

The White House: Remarks by President Biden during virtual meeting on accelerating infant formula production through Operation Fly Formula

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THE PRESIDENT: Good afternoon, everyone. Thank you all for — for doing this today, including our Secretary, Xavier Becerra, who is here; the Surgeon General, Vivek Murthy; and our Deputy Director of Domestic Policy, Christen Young; the Deputy Director of the National Economic Council, Sameera, who is going to sit right behind me and — and do all the hard work; as well as a group of manufacturers from infant formula joining us virtually. Thank you all again.

Look, as a father and a grandfather — and I'm sure we all feel the same way — I understand how difficult this shortage has been for families all across the country. There is nothing more stressful than the feeling like you can't get what your child needs — what he or she needs.

And it's why I've directed my administration to use every tool available to increase the supply [and] get more formula on shelves as quickly as possible, working with manufacturers to re-open factories that have closed and ramp up production quickly so we can increase the availability of infant formula and lower the costs for American families.

We're — we're here today to hear from these manufacturers and to get updates on the progress we're making together.

The shortage of baby formula is due to the closure, back in February, of one of Abbott's infant formula plants, and we need to take immediate action to stop contaminated formula from hitting store shelves and putting American children at risk.

The last thing we should ever do is allow unsafe formula to be sold to parents. Instead, we should increase the production of safe formula to make every American family — so they can get what they need for their child.

That's the approach we've taken. The Food and Drug Administration acted quickly to bring Abbott back into compliance with safety standards, but it takes time. Abbott accounts for about 40 percent of the overall infant formula market in the United States. And this factory was one of their leading plants.

So, since February, my administration has been working diligently across to — every spectrum we could find to address this shortage and to bring more infant formula into the country and onto shelves.

We've taken three key actions. First, we invoked what is known as the Defense Production Act, a measure that makes sure that manufacturers are the first in line for the material and ingredients they need to make safe, high-quality infant formula at home.

To date, Secretary Becerra has approved three authorizations of the Defense Production Act — three — so that companies like Reckitt's, joining us here today virtually, can now get oils and filters they need to increase production of their — in their factories in Indiana and in Michigan.

Second, we launched Operation Fly Formula, the major effort to airlift infant formula that meets American's health standards and safety standards.

Today, I am proud to say that because of these flights, high-quality formula is already on the way to American shelves. We've already conducted two flights with 1.5 million 8-ounce bottles of Nestlé and Gerber's hydro- — excuse me, hypoallergenic formulas for children with severe allergies.

Without Operation Fly Formula, we wouldn't have taken — it would've taken — we've — taken three weeks to get this product to the United States. Because of our

actions, it took three days. And it's heeded the request that people had, and it's headed to American shelves.

And I want to thank the Department of Agriculture for helping fund and support Operation Fly Formula. And today, I'm announcing plans for a third flight with Bubs Australia. And — and the CEO of Bubs, Kristy Carr, is with us today — virtually today.

This flight would bring 4.6 million bottles of infant formula and pave the way for up to 27.5 million total bottles of Bubs infant formula to be supplied to American families in the weeks ahead.

Third, the Food and Drug Administration is reviewing applications for another new, high-quality imports to increase our supply.

In addition to getting Bubs formula through the process, on Friday, the FDA announced that — that Kendal Nutricare would be able to import formula from the UK.

Today, we're announcing that United Airlines has agreed to offer cargo space for Kendal Nutricare for the delivery of 3.7 [million] bottles of the formula here in the states. And I want to thank United Airlines for partnering with us to get this done — they're doing it on their own — with the first flight next week, continuing over the next two to three weeks.

And Target, the department store, has agreed to partner with Kendal Nutricare to distribute this formula quickly to American families in stores and online.

And still, we have work to do though, but we're making critical progress. And today, I look forward to hearing from these leading manufacturers to learn more about their actions they're taking to increase supply to American families and to discuss how my administration can continue to support their efforts — speeding up manufacturing, helping move goods faster from factory floors to store shelves.

In addition to the companies I mentioned, I also — we'll also hear from ByHeart operation, out of Pennsylvania. We need more new entrants into the infant formula market like them — like ByHeart.

And finally, we're going to hear from the Surgeon General on what he's doing to help families get information they can trust as we continue making progress to

resolve this shortage.

The work ahead is not going to be easy, but we will continue to work around the clock with manufacturers, states, doctors, and families. And that includes working with states to ensure that, with the help of the Department of Agriculture, we continue to cut red tape for families that participate in the Women and Infants and Children program — the so-called WIP [sic] — WIC program.

I recently signed legislation to help make it easier for families to get the formula they need through the WIC program. I called on all 50 states to take action, and all 50 states answered the call — working with us to make that program more flexible. And we're going to stay focused on go- — on doing even more.

I'm going to make sure that families in every part of the country can get the formula they need. And I look forward to our conversations today. So I want to thank you all.

And now you — I'm going to hand it over to Secretary — Mr. Secretary, I'm going to have you speak now and — your remarks, and then we're going to hand it over to — to Sameera to my — behind me here.

But all yours, Mr. Secretary.

