Testimony of

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I. INTRODUCTION

Masimo's story is just one example of a systematic problem that excludes competition, and blocks innovative products in favor of the status quo. Masimo is a typical American start-up: It Started in our garage with a second loan I got on my home. Since then, $90 Million has been invested in our company.

Pulse oximetry is a highly sophisticated technology to noninvasively measure blood oxygen. If a person's blood oxygen is low, they can get brain damage or die within 3-5 minutes and in case of premature babies if blood oxygen is high, they can get eye damage or even become blind. Masimo is an innovator in pulse oximetry. Our technology works on the most ill patients, patients that are moving, like babies and patients being transported. Before Masimo, this was not possible. In addition to improving patient care, Masimo's technology also decreases cost. But, the Senators shouldn't have to decide that, rather individual hospitals and clinicians should in a free market.

I am here to ask for reform of a system that precludes our devices, and many others, from reaching patients, even when responsible clinicians decide it is best for their patients. The fact that our primary competitor, Tyco-Nellcor, one of the largest companies in the world and already having 90% of the pulse oximetry market, can pay GPO's to exclude Masimo, is wrong. It is not good for us, and it's not good for society.

The title of this hearing is interesting. "Hospital Group Purchasing: Lowering Costs at the expense of Patient Health and Medical Improvements." This title assumes that GPO's are saving hospitals money. In many instances, the two biggest GPO's are eliminating competition, so it is hard to understand how they can be saving money. To exclude competition, the two biggest GPO's (Premier and Novation) who control over 70% of the nations hospital purchases have discovered how to use the kickbacks to work with the powerful companies to shut out their competitors. Their strategies maximize both the GPOs and their largest suppliers mutual revenues, at the expense of other vendors, hospitals, patients, and payers. One of those payers is the government, who pays over 40% of the healthcare expenditure.

The results of this situation is that competition and innovation is being stifled. Powerful companies are becoming more powerful. Prices are being kept artificially high. And patient care is being harmed because clinicians are not allowed to use the products they conclude are best for their patients.

In the following pages we will examine in detail our company, its experience and why we have come to these conclusions.

II. MASIMO CORPORATION IS AN INNOVATOR IN PULSE OXIMETRY

Masimo Corporation is a medical technology company headquartered in Irvine, California. Founded in 1989, Masimo designs, develops, licenses, and manufactures "pulse oximetry" equipment incorporating technology (called "Signal Extraction Technology®" or "SET®") invented by Masimo's founders, Joe E. Kiani and Mohamed Diab. Pulse oximetry involves the use of sophisticated electronic circuitry to convert the output from an optical sensor attached to a patient's finger, toe, or ear into a visual readout of the patient's pulse and blood oxygen level. Typically, a pulse oximeter is incorporated in a multi-parameter patient monitoring device. Since the late 1980s, pulse oximetry has been the clinically preferred method for non-invasively measuring and monitoring the amount of oxygen in a patient's blood.

Pulse oximetry was originally introduced in the U.S. in the early 1980's. By the late 1980's, pulse oximetry had become a recognized standard of care for monitoring blood oxygenation on all critical patients in the operating room, post anesthesia recovery room and intensive care units. Many clinicians consider it the fifth vital sign and candidly admit that the pulse oximeter is the most important monitor and the last monitor they would give up.

Early pulse oximeters gave unreliable readings when patients moved (shivered, convulsed, etc.) or were moved (as in an ambulance or on a hospital gurney), and when patients had low peripheral blood flow ("low perfusion"). Since these conditions were pervasive among the most critically ill patients, such as those in shock, patients being transported or undergoing CPR and patients with a very weak pulse (such as premature babies), these deficiencies substantially limited the value of the technology. It was widely reported in published studies that 10 percent of the time pulse oximeters did not work in the operating room and up to 70 to 90 percent of all pulse oximeter alarms were false outside of the operating room. The implications of these problems are poor, inefficient patient care and medical errors, because the pulse oximeter is either causing clinicians to run around the hospital checking on false alarms or the clinicians are ignoring the alarms because they no longer trust the monitor alarm (like the "Boy Who Cried Wolf"). This is a serious problem because the lack of adequate oxygenation can lead to brain damage or death within 3 to 5 minutes, and over-oxygenation causes eye damage and blindness (known as ROP) in neonates. Although there were many attempts to overcome these weaknesses in pulse oximetry and various solutions to these problems were offered over the last 20 years, no technology developed prior to Masimo SET was clinically proven nor cleared by the FDA to monitor accurately under conditions of motion and low perfusion.

