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This Mom-invented product Solves a Condition that Affects 2/3 of Babies

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Interview conducted by:
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CEOCFO: ***Ms. Diaz, what is the idea behind Bittylab®, LLC?***
Ms. Diaz: Hi Lynn, thank you for this interview. The idea behind Bittylab is to bring a product that solves gastroesophageal reflux to Moms and babies. Statistics show that two out of three full-term babies suffer from severe gastroesophageal reflux symptoms (GER). For these babies, parents, and doctors, the first year can be challenging as the symptoms cause much distress. As you can see, GER symptoms happen in the majority of babies. After several years of research, we have learned that air-swallowing could be the biggest contributor to its cause. GER should not be considered normal, and it can be treated and prevented. Our patented device is getting attention from the medical community because it shows to be effective at decreasing GER symptoms.

CEOCFO: ***Why has this been overlooked for so long? I never realized that two out of three babies have digestion problems. That should have engendered a lot more remedies than we have.***
Ms. Diaz: I agree! Gastroesophageal reflux is not a condition that should be taken lightly. There's an understanding in our society that if something occurs in most of a population, it must be normal. This train of thought and the fact that babies "outgrow" GER between 12 and 18 months of age has resulted in overlooking GER in young infants. A superficial look at this phenomenon indicates that humans are born sick and must endure digestion problems for the first year of their lives, which –of course— sounds unnatural. If we look at statistics, we find that the percentage of breastfed babies who develop GER is much less than babies who are bottle-fed; but breastfeeding drops around the second or third month, usually when maternity leave is over. This curve coincides with GER peaking at 4-months of age. To me, it is evident that baby bottles have a big impact on GER increase.

I personally saw the dramatic change in my baby after introducing baby bottles to my breastfeeding routine. He became fussy, crying all the time, day and night. What made this problem worse was that there weren't any solutions, which made my first days of motherhood very difficult. I didn't accept the fact that this should be normal and decided to start my research.

CEOCFO: ***What have you developed at BITTYLAB?***
Ms. Diaz: After all the research done for several years, I learned that air-swallowing while feeding creates many of the problems associated with gastroesophageal reflux. While air-swallowing can happen for many reasons, it is particularly harmful when it occurs during feeding. It could happen while breastfeeding if the baby is not latching properly. The constant air-infiltration from traditional baby bottles evidently exacerbates GER. Despite the sleek marketing claims, air-

vents introduce air inside the bottle, which mixes with the milk, and the baby will ingest it. Bottles with bags, disposable liners, silicone cups, etc., retain air, which mixes with the milk, and the baby ingests it. The most important feature of Bare® Air-free is to dispense true air-free milk while the baby feeds to minimize or prevent air-swallowing. There is not much research done on air-swallowing and its consequences primarily because there wasn't an available feeding system that prevented air-swallowing. This was the reason why we focused on air-free feedings. If the air introduction in a baby bottle causes problems, then… no air inside a bottle should not cause such problems.

Simultaneously, research indicates that when babies are fed in a horizontal position, AKA lying down, they tend to regurgitate much more. That literature implies that changing the feeding position from horizontal to more vertical helps gravity keep the food in the belly. Bare® Air-free is designed to feed in a 100% vertical-upright position.

The invention is a feeding device that allows the user to expel the air from inside the container, like a syringe. I actually worked at my kitchen table for three years to design and engineer this kind of solution. It is very novel and took a long time to develop and manufacture. If you think about how syringes work, the nurse or doctor expels the air from inside the container before injecting it into your veins, so that it is completely air-free. Bare® Air-free works in a similar way. You first install the Air-plug®, a silicone plunger, then fill in the container and close it. Then, push that Air-plug® from the bottom up to expel the air, like a syringe. Once you get rid of all the air, it's ready to feed. When the baby creates the suction, the Air-plug moves automatically to dispense air-free milk while the baby is in 100% vertical-upright position, with face tipped down a bit and feeding against gravity.

"75% of babies in the GERD group no longer met GERD's clinical criteria after using Bare® Air-free for two weeks." Priska Diaz

CEOCFO: ***Your site indicates that with Bare science seventy five percent of babies no longer had GERD symptoms after using Bare® Air-Free for two weeks. That is pretty remarkable!***
Ms. Diaz: It is! It is an unprecedented and revolutionary discovery! It has changed the whole pediatric feeding industry. There is a dearth of good quality studies regarding air-swallowing while feeding, so Bare® Air-free is changing the way parents and doctors manage infant GER. Dr. Ramirez, an independent researcher, designed, executed, and recruited the subjects for the study. She then analyzed the data and concluded that 75% of babies in the GERD group no longer met GERD's clinical criteria after using Bare® Air-free for two weeks, which stands for gastroesophageal reflux disease.

