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Questions for the Record
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QUESTIONS FROM SENATOR BOOKER

1. Several small formula manufacturers aim to expand capacity and sales within the U.S. Many of these small manufacturers have committed to the World Health Organization (WHO) International Code of Marketing of Breast-Milk Substitutes, which prohibits the marketing of formula to mothers with infants ages zero to six months.

   There is an understanding that large, consolidated formula companies in the U.S., including Abbott, Nestle and Mead-Johnson do not adhere to this code and actively market to mothers as soon as they become pregnant, throughout their pregnancy, and even once they have had their baby. This issue becomes even worse along racial lines.

   A recent study found that Black mothers are nine times more likely to be given formula in the hospital than white mothers. They also receive less lactation support, encouragement, and training on how to breastfeed. These smaller companies share they simply cannot compete in the marketplace when their competitors would have such an overwhelming advantage from them from the start.

   a. Do you think we should require all formula manufacturers to adhere to the WHO Code?

I absolutely believe that the United States should require infant formula manufacturers to adhere to the WHO Code. This single policy change would have significant public health impact on both maternal and child health. To be candid, infant feeding in the United States has focused first and foremost on revenue generating capacity with public health a secondary goal.

The International Code of Marketing of Breastmilk Substitutes from the World Health Organization (the Code) covers marketing and promotion of products meant to substitute for breastfeeding. It does not ban their sale or use; it simply restricts how they may be promoted and marketed in order to protect the health of infants and young children by supporting breastfeeding/nursing. The Code is a World Health Assembly Resolution---a recommendation that nations pass legislation to implement the guidance in the Code so that it is enforceable. The Code is needed to support infant health and prevent unscrupulous practices which may undermine breastfeeding in the production, promotion, and sale of breastmilk substitutes.

The Code covers any formula, food, and drink that would substitute for breastfeeding targeted to babies under 6 months, or formula at any age up to 36 months. It also covers the marketing of bottles and nipples. Labels on products must be written in local language, without using images or wording that would idealize the product. The label must also include the hazards associated with artificial feeding and the appropriate use of formula with safe preparation for babies who need it without discouraging breastfeeding. Hazards of improper mixing must be stated. In addition, the label must state the

superiority of breastfeeding and that the formula must only be used on the advice of a healthcare professional.

The Code forbids promotion to parents, including advertising and free samples, and does not allow gifts and free samples to healthcare professionals, nor to healthcare facilities. The Code addresses those that manufacture any of these items. It also calls for healthcare workers and systems to follow the Code.

A recent report released by UNICEF and WHO outlines the often deceptive and financially driven marketing practices of infant formula manufacturers and the affect of these actions on infant feeding decisions. We are in an era of big data and simultaneously that of individualized and targeting marketing. Retailers are able to use key metrics to easily identify which customers are pregnant and begin sending coupons, offers and other helpful information in a manner that is just general enough to hide the intent from the consumers that are targets. An expectant mother may not know that coupon offers she receives for a store that happens to contain baby or pregnancy items is any different from the offers given to another shopper – but they are. They are cunningly similar enough that women don't feel an invasion of privacy yet targeted enough that the retailer can begin courting the family and, in some cases, sharing their pregnancy status with partners and vendors.

It doesn't stop there. Once parents-to-be are identified, efforts are made to include them in social media groups and communities which on the surface portray themselves as places of exchange and dialogue while secretly taking steps to instill doubt in women that they can't successfully breastfeed and therefore should have a back-up "just in case."

Because of the influence that formula manufacturers currently have on parents and the healthcare industry, it is easy to understand why so many that initiate breastfeeding (over 80% of births in the U.S.) later choose formula over the healthier option. Our country faces many challenges with nutrition security and economic stability for families of color. The Code would help decrease disparities in BIPOC communities and would eliminate social injustice that results from deceptive marketing that result in long-term health consequences.

We need safe infant formula that is designed to support nutrition when breastfeeding is not feasible, it is not an in lieu of decision.

b. Please share your observations of hospital practices when offering formula to mothers for their infants. Have you observed inequities in formula marketing practices?

The decision regarding how a baby will be fed is often made during the second or early in the third trimester. This means that while hospital practices are important to consider, we must also look at the entire continuum of care. It is exposure to formula messaging along with inadequate or ambivalent prenatal breastfeeding support during pregnancy that make hospital practices simply the next step in the undermining of breastfeeding and acceptance of formula as an alternative. The National Association of County and City Health Officials partnered with the United States Breastfeeding Committee to launch the Continuity of Care in Breastfeeding Support: A Blueprint for Communities.