Kiani and Diab undertook intensive research to design a more reliable pulse oximeter. Mr. Kiani utilized his savings, mortgaged his home, and convinced his friends and family to help finance this venture. As steady progress was made on the technology, Masimo was able to attract outside investors of increasing stature to complete the development of its revolutionary technology. With the resulting products, false alarms are virtually eliminated, and detection of true life threatening events is greatly improved, even during movement and low blood flow.

III. MASIMO'S TECHNOLOGY HAS BEEN SUCCESSFUL AND WELL RECEIVED BY CLINICIANS

Masimo SET pulse oximetry technology was the first pulse oximetry to be cleared by the FDA to specify accuracy during motion and low perfusion. Monitors with Masimo SET technology were first sold in the U.S. in 1998. More than 50 published clinical studies by leading independent researchers confirm that Masimo's innovations have significantly improved the reliability of pulse oximetry (exhibit 1). Masimo and Mr. Kiani have received many awards, including Technology Excellence from the Society of Critical Care Medicine. ECRI, known as the Consumer Reports of the medical industry, issued a report on pulse oximetry in October 2000, and gave its highest rating to Masimo SET (exhibit 2). This was the first ECRI report on pulse oximetry in 11 years (and the second ECRI report on pulse oximetry ever) and it helped to confirm the growing body of literature finding that Masimo SET was a breakthrough in pulse oximetry that improves patient care.

Monitoring equipment incorporating Masimo SET technology is also proven to result in dramatic cost savings. The cost savings claims by Masimo are not merely hopes, but are validated through cost studies by both leading researchers and at hospitals (non-GPO) that switched from Tyco-Nellcor to Masimo (exhibit 3).

Masimo has the best product of its kind in the world and Masimo offers the best cost of ownership. Masimo has outstanding manufacturing, sales and marketing capabilities. Masimo has been a great success by many measures, and has marketed over 70,000 of its revolutionary pulse oximeters. However, Masimo firmly believes that it could be doing much better at bringing its revolutionary technology to more patients if there were free and open competition in the market.

In fact, Masimo has hit a brick wall in a sense in the form of so-called "sole-source" contracts between the largest group purchasing organizations (GPOs) in the country and Masimo's leading and large competitor, Tyco-Nellcor. These arrangements effectively preclude Masimo from marketing its products to over 80% of the hospitals in the United States. For many of these hospitals, Masimo is not even allowed to present its technology, due to the sole-source contracts with the largest GPOs.

IV. THE GPOS ARE PREVENTING COMPETITION

The superior performance of Masimo's technology led many hospitals' clinicians to want to replace existing monitors with monitors incorporating Masimo SET technology. These hospitals included hospitals that are members of Premier and Novation, which are the two largest GPOs. However, Masimo quickly discovered that those GPOs act as the gatekeepers for sales of medical equipment and supplies to at least two thirds of the hospitals in the United States. These and other GPOs have entered into sole-source contracts (i.e., contracts that exclude all competing pulse oximetry technology, including Masimo SET) with Tyco-Nellcor. These sole-source contracts between Tyco-Nellcor and Premier and Novation require member hospitals to purchase 90-95% of their pulse oximetry needs from Tyco-Nellcor in order to obtain the best contract price. The purchasing arrangements, as explained further herein, are formulated so as to make non-compliance financially punitive for the member hospitals. The most aggressive GPOs in excluding Masimo and protecting Tyco-Nellcor's market share are Premier and Novation.

Tyco-Nellcor claims to have maintained an 80-90% market share in pulse oximetry for many years. We have been informed that under the sole-source vendor contracts for pulse oximetry, Tyco-Nellcor pays Premier over 3% and Novation between 12 - 23 % in "administrative fees" and other payments - essentially, kick-backs - on purchases of Tyco-Nellcor equipment. In exchange, these GPOs have granted sole-source contracts to Tyco-Nellcor. Tyco-Nellcor has sole-source contracts with at least five buying groups in all, which Masimo estimates account for at least 80% of the total pulse oximetry market.

