Testimony of

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Patient care is dependent on the availability of equipment designed specifically to meet patient needs. The individual needs of patient care are often subservient to the contracting demands of institutions. Without doubt, the need to decrease cost is a powerful drive to achieving better access to health care. A better balance sheet allows a hospital to more efficiently meet its needs. Group Purchasing Organizations operate in the middle ground selectively contracting with manufacturers and supposedly providing discounted pricing to hospitals. However if the equipment available doesn't provide for the individual needs of the patient, at what price is cost savings achieved?

During my training and early practice as a Neonatologist, pulse oximeters (devices designed to measure the amount of oxygen in the blood) had been more than a casual annoyance. The incessant beeping and alarming of the non-functional devices were more of a distraction than a useful clinical tool. During one outbreak of retinopathy of prematurity (blindness caused by too much oxygen given to premature infants) an associate of mine went through the neonatal intensive care unit, shutting off every oximeter in the room. These devices were the cause of inappropriate oxygen administration. Several weeks later I was discussing our frustration with a manufacturer of newborn hospital equipment and expressed my concern that no one in the field was working to enhance the state of the art. He gave me contact numbers for Masimo. This was the beginning of my interest in their technology.

Since 1994, I have been involved in clinical studies with Masimo Signal Extraction Technology (SET) pulse oximeters. My early studies demonstrated the practicality of a "Novel Pulse Oximeter Technology Resistant to Noise Artifact and Low Perfusion" and that this technology was "...Capable of Reliable Bradycardia (low heart rate) Monitoring in the Neonate". Subsequently, I was able to demonstrate a 90% reduction in false alarms in neonatal patients using Masimo technology. I showed that "Conventional Pulse Oximetry Can Give Spurious Data in a Neonatal Population at Risk for Retinopathy of Prematurity (ROP)," demonstrated the feasibility of reliable pulse oximetry operation during neonatal transport, and revealed that Masimo SET reliably tracks neonatal heart rate variability. We investigated and concluded that "Selective Inattention to Pulse Oximetry Alarms is Unsafe in Infants at Risk for Apnea of Prematurity". In studying Nellcor alarm management technology, SatSecondsTM, we showed that in an effort to limit "nuisance" alarms, the Nellcor N-395 misses relevant desaturations and jeopardized the detection of the infant at risk for sudden infant death syndrome.

Other groups have looked critically at the emerging pulse oximeter technologies. Dr. Barker has shown significantly fewer missed true events and false alarms using Masimo SET technology in adults. He has demonstrated that Masimo SET is on the top of the curve relative to performance when compared to other oximeter technologies using a model of motion and low perfusion. Dr. Torres's group has shown the failure rate of the Nellcor 395 to be four times that of Masimo SET.

Dr. Brouillette has shown that Masimo SET is more accurate for monitoring breathing obstruction during sleep in children and that the Nellcor 395 is not adequate for a sleep laboratory setting. Dr. Hay has shown decreased false alarms, missed true events, and measurement failures by Masimo SET relative to other technologies. Dr. Sola has demonstrated a significant decrease in retinopathy of prematurity. Overall looking at major independent studies, Masimo SET has been shown to be overwhelmingly superior to its competition.

Despite this plethora of evidence, Masimo SET has not been placed on the GPO's availability list. Those of us physicians who have tried to lobby for purchase of Masimo SET in GPO dominated hospitals have dealt with the incessant "smoke and mirror" techniques. One former associate of mine at an area Childrens Hospital has indicated in a national neonatal forum that his hospital's GPO contract prevents them from acquiring more than a certain percentage of the "superior" Masimo SET oximeters. His hospital has also requested that he not speak publicly about these constraints. Dr. Sola's experience, as reported in the New York Times article, caused him to question the entire buying process. '"In country with freedom of choice, this was the hardest thing for me to understand," said Dr. Sola. "If the baby was choosing consciously, we know what the baby would choose."'

Several years ago, I was involved in the care of a newborn several weeks of age. The baby presented to the emergency room in extreme condition. The skin was poorly perfused and blue. The blood pressure was not measurable. The baby was brought to the newborn intensive care unit immediately. Artificial ventilation was provided, central lines were placed, and fluids and cardiac medications were given. The conventional monitors gave no indication of improvement. I had approached the parents about the seriousness of the situation after working on the baby for over a half hour. The nurses and respiratory therapists questioned the wisdom of continuing the resuscitation. The pulse oximeter could not measure the infant's oxygen saturation. The baby still appeared blue and poorly perfused. No amount of effort appeared to improve the situation. Out of desperation, I attached a novel new oximeter (which only available to me on a research protocol) designed to work through poor perfusion.