SECRETARY BECERRA: Mr. President, let me start by thanking you for convening today's roundtable. At your direction, we are working 24/7 to get infant formula into the hands of parents across the country.

As my team at HHS recently told Alexa, a mom from Leesburg, Virginia, whose sons — a one-and-a-half-year-old and a six-month-old — require specialty infant formula: Getting more formula, particularly specialty formula, on shelves quickly and safely is a priority for us.

Mr. President, thanks for your leadership. And thanks to that leadership, we have partnered with federal colleagues across the administration to support Operation Fly Formula to bring formula in from other countries and bring it in swiftly and safely.

In addition, the FDA is working with Abbott to get its facility to reopen safely. And we are working to quickly and safely bolster the supply of products so that the industry can get them to people in urgent need, with a focus on specialty formula.

Under a consent decree with the FDA, Abbott agreed to take corrective actions following an FDA inspection of its Sturgis, Michigan, facility — actions that are expected to ultimately result in an increase in the safety of infant formula.

As I have invoked the Defense Production Act three times already, that was done to accelerate delivery of raw materials needed to manufacture infant formula for Americans — America's families.

And one more important point: At HHS, we have launched a new online hub — [HHS.gov/formula](https://www.hhs.gov/formula) — to help parents and caregivers navigate their baby formula options.

At [HHS.gov/formula](https://www.hhs.gov/formula), parents and caregivers can connect to community resources, such as community centers or an accredited food bank. They can connect to preliminary recommendations from physicians and clinicians, and they can check if the brand of formula they rely on was affected by Abbott's recall. We invite feedback from the public and plan to update this page further in the coming days. And all of this information can be found in multiple languages.

We're engaging governors across the country so that they too have the latest information on how to help families in their states navigate their needs. And we're working closely with the U.S. Department of Agriculture to support the Special Supplemental Nutrition Program for Women, Infants, and Children — the WIC program — to ensure WIC families can access new supplies of baby formula as they become available.

We will keep working 24/7 to make sure parents have the infant formula they need. But remember: HHS, FDA, USDA — we're not manufacturers. We need infant formula manufacturers and the industry as a whole to keep stepping up and working with us.

As you've made clear, Mr. President, only together can we solve this challenge and get families the infant formula they need.

And with that, let me now turn to Deputy Director Sameera Fazili for her comments.

DEPUTY DIRECTOR FAZILI: Thank you, Secretary Becerra. Thank you everyone for joining us today. We — what we'll do now is turn to the manufacturers and get some updates. We last spoke to you in mid-May, heard about the work you were

doing building upon a lot of the work that the administration had been doing diligently since February.

But I want to begin with Robert Cleveland. And since we last spoke to you, we've now invoked the Defense Production Act and want to hear how the Defense Production Act is enabling Reckitt to speed up its production of infant formula.

MR. CLEVELAND: Sure, I'd be happy to address that. And thank you for convening this roundtable.

So, you know, as the next largest manufacturer of scale after Abbott United States, getting as many feedings to shelf as possible has been an enormous priority for us. We've left no stone unturned in the way we can do that safely and in a high-quality manner.

And since the — since the recall event occurred, there are a number of actions we've taken. First and foremost, our plants are running 24/7 with unlimited overtime. We've optimized our portfolio to focus on those products that move through our plants the fastest. And we've worked with our retail and our distribution partners to ensure that our trucks are getting to distribution centers and prioritized with our retail partners — like Walmart and Target, Kroger — such that our trucks are unloaded first and feedings get to shelf faster. Because it's not just about more, it's about how much more we can put at shelf.

And since the recall began, or since the beginning of the year, we have been able to increase the amount we've put to market by over 30 percent and to do it 40 percent faster.

To (inaudible) that a little bit more: That's about 211,000 more infants that we're feeding after the recall than before the recall.

But to address your question directly on the impact of the Defense Production Act: When we spoke to the White House middle of last month, there were a number of very rapid actions that the government took, and we're very appreciative of them. Part of it is the Defense Production Act. We have been a ben- — the beneficiary of one implementation of that, that got us some essential oil to our manufacturing process. But there have also been calls from staffers from the NEC and HHS to other manufacturers who supply to us. And those calls alone have been helpful.

And because of those calls, because of all that's been done, we now have a production schedule in June where we're looking to produce 40 million feedings per week.

And that's because we have a special response for a special and temporary responsibility to produce more than half of the infant formula in the U.S. And our employees are dedicated to meeting that responsibility and, in fact, over Memorial Day weekend, worked to produce another 5 million feedings at our plants in Michigan and Indiana. And they couldn't have done that without all the efforts to get us more inputs through the DPA and the efforts of the staffers at HHS and NEC, and we're deeply appreciative.

But the other thing I wanted to lead to is that we can do even more. So, we have a unique opportunity with our brand Enfamil, which has fed generations of infants in the U.S. and is the most trusted by pediatricians and mothers. And with that unique position, we've submitted applications to the FDA to bring formula in from our world-class facilities in Singapore and Mexico. And if those applications are approved, we believe we can bring enough formula in to add an additional 250,000 infants to the ones we were already feeding post the recall and come a long way to substantially ending this crisis. And if those approvals happen fast enough, we can make an impact as soon as this month.