Outside of GPO controlled hospitals operating under sole-source agreements with Tyco-Nellcor for pulse oximetry, Masimo and its licensees sell Masimo SET to nearly all of the hospitals that they approach in direct head-to-head competition with Tyco-Nellcor. Almost always, the resulting pricing is below the best GPO prices offered by Tyco-Nellcor through Premier and Novation (exhibit 4). On the other hand, in Premier and Novation hospitals, Masimo sales are extremely limited to a few very prestigious Novation hospitals that seem to be willing to challenge the GPOs, and other GPO hospitals purchasing quantities small enough to stay in compliance with the sole source contracts . Where the purchases are so limited, Masimo constantly observes hospital care givers facing tough decisions on which patient will get a Masimo unit. Masimo has even observed very upset parents in neonatal ICUs because their child was not being monitored with Masimo SET and were thus being subjected to unnerving false alarms, while other babies were not having these problems while being monitored with Masimo SET.

Last year, Masimo was turned down at 48 hospitals, 46 of which were Premier and Novation accounts and the other 2 were Consorta accounts, another GPO with a Tyco-Nellcor sole-source commitment. All of the hospitals that turned Masimo away involved clinicians and departments asking for Masimo SET. The purchases of Masimo oximeters were only rejected when materials or purchasing learned that Masimo was not on contract with Premier or Novation. Tellingly, Masimo was not turned down in any accounts where free competition was not hindered with sole-source contracts with large GPOs. Masimo placed units in 65 new hospital accounts. Fifteen of these were for hospital-wide conversions. Of the hospitals approached, Masimo was successful in fully converting 0% and 10% of Premier and Novation hospitals, respectively, as compared to 53% of those hospitals where there was open head-to-head competition (no sole-source GPO contract) between Masimo and Tyco-Nellcor. 41 (63%) of the new hospital accounts were with Premier and Novation hospitals buying units under the 5-10% allowable range. These purchases show that the hospitals want Masimo technology, but are constrained in their ability to purchase them. The 5 conversions of Novation hospitals were not without struggle, and can be credited to the fact that these were very large and prestigious institutions such as Massachusetts General who were willing to challenge the GPOs (exhibit 5).

If Masimo is unable to gain fair access to the rest of the market due to artificial restraints on competition imposed by the GPOs acting in concert with Masimo's principal competitor, not only are Masimo's chances of profitability and sustained growth significantly limited, but it will be at the expense of patients and payers, since Masimo SET technology has been proven to improve care and reduce the cost of care. Masimo's unbelievable experience is unfortunately only one example. We have learned that there are many other innovative products, such as pacemakers and safety needles, which are artificially kept out of the reach of clinicians. This scenario stifles

innovation in the medical technology arena because investors and entrepreneurs are becoming increasingly unwilling to devote their time and money to develop breakthrough products when there is little or no opportunity to recoup their investments.

V. MASIMO HAS TRIED DILIGENTLY TO GET ITS TECHNOLOGY ACCEPTED BY THE GPOs

Masimo has made diligent efforts to get its products to patients and clinicians by attempting to work with the GPOs, including Premier and Novation. Notably, Masimo has not been asking to exclude its competitor in its attempts to obtain contracts with Premier and Novation. Masimo has just been seeking an opportunity to compete for business from the hospitals. A brief summary of Masimo's interactions with Premier and Novation follows:

A. Premier:

Masimo first met with the technology assessment group of Premier in December 1998. Masimo recently obtained a copy of Premier's internal evaluation report dated May 9,1999 (exhibit 6) that states that Masimo SET technology is superior, and recommends to Premier's corporate management that Masimo's technology is needed in several high acuity areas of the hospital where motion and low perfusion are a concern. Shortly thereafter, Masimo was informed that Premier management had decided to not consider Masimo as a potential vendor.

