US Food and Drug Administration also known as the FDA received several notifications about infants that had suffered and sadly two that had died from bacterial infections potentially related to their consumption of formula. During the same time the FDA received a report from a whistleblower at Abbott's infant formula manufacturing facility in Michigan, accusing the company of condoning and concealing safety violations. The FDA conducted a for cause inspection of the plant at the end of January of this year. Abbott recalled its formula in February. After its investigation, the FDA found that Abbott's facility had violated several safety regulations, including the discovery of five strains of bacteria. However, the bacteria collected at the plant did not match the strains taken from the infected infants still avid shut down its factory to correct the sighted issues. This in the midst of other global economic issues sent a shock wave a panic across the United States, as the supplier formula can no longer meet the demand and families across the nations struggle to pay for the rising prices of this crucial commodity. Today we will discuss the cause the effects and potential solutions to this ongoing crisis. To do this, we have invited health and food regulatory experts Stuart pape, onto the show. Stuart is a 1970s graduate of the University of Virginia and in 1973 graduate of its law school and his everyday work, stern helps clients understand and face challenges presented by regulations imposed by the FDA, the US Department of Agriculture, also known as the USDA, and similar health and safety regulatory bodies worldwide. He regularly appears before the FDA, the USDA, the Consumer Product Safety Commission, the US Customs and Border Protection, and the Congress of the United States. Previously, he served in various positions and the Office of Chief of counsel at the FDA, including as Associate Chief Counsel for food. He also served as executive assistant to the

former FDA commissioner Donald Kennedy. Stuart is ranked in chambers, USA America's leading lawyers and business food and beverages regulatory litigation to one and included in Super Lawyers, The Best Lawyers in America, FDA who's who in America and who's who in the world, and 2012, he received the judge Learned Hand Award from the American Jewish Committee. In addition, Stewart served for many years as Vice Chair of the Board of Directors of the Elizabeth Glaser Pediatric foundation. As a disclosure to our listeners, these are the personal views of Stuart pape, and are not a reflection of his employer's clients, organizations or other individuals in which these opinions can be imputed. Let's start from the top what are the oversight responsibilities of the FDA when it comes to ensuring the safe manufacturing procedures of baby formula?

Stuart Pape (Guest) 3:59

The FDA has special authorities over infant formula under the Federal Food Drug and Cosmetic Act and those authorities derived from the infant formula act of 1980. Under that act, FDA is required to set specific nutrient requirements for infant formula and to ensure that marketed infant formula meets those nutrient requirements and quality standards. The overall objectives of those requirements is to ensure that the formula will support normal growth and development of the infant. There are no other foods that are subject to similar requirements.

Alexander Naum (Host) 4:41

And why is it that baby formula is unique from other foods? And why does regulating it have unique requirements?

Stuart Pape (Guest) 4:47

Well, unlike all other foods, infants, if they're being fed formula may be that may be their only their sole source of nutrition or a substantial source of their of their nutrition. For everybody else. Typically there's a variety of foods available. So it's not that critical. It's a critical little wall that any particular food that that an older child or an adult consume contain certain nutrient requirements. But by definition, if an infant is relying on infant formula for its source of nutrition, the infant formula has got to provide that nutrition. Otherwise, we have a problem that and we did have a problem even it's dead. That's not a hypothetical question in in 1978 1979, I was at FDA at the time, and I recall this pretty vividly. The syntax company made some changes in the formulation of an infant formula that it was marketing at the time and didn't test the reformulated infant formula to ensure that it contained all of the nutrients essential to normal growth and development in an infant. And it turned out that the reformulated formula was lacking in chloride, and it led to a growth deficiencies in the infants. And that episode, unfortunate episode led directly to Congress enacting the infant formula act of 1980.

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Alexander Naum (Host) 6:32

Can you dive more into that act?

