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AUGUSTO SOLA, M.D.
Professor of Pediatrics
Division Director

April 19, 2002

Honorable Herb Kohl
Senate Antitrust Subcommittee
SH 330 Hart Senate Office Building
Washington, DC 20510-4903

Dear Senator Kohl:

Thank you for giving me the opportunity to address what I feel to be a very important health care issue for our preterm babies.

Enclosed you will find my comments in follow up to our phone conversation of April 11, 2002. Please let me know if I can provide you with any other information.

Sincerely,

Augusto Sola, M.D.
Professor of Pediatrics and Obstetrics and Gynecology
Director, Division of Neonatal-Perinatal Medicine
Emory University School of Medicine

AS/ksp

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Dear Senator Kohl:

I am writing to you as a Neonatologist in relation to anti-competitive practices that I learned interfere with health care delivery. I also understand that such practices impact medical technology, delay development, and affect negatively healthcare costs and expenditures a whole.

How did I become aware of this problem?
By personally living through a difficult time trying to improve care and outcomes for preterm babies.
Summary: After my arrival as Division Director of Neonatal Medicine at Cedars Sinai Medical Center, we identified several clinical outcome variables that needed to be improved rapidly in small fragile pre-term infants who were treated in the Neonatal Intensive Care Unit (NICU). One of the significant problems was Retinopathy of Prematurity (RoP), which leads to the most common cause of blindness in the USA. The rate of such condition in this NICU was very high for surviving infants in the lowest birth weight groups.
It was my objective, as part of quality improvement and continuous quality outcomes assessment, to establish and implement all known clinical factors that have been associated with lower rates of RoP. In the process of trying to do this, I learned of this unfortunate interference with adequate delivery of care.

Process to decrease RoP in tiny pre-term infants:
With current knowledge, the main clinical issue to decrease high rates of RoP is to establish a "minute to minute" system of care to avoid hyperoxia (high oxygen levels) and to decrease or avoid repeated fluctuations in oxygenation levels in the blood of tiny infants.

The steps required to achieve these two goals 100% of the time in 100% of the tiny infants are not simple, and require a combination of several factors. Among them are:

1) Education of staff (Medical, Nursing and Respiratory Therapists)
2) Changing guidelines and policies
3) Ensuring compliance with such guidelines and policies
4) Provide best available technology to:
    a) administer oxygen (blenders)
    b) monitor oxygen administration (oxygen analyzers), and
    c) monitor oxygen levels in tiny infants (oxygen saturation monitors – SpO_2)

None of each of these steps is sufficient by itself to accomplish the objectives mentioned before. None is sufficient by itself to decrease the GAP BETWEEN KNOWLEDGE AND CLINICAL PRACTICE . This gap leads to significant morbidities in the case of RoP, and in other cases it may even be lethal. Decreasing the gap, improves the care received 100% of the time by 100% of the infants.

Technology:
I will not take your time to summarize the lengthy process we established and developed in relation to items 1-3 above. However, I emphasize that none of them is sufficient by itself to achieve improved outcomes.

In relation to technology: I explored the best available for such cases. We had a team looking for new developments, analyze and evaluate the literature for each of them, observe and perform clinical trial of each of them, etc. After a fairly lengthy process, we decided what was the best at the time for these fragile tiny infants at high risk for RoP.

In relation to (a) and (b) above, we extended and made universal their use, starting in the delivery room at the time of birth, through transport and during the whole stay in the NICU.

In relation to the possibility to monitor accurately the oxygen levels 100% of the time in 100% of tiny infants, we decided we needed to change the oxygen saturation monitors (SpO_2) that were being utilized.

Here is where the difficulties started and what led me to become aware of interference with clinical practice that I have never realized before.

Summary of difficulties:
We requested the most adequate SpO_2 monitors (Masimo). We justified the request. We provided evidence. This technology, revolutionary at the time, solved many if not all of the problems we have faced with SpO_2 monitors in the care of tiny babies until then. We presented all aspects in meetings. We talked, we discussed, we argued. But each time any of this happened, I was asked for more information or for something else, usually by different people, at different times, at different levels. It was tiring and draining.