However, Masimo did not give up. Masimo met with the senior executives for Premier, Greg Lauder, and Janet Roach in May of 1999. Masimo was told that the day before this meeting, Tyco-Nellcor officials and Premier officials confronted Carol Davis-Smith, the head of the Premier's technology assessment group, about her recommendation of Masimo SET. We understand that Ms. Smith strongly argued that Masimo was a breakthrough and should be made available to Premier's member hospitals. The next day Janet Roach and Greg Lauder of Premier told Masimo that the technology assessment group had turned in a report but had not done a "good" analysis, but Masimo could apply for a contract under Premier's "breakthrough technology" provision. They also told us that they would not let Masimo start the "breakthrough technology" process until Tyco-Nellcor introduced its N-395, which Tyco-Nellcor had assured Premier would be equivalent to Masimo SET. Masimo earnestly tried to proceed with this application, but was never actually allowed to participate in the process. For over 24 months, Premier simply delayed. Finally, after Nellcor released its N-395, Premier informed Masimo that it was no longer considering Masimo SET for their "breakthrough technology" process. Masimo was told that it did not qualify as a breakthrough technology because Nellcor had released an equivalent product and because of the results of a member survey. Premier indicated that the breakthrough technology process would not continue, and that it had renewed Tyco-Nellcor's sole source contract for another five years for pulse oximetry.

It now appears that hospitals that had expressed interest to Premier in Masimo's technology, were excluded from the survey. We know of at least two hospitals that complained to Premier, asking why they were not part of the survey, since they had expressed their desire for Masimo SET to Premier before the survey had started. A couple of the hospitals that were surveyed surprised Premier and dramatically favored Masimo and some hospitals even wrote letters to Premier indicating that Masimo was a must for their patients (exhibit 7). Through the investigative work

of NY times, which was reported on March 4th we learned that actually 15 of the 20 Premier hospitals that were familiar with Masimo's technology said it was more accurate than other pulse oximetry devices or eliminated false alarms. Yet, this "survey" was a principle justification cited by Premier for maintaining its sole-source relationship with Tyco-Nellcor.

We have been told that during this two-year period, Premier continually threatened Masimo's licensees and potential hospital customers that they would face contract retribution or financial penalties if they demonstrated or used Masimo technology. For example, Premier offered one of Masimo's licensed monitor manufacturers, Medical Data Electronics (MDE), a payment of at least $200,000 from Tyco-Nellcor if the licensee would integrate Tyco-Nellcor's latest pulse oximetry technology in its monitors. Premier threatened this same licensee that its Premier contract was at risk if it did not stop demonstrating Masimo SET monitors to their member hospitals (exhibit 8). The licensee didn't yield to the pressure, firmly convinced through its extensive testing of both Masimo and Tyco-Nellcor's latest pulse oximetry technology, that Masimo's technology provided better patient care. Premier carried through on its threat, and this licensee's Premier contract was not renewed. There have been numerous instances in which Premier hospitals purchased or attempted to purchase Masimo, only to be threatened by Premier with loss of discounts, penalties, and expulsion from Premier (exhibit 9). We have been told that Premier has even pushed hospitals to return purchased monitors that contained Masimo technology. Some Premier member hospitals and suppliers, in the face of threats of punitive action, have told Masimo that they refuse to even evaluate monitors with Masimo technology for this reason.

Amazingly, in all of its interactions with Masimo, Premier never once asked Masimo about price or cost of ownership. Purchasing Masimo SET-equipped pulse oximeters would have resulted in substantially lower costs for Premier members (exhibit 3). To date, Masimo continues to observe Premier aggressively policing its member hospitals for using only Tyco-Nellcor pulse oximetry. As stated earlier, in 2001, Masimo fully converted 15 US hospitals to Masimo SET, but not one Premier hospital was able to convert to Masimo SET, despite strong interest by many Premier member hospitals to do so.

To enforce compliance among member hospitals, Masimo has observed many tactics by Premier. Economic penalties have been used most prevalently with expulsion also being threatened by GPO representatives. The most effective economic means of forcing compliance appears to be bundling programs. Tyco-Nellcor has bundled several products together under its sole-source contract with Premier. The product bundle enables Tyco-Nellcor to tie the purchase of several of its products to the purchases of other products in the bundle. If the member hospital buys Masimo pulse oximeters, it will lose substantial discounts on all other products in the Tyco-Nellcor bundle. We have seen no evidence that the bundling arrangements produce any desirable results.