Stuart Pape (Guest) 6:35

Well, so that act, the infant formula act is what is what requires FDA to develop nutrient requirements that are FDA regulations that specify infant formula has to contain all of these nutrients, list of nutrients and quantities. And in order to get what is called the non exempt infant formula, there were some special infant formulas that are exempt from those requirements. If you want to get a non exempt infant formula to the market, you have to submit to FDA what is called an infant formula notification that shows that all of the ingredients that you're using in the infant formula, are are appropriately determined to be safe. So you have to demonstrate the regulatory status of each of the ingredients you're using, where you're getting the protein from, where's the Fed coming from? Where are the vitamins and minerals coming from? You have to go through all that, then you have to show the compass, what's the ultimate end composition of the infant formula? Does it have all of the nutrients in the required amounts? Does it have those amounts throughout the shelf life of the formula? Because it would obviously be a problem if you hypothetically, you had all of the nutrients required to be in an infant formula for the first week after you made it. But over the course of the months that the infant formula was in distribution or in a mom or dad's pantry, the nutrients were degrading so that when you fed the formula to the infinite didn't have the nutrients at the levels. And then you have to do a growth study in infants in which parents enroll their infants in these trials in the infant would get fed the formula that a manufacturer would like to introduce on the market, and there'd be control infants on the control sample who were fed in already approved already marketed formula to make certain that the quote unquote new formula is going to produce adequate normal growth and development in the individuals. If it does, then the manufacturer is in a position to submit a new infant formula notification to FDA, you have to do that 90 days before you intend to introduce the new infant formula into interstate commerce. Theoretically, on the 91st day a manufacturer could if it hadn't heard from FDA could say I'm going to mark it in practice in normal times. That's not what a manufacturer would do. It's not what someone like us like I would ordinarily advise a client to do because you don't want to run if you do that you're running the risk that you know you go to market and then on the 95th day or the 90 day or whatever day FDA says oh we have a problem and now you're in the market and they say they have a problem and they can say you need to pull that product back you need to recall it you need to do whatever you need to do. So in the vast majority of cases what a manufacturer is going to do as a practical matter is waiting to hear from FDA and you it's not like 90 days will pass and you won't have heard they will let you know hey, we have a few more things we need to look at standby. It's not You're not sitting in the dark. Trying to wonder what what is going on. So typically you wait until FDA says, We have no questions, then you can work it safely knowing that FDA is comfortable that your formula meets the requirements of law. There's literally no other food that has a regulatory regime that is remotely close to that. Yeah.

Eva Bogdewic (Co-Host) 10:18

I mean, it sounds like the FDA and the industry both have an incredible amount of responsibility to make sure that baby formula is safe. And so let's talk about what's going on right now. The FDA is currently the subject of a federal investigation. And can you talk about that a little bit? What is HHS looking for? What are they trying to answer in this investigation?

Stuart Pape (Guest) 10:41

This is one of those things that is becomes confounding, the more you look into it, there's a lot of concentration in the infant formula world, the only three or four manufacturers who have 90 plus percent of the market. One of those companies Abbott, which is you know, fundamentally a medical device and pharmaceutical company, most of the rapid antigen tests for COVID were Abbott tests. And the AVID facility in Sturgis, Michigan began to have some problems late in 2021, fall of 2021, there's like a half a dozen things you can point to here as to what happened. In no particular order. During the pandemic, regulatory inspections were mostly suspended. So that men across a whole array of FDA regulated industries, inspectors weren't in facilities looking around. And there's really no substitute for an inspector periodically looking around. Even the best companies need sort of that risk of an FDA inspection to keep them on their toes. So those inspections were mostly suspended or if they occurred, were virtual, somebody walking around a facility holding, you know, holding an iPhone on FaceTime and and an FDA inspector on the other end. And so, you know, that's better than nothing but not, not not, not by a lot FDA learned in the fall of 2021 that an infant who had consumed and Abbott formula made at the Sturgis Michigan play it had gotten a cronobacter infection and cronobacter is a bacteria that can show up in in infant formula. It likes the environment of infant formula, if you will. In October of 2021, a whistleblower of former employee of that Abbott facility sent a written whistleblower complaint complaint to a number of senior FDA officials, the acting commissioner, the head of the Center for Food Safety and Applied Nutrition, who would have been the lead regulator for food related matters, including infant formula, that whistleblower complaint got a quote last close quote in the FDA mailroom and didn't make it to FDA officials in a timely fashion. And so, you know, that's one of the things that the HHS Inspector General is looking at. Nothing was FDA planned to inspect the Abbott facility in December of 2021. And there was, but there was a COVID outbreak at the facility. So the investigation inspection was postponed and then FDA didn't inspect the facility until January of this year, when it found major problems. So the Inspector General is looking at the actions taken the timeline to determine why it took FDA so long to inspect the Abbott facility and then do something about it. There was an earlier inspection that didn't find any problems. And then the inspection in January, there are what we call routine inspections that FDA does, just sort of on a normal cycle. And then there are for cause inspections and usually for cause inspections are more detailed, they're lengthier, there might be more inspectors, you know, if you having a routine inspector, it might be one or two, if there's a for cause and it's a serious problem and might be one or two or three and instead of