This study serves as a good foundation for further studies and understanding more about the effects of air-swallowing vs. air-free feedings. Dr. Ramirez separated the groups according to a well-established score-based instrument. If a baby scores above sixteen, he is clinically diagnosed with gastroesophageal reflux disease and placed in the "GERD" group. If a baby scores below sixteen, then he was placed in the "Control" group. It's worth noting that babies in the control group also have symptoms but are clinically labeled "gassy/fussy." According to available literature, all babies are going to have a range of symptoms. They are all going to spit up at one point. They are all going to have pain at one point. Therefore, there wouldn't be asymptomatic babies.

This instrument, iGER-Q revised measures symptoms on a scale so the researcher can systematically create two separate groups. Then, Bare® Air-Free was given to both groups and let the caregiver feed their babies for two weeks. Clear instructions on proper assembly and usage were given to all participants. It is important to use the product correctly. Bare® Air-free is not a baby bottle and should not be used as a baby bottle. After two weeks, the questionnaire was given to the caregiver, and answers were compared against the base-line. The data collected was analyzed and properly quantified via computer programs for validated conclusions. Dr. Ramirez stated that 100% of participants in both groups showed a 49% reduction in symptoms. This caused 75% of the GERD group subjects to score well below the clinical cut-off for GERD.

CEOCFO: ***Is it difficult to hold the baby in a vertical, upright position?***
Ms. Diaz: No, not at all. Thanks to our educational marketing, and research publication in 2017, the feeding industry began to recommend the vertical-upright position while feeding. Semi-reclined position does not help as much as vertical-upright position. The semi-reclined position comes from the traditional baby bottle. Those bottles have to be turned upside down, so it is uncomfortable to feed the baby in a vertical-upright position. Bare® Air-free works with suction

instead of gravity, so you do not have to turn it upside down or hold it horizontally to feed. You just hold Bare® Air-free right side up, pretty much like a straw cup. The baby's face should be tipped down a bit, just like you and I drink coffee. Chin off the chest and let the baby feed with suction while in 100% vertical-upright position.

Young babies cannot hold their heads up, so the caregiver should hold the head to ensure the chin doesn't touch the chest. We have step-by-step instructions for new parents, and it is not difficult to hold the baby in a vertical upright position. We recommend to tip the baby's face down a little, so he or she **only** feeds with suction and can control the flow and pace of feeding, just like babies naturally do with breastfeeding. Instinctually, babies create and vary suction strength to breastfeed to control the outflow of milk. Traditional baby bottles contradict this natural instinct as they must be inverted to feed and drip with gravity, which leads to gulping and swallowing, increasing air-swallowing as they gulp the --already-- mixture of air and milk. Bare® Air-free is closer to the breast than it is to traditional baby bottles. The baby can feed against gravity while in a vertical-upright position, and that's how they control the flow and pace. Babies end up being much more aware after feeding with Bare® Air-free, rather than just falling after a bottle. They have actually stayed up for a little bit longer. They do not have the symptoms. They do not get fussy; they do not cry; they are actually very content and happy.

On our website, we have numerous testimonials of Moms whose babies have been diagnosed with reflux and always cry in pain after feeding, babies with different reflux kinds and severities, and a range of feeding difficulties. Bare® Air-free has been a life-changing experience for these moms. For a Mom or a caregiver, feeding the baby in a vertical upright position is not an inconvenience at all.

CEOCFO: ***Are they reusable?***
Ms. Diaz: Yes, Bare® Air-free is designed to be sterilized and reused hundreds of times. It is dishwasher-safe, made of medical-grade, FDA-approved silicone and polypropylene.

CEOCFO: ***What is the Perfe-latch nipple? Where does that come in to play?***
Ms. Diaz: We have two different nipples; the Perfe-latch and the Easy-latch. When I first had my baby, I wanted to breastfeed. After a week, my son had lost weight, was dehydrated, and showed signs of poor health. The doctor explained I had a low-milk supply condition and advised me to supplement the feedings. I immediately bought formula and baby bottles. That's when other problems began. Aside from the gas and the colic and the crying, I noticed that my baby did not want to breastfeed anymore. He did not make an effort to latch; he just waited for the milk to drip in his mouth. He would literally open his mouth and wait. This was a dramatic change for me. Just a few days ago, he knew how to latch and create suction to transfer milk from the breast. After searching the internet for an answer, I learned all about nipple confusion, premature weaning, and free-feeding from baby bottles leading to abrupt breastfeeding disruption. Traditional baby bottles create many problems for breastfeeding mothers.

Along with all of the features that I was designing in Bare® Air-Free, I also wanted a feature that promoted breastfeeding. That is why I designed a nipple that was much more similar to my own breast than the traditional bottle. I thought the typical baby bottle nipple was a little unnatural, so I designed the Perfe-latch® to be a lot more ergonomic, with movements similar to a mother's nipple. The Perfe-latch® nipple features a short tip, which measures about half an inch. Its geometry is designed to elongate when the baby creates the suction. The tip extends insides a baby's mouth, much like the breast does. We know that the mother's nipple extends up to three times inside the baby's mouth. The Perfe-latch® nipple extends two times inside the baby's mouth. It also teaches the babies how to keep the proper seal and suction needed for successful breastfeeding.