And we're really, really looking forward to working with the HHS and the FDA in processing those applications as quickly as we can.

But, you know, in closing on my opening remarks, I just wanted to recognize the efforts of the USDA and the local governments that implement the program.

We've been working to fill the gap created by the shutdown of the Sturgis facility ever since it happened and the flexibility of the administration of that program has allowed manufacturers like ourselves and our retail partners to be able to put products out the shelves that WIC participants can more easily access. And since they are the most vulnerable in our society, I just want everybody to know those efforts have been fruitful, meaningful, and I know we're feeding more WIC participants because of them.

So, thank you for the efforts for the government — from the government, the USDA to improve flexibility in that regard.

And if there are other questions later, I'm happy to answer them.

THE PRESIDENT: All right. I'd like to ask question, if I may. What — tell us about what changes you've made to move the formula faster from your factory to the floor shelves. I mean, what — you talked about the trucks and other priorities. Are there other things you've done as well?

MR. CLEVELAND: Yes, sir. So, typically, the process would — the way our process would work is we would make our product, it would go through its normal quality release checks, be released into a system that then eventually becomes visible to retailers to order from.

What we've done now is to make sure that every retail partner we have is aware of — the moment that product is released from quality, their order is waiting for it, the truck is booked to ship it to their facility, and once it gets to their facility, it's prioritized among all the other deliveries that they receive to get to shelf as fast as possible.

And again, those changes, in totality, we believe we're now delivering product to market 40 percent faster than we were prior to the recall.

And again, it's — it's partnership up and down the line, sir.

THE PRESIDENT: One last question. Did you — and I'm going to ask this to your other colleagues — did you anticipate that the closure of the Abbott facility because it was produced — not producing the quality that was necessary, that it would have this profound an effect immediately? Or did it — or did it take a little time to —

MR. CLEVELAND: I think — no, sir. We were aware of the general impact that this would have. And so, from the moment that that recall was announced, we reached out immediately to retail partners like Target, Walmart to tell them this is what we think will happen and this is the inventory we have on hand right now. You should order it. And any inventory in your distribution centers should be pushed to shelves as fast as possible.

And they've been great partners in taking all of those actions. And then, of course, as the recall has gone on, more specific impacts have been felt and we've learned and adjusted to those as well.

But — no, we knew from the very beginning this would be a very serious event.

THE PRESIDENT: I met early on with those CEOs and they were — they were trying to figure out how they could move quickly.

And you've been very helpful, so thank you.

DEPUTY DIRECTOR FAZILI: Thank you, Robert.

MR. CLEVELAND: Thank you.

DEPUTY DIRECTOR FAZILI: Thank you. Thank you for that. Forty percent faster is incredible and just a testament to the work that you and your team have been doing with all of your partners.

Tarun, I'm going to turn to you next. You know, while most of us here in the U.S. know of your company as Gerber, we know that Gerber and Nestlé are essentially the same — the same brand.

I wanted to get an update from you on the work that Gerber has done since Operation Formula helped them bring so much Nestlé specialty formula to the U.S. market. Can you give us an update on your ability to distribute that product to the families that need it?

MR. MALKANI: Thank you, Sameera. Thank you for the opportunity speak with yourself, the President, and members of the administration.

I'm going to first start by saying we take this responsibility very seriously to be part of the solution there. And in fact, without overstating it, at Gerber we feel this is our national duty. And we have crisis teams that are operating today, three and a half months after the recall, with the same level of urgency as we did when I got that first phone call informing me of the crisis situation.

This is demonstrated by our factories that continue to run 24/7. We have, in fact, from our domestic demand, increased 60 percent additional supply to the marketplace since the recall.

And as you mentioned, Sameera alluded to, the broader Nestlé — we're leveraging the full power of entire Nestlé network to be able to come to our aid in — at this time of crisis.

One of the things we will not compromise on, obviously, is quality and safety.

That's a core, core principle at Nestlé. So everything we do, even in these very dynamic and fluid times, we make sure that every product that goes out meets our highest standards. And the President alluded to that as well, when referring to Operation Fly Formula.

That has been a very powerful statement. The same urgency was shared by the administration. And since we received — to your specific question, Sameera — since we've received 60 tons of that product on one shipment and another shipment with the with Nestlé Health Science product, we have been rapidly moving those products through our distribution centers into the marketplace.

In fact, the product — and it was a privilege and a very proud moment for me to be with our First Lady, Dr. Jill Biden, and our Surgeon General, Dr. Murthy, to get that. Since that time, those — 40 percent of those cans that were received have already been — made their way to the store shelves, to hospitals, and other high-need areas.

So, from our perspective, Fly Formula has been very helpful for us. Again, the President alluded — we shaved off weeks from normal transit time. We're getting product off the shelf as quickly as we can turn it around.

And then finally, if I may add, is the same point that Robert alluded to earlier and the President alluded to as well: Working with the FDA under the enforcement discretion, we have submitted multiple proposals of, again, high-quality formula that has the potential of bringing in nine and a half million individual eight-ounce servings over the course of the next month and a half.