accomplishing the inspection in two days, they might spend a week right and so there you go, so they found these problems and shutdowns shut the you know, basically said we gotta you gotta fix these problems. One of the things the wonder of that is why were Why were those problems. The problems from what I've read in the papers don't sound like they were subtle, right? You know, they Look, they look pretty obvious. And one would want to wonder why Abbott didn't anticipate that some of the conditions of this facility were problematic and should have been dealt with without having a problem without creating the problem that it led to, but they did,

Eva Bogdewic (Co-Host) 15:16

looking at the bigger picture a little bit aside from, you know, some of the unforeseen things that COVID Cause like the inability to, to inspect in person, why wasn't the FDA prepared for something like this happening? Why didn't it occur to them, that there could be an infant formula shortage in the future? Good? It's

Stuart Pape (Guest) 15:39

a great question. You know, on the medical side of FDA, uh, one of the things people need to remember about FDA is the drug center is different from the Device Center is different from the animal drug center is different from the food senator. So they're all part of the same agency, but the way they relate to the industries they regulate in the in the things that they assume about everyday activities are different depending on the Senator. So on the drug side, there's a formal mechanism for reporting drug shortages. It's part of the fabric of drug regulation, that there could be shortages. When company sees shortages arising, there's an interruption in an ingredient availability, there's a problem in a facility, they're gonna have to shut the facility down for some reason, they have an obligation to notify FDA. And you can literally go to a website that FDA maintains and see what drugs are under shortage from what manufacturers and what's the estimated back on the market timeframe that permits doctors and physicians and patients to adjust their behavior to shortages, they can. Doctor can say, Alright, there's a shortage here, I'm going to change your blood pressure medicine from this to this, there's no equivalent on the food side, because there's it's a different, it's a different animal altogether. If a company shuts down a potato chip factory, you don't have to tell FDA. I mean, if we, you know, we had to go without a particular brand of potato chips for a couple of weeks, we either wouldn't eat potato chips, or we switched to something else. We wouldn't have to call our doctor and say, Can you switch me to a different brand of potato chips? But so so it was a it's really a foreign concept for the food folks to have thought about that as obvious as I think it seems in hindsight, because I think it all seems to us now. Well, why didn't you see that you were going to precipitate a shortage that closing this facility? Well, it's easy for us to see that because we know there was a shortage. And so that's not really insightful. That's just observing what happened. And I suspect that the time that this happened, FDA wasn't focused on the fact that there are only a handful of companies that control all the market. They weren't, they weren't focused on the fact that at this Abbott facility, there are certain formulas made that are made for infants who have special nutritional needs, because

that's really where the problem has been most acute. And real, you really, you have to empathize with parents with parents who need a particular formula to feed their kids. Because if your infant is being fed a general infant formula, and there's a shortage of that you can adjust to another company's general infant formula, you know, there might be a couple of days in which your infant is overly cranky or has some GI distress. But it's not a it's not the same challenge a parent faces, if your child has to be fed a certain formula that is made without a nutrient to which your infant is allergic, you don't have that choice. And I think FDA just didn't focus on the fact that avid essentially was the sole source of some of those formulas. I mean, I don't know, even if they had focused on that fact, that there are lots of things that may be anything that they could have done. You know, you can't say, Well, this formula, this factory makes formula that is only available for this factory. And even though we think there are conditions in this factory, they're giving rise to a substantial risk of bacterial contamination to the formula. We're going to look the other way I mean, that doesn't strike me as an option but you might have been able to work with and I suppose to, to cordoned off a part of the facility. Sometimes you can segregate a part of a facility and say, let's put up a week's worth of special effort into this one part of this facility so that you can run these specialized formulas there but I I just think they didn't None of that occurred to them until well after the shortages had occurred.