Babies who are having trouble breastfeeding or do not know how to latch can be trained by using the Perfe-latch® while feeding. Parents who used Bare® Air-free with Perfe-latch® say they have reinstated breastfeeding or their babies latched at the breast for the first time. We have many beautiful stories on initiating and reinstating breastfeeding on our testimonial section of the website. We have plans to initiate a more robust, quantitative test to understand how much the Perfe-latch® nipple helps babies transition back to the breast or helping breastfeed for the first time.

CEOCFO: ***What has been the response from pediatricians?***
Ms. Diaz: Pediatricians are curious and want to learn more. They ask for samples so they can treat their patients. The unprecedented conclusion of our clinical trial definitely gets their attention. I have spoken to Pediatric Gastroenterologists

(PedGi), pediatricians, and neonatal doctors that have an opinion on how the next trial should be conducted. The pilot clinical trial was based on parental feedback. The next phase for us is to do a study with Pediatrician assessment and feedback. We are in conversation with research institutions that want to be involved in our next phase of studies.

Infant GERD is presenting a challenge for doctors because of the lack of solutions available. Most recently, the pediatric guidelines no longer approve common interventions because they have been linked to having many side effects and causing life-threatening conditions. Infant GERD affects 80% of premature and 66% of full-term babies, incurring a $41 BN annual expense in the US alone. Standard of care is proven ineffective and suggests treatments like: Multiple cocktails of different drugs (H2 blockers and PPI's), which cause dangerous side effects such as lethargic behavior, blood in the stool, liver disease, bone fracture, pneumonia, gastroenteritis, candidemia, and necrotizing enterocolitis in preterm infants. Latest Pediatric guidelines strongly discourage the use of these prescription drugs. Commonly used pre-thickened formula or additives to thicken breastmilk or formula are no longer recommended by the latest pediatric guidelines in infants younger than two months due to its strong link with necrotizing enterocolitis. Branded infant formulas can only address possible allergies, OTC gas drops, homeopathic remedies, supplements, and "gimmicky" bottles offer zero relief and have aggressive, slick, and unsubstantiated marketing preying on desperate parents.

Bare® Air-free is a safe, non-pharmacological solution for GER and GERD symptoms, and we are very proud and happy to provide samples for the doctors to treat their patients.

CEOCFO: ***How are you reaching out to parents?***
Ms. Diaz: We sell on our website bittylab.com/shop. Bare® Air-free is also available on retailers like buybuybaby.com. We rely on word of mouth as organic marketing. We do not do much paid-advertisement. Moms who have success with Bare® Air-free usually describe it as a life-changing event. Imagine having a baby that cries from intense pain for hours, vomits daily, and can't even sleep due to colic and reflux exacerbating in the middle of the night. Then you try Bare® Air-free, and your baby is a whole different person with smiles after meals and peacefully resting through the night. Bare® Air-free is very effective at mitigating GER symptoms, and we want all babies to live in GER-free world. We want to help premature babies since the percentage of GERD is much larger in this population. Hospital's NICUs have a very high rate of babies with GERD. Almost 85% of premature babies suffer from severe symptoms of gastroesophageal reflux and complications due to GERD. Every day that a baby with GERD has to stay in the NICU translates into thousands of dollars for insurance companies, negative scores for hospitals and unmeasurable distress for families.

In this country alone, we spend about **$41 Billion per year** treating gastroesophageal reflux in the first year of a baby's life. I think we have a very affordable solution, and it can cut that cost for our healthcare system by more than half.

CEOCFO: ***Are you seeking funding, partnerships or investments as you move forward?***
Ms. Diaz: Yes. We are actually in the midst of our seed fundraising campaign. We are looking for $1.5 Million. We are also working on developing smaller devices for the babies in the NICU. They have smaller mouths; their suction levels are different, so we need to develop a special Bare® Air-free for them.

CEOCFO: ***BITTYLAB was recently certified as a Woman Owned Business. How do you see that as being helpful?***
Ms. Diaz: Bittylab received the national certification as a Women's Business Enterprise (WBE) and Women Owned Small Business (WOSB) in August and November of this year. These certifications are important because it helps level the playfield. Large corporations have the funds to easily enter the large retail chains, hospital conglomerates, and media. Legalities to favor the small businesses with diversity-certifications opens opportunities for startups that do not have large funds. In the baby bottle/formula industry, for example, there are only a handful of global giants that dominate the entire market.

Besides our national certifications, Bittylab is one of the very few Latinx-led and founded MedTech startups in the US.