We're of course following all process. We have to follow the details here — make sure the recipes are compatible with our current recipes. We can track the product, as well as make sure that the label is in English for easy translation and obviously easy comprehension and have no translation issues.

So again, we're a small player at Gerber, but we believe now is the time to go above and beyond.

THE PRESIDENT: Can I ask a question? How — how are you supporting families that participate in the — in the WIC program, the Special Supplemental Nutrition Program — you know, Women, Infants, and Children?

When I spoke with the — with the retailers, we talked about making sure that they could be able to purchase — you can limit what you purchase under WIC and — based on the size of the container and the like. And we worked out a deal where they could — whatever container was available would be the ones that we used, and they would not be limited to being able to be stuck with — if you only had an X ounces or what- —

What have you been doing to accommodate that or talk about that with your — with your customers?

MR. MALKANI: Mr. President, that hits to the heart of the matter. In terms of WIC families, Gerber currently has seven contracts. However, working very closely — and big thanks to the USDA's flexibility, specifically referring to what you alluded to in terms of substitution opportunities, can size flexibility.

We now have, in addition to our seven WIC contracts — which we must protect to ensure product is available where we have contracts. But today, you will find Gerber product available in all 35 Abbott WIC contract states.

That comes through a lot of work on the ground with — again, I represent a large number of teams, a number of colleagues across the U.S. and across even Europe and across the world supporting us in this matter, working with the WIC offices on a local level, making sure our products are available for them in their formularies.

The WIC parent may shop at a WIC office; they may shop at a retail. They have multiple different distribution options. And we make sure our product is available through all of those means.

So we've been able — again, taking advantage in full partnership with the USDA, to get our product available — both the product that is normal-term usage, but also the specialized products that we have, because there are WIC families that have needs for those products as well. In fact, that is a core, core part of how we want to move forward — is make sure products available for the WIC families.

And then if I can build on that a bit, we're also making sure our specialized products, which have a unique need in the marketplace, is available through children's hospitals and other home healthcare partners where it's not the traditional (inaudible).

So it really is a number of different initiatives across multiple touchpoints where the WIC family has to be supported to make sure that they get the product, and we believe we're working very closely with the administration and having good success on that, sir.

THE PRESIDENT: It's really important. Thank you. Thank you.

I'm sorry for interrupting you.

DEPUTY DIRECTOR FAZILI: No, and USDA has done incredible work to approve a lot of those waivers in 24- to 48-hour timelines since February. And as the President laid out, all 50 states finally took action after — after he called them to task a few weeks ago on that.

And, you know, the 35 Abbott states that you mentioned, some of that was also due to USDA's effort to work with Abbott to make sure that companies like yours were able to get your product into those store shelves.

So thank you, Tarun, for that update.

MR. MALKANI: Thank you, Sameera.

DEPUTY DIRECTOR FAZILI: Murray, I'm going to turn to you next. A lot of families might not be familiar with the name "Perrigo," but I know that you provide a lot of the manufacturing for the private-label brands that they may be buying at a Target or a Walmart. So can you speak to us about what you've done to scale up production since February and the result of all that effort that you and your company have taken?

MR. KESSLER: Sure. First off, thank you for the opportunity to be here, Sameera. And thank you, Mr. President, for your leadership in this crisis. We all appreciate it. We are indeed a private-label manufacturer. And for those who aren't familiar with that, we don't actually market a national brand ourselves. We enable competition and we pack for 18 national store brands. Those are the retailers' brands and several national smaller brand and marketers.

So, in essence, we are creating competition, and those store brands sell for about half the price of the national brand. So we're — we're proud that we provide an affordable, accessible, while still maintaining superior quality. Consistent with our vision to make lives better, we play a vital role in providing access to affordable

infant formula. And we — as I said, we also foster competition.

Now, when I joined the company about three years ago, we saw the need for strengthening the resiliency of our infant formula business. And over the last three years, we've put about \$100 million into the facilities so that they would be reliable and they would be resilient. And that's benefiting us tremendously right now.

Like what you heard from everyone else so far, our 500 associates and our manufacturing facilities in Ohio and Vermont are running 24 hours a day, 7 days a week, and have done so all while navigating global supply chain shortages and tight labor market.

Let me walk you through the specific steps to increase output. The very first thing we did when we heard about the Abbott recall was — we could foresee that this was going to create a tremendous shortage. We significantly increased all our material orders. We began communication with the FDA immediately. We began collaborating closely with the — you know, the FDA, our retail customers, and other stakeholders to identify and prioritize what was most critical. And we've been meeting, by the way, weekly with the FDA ever since.

The very first thing that we did was take one facility and run a year's worth of hypoallergenic formula, because we believed that was most critical. After that, the second thing and what we've done ever since is focused on the highest four formulas — volume formulas in the category to feed as many babies as possible with a formula that most closely resembled what the babies were already eating.