Finally, we had a number to work with. Despite the fact that the other oximeter was attached, for the next several hours, until the blood pressure was in the normal range, there was no saturation readout. If not for the presence of the Masimo pulse oximeter, life-sustaining efforts would have been discontinued. The baby, who was subsequently diagnosed with a complex heart defect, would have died instead of receiving a life sustaining heart transplantation. At this hospital, the same pulse oximeters that failed to measure this baby's vital signs are still in use despite my years of research demonstrating the superiority of Masimo's technology. GPO related incentives prevented the introduction of a better product.

Is this an isolated case? No, there are numerous other clinical examples of oximetry failure. Within the past several months at yet another hospital, I have had the displeasure to witness another device's failure nearly costing several small premature babies' lives. In one case, this device reported a near perfect saturation, when the baby had no oxygen in her blood. While these occurrences have been reported to the manufacturer and subsequently to the FDA, these oximeters are still in clinical use in this particular hospital. Why? Because despite the manufacturer's admission that the oximeter was not designed to work in this type of situation, a

GPO mandated contract stipulates that this hospital cannot engage in contracting to purchase another manufacturer's pulse oximeters.

There are additional examples. In the area of assisted ventilation, GPO mandated contracts have restricted innovation. Bunnel Incorporated has for many years produced a state of the art newborn ventilator that helps prevent chronic lung disease by delivering very fast but very small ventilator breaths. An innovative device under development that would have produced improved ventilation with better monitoring has been put on the shelf for lack of funding. The reason? Venture capitalists will not advance the funds necessary to continue the development of the ventilator because the manufacturer does not have a relationship with any of the GPO's. Efforts to produce a ventilator for adults have met with similar outcome. Because of predatory tactics, the GPO's have not only restricted market access to only a select few companies but have discouraged and prevented research and development of newer innovative technologies.

Infrasonics Corporation manufactured one of the more popular neonatal and pediatric ventilators. The InfantStar and InfantStar 950 were in widespread use in neonatal units across the country. These ventilators distinguished themselves in being the "workhorses" of neonatal ventilation. With the rise of GPO related contracting, Infrasonics had decreased ability to sell to its market. Despite the fact that the 950+ was under development and provided many new and innovative modes of neonatal and pediatric ventilation, further sales and development of the product line were ultimately scuttled. These new "market pressures" decrease the number of options available to provide patient care.

Utah Medical Products makes special newborn central line catheters designed to ease insertion, reduce the risk of perforating blood vessels, and prevent complications such as catheter breakage, clotting, or adhesion to the wall of these blood vessels. In some hospitals, these catheters are smuggled in or kept under lock and key so that they can be available for "only the sickest" patients." Physicians are discouraged from "officially" approaching the vendor for in hospital competitive trials. Hospitals are falsely led to believe that they can rely on a consistent pricing schedule offered through the GPO's to meet physician expectations for choice and quality. Hospital costs can increase secondary to related complications, and again patient care suffers.

The argument that the GPO's offer for standardization of patient equipment across a hospital or across a hospital network is persuasive. Put the same equipment in numerous centers across the country, standardize the equipment in the hospital so that you decrease the cost of training nurses and respiratory therapists, achieve the efficiencies of being able to order in large quantities, and increase the amount of money supposedly available for research and to "improve patient care". But, there is a significant downside. Who is it after all that decides which equipment is carried by the GPO contract? What criteria are used? What happens to the research and development process? If the proper equipment is not made available, how does the individual patient suffer? In the case of my field, the answer is clear. Take away the incentive to develop newborn appropriate devices, pulse oximeters, ventilators, catheters, and other equipment, develop only for the highly profitable product lines, cater to the lowest common dominator; and patient care will be compromised to the point that babies go blind from being exposed to inappropriate

amounts of oxygen, flail helplessly while convulsing on ventilators designed principally for adults, and once again lose their lives to the ravages of premature lung disease.

As physicians, we learn to weigh thoroughly our choices for care and medical therapeutics. Where medical care has become subservient to contracting demands, our ability to practice medicine is curtailed. Give us the option, the freedom of choice, to select the medical equipment that will most adequately meet our patient's needs at the best possible price.