UNITED STATES SENATE

COMMITTEE ON THE JUDICIARY

SUBCOMMITTEE ON ANTITRUST, COMPETITION, AND BUSINESS AND CONSUMER RIGHTS

HOSPITAL GROUP PURCHASING: LOWERING COSTS AT THE EXPENSE OF PATIENT HEALTH AND MEDICAL INNOVATION?

SENATOR HERBERT KOHL (D-WI) - CHAIRMAN

APRIL 30, 2002

CHAIRMAN KOHL: This hearing will come to order. I've held it for Senator DeWine who is unavoidably detained for just a few minutes and he has requested that we proceed.

Today this Subcommittee turns its attention to an issue affecting the health and safety of every American who has ever or will ever need treatment at a hospital, in other words, every one of us. This issue is how hospitals form buying groups to purchase nearly everything used by hospitals. Everything from--pacemakers to thermometers, from surgical devices and CT scanners to needles and Band-Aids, and how these groups affect the cost and quality of patient health and medical innovation throughout our country.

These buying groups known as group purchasing organizations, or GPOs, are at the nerve center of our health care system. Because they determine what products are in our hospitals, they directly affect patient health and safety. Because they control more than $34 billion in health care purchases, they impact the cost that we all pay for our health system.

Because they represent more than 75 percent of the nation's hospital beds, they are a powerful gatekeeper who can cut off competition and squeeze out innovation. Getting a GPO contract is essential for any medical equipment supplier. GPOs determine which medical devices will be used to treat us when we are sick or inured, which manufacturers will survive and prosper, and in fact, which ones will fail.

It does not do any good to invent the next great pacemaker or safety needle if you can't get it to patients because a GPO stands in your way. With that kind of power comes responsibility. But, too often, it seems the GPOs have failed to serve as honest brokers seeking to serve the best interest of hospitals and patients.

We are going to detail three major concerns. First, conflicts of interest raise a specter of critical health care decisions being influenced by financial ties to suppliers. We have heard allegations of scandal and conflicts of interest that have infected the GPOs.

Premier's chief executive received a million--received millions of dollars worth of stock options from a company with a contract supplying pharmaceutical services to Premier hospitals. His response that he recused himself from contracting decisions with respect to the company at issue and that his financial interests were disclosed and approved by Premier's board is good but not good enough. He should have severed all ties to the company when he joined Premier.

On another occasion, Premier steered business to a pharmaceutical supply company and thereby helped turn it's $100 investment into a stake worth $46 million last year. Novation today demands that medical suppliers it contracts with sell their products on a for profit e-commerce site in which Novation has a substantial and in which many of Novation's senior executives holds personal stakes.

These practices in our judgment are appalling and should not be tolerated. We cannot accept a situation where a decision on which medical device will be used to treat a critically ill patient could conceivably or even theoretically turn on the stockholdings of a GPO executive.

Second, contracting practices may reduce competition and innovation in health care and narrow the ability of physicians to choose the best treatment for their patients. In one case we know of, a hospital denied a physician permission to use a vital pacemaker for a patient on the operating table but not yet anesthetized and all because there was no GPO contract for that particular pacemaker.

The pacemaker that was on contract that the hospital required him to use was in the midst of an FDA investigation into its effectiveness and safety. Hospitals have failed to buy safety syringes which prevent accidental needle sticks because doing so would mean--would mean buying off the GPO contract. And as a result, nurses have suffered easily preventable injuries and have developed HIV and hepatitis.

GPO contracting policies have created a system that keeps many good products out of circulation while enabling large manufacturers to entrench their market positions. Practices such as sole sourcing, high commitment levels, which require a hospital to purchase as much as 90 percent from one company in order to get the maximum discount, and bundling, which gives hospital extra discounts and bonuses for buying a group of products, can seriously damage the ability of doctors to choose the best products for their patients, and for competitive manufacturers to survive and innovate.

And third, the General Accounting Office today revealed that these buying groups, whose goal after all is to save money, do not always get the best deal. We all support the basic purpose of GPOs to hold down health care costs with volume purchasing. But the GAO study raises serious doubts as to whether GPOs are doing a good enough job in achieving this goal.

In many cases, hospitals can get a better deal if they go outside the GPO. It seems like sometimes GPOs may produce the worst of both worlds, little savings and fewer choices.

We, therefore, call on the entire GPO industry to work with us to create a code of conduct that will address these ethical problems and contracting issues. The industry should clean up its own

act and we believe they want to. But without quick and effective self-regulation, we would have to consider Congressional action.