Remember, as a private label manufacturer, it's our job to — to — and we strive to develop products that are designed to be almost exactly the same as the national brands, so it wouldn't be a change for infants. And because of that, we felt we had a unique responsibility. And it was in collaboration with our — our customers and the retailer that we pick the four that we focused on.

By focusing on four, we were able and still today are running at 115 percent of our maximum capacity. So our theoretical capacity, we're — we're running millions of pounds more. And in the four months of 2022, our output is up 32 percent. That is, we shipped 32 percent more product than a year ago through the combination of that higher output and the use of the safety stock inventories we had. That's gigantic for us.

Mr. President, we appreciate you making your staff, the FDA, and, most recently,

HHS representatives available to us right from the beginning — like I said, it was within a matter of days — to help get through this crisis. And I can assure you that Perrigo is doing everything that can be done in order to help.

We are well prepared. We are not having supply problems. We are not having supply issues. We are running full out and will continue to do so for as long as needed. And we are continuing to make investments and will continue to invest going forward to support increased reliability and capacity in the — the industry.

Our company is proud to be part of the solution to this shortage, as no family should have to worry about being able to feed their baby.

So, once again, thank you for your leadership on this crisis.

THE PRESIDENT: Well, thank you for doing such an incredible job moving so quickly. Thank you.

DEPUTY DIRECTOR FAZILI: Okay. Well, it was helpful to get an update from the, kind of, leading domestic manufacturers. But we're — we're going to switch gears a little bit and switch countries and talk about — one of the new actions that we've taken is that the FDA has put in place new flexibilities to allow imports to bring new entrants into the market.

And so, Kristy, I want to turn to you next to tell us about — about your company, about Bubs, and the formula you make, and how soon we're going to be able to get that formula here in the U.S. now that the FDA has approved you for sale and distribution.

Although I should probably ask you first: What time is it down there?

MS. CARR: (Laughs.) It's — it's around four o'clock in the morning. But now that we run a 24/7 operation, and — I think most of the Bubs team now feel like they're on Washington, D.C., time. So — so that's perfectly okay.

And, Mr. President, I'd like to start by saying just what an honor it is to be able to be here and talk to you personally. And thank you for inviting myself, on behalf of Bubs Australia, to participate in this important roundtable conversation.

So, Bubs Australia is Australia's leading, vertically integrated brand of infant formula. I first founded the business 17 years ago when my first daughter was

born. And over those 17 years, we have been nourishing children, both here in Australia and in the 10 markets that we export, over 1 million babies without incident.

We are very passionate about feeding the next generation of children with clean, safe, and reliable infant nutrition products.

So, we already sell our Aussie Bubs toddler milk formula products in the United States — in many retailers across the states. And as we've started to see this infant formula shortage unfold — and I've visited the States a couple of times already this year — we knew we wanted to help.

I'm sitting here in our Bubs Australia facility in Victoria, the dairy capital of Australia. It is a FDA-approved facility. And we had already started the journey for having our three lines of infant formula products approved for export into the United States.

We knew that our products already met the FDA nutritional requirements, so we would make contact with your sales, with the administration, and with the FDA. And I am very — I'm very pleased to be able to now be in a position where we can help — help the situation. And I commend you, Mr. President, on being able to bring government and regulatory — and industry together to help solve this problem as one collective group.

Obviously, logistics in moving this quantity of infant formula in a short period of time is complex. And I'd like to take this opportunity to thank you for including Bubs Australia in Operation Fly Formula.

So, as you mentioned, the White House has announced today that we are now in a position to fly our first two air cargo carriers over to the United States. We will be sending two planes full of our infant formula products next week, with the first plane leaving on June 9 to fly into Pennsylvania and the second plane leaving on June 11 to fly into California.

Across those first two planes is about 380,000 pounds of infant formula — or the equivalent of 4.6 million standard eight-ounce baby bottles.

We are now working alongside the HHS to wo- — to determine when the first possible time is to bring in the next two planes, and we plan to do that in the

coming weeks.

So, our plan — our strategy around distribution is to be able to initially put our products into the distribution centers on both the West and the East Coast. We will be distributing our products to both the major retailers of infant formula, as well as some of our smaller retail partners, to make sure that we prioritize the states that are most in need and, of course, the vulnerable population areas who need infant formula most.

So, again, I'd just really like to take this opportunity to thank you, Mr. President, and your administration. Both the HHS and the USDA have been working with us around the clock since this new initiative took place. And we are delighted we're able to help out in some way and bring Bubs infant formula products to American families.

THE PRESIDENT: You're helping out a great deal. Thank you.

MS. CARR: Thank you.

DEPUTY DIRECTOR FAZILI: And, you know, that partnership is going to continue what — with these Operation Fly Formula flights. We continue to work to make sure there aren't regulatory barriers, border barriers to bringing this stuff in quickly. So, we will continue to be working with you, Kristy, and others.

Well, let me turn it next to — to Ron, because it's not like new entrants are only sitting overseas. There's a lot of entrepreneurs and innovators here in the U.S.

So I want to hear from you about how your company was recently able to receive FDA approval and the steps that you're now able to take to ramp up production as one of our, kind of, first new companies in this space in a long time.