One of Premier's bundling programs of which sources have informed us of, has an interesting history. A few years ago, Premier's contract price of contrast media offered by Premier's vendor, Mallinckrodt (the parent of Nellcor-which will be referred here as Tyco-Nellcor), was tied to market price. Because of Tyco-Nellcor's patent expirations, the price of competitive contrast media had dropped by 80% below Tyco-Nellcor's initial sole-source prices through Premier. The

language in their contract allowed the prices to be adjusted to market, but Premier and Tyco-Nellcor chose a different way to deal with this problem. Tyco-Nellcor and Premier struck a new deal to stop the Premier contract prices from being adjusted down due to market price and agreed to instead re-price the contrast media approximately 60% below the contrast media price before the patents had expired. They also formed a bundle with four product categories, including pulse oximetry and contrast media. Reportedly, the incentives on the bundle were such that their member hospitals could earn approximately 12% in contrast media rebates (for a total of 72% savings, but still 8% higher than the market price) and smaller rebates on the other products if they purchased at least 90% of all products in the bundle from Tyco-Nellcor. The rebates were dramatically reduced if the member missed the 90% target on even one of the products in the bundle. This bundle has been a very effective tool for Premier in excluding Masimo. A typical 250 bed hospital purchases $2M-$3M worth of contrast media and $500K worth of pulse oximetry sensors annually. Premier hospitals typically tell Masimo that the bundling rebate they would lose if they switched pulse oximetry is over $500,000 per year from the other products in the bundle. Premier hospitals cite this as the sole reason they will not buy more than 10% of their pulse oximeters with Masimo SET.

Premier also uses discount/rebate schemes to push compliance with its sole source contract with Tyco-Nellcor. The discount/rebate schemes are based on reaching percentage compliance levels in purchasing exclusively from the sole-source vendor. In many instances, the hospital faces significant price increases or lost rebates for only slightly missing the compliance level. In our situation, Premier has a 90% sole-source contract with Tyco-Nellcor for pulse oximetry. Under this contract, a member gets the contract pricing if they purchase at least 90% from Tyco-Nellcor. If they do not achieve at least 90%, irrespective to volume, Tyco-Nellcor may charge list price. So, if a Premier hospital is only 80% compliant, then that hospital risks a significant price increase (list price) on a large portion of its business.

With a GPO closely affiliated with Premier, Masimo had a similar experience. The majority of children hospitals in the US (38 hospitals) belong to Child Health Corporation of America, CHCA. CHCA is the GPO for these hospitals and a shareholder member of Premier and passes the Premier contracts to its members. CHCA also gives their seal of approval to products. CHCA approached Masimo in 1997, and after evaluating Masimo SET in the NICU, concluded Masimo made a clinical difference. CHCA representatives then told Masimo that Masimo would be given the seal if Masimo paid them 6% on all sales of Masimo SET products in all of CHCA and Premier's hospitals, all other hospitals, and on all sales by all Masimo licensees. We thought that this was unfair and illegal, and refused the offer. Despite CHCA admitting that Masimo was better and made a clinical difference compared to Nellcor and all other competing products, they ended up renewing their agreement with Tyco-Nellcor and gave them the seal of approval.

B. Novation

Novation represents all of the university hospitals and various other hospitals. Masimo saw a significant opportunity two years ago when Novation invited bids for the dual-source pulse oximetry contract renewal. Novation representatives stated that they were not going to agree to a single vendor for pulse oximetry. And Masimo thought this is due to the fact that Novation

represents all University Hospitals and that these hospitals pride themselves in using the latest and best technologies.

Masimo heard from several significant Novation hospital member clinicians, including one on the selection committee, that Masimo SET was being requested by many hospital members of Novation. Masimo made it very clear to Novation officials that it would make its pricing competitive with that of any other bidder so that cost would not be an impediment to adding Masimo as a second source vendor. Despite Masimo's "can't lose" offer to Novation, and the internal clinical support from Novation member hospitals, Novation chose to award a sole-source (95% compliance) contract to Tyco-Nellcor. Soon after, an insider told Masimo that up until 6 weeks before the grant of sole source contract to Tyco-Nellcor even Tyco-Nellcor believed they would not be able to get a sole-source contract. At the last minute, Tyco-Nellcor increased its total fees to Novation by at least $6 Million, to entice Novation to exclude all competitors (grant a sole-source contract to Tyco-Nellcor), and Novation did grant Tyco-Nellcor a sole source contract.