In addition, Senator DeWine and I are today writing to the Justice Department and the Federal Trade Commission to request that they reexamine their guidelines that protect GPOs from federal antitrust scrutiny in most cases. Our goal should be to ensure that the GPO system truly achieves cost savings in the cost of medical equipment and that these savings do not come at the expense of patient health and medical innovation.

We thank our witnesses for coming here to testify and we look forward to hearing their views.

I call now on my colleague and the Ranking Member of this Subcommittee, Senator Michael DeWine.

SENATOR MIKE DEWINE (R-OH): Mr. Chairman, thank you very much.

Let me begin by saying that I am also quite disturbed by some of what we've learned in our investigation of group purchasing organizations. There is certainly some indication that GPOs in some cases have strayed from their original purpose of allowing hospitals to work together to limit costs. We clearly have some specific incidents that we need to explore today, and I know we will. And we need to decide how to prevent them in the future.

In addition, we need to examine the enormous changes in the medical supply marketplace and the changes that have occurred in GPOs. As medical costs have skyrocketed, many hospitals struggle on a daily basis. They struggle to reduce costs while attempting to maintain high quality health care.

GPOs have become an increasingly important part of this effort to reduce costs. However, I think it is fair to say that due to consolidation and other changes in the GPO system, GPOs today look very different today than the system that was originally planned and contemplated. Some reports indicate that hospitals channel as much as 70 to 80 percent of their non-labor expenditures through GPOs. And within that 70 to 80 percent of purchasing, two large GPOs, Premier and Novation, handle purchasing for over 60 percent of the nation's hospitals.

This level of concentration gives these two firms a very important role in the medical device market, and their buying arrangements have a tremendous impact on the market. This importance is magnified by the fact that Premier and Novation will often have only one or two suppliers on contract for a given product or product category. For the one or two suppliers who are able to make a deal with them, they are virtually assured a very big market for their products. The others, however, will face real problems in gaining access to the large or significant segment of the market.

As long as these contracting and purchasing decisions are based on a reasonable mix of quality and cost factors, these outcomes are not necessarily troubling. And we have been told that often health practitioners do play a significant role in determining which products are placed on GPO

contracts, a role which helps to assure that product quality and patient care are part of the decision.

However, there are some indications that other factors have sometimes been considered, factors that have more to do with the financial health of the GPO than the health of the patient. For example, information provided to this Subcommittee demonstrates that executives of some GPOs have a financial interest in companies that have been granted GPO contracts. Obviously, it is completely unacceptable for private financial interest to play any role in contracting decisions.

More broadly, I am concerned about the extensive range of businesses and programs run by GPOs and the manner in which they are funded. Approximately 15 years ago, Congress gave the GPOs an exemption from the anti-kickback laws in order to allow them to collect administrative fees from suppliers. But the result of that decision is a system in which some believe the GPOs have conflicting interest and mixed incentives.

It is not always clear whether the GPOs are serving the hospitals who own them or the suppliers who have in some ways become their clients. We need to explore this issue today.

Furthermore, Mr. Chairman, we need to examine the competitive implications of the GPO system. It is critical that we maintain a competitive environment in which new and improved medical devices are able to gain a foothold in the marketplace. However, many have complained that the GPO structure is acting as an impediment to innovation by allowing incumbent suppliers to lock in large portions of the buying market for their products.

That assessment seems to have some support among those in the investment community. In fact, we will hear testimony today that investors are increasingly unwilling to fund startups, the kind of companies that often provide technological improvements, because the odds are stacked too heavily in favor of incumbents on GPO contracts. This is a very troubling possibility.

On balance, it does seem likely that GPOs have delivered savings to hospitals. Many of the hospitals in my home state of Ohio have reported that to me. Although, as the recent GAO study indicates, GPOs do not necessarily always save money for hospitals, and as I have noted, legitimate questions have been raised about what impact the current structure of the GPO market is having on innovation and health care.

We cannot overlook the long-term cost that we will pay, both in dollars, and in quality of care, if we allow our purchasing structure to impede innovation in medical devices.

So, Mr. Chairman, I look forward to hearing from our witnesses. I will closely evaluate everything that we hear today. Certainly, we must remain focused - focused on making health care affordable to all Americans. It is equally important to ensure that the system operates in a way that will provide the best possible health care for patients. As an initial step, as Senator Kohl has already indicated, the Chairman and I are--both do in fact agree that a code of conduct addressing a number of specific practices will help address our concerns.

In the meantime, Senator Kohl and I have sent a letter to the Justice Department, Antitrust Division, the Federal Trade Commission, asking them to examine the competitive effects of the GPO system. If, after careful evaluation, we determine that further changes are in fact necessary, we will work closely with all interested parties as we seek a system that will provide our hospitals with the best products at competitive prices.