Although I should also say, like, you might also not know what time it is, I hear, because I hear you may have a new entrant in your family as well. So, thank you for joining us despite being a new father, I think, as of last week.

MR. BELLDEGRUN: Yes, correct. Well, look, first of all, thank you for having me at this important discussion.

You know, we launched in an unprecedented time, when parents are more anxious than they've ever been. You know, no parent should have to experience a shortage of sole-source nutrition for their baby. And I say that not just a CEO by heart, but,

as you point out, as a parent myself. My wife and I just had our second little one this past weekend.

My co-founder and sister, Mia Funt, and I started ByHeart six years ago to translate major advancements in nutrition science and breast milk research into infant formulas that are the most wholesome and functional alternative to breast milk. You know, all parents deserve to feel proud in how they feed their babies.

With ByHeart's launch earlier this year, we became the first new infant formula manufacturer to be registered with FDA in this country in over 15 years. We started this work, you know, well before a shortage, with a motivation really to innovate. And we're grateful to the Biden administration and this FDA's kind of recognition for the need for new manufacturers.

You know, with our launch, this became the first administration and FDA to register a new infant formula manufacturer in over four administrations.

Having been immersed in this category 15 years, we knew full well the barriers to entry we were up against. You know, infant formula is appropriately the most highly regulated food in the world, and the consolidated supply chain makes it nearly impossible for new entrants.

There were just four companies that manufacture infant formulas. Three of those dominate 90 percent of the category. And so every new entrant in decades has taken the same path: to outsource to the one and only contract manufacturer in the country and rely on an expedited generics-like path to market, which only allows for incremental change based on existing recipes.

Now, had we taken that path, we would have been on the market four years ago, but we didn't get into this for incremental change. We knew there was only one way to truly innovate for babies, and that was to build from scratch.

And so, we acquired and built manufacturing in Reading, Pennsylvania. We directly sourced all our ingredients to ensure we have complete oversight and highest quality. And we brought together the world's experts to completely rewrite the recipe and conduct the largest clinical trial from a new brand in 25 years to clinically prove our benefits. That's why it took us five years and not one.

Well, now, we are just one of five companies in this country that manufacture infant

formula, and we take that responsibility very seriously.

Just two months into our launch, which saw unprecedented demand, pacing at 15 times our most aggressive projections, we are investing heavily into initiatives here at home in the U.S. that can enable an additional over 500,000 new babies to be fed and put us in a position to feed some 15 percent of new births.

We're investing heavily into Reading, Pennsylvania, with a new \$30 million investment. We're hiring relentlessly, adding a whole new shift. We're already working 24 hours a day, 5 days a week. We're in processed of moving to 24/7.

Within days of the enforcement discretion policy being announced, we had two submissions into FDA to expand our manufacturing footprint and accelerate fulfillment to get parents formula quicker, all here in the U.S.

You know, we're throwing everything we have at this crisis, but we can't do it alone, and we're grateful for the support we've received to date from the Commonwealth.

Mia and I are in this moment ourselves. You know, Mia's third baby, Simone, is 10 months and actually drinking ByHeart. And my wife and I just had our second this past weekend. So we know personally and professionally that this country can never be in a situation again where one company has a recall and 40 percent of the country is without infant formula. And the only way we ensure that doesn't happen again is to invest in new domestic manufacturing, diversify the supply chain, and create that ecosystem for innovation in infant nutrition here in the United States.

So that's what we've done. And that's what we plan to continue to do.

THE PRESIDENT: Good luck with the new babe, ol' buddy.

MR. BELLDEGRUN: (Laughs.) Thank you.

DEPUTY DIRECTOR FAZILI: Thank you for that. I will say, as a — as a parent myself, hearing the kind of rigorous standards that the FDA has in place to bring new entrants into the market is reassuring and — and shows how we have this science-based policy here to make sure that the formula that's available for families, whether it's through new imports or through new domestic entrants, is safe and healthy for families to have.

Let me — now that we've had that update from the manufacturers and have a

sense of how production is increasing, how new entrants and new supply is now on its way and already making its way to store shelves, I want to turn to have us talk a little bit about parents and what they're going through right now.

Again, as a parent myself, who had a child who was on a specialty formula and pretty recent — recently weaned, I know that the administration has been taking a lot of steps to work with families to make sure they're — they're getting the support they need to make their way through this crisis.

So I'll turn it over to Christen.

DEPUTY ASSISTANT LINKE YOUNG: Great, thank you. Thank you so much, Sameera. And thank you to all that — that you all are doing as manufacturers to bring new supply to market and help us serve Americans parents.

But as we heard from all of you, this is just an incredibly challenging time for — for American families. I, too, am a parent, and I'm expecting my second child at the — at the end of this month. And we — we know — we know how difficult and how scary this time can — can be for folks.

Dr. Murthy, you have been talking to parents and doctors across the country about the challenges of this moment. Can you tell us a little bit about what you — what you think the key messages are that parents need to hear who are worried about finding formula for their families?