Eva Bogdewic (Co-Host) 20:04

Yeah, that's it's really unfortunate. And, you know, aside from the special nutritional needs that some infants have, but just in general, why do for companies control almost the entire industry in the United States is regulation preventing smaller companies from succeeding and competing fairly in the market?

Stuart Pape (Guest) 20:27

Maybe, I think most of the reason for the concentration comes from the history of how infant formula came to be. Because before the 1970s, most parents who chose not to breastfeed or moms who couldn't breastfeed, used condensed milk. And then in the beginning, really in the 1970s, pharmaceutical companies that owned the large infant formula, brands came upon the idea it's really derivative of the way they market medical products, to hospitals. And so you know, there's a there's a salesman and a pharmaceutical salesman is traditionally called a detail man today, I think we'd say detailed person, and they sell pharmaceuticals to hospitals and doctors offices in the light. And so the, the pharmaceutical companies that own these major brands of infant formula came upon the idea of selling formula to the hospitals, because they already had a built in Sales Force. And so they kind of made infant formula a line extension, in addition to selling on these drugs we make, and you sell them these formula. And so they began distributing the products to the hospitals. And then when, when a mom was discharged from the hospital with her new infant, she would get a bag that would have typically diapers and, and free formula and coupons and all the rest. And so, essentially, what they were doing is marketing through the hospitals and creating ready customers. You know, if the, if the hospital thought this

formula was best for my baby, then that's the formula I'm gonna buy. Well, so then, you know, the parent left the hospital thinking the hospital has blessed, not only had the blessed event of a baby, but the hospital had blessed the infant formula, because the pharmaceutical companies had preferential access to the hospitals and teams of employees who sold those products to the hospitals, other manufacturers found it difficult to get access and therefore access to get market. The other thing that contributes to the concentration is the WIC program, where lots of formula is purchased through the WIC program. And that's a competitive bidding process run by each state. Again, this sort of the law of unintended consequences is playing a large role here. The WIC Program has traditionally used a competitive bidding process. So the state of whatever puts its weight contract out for bid and it's going to sole source, there's going to be one winning bidder based on cost, who's willing to provide infant formula to the state at the best price, whoever wins that contract is going to have preferential space in the grocery stores in that state. Because you got to have the, you know, if it's a WIC infant formula, you got to make it available to moms and dads who were getting infant formula for their infants through WIC. And so they get shelf space, they get more shelf space, and therefore drive the market. You put those two things together, and I would say they account for 90% of the market concentration. That's a lawyer's estimate, not an economist estimate. And I think regulation plays a little bit of a role in accounting for the for the remaining 10%

Alexander Naum (Host) 24:25

That's really interesting. How do you see the WIC program being reformed or changed in any way to provide better competition?

Stuart Pape (Guest) 24:33

Well, I think the bidding program doesn't have to produce a single winner, I think you can balance the need to conserve governmental resources in infant formula approaches to the WIC program by opening it up to multiple players. But you wouldn't be dealing with the concentration in the marketplace. If if what you did was open it up to multiple players who were the already have the large market share, that you're just taking the monopoly and still in, you know, cutting the pieces slightly differently. So I so I think what you have to do, because there are non big players in the market, and there's actually been something of an explosion in sort of new infant formula companies, innovative smaller infant formula companies trying to come into the market. So one idea would be to sort of have and there's plenty of examples of this in other government contracting programs, to have a small business set aside to say, in each in each state, X percent 10% 20% of the purchase has to go to infant formula manufacturer that qualifies as a small business, a minority owned business, a woman owned business. I mean, there's lots of ways that you can slice that up so that you give some of these newer innovative companies that don't already have huge chunks in the market and opportunity to build up their business. I think that's a good idea. And I think that's something that Congress should do.