Thank you, Mr. Chairman.

CHAIRMAN KOHL: Thank you, Senator DeWine.

And now to our witnesses. I'll introduce the seven and then we'll start with their testimony. Mr. Richard Norling is Chairman and CEO of Premier, Inc. He joined Premier in 1997, first as Chief Operating Officer, and before that Mr. Norling was President and CEO of Fairview Hospital and Health Care System, headquartered in Minneapolis-St. Paul Minnesota.

We have with us Mr. Mark McKenna, President of Novation. He served on a management team that structured the joint venture between VHA and UHC, resulting in the creation of Novation. Prior to joining VHA in 1987, Mr. McKenna was Director of Marketing for IMED Corporation of San Diego.

Ms. Trisha Barrett is a registered nurse and Assistant Director of material Services and Value Analysis Facilitator at the University of California Medical Center in San Francisco. Ms. Barrett serves on the Novation Nursing and Clinical Practice Council.

Mr. Joe Kiani is the cofounder and CEO of Masimo Corporation, a privately-held medical technology company. He is also an inventor on more than 30 patients related to signal processing sensors and patient monitoring.

Dr. Mitch Goldstein is a physician at the Citrus Valley Medical Center, the University of California, Irvine Medical Center. He specializes in neonatal medicine.

Ms. Elizabeth Weatherman is the Managing Director of Warburg Pincus, where she has been a member of the health care group since 1988. Ms. Weatherman also serves as the Vice Chair of the National Venture Capital Association Medical Group.

Mr. Lynn Detlor is the Principal of GPO Concepts, Inc. He served as President of Premier Purchasing Partners from 1986 to 1999. Mr. Detlor joined Premier through a merger with the American Health Care Systems, where he served as President.

We welcome you all here today. We request that you hold your statements to five minutes.

Before we commence, I would like to ask the Chairman of our Committee, Senator Leahy, if he has an opening statement.

SENATOR PATRICK LEAHY (D-VT): Mr. Chairman, I'm just hearing your comment about keeping it--.

CHAIRMAN KOHL: --Brief--.

SENATOR LEAHY: --Brief. Although I just want to compliment both you and Senator DeWine and I saw on many occasions the two of you have Subcommittees that should be a model for the rest of the Senate in the way you handle it. I--one, we all agreed that we weren't escalating health care costs, whether you are a legislator or a provider--you're a consumer or anything else.

I am concerned on this one issue. I'm sorry. I'm concerned on this one issue. Do the GPOs contracts with the practices of large established medical and pharmaceutical supply companies keep newer and smaller companies from bringing innovative--items in? Do the fees paid by suppliers to the GPOs act as go-betweens and will they exceed--some GPOs have officers, employees--inappropriate with connections of large medical suppliers. Should they be divided by the--should they be divided by the suppliers at all, rather than the number of hospitals?

So, these are issues I will begin in our other hearing and will leave most of these for the record. But I do want to, Chairman, you and Senator DeWine, I do want to compliment you and thank you for holding this hearing. If I could put my whole statement and my questions in the record.

CHAIRMAN KOHL: It will be done and we thank you for your appearing here, Senator Leahy.

Now, we start with testimony. First, Mr. Norling?

MR. RICHARD NORLING: Thank you, Chairman Kohl, Senator DeWine and Senator Leahy.

I am Richard Norling, Chairman and CEO of Premier. As a former hospital CEO who has spent 28 years in not-for-profit health care, I know that hospitals are under enormous pressure from Medicare, Medicaid and other payers to deliver high quality care at the best possible price for their patients and hospitals need all the help they can get.

Premier provides them with a very important tool, namely group purchasing services. I'd like to talk to the Subcommittee specifically how that works. Premier is an alliance of some 1,600 not-for-profit hospitals and health care systems, from major medical centers to small rural community hospitals. To put it simply, our mission is to do everything we can to help our not-for-profit hospital members provide the best patient care at the best possible price.

We are a performance improvement organization. One important part of what we do is negotiate contracts with suppliers for our hospitals. But we are not a middleman for hospital purchasing. In addition to our contracting program, we offer many other valuable services to our hospitals. For example, Premier has the most significant health care data base available in American today to help hospitals share information and implement best clinical practices.

We estimate that we save our member hospitals over $1.5 billion per year to involve our programs. Premier is a driving force for innovation. Premier hospital systems, like Aurora

Health Care in Wisconsin, Cleveland Clinic in Ohio, demand immediate access to the newest and