SURGEON GENERAL MURTHY: Absolutely. Well, thank you, Christen. And, yes, talking to communities, our public, you know, information efforts have been a key part of this overall effort. I just want to say, also, thank you to everyone who has joined the manufacturers from around the world, really. This has been a team effort. And, you know, President Biden, thank you for making this a priority and for instructing everyone in this administration that no stone should be left unturned in solving this problem.

Our military servicemembers have moved mountains to make sure we can get formula to shelves here, and our departments like HHS, DOD, USDA have also just pulled out the stops to increase production.

All of this has made the progress possible that we've seen today, but we're not going to stop now. Because a key group that's been involved in the — in these

efforts has been community groups, doctors and nurses, medical and nursing organizations, community institutions which have stood up to help reassure patients and get them accurate information. And I want to thank those groups because we are really pulling together in this crisis.

To all the parents out there who might be worried at this point about the food supply for your child, there are a few key messages I'd like to share with you today. The first is to know that while we are moving fast and pulling out the stops here, safety is still our priority.

We are bringing in formula from abroad but only formula that meets the FDA's gold standards for safety. The FDA knows how important those standards are. It takes its responsibility to provide safe formula to families very, very seriously.

The second point I want to share is that for safety reasons, we are recommending that there are certain things that you not do, like water down formula or make formula at home, or use toddler formula for infants. I can absolutely understand why people may consider some of these options, but the FDA does not consider those safe at this moment, which is why we're not recommending them.

The third point I'd like to make is that it is okay to use a different brand of formula if the one that you're used to isn't on the shelf. And look, as a parent whose child is recently on formula, I know how scary it can feel sometimes to switch brands of formula. The key thing to know is that if you find formula on the shelf, it is formula that has met the FDA's standards for safety. So that is the good news here.

And the last point I want to make is that if you're a parent out there who's worried about food for your child, I want you to know that we are right here with you. We are standing alongside you, and we are not going to give up until this challenge has been met — until every parent has the formula that they need for their children. We're going to continue to pull every lever that we have.

And I want you to know that we approach this not just as public servants, but as parents as well. This is very personal to many of us who are parents or grandparents. And you've heard that already from the folks here today.

This is — a few years ago, my son was on infant formula. And I can just imagine how I would have felt if that formula had not been available to him.

So, I just want people to know that — while we have made progress in increasing production, while we've made progress in bringing supply in from abroad and taking steps to reopen the plant that was closed in Sturgis that the company is now working to get back into production — we are not going to stop until every family has a formula that they need for their children. That's our commitment to the public not just as public servants, but as parents ourselves.

So, I'll turn it back to Sameera.

DEPUTY DIRECTOR FAZILI: Thank you.

Mr. President, I'll turn it back to you. A few weeks ago when we met with you, you told us: Pull every lever, find new levers, do what you can do to solve this challenge. Because it was weighing on families and it was important that we showed people what the government can do when it kind of is put to the test and brings everyone together.

So, since then, HHS, the USDA — the U.S. Department of Agriculture — the FDA have continued to pull together. Working closely with manufacturers, as you've heard, we've brought some new ones to the table. We've worked closely with states. We got all 50 to take action. And we continue to work closely with the retailers to kind of answer your charge.

But I would turn it back to you now that we've given you this update on where we've — where we've gone and where we're headed.

THE PRESIDENT: Well, I'll be very brief. Look, I used to have a friend — and Vivek has heard me say this before — used to say, "You got to know how to know." "You got to know how to know," meaning that we need, what I've found, as parents come up to me in the street and I talked to my family about it — and I don't have any infants in my family; I have a two-year-old grandson, but that's — he's beyond that and — but there's a lot of kids in my family.

And people will come up to me at church or wherever, and they want to know whether or not, even though they're not on a particular formula, that — can they switch a formula? And — and because they hear about all the safety requirements, Doc. And you talked about it a little bit. You le- — let people know that there are things, there are options within even the limited supplies that occurred, or you may not have the exact brand you used before, but another brand is in fact able to be

used.

And so, I think that's an important thing to — because the anxiety that men and women have — mothers and fathers, grandmothers and grandfathers with infants — is pretty profound. No one ever wants to make a mistake. And it's — so I think part of it is just relieving a little bit of the anxiety.

Once we have — we have significantly more formula available now, and we'll have significantly more in the next month or more. And as we get Abbott back online, there's going to be a whole lot more. We're going to solve the problem.

But, you know, ensuring safety of a newborn child is — is a mother and father's top priority. I mean, it's — it's a basic, basic thing. It has been my top priority as a father and grandfather, and it remains at the top of my priorities today as President of the United States.

You know, as we close, I want to thank all of you — I really mean it — I want to thank all of you for the updates on the progress you've made because, you know, we've had other crises that I've dealt with as President and as Vice President, but I find that this is almost personal to everybody — to the manufacturers, to the — just it's — it takes on a personal aspect to it.

And, you know, the hard work your employees have made an important difference in restoring the supply for infant formula. But there's still a lot more to do. So, I ask you to keep focused, stay focused, stay in high gear. We can't let up on the infant — on the infant formula market back — until it's all the way back to normal. And that's going to take a couple more months, but we're making significant progress.