Alexander Naum (Host) 26:13

Yeah, I definitely agree. That sounds like a really innovative idea. But like another big issue revolving around this is price gouging, which has been especially harmful for low income families who struggled to afford baby formula, even prior to the shortage. In May, the FTC launched an inquiry into quote, the information and nature and prevalence of any deceptive, fraudulent or otherwise unfair business practices aimed at taking advantage of families during the shortage. Do you see the FTC, the FDA, or another federal agency having the power to prevent or even punish retailers who are engaging in these types of practices?

Stuart Pape (Guest) 26:50

I don't see FDA having any role they are most price gouging when it occurs, not just with respect to infant formula, but in general, occurs online. You know, when the pandemic was sort of roaring along and in early 2020, April, May, and there were shortages of all sorts of things. You couldn't find Clorox wipes, you couldn't find necessarily toilet paper, you couldn't find them. Well, you might be able to find them on Amazon, but you you could see, you know, a price you thought you were buying an automobile for what they wanted for a three pack of, you know, wipes. So most price gouging occurs, there were people who've either just happened to have a supply or were ahead of the curve, you know, I'm sure there was somebody sitting somewhere in the first day of the pandemic, who said, you know, in March of 2020, said, you know, what Clorox wipes is going to be a hot thing, I'm gonna go buy up every container, I can and then resell it, you know, you see that all the time. So most of it is on the line, and most states have price gouging laws, that limit price increases in times of shortage. It's not the easiest thing to go after, however, and but I suspect some state agencies will, in fact, you know, go after some price gouging for infant formula. I'd be surprised at the end of the day if the FTC did anything.

Eva Bogdewic (Co-Host) 28:27

Gotcha. So let's let's talk about what the FDA is doing. What steps are they currently taking to mitigate this crisis? And what benefits and drawbacks do you project for the efficacy of those solutions?

Stuart Pape (Guest) 28:42

There are lots of formulas marketed in places like Europe in Australia, that have not been marketed in the United States. FDA has adopted in light of the shortage of infant formula, several policies designed to facilitate the importation of some of those foreign infant formulas while waiving some of the strict requirements of the law so they're not requiring them to submit the full infant formula notification and weight 90 days, but while they review it, because that

would be counterproductive to solving the shortage of infant formula. So what they're what they're requiring is a, if you will a short form, if you're taking a formula that is successfully marketed in, in Europe, for example, you really and so it's been reviewed by European regulators, your presumption would have be that it meets the needs of of infants in terms of nutrient requirements and growth. So they're getting those companies to submit sort of short form applications. And then using FDA has discretion to waive requirements under certain circumstances, they're waiving the requirements and then permitting those shipments to come in, I view that as mostly a stop gap, most of the formula that is coming in that way from Europe and Australia, predominantly, our our general infant formulas, general purpose infant formula, so it doesn't get at the specialized infant formulas. I think FDA has been working with Abbott to try and get that facility going again, particularly with respect to those specialized formulas. FDA is also doing some outreach to the foreign, mostly European infant formula companies to encourage them to become regular suppliers of infant formula. To the US, I'm not convinced that that's going to work because there's a reason why those companies haven't tried to comply. Some of these are big infant formula companies, there are reasons why they haven't sought to market in the US before regulation may play a role here. And a potential product liability may play a reason as well, they may or may not want to routinely subject themselves to the product liability risk in the United States. So we'll see if that happens. One of the things I've been disappointed that FDA doesn't seem to be as focused on as I believe they should be, is facilitating the growth of the domestic market for infant formula production, the the smaller, newer, Small Business Women Owned minority owned up and coming infant formula companies, because I think the insurance policy to ensure that this doesn't happen again, or to make the likelihood that you could have a shortage of infant formula, again, as low as possible comes from building domestic capacity, not foreign capacity, If we learned anything, during the pandemic, that maybe we did, but If we learned anything during the pandemic, we're relying on 100% on foreign source or, or 90%, or 80%, on pharma and source for things that become essential is a very dangerous strategy, particularly if there's a problem that is worldwide. Because when that happens, your foreign sources Well, we'd like to send you these patient exam gloves you need, but we need them. Right. And so your your supply gets interrupted, where if you have domestic supply, then you can turn to those folks and say you can use the defense production Act which the President invoked here, you can use the defense production Act and other authorities to facilitate expansion of domestic capacity if it exists. But you can't, you can't, if you don't have domestic capacity that can be increased. If all the domestic capacity is running 24/7, then if you have a crisis, you have no way to crank up production. So you got to have more availability of domestic production that can be expanded, if the circumstances are and arguably that coupled with some other things, drives the concentration down. So it's not such a concentrated market, then you have more manufacturers more opportunity. And so what you have to watch out, because I think if if some of these smaller infant formula companies found a very successful niche in the market, the bigger players would be tempted to acquire them. Right, then you're back where you started.

