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## Reflections on Finding a Baby's Heartbeat

*Nick Orenstein*

I thought I was going to design racecars. Sure, the job was fun and other men thought it was cool, but at the end of the day the fruit of my labors was simply a faster car. But about two years ago my path changed when Dr. Jack Stecher, now my partner in Lono, called me to see if another part of my background, acoustics, could be applied to detecting a fetal heart rate. He told me of a myriad of technical and health problems with the ultrasound-based external sensors currently used as a standard of care in labor and delivery. He and Dr. Chuck Brodsky, also now my partner, had long wanted to replace the energy-emitting, cumbersome, skill-intensive, and gap-prone products they and colleagues across the world were forced to use.

They told me of once in the 1990s when the ultrasound devices mistakenly displayed the mother's heart rate in place of the baby's — a well-documented malfunction. "After the loss of another innocent life," Chuck said of that situation, "Jack and I asked ourselves a basic question: could we create a new fetal monitor that does not rely on reflected sound waves, but one that measures the *actual* heartbeat of the *in utero* infant? We thought it would be better to build a new diagnostic platform that would completely circumvent the problems inherent in Doppler monitors." I reflected upon my chance to use my knowledge to save newborn lives and quickly changed gears. Often it is only circumstance that puts us in a position to help on a grand scale, and I did not hesitate to seize the opportunity. It was through our collaboration, between clinicians caring for patients and engineers possessing unique vision, that Lono Medical Systems was born.

The limitations of the current technology come at a real and unacceptable human cost. As I talked more with Jack, Chuck, and nurses in Dallas, New York, and Los Angeles, I found that there were some surprising — if not alarming — concerns that have gone unanswered in the three *decades* since fetal heart monitoring began using ultrasound to detect the fetal heart rate. The product manufacturers, the American Institute of Ultrasound Medicine, and the FDA still don't fully understand the effects of prolonged ultrasound exposure on human fetal development. But they have long suspected direct influence on brain development — which could lead to a variety of neurological or

psychological defects. This sentiment was reinforced when Jack and I traveled to Washington, D.C. in March 2006 to attend an FDA conference on ultrasound's use in fetal heart monitoring. Then, several months later in August 2006, the Proceedings of the National Academy of Sciences published a seminal study on mice linking prolonged ultrasound exposure to improper fetal brain development. Mainstream media, from MSNBC to the Wall Street Journal, picked up the story. The correlation to the effects on tens of millions of Americans, myself included, who were monitored by ultrasound when their mother was pregnant may never be known, but is nonetheless quite worrisome.

Other pains with the products out there are many, and our research and development did not start and finish in an isolated lab. Nurses complained to me about the excessive time spent readjusting the messy gel-covered "pucks" that rarely stayed in place for more than 30 minutes. New mothers complained of the uncomfortable elastic belts that attempted to hold the device in place, and of the multiple wires that made them feel trapped and tethered to the hospital bed. Baylor's purchasing department told me they routinely send dropped, broken ultrasound sensors in for expensive refurbishment. And a hospital administrator discussed how a large number of obstetric malpractice suits — with the highest settlements in the medical industry — cite the multi-second or -minute gaps in the fetal heart rate data inherent with the directionality of ultrasound. How can a product used on 85% of American women in such an intimate setting have so many faults without the general public being better informed or demanding change? Chuck is regularly questioned by colleagues and patients with "Are you done with that fetal monitor yet? When are we going to get it?" It's time to educate everyone else.

Yet despite all of the warnings, a number of women testified at the FDA conference last year that in addition to accurate hospital monitors they also continue to want a way to listen to their baby's heartbeat at home. For mothers with previous complications, such a product could provide a reassuring emotional connection with their baby. Ultrasound, the FDA responded, is just not the proper technology. With Lono's passive sensor, fetal heart monitors can become a feel good device for people who have access to health care, and a life saving device for people who may not.

We also hope that our innovative platform will have significant impact on other medical disciplines in need of diagnostic bioacoustic monitoring, ranging from

cardiology to pediatrics to transplantation surgery. Dr. Kristian Olson, an expert in global health initiatives at Harvard Medical School, enthusiastically believes that applying our technology to other medical challenges in maternal and child healthcare can save thousands of lives. Lono's desire to help extends beyond the boundaries of country, race, economic status, social class, or culture because a new, healthy life anywhere has unspeakable potential. As many newborns worldwide die within the first month of life as are born healthy each year in the US. In developing countries, where the WHO advocates hundreds of thousands of skilled birth attendants to be added to the workforce in the next 15 years, we foresee our monitor seamlessly instructing these medical professionals as to which of hundreds of waiting patients needs the most immediate care.

It is not enough to think about Lono and our product only in standard business terms. Instead, one must also marvel at the opportunity for something developed in Texas to save the life of a baby in any country worldwide. My own life is brighter every day knowing of the *chance* for something I've created to do this. I anxiously await the day when Lono's product is a reality fulfilling this dream. Jack agrees: "It is exciting to realize that our early idea is flexible enough, and broad enough to grow in ways we, at first, had not imagined. It has the potential to improve the health care of millions of women and children all over the world."

Every time I describe what I'm working on to new people I meet — from seasoned doctors to a tattooed guy and his wife at a bar — the reaction is both humbling and exciting. I see in their eyes the sympathetic human understanding of wanting to protect mothers during childbirth, and to ensure a newborn's safe development and healthy delivery into this world. I think that Chuck sums it up best: "The reason why I went into OB/GYN is because it's really a joyous field. The energy that accompanies the birth of a child is quite contagious, and the thrill of being part of that process has not dulled with time. The flip-side of being allowed to be part of something so wonderful is that I have to occasionally bear witness to great tragedy, too. In a career now spanning 15 years, it becomes all the more agonizing when I know, deep in my heart, that a baby's death was probably preventable. Now, like never before, I am capable of altering that outcome."