And — and I thank the folks from Down Under as well. Kristy, thank you very much and for all the — all the way in which that we're bringing in formula from around the world. That is, again, letting our constituents know, Doc, that it meets the standard. We're not bringing anything in that doesn't meet the highest standards.

And so, as my grandfather would say, "With the grace of God and the goodwill of the neighbors, and the crick not rising," we're going to make a lot more progress and ease the anxiety — a significant amount of anxiety on the part of moms and dads with newborns, so —

And we particularly want to ease that anxiety on the staff. You know, we're going

to — that's going to be coming pretty soon.

So, thank you all very, very much. I truly appreciate it. And you've really answered the call. Thank you, thank you, thank you. Appreciate it.

Q Mr. President, will anyone at the FDA be held accountable for how they handled this?

THE PRESIDENT: (Inaudible.) The — the question is whether or not there was a — this could have been moved quicker. You know, the question you always love to ask me is, on every single thing: Why didn't you act sooner?

Well, I don't think anyone anticipated the impact of the shutdown of one facility in — the Abbott facility. And it was accurately shut down because it was — the formula was questioned, in terms of its purity.

And so, once we learned of the extent of it and how broad it was, we kicked everything into gear. And I think we're — I think we're on the way to be able to completely solve the problem, but —

Q But didn't those —

Q But, sir, the executives said that they knew it immediately.

Q Excuse me, Mr. President, didn't those CEOs just tell you that they understood it would have a very big impact?

THE PRESIDENT: They did, but I didn't.

Q But shouldn't the FDA have been more aware of that when they took months to conduct the inspection to interview people at this plant after the complaints were made and then only shuttered it in February?

THE PRESIDENT: Well, the real problem occurred when it started — when it got shuttered. So, you're saying we — they should have anticipated it would be shuttered.

Q They got complaints about —

THE PRESIDENT: The answer is —

Q — the facility last fall, Mr. President.

THE PRESIDENT: Well, here's the deal. I became aware of this problem sometime in — after April — in early April, about how intense it was.

And so, we did everything in our power from that point on, and that's all I can tell you right now. And we're going to continue to do it until we get the job done.

Q Mr. President, on another topic: gas prices. When are gas prices going to start coming down? Record high today.

THE PRESIDENT: (Inaudible) record high. It could be higher, but we were able to keep it from going higher.

But, look, there's a lot to do. We're in a situation where, you know, because of a war in — in Ukraine, gas prices and food prices are extremely high. For example, we have millions of tons of wheat that is not able to get out and get to market, causing everything from a loaf of bread to cost so much money to food shortages all across the world.

And so, we're trying to work through, you know, a war. We're trying to work through how we can get that harbor opened and get — get the, you know, tens of thousands of tons of grain that are there.

The same with gasoline. You have the — the issue that is occurring now is you have Europe deciding that they're going to further curtail the purchase of Russian oil, and there's a whole lot of consideration going on about what can be done to maybe even purchase the oil but at a limited price so that it has to be sold. There'd be an overwhelming need for the Russians to sell it, and it would be sold at a significantly lower price than the market is generating now.

There's a lot going on right now, but the idea we're going to be able to, you know, click a switch, bring down the cost of gasoline, is not likely in the near term, not is it with regard to food.

But here's one thing we can do. Look, and I'll talk about this a little bit tomorrow, and I'm going to stop. One of the things — one of the things that happens, when you talk about gas prices — the cost of a ga- — a gallon of gasoline or the price of a loaf of bread, there are things that affect families in their everyday budget. You know, their standard of living are affected by that. They have X amount of dollars

they make and — although, thank God, employment is up and wages are up. Notwithstanding that, inflation is running at a high rate.

And they have all these needs and concerns. There's more than one way to change — to maintain the standard of living for people, in the sense that the overall, out-of-pocket money needed to be able to make sure that they're able to get through all their needs for — on a monthly basis.

You can compensate — you can compensate, for example, by having drug prices drop significantly or impact on child care or impact —

The bottom line is the bottom line: how much it costs you to maintain your household and your standard of living. And there's not — we can't take immediate action, that I'm aware of yet, to figure out how we bring down the price of gasoline back to three dollars a gallon. And we can't do that immediately with regard to food prices either.

But we can compensate by providing for other necessary costs for families by bringing those down. That reduces the inflation for that family. And we can do that — we can do that, at the same time, by increasing the tax rate that should go up on some corporations that are paying no taxes at all — have a mini- — pay a minimum tax — and the very wealthy. No one under 400 grand would have to pay another single penny in taxes, but it would not be inflationary. It would help pay for — it'd reduce the deficit even further, and it would provide relief for families.

But I'm going to talk more about that later. Thank you very much.

Q Are you confident Congress will take action on gun legislation, sir?

THE PRESIDENT: I served in Confre- — Congress for 36 years. I'm never confident, totally. It depends. And I don't know. I've not been in — on the negotiations that are going on right now.

Q Are you going to get in on the negotiations?

Q Do you plan to get involved?

THE PRESIDENT: I've been involved. I'm just not confident.

3:43 P.M. EDT