At one time I was told higher cost of this new technology compared to older technology was the issue. I asked the company to present several proposals for me to analyze. At least a couple of them were actually less costly than the older technology. Actually, I was told "yes" several times. However, other people without me being present, were told that this was not going to happen, and many "excuses" were given. In fact, it did not happen.

Each time, after a few weeks or months of delays, I asked again and we were back to "square one". I had never witnessed such a process previously in many years of my career. I just could not understand what was going on. At times I thought it was a delaying strategy due to budgetary constraints. Other times I thought it was lack of adequate administrative processing. However, it was much worse than this.

The delays continued. I never got a real straight answer. I brought this issue to several meetings, I sent many e-mails, and wrote several letters. I also had some heated discussions after waiting for so long and I almost gave up in my objectives.

To my surprise, what I learned after a difficult, lengthy and energy consuming process, was a sad eye opener to me and, in my perspective, extremely sad not just for myself, but for healthcare as a whole.

Here is what was going on, and what I learned for the first time. The Hospital, I was told, has agreements (contracts?) with group purchasing organizations (GPO) that provide discount prices for many items that the Hospital purchases. I was also told that if the Hospital "goes off" and buys, purchases or leases products from companies not included in the GPO, there could be important economic repercussions and the loss of "discount of prices" in many of the products the Hospital needed. I was also explained it was hard if not impossible for them to buy one SpO_2 equipment that was not what was used for the whole Institution because it was "out of contract" and the Hospital would then lose other benefits.

I cannot summarize my surprise, anger, frustration, and my sadness at the time. I can understand "lack of knowledge","lack of funds" and/or "budgetary reasons" as reasons for not providing the best technology available to human beings in order to decrease a major morbid problem (like RoP). Those issues can be improved, and they can be overcome through education, charity, donations, etc.

However, I was unable to grasp this concept of GPO, contracts, "exclusive" products, "loss of benefits", in which every reasonable and scientific argument I made was literally ignored.

I would like to share with you that in the USA I have never felt so saddened and so bad in issues related to healthcare until that time. I became aware then that in this country of freedom, unfortunately my freedom as an educated professional, to ensure that babies received what we thought was best for them, was very limited. Actually, I came to realize that if babies had been the ones choosing, they would not have been allowed to choose what they consider to be best for them. I learned of new (hidden) forces that prevented freedom in the system of care: monopoly and corruption. I learned of completely unfair anti-competitive conduct.

At the time, I thought I had at least three options:

a) be honest with myself, become as inflexible as I could and give as much as I could from myself to try to get this technology for tiny fragile babies at this institution;
b) "give up" and be able to devote my time to my other administrative, research, educational and clinical responsibilities, or
c) "buy into" this concept, "understand it" and become part of it.

I chose option (a) and a few months later, fortunately, the babies were treated with the newer and much better technology, though not without personal cost.

Summary of results:

Since 1999 the outcomes not only improved but the results in this NICU are amazing:

a) No baby over 750 gm developed severe RoP (stages III-IV). (Down from 12% to 0%)
b) Decrease in the rates of severe RoP in the tiniest (at highest risk babies, birth weight 500-750 gm) from about 30% to 10%.
c) No preterm infant required laser surgery for RoP. (Down from about 5%)
d) No blind babies.

Acknowledgement:

I know now that this is a conduct that affects many areas and not just the particular area that I described above.

I also know many physicians and RN's are not even aware of how this issue impacts their practices. More importantly, patients are not aware. In some cases, like the one described, patients continue to receive care for a long time with equipment and medications not chosen by their MD's, or actually used against their MD's recommendation.

I now know that in many cases the equipment and medications are chosen by GPO's/Hospitals for their own selfish reasons. In many cases their decisions do not lower costs and delay improving patient care: The two worse combinations in health care.

I acknowledge your commitment to trying to solve this huge problem. As I told your staff member, Mr. Seth Bloom, if you all fix this issue, many infants and many other patients will owe to your efforts their improved health outcomes. The beneficial impact of a definitive solution to this serious problem would be much greater than what I or many other physicians I know could do through their lifetime for the patients under their care.

Sincerely,

Augusto Sola M.D.

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