Alexander Naum (Host) 34:05

Yeah, that that really reminds me of an earlier conversation that we had when we talked about the broader supply chain issues that nations across the globe have been grappling with, as a result of the COVID 19 pandemic, specifically the concept of just in time manufacturing. Can you dive deeper into that just the issues that have created this?

Stuart Pape (Guest) 34:24

This whole supply chain subject is become quite fascinating. I used to think it was one of the most boring things that MBA students in business school learned. But it's not. So just in time or continuous flow manufacturing is basically used by companies to increase efficiency and decreased waste. And so what it means is you get if I'm making infant formula, I get ingredients roughly in time as I need them. So I don't have a huge warehouse full of ingredients that I'm pulling from ingredients are arriving on a weekly or bi weekly or monthly basis, and they get used. And the same thing would be true in automobile manufacturing, or computer manufacturing, or whatever it is, you get the chips when you need them, you're not storing hundreds of 1000s of chips, until you need that works great until there's an interruption in the supply chain. And now you can't get your ingredients. So if I'm an infant formula company, if all of a sudden I can't get what are called the vitamin and mineral premix. So it's a it's an it's a combination ingredient that consists of the specified vitamins and minerals that I need to add to my infant formula. Well, now I can't make an infant formula. And I can't, I can't say to somebody go down to the warehouse and get us more vitamin premix. Because we used up all we had and we didn't have months and months worth because that was inefficient, you know, why is it inefficient? Because you paid for the vitamin premix. So you're out the money, and you're just storing it, you're having to have a warehouse and pay for the storage and all the rest. And it's not until you use it and incorporate it into an infant formula and send that infant formula out into the market, that you start to generate the revenue to cover the expense for the the ingredient you acquired. So so what happens is that and then the pandemic caused changes in consumer behavior that we're still that gone back into equilibrium. So we all started working from home. And so for if you're a food manufacturer, let's say I was in the food business, and what I made was food that went to cafeterias and in offices and colleges and universities, well, all of a sudden, there's nobody there. So I'm not selling these humongous containers of pasta sauce to colleges and universities because their cafeterias are closed down because they sent the students home. Well, I can't send those humongous containers of pasta sauce to the grocery stores, because who's going to buy up? I don't know, a 50 pound container of pasta sauce, what are you going to do with that? So So you have you get a supply imbalance in which there's a surplus of things that nobody wants and shortage of things that everybody needs. And now what you're seeing with retailers is it's flipped around, the retailers have a lot more of things that people don't want now, because consumer spending is shifting from goods back to services. And so the retailers are now have an overabundance of things that they once thought they needed to get as quickly as they could and got them as quickly as they could. But it's now. And now of course, consumer preferences have shifted. And retailers are stuck with a lot of things that people

don't want anymore. And that's sort of a ying and yang thing in the supply chain, which is really tough for manufacturers and retailers to want to manage. But the infant formulas, you know, supply remains not where it needs to be. And it'll it's going to take another bunch of months, I think before you start to see supplies in grocery stores across the country at levels that are what retailers and consumers would like them to be, which is if I'm a mom or dad and I'm going into the store to buy infant formula, I want to go to the infant formula section and I want to see the shelves stocked with everything I might want. We're not there yet.

Alexander Naum (Host) 38:48

So if it's not economically feasible for these manufacturers to stockpile on these useful components of their products, would it be useful for the government to stockpile on these useful components or even baby formula itself? I mean, the Department of Energy maintains a strategic petroleum reserve in the event of petroleum shortages. The Bill Emerson humanitarian trust maintains a stockpile of up to 4 million tonnes of wheat, rice and other green resources and a lot of other government agencies and different components of stockpile on a lot of useful products and in the event of shortages. So do you see a baby formula stockpile as a reasonable thing to do and any logistical challenges that could come with that?