"The Blueprint, developed with a public health lens, aims to increase local capacity to implement community-driven approaches to support chest/breastfeeding, centered on the needs of populations disproportionately impacted by structural barriers that leads to low rates of breastfeeding. The goal of this resource is to ensure that chest/breastfeeding support services are continuous, accessible, and coordinated,

and that community spaces are consistently supportive of chest/breastfeeding families" notes the NACCHO website.

In my career in the care of mothers and babies, I have been aware of the lower breastfeeding rates in the non-Hispanic Black population. There are certainly challenges that this group of mothers face, including poor support at home and in the workplace, along with a need to return to school or employment before breastfeeding can be successfully established. However, many of these mothers are provided with formula in the hospital setting "just in case it doesn't work out." I've seen and heard this many times from mothers who have reported that they are given gift packs of formula as they leave the delivery hospital which can subtly imply that they will not be able to reach their breastfeeding goals and subsequently plants the seed of doubt in their ability.

The use of formula early on can sabotage a mother's milk supply if she is not provided with guidance from an experienced lactation professional. Many mothers do not receive the pre-natal information that would educate them on how supplemental formula could disrupt breastfeeding. Also, many of these mothers are not empowered with self-efficacy behaviors and they are easily influenced, especially from nurses or other healthcare providers who provide formula as a good-will gesture without realizing the disruption it can cause with the establishment of breastfeeding. Those on the WIC program know that they are eligible to receive formula with their vouchers and so may not worry about infant feeding if breastfeeding "doesn't work out." In addition, many WIC clinics do not include a clinical lactation expert, namely an IBCLC, who is able to provide the kind of support that many WIC clients need to help them work through the breastfeeding challenges they face.

c. How has the consolidation of baby formula manufacturers impacted the ways in which large institutions like hospitals are able to acquire and provide baby formula?

Because these manufacturers have such a stronghold on the production of infant formulas, they can produce large quantities so that prices can be very competitive and many hospitals, including delivery and children's hospitals, can even acquire some infant formulas free of charge. These companies know that if mothers begin using their product shortly after birth, not only will any attempts at breastfeeding be disrupted, but mothers are likely to continue to buy the formula product after they go home from the hospital and likely for the full first year of the baby's life.

The manufacturing and dissemination of infant formula is tightly controlled by those entities that can align themselves and contract with government programs such as the Women, Infants and Children's Supplemental Nutrition Program through which participants purchases over 50% of the nation's formula. This emphasis on a few very profitable companies along with stringent FDA processes for new manufacturers make entry into the market by smaller manufacturers nearly impossible.

Having a supply of free formula provided to a hospital's inventory makes dealing with these companies very attractive to such institutions. They don't necessarily have incentive to promote and protect breastfeeding. Even though the CDC keeps breastfeeding data through the mPINC survey (Maternity Practices in Infant Nutrition and Care) which assesses maternity care practices and provides feedback to encourage hospitals to make improvements that better support breastfeeding, this does not do much to deter them from receiving free formula, and so the formula manufacturers can continue to provide "free-flowing" product without much discretion from hospital workers.

Unlike other types of pharmaceutical products and samples which must be tracked and their promotion limited in hospital and provider settings, infant formulas are readily available and although they are a

"loss leader" for an infant formula company, most know that if they can hook the family on the brand prior to discharge they will have a loyal customer, likely for the first year or as long as the infant receives formula.

An exception to this entire process can be found in hospitals that meet the Baby Friendly USA designation. These facilities agree to refine and uphold the standards/criteria for successfully implementing the "Ten Steps to Successful Breastfeeding." and a commitment to follow the International Code of Marketing Breastmilk Substitutes in an effort to increase the likelihood of breastfeeding initiation and duration. The designation is not an easy one to acquire, however. Institutions seeking this recognition must adhere to policies which restrict the use of artificial feeding and assure that all staff are educated on how to support breastfeeding in the hospital.

d. What are the reasons for which an infant might require specialized or specialty formula as opposed to traditional formulas?

A number of medical diagnoses, conditions and intolerance to standard infant formula require specialized formulas to support normal growth and development of infants.

Some infants born with genetic diseases or inborn errors of metabolism may not tolerate human milk and would require a special formula. There are a variety of formulas that eliminate a specific nutrient or nutrients that the baby cannot metabolize or absorb. These are necessary for the life-long health and survival of these children. Examples are children born with phenylketonuria (PKU), or maple syrup urine disease (MSUD). Other formulas may be needed only temporarily until the baby's digestive system matures or to sustain them through a specific time of illness, or slow growth. These examples include short gut syndrome (where part of the intestines die and must be removed), or malabsorption from chemotherapy (as in the case of childhood cancer). These formulas are necessary to assure that the baby/child is provided with the adequate nutrition for proper growth and development.