Since that time, Masimo has uncovered information that makes this contract award even more revealing. The Novation selection committee member, Paul Montague, from the University of Wisconsin, an outspoken supporter of Masimo, was removed from the committee just before the final decision was made. In addition, upon reviewing the final Tyco-Nellcor contract pricing under its sole-source supplier contract, Masimo discovered that Tyco-Nellcor's best sole-source contract pricing was in-fact over 30% higher than the pricing Masimo's licensee had offered. However, under the final contract, Tyco-Nellcor offered a Novation "Novaplus" private labeled line of sensors. A source has informed us that Novation gets an extra $1.00 per sensor fee on those products sold to its members. That amounts to an extra 11% fee on a $9 sensor. Novation then justified their decision based on a questionable member survey where Novation ended up ignoring their own members indication of the three most important criteria (accuracy, motion performance, and price) (see exhibit 10 for further analysis of the Novation contract award). Our understanding is that Tyco-Nellcor is paying between 12% and 23% fees to Novation to exclude Masimo.

Similar to Premier, Novation has also been aggressive in policing its hospitals to have them purchase at least 95% of all pulse oximetry requirements from the sole source vendor Tyco-Nellcor (exhibit 11). As with Premier, Masimo has observed several tactics used by Novation to push its member hospitals to purchase at least 95% of all their pulse oximetry requirements from Tyco-Nellcor.

One of the most effective tools used by Novation to exclude Masimo from having hospitals even evaluate its technology is another bundling program. Novation's bundling program that ties several companies' products together. Novation's Opportunity Spectrum 1 Portfolio requires members to purchase at least 95% of all products from 12 categories, offered by 5 different vendors, in order to qualify for a 5-7% rebate. We have been told that this 5-7% rebate is paid to the hospital, but is in addition to the 12% to 23% fees paid to Novation by Tyco-Nellcor. Once in the program, the member must stay compliant for the term, through March 2005. If the member ever fails to meet the compliance level or chooses to leave the program, they must pay back all previously earned rebates from all companies in the bundle. So if a hospital chooses to buy

Masimo pulse oximetry, a product not in the bundle, the hospital must pay back a significant sum to every company in the bundle, which can easily be in the millions of dollars. And under the terms of the Opportunity Spectrum bundling contract, members are forbidden from even trialing competitive products (see exhibit 10 for analysis of Novation's Opportunity Spectrum program) during the entire 5 year period.

Also similar to Premier, Novation uses penalties for non-compliance with the sole-source contract with Tyco-Nellcor. As explained, Novation has a 95% compliance contract with Tyco-Nellcor, and their members risk a 15-30% pricing penalty for non-compliance. The Novation hospitals tell us that they cannot go over the 5% threshold with Masimo technology because of the price increases and loss of rebates on the other 11 products in the bundle.

VI. THE CONSEQUENCES OF THE CURRENT SYSTEM ARE EXCLUSION OF COMPETITION.

In Masimo's case, the sales commission-style "administrative fee" structures of Premier and Novation have, invited them to sell exclusive access to their members to Tyco-Nellcor. Premier and Novation then use bundling from Tyco-Nellcor (and even combined with other suppliers) to enforce compliance with member hospitals. These GPOs actually maintain sales forces to promote Tyco-Nellcor products and to enforce compliance among their members.

The economic effect of the current "administrative fee" commission structure for GPOs is illustrated by the following calculations:

Scenario 1 - Current scenario-Novation gives Sole Source Contract with Nellcor
? Tyco-Nellcor sells 40 million sensors per year in the U.S.
? About one-third of those are sold to Novation hospitals at $10 each.
? 40,000,000 (1/3)($10)(12%-23%) = $16,000,000 -$30,636,000 Administrative Fee to Novation

Scenario 2 - Dual-source agreement - Tyco-Nellcor may withhold administrative fees since the GPO is not bringing it value (exclusion of competition)
? GPO loses Tyco-Nellcor's administrative fees
? Masimo sells 500,000 sensors per year in the U.S. and pays a 3% administrative fee
? 500,000(1/3)($10)(3%) = $50,000 Administrative Fee to Novation
Novation would see its annual administrative fees decline by approximately $15.9 million to $30.1 million - a very serious threat to the GPO!