Stuart Pape (Guest) 39:36

Yeah, I don't think a stockpile of infant formula is necessary or practical. I think we have the tools to avoid shortages in the future. And that's more sources of supply, both foreign and domestic heightened awareness on the part of policymakers have the potential for shortages. You know, there are many different kinds of infant formula, as we've alluded to, including those specifically formulated for infants who have unique nutritional needs. So if you're going to have a stockpile, you'd have an enormous challenge of making sure that you had an adequate stock of all of those different supplies of infant formula. And of course, infant formula has a shelf life. So you'd have to be rotating that stock periodically, because it's not going to do you any good if you have five year old cans of infant formula that are well past their useful shelf life. So I think, I think creating a stockpile is a logistical challenge without a commensurate benefit, I put my effort into making sure we had an adequate supply. And that would be, among other things, focusing on and maybe the government should provide some economic incentives to ensure that there are multiple suppliers of these specialty infant formulas, or at least that there are multiple suppliers who are capable of supplying so if you had the problem with the Abbott facility, where some of these specialized formulas are made, you could go to different manufacturers, you the government could go to different manufacturers and say, you you have been pre authorized to produce this formula. And that formula, there's now about to be a shortage you need we can issue you in order to have you gear up to switch from whatever formula you were making to this other formula. And you would have prepared that facility in advance. So they would have been certified to do that it was wouldn't be like they would suddenly have to scramble and say, how do we do this? Where do we get these ingredients? What does this make? How do we get FDA

clearance? All of that would be in place? And if they weren't currently making it, they could quickly gear up. I think that's a better strategy.

Eva Bogdewic (Co-Host) 41:54

Yeah. On the supply side, you mentioned that the President has delegated the HHS the ability to use the defense production act in order to produce infant formula. Has the ACT been used this way before? And is this within the President's authority? Well, the

Stuart Pape (Guest) 42:11

defense production Act has been interpreted to extend beyond national defense and to include enhancing and supporting domestic preparedness, response and recovery from national hazards, natural hazards, terrorist attacks, other natural emergencies. I haven't seen anyone suggest that the President's use in vocation of the defense production act here exceeds his authority. And the way in which he used it was to permit companies to issue what are called directed orders, to ingredient suppliers. So one of the things you worry about here is a shortage of ingredients I referenced the vitamin and mineral premixes, those are sold to lots of other companies, energy drink companies buy vitamin and mineral premixes, for example, what the invocation of the presidents of the defense production Act means that the President can authorize an infant formula company to place an order for a vitamin and mineral premix, for example, or any other ingredient that is needed to produce an infant formula. And the recipient of that order, the rated order record is required by law to give preference to filling that order. So if I'm in the vitamin and mineral premix business, I can't say you know what, I got an order that I made for that, or I'm about to make for that energy drink company. And I'm going to make that before I fulfill this infant formula order. You can't do that, that violates the law, you can get into a whole bunch of trouble for doing that. So that gives priority to the ingredient needs of infant formula companies.

Alexander Naum (Host) 43:58

That's very interesting. Thank you, Stuart, for this very informative conversation. Before we end our discussion, do you have any parting words for our listeners?

Stuart Pape (Guest) 44:07

No, you know, this problem will resolve itself. Eventually it's been, you know, painful, for sure. And there'll be no shortage of lessons learned and hopefully, the right people learn the lessons and this will be one time event.

Alexander Naum (Host) 44:26

Yeah, definitely, hopefully Hindsight is 2020 in this situation. I would like to thank our guests for substantial contributions to our discussion today, the American Bar Association's Administrative Law Section, the Administrative Law Review, and of course, our podcasts own Eva bhoga wig for her assistance and support and creating this episode. If you're new to our show, and enjoy this episode, give the episode a life. And be sure to follow in Show podcast with your colleagues, friends and family. Thank you and you'll hear from us soon as we discuss other topics impacting administrative law