Of note, if the specialized formula is not available and standard formula is the only option, infants experience everything from bloody stools, gas, colic, rashes and reflux that can ultimately cause hospitalization in addition to making early infancy extremely stressful for parents who find themselves devoid of sleep while depleting financial resources.

e. Why is the production of specialty formulas as limited as it is, for example with some specialty formulas only produced by Abbott Laboratories?

These formulas are expensive to produce and not used in the quantities that standard formulas are used. Upon researching, I found the following companies as the top producers of specialized formulas, and although some are not American companies and may be more expensive if imported, a wider market may allow price reduction in the U.S.

Cantabria Labs, Abbott Laboratories, AYMES International Ltd., B. Braun Melsungen AG., Baxter International Inc., Cambrooke Therapeutics, Inc., Danone Nutricia, Fresenius Kabi AG, GlaxoSmithKline plc, Kate Farms, Inc., LLC, Medifood GmbH, Medtrition Inc., Meiji Holdings Co., Ltd., Nestlé S.A

The nation's healthcare system isn't built to easily accommodate people with rare disorders, and don't have the research and money behind them that other diseases do. Medical foods started out as a prescription drug, but manufacturers re-classified them as a food in the 1970s to cut down on research costs. Formula manufacturers are profit-driven businesses, and many insurance companies do not cover the cost of these formulas, so people with rare genetic diseases are left to purchase this on their own. Since there is not much profit in these products, many companies are hesitant to produce them.

f. How long does it take for infants to start to experience dangerous symptoms and health issues as a result of being deprived of baby formula, and what alternatives do parents have when baby formula is unavailable?

Let's start with the early symptoms. Babies communicate through crying when they are hungry. Eventually if this hunger is not addressed and nutrition is not provided, they will become lethargic and dehydrated. Parents are facing the unimaginable situation of knowing that they must feed their babies, they don't have the resources and they are told not to feed homemade formula or toddler formulas. No parent wishes to see their baby suffer from a lack of nutrition; no member of your committee wishes to see that. Parents are desperate to find alternatives, but I would be naive to think that some parents are giving what we know happens even outside of the pandemic, soda, cow's milk and even sugar water to keep their babies pacified.

Infants cannot go long without nutrition since their body size is small and they require adequate hydration and nutrients for proper growth and development. Young infants (0-6 months) may require up to 8-10 feedings a day to maintain their hydration status. Adequate nutrition provided by human milk or infant formula is necessary for their growth and well-being. It would only take a few hours before a young infant faces danger and possibly perish if no feedings were given in 24 hours. If an infant is receiving a specialized formula that becomes unavailable, they may begin to show signs of malabsorption (vomiting, diarrhea, poor growth) in a matter of hours or days. Parents who are experiencing a formula shortage or unable to find the usual formula they feed their infants have a few choices:

- *First and foremost, parents should talk with their health care provider about their situation and seek guidance and counseling.*
- *While physicians and nurses can offer advice about alternatives, it is registered dietitian nutritionists that can work with the families to overcome challenges with new formulas and identify alternatives if the trials are not successful.*
- *Parents can check smaller stores/pharmacies if larger grocery stores are out of formula*
- *Check online sources to find formula, but avoid purchases from unknown sources, retails or internet communities. These products may not be safe.*
- *Social media groups may alert followers to stores where there is a supply*
- *Substitute a similar formula after checking with a healthcare professional for guidance*
- *If the baby is >6 months of age and eating other foods especially high in iron, whole milk can be used for a short period until formula is located (no more than 24 oz/day)*
- *Newborns should be breastfed to reduce the demand for formula and preserve supply for infants who are not breastfed, and seek access to registered dietitian nutritionists and lactation consultants for guidance and support*
- *A mother can consider re-lactating with the help of a lactation expert (a younger baby increases the chance for success) who will carefully monitor milk production and growth.*

- *Contact a regulated milk bank (HMBANA) to inquire about purchasing donor human milk (if resources are available)*
- *Parents sometimes ask about obtaining human milk from a friend or relative, or even someone they don't know. This is highly discouraged as the milk can contain medications, viruses, or bacteria that could be harmful to a baby. If used at all, only milk that has been pasteurized properly should be fed, and only under medical guidance.*

I hope that I have answered your questions sufficiently. Please let me know if anything needs clarification or further explanation. I appreciate your concern and advocacy to resolve the formula shortage issues so that it can be resolved and prevent this from happening again in the future.

Thank you for the opportunity to respond to your questions,

Respectfully,

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