Scenario 3 - Multi-source agreement, all suppliers pay a 3% fee
If Tyco-Nellcor and Masimo were to coexist on a dual-source agreement and each pay a 3% fee, the revenue impact to the GPOs would be as follows:
? Tyco-Nellcor sells 39.5 million sensors per year in the U.S.
? One-third of those are sold to Novation hospitals at $10 each.
? 39,500,000 (1/3)($10)(3%) = $3,950,000 Administrative Fee to Novation
? Masimo sells 500,000 sensors per year in the U.S.
? 500,000(1/3)($10)(3%) = $50,000 Administrative Fee to Novation

Novation would earn approximately $4 million annually from Tyco-Nellcor and Masimo. This is $12-$28 million less than scenario one, but $4 million is more than enough to cover the GPO's real administrative costs for creating one contract for this one product. Even if Masimo assumed a greater percentage share of the mix over time, the GPOs would continue to earn their $4 million annually based on the aggregate business - but the open competition would drive innovation and lower prices as the companies strived to differentiate themselves. Arguably, lower prices would ultimately reduce the GPO's administrative fees, and that is precisely one of the key flaws in the system.

These amounts are Masimo's estimates and, while Masimo cannot know Tyco-Nellcor's actual volume or the actual amounts being paid to the GPOs by Tyco-Nellcor, Masimo believes that the scale of comparison presented here is fair and representative.

The threat of losing $16 to $30 million in fees is significant, but this is only for pulse oximetry. The Tyco product portfolio includes many other products that aggregate to total fees of much more than this amount.

While the figures provided above are compelling in their own right, there is reason to believe that the actual amounts being paid by favored vendors to GPOs are even greater and include large amounts characterized as "Research Funds" or "Grants," in addition to amounts paid for being a "Corporate Partner". One of the difficult issues in this debate is that the facts seem very convincing against GPO practices, yet there seems to be few parties complaining and many supporting GPOs. The major vendors that pay the biggest administrative fees to GPOs are unlikely to complain about doing so, in fact arguably they have created the current GPO system. They benefit most from the barriers to competitive suppliers that their administrative fees allow them to obtain. Hospital administrators are responsible for their GPO relationships and are expected to support the GPOs; if they don't they can be terminated. Clinicians are almost universally against GPO practices, but feel heavy pressure not to complain. Small companies who do not threaten product categories dominated by significant vendors may have access and no reason to complain. Companies who have been denied access, like Masimo, also have to be very reluctant to come forward and challenge the status quo because of the potential for permanent retaliation if they do so.

VII. SOLUTIONS

The solution will require eliminating entirely the conflict of interest inherent in having the GPOs serve as commissioned sales organizations for the vendors. We suggest the following reforms:

? Repeal the anti-kickback exclusion for GPOs and do not let them be paid by the suppliers/ vendors, when they are supposed to be representing the hospital members. The member hospitals should pay the fees directly and insure the loyalty of their group purchasing organizations. The payments could be varied depending on the size of the hospitals. According to HIGPA members, the cost for a 150 bed hospital to get GPO's to do contracts for them is $10,000 and to provide all of the other services some GPO's have will be an additional $30,000 per year.
? Eliminate sole-source and other committed volume contracts. Each hospital should have the ability to commit to any product it wants without facing bundling schemes designed to prevent their choice. 2,000 hospitals should not be committed to one product without their individual

hospital decision, because the supplier paid the GPO hefty sums to exclude its competitors. Multiple source contracting also allows the hospital to get the competitors to compete, which should only improve their prices and products.
? Eliminate all product bundling so that clinicians are able to select products based on their individual merits.

IX. CONCLUSION

In theory, group purchasing through GPO membership could help reduce the cost of care and should be beneficial to hospitals and patients. However, those benefits are today being denied as a result of the distorting effect of kickbacks, sole source contracting and bundling and other anti-competitive practices that would be illegal if Congress had not legalized kick-backs in 1986 for the GPO industry. There are potential solutions that do not require abolition of group purchasing, but rather some basic changes to GPO practices. The primary change needed is elimination of the GPOs' current dependency on volume-of-sales-based payments by vendors to GPOs and the related exclusionary practices intended as quid pro quo for the payments.

However, if the necessary changes are not made, the current system will continue to keep prices artificially high, stifle competition and innovation and prevent clinicians from following through on what they determine to be the best treatments available for their patients.

We urge you to make the necessary legislative changes so that we can restore our free market and secure for our parents and children the best health care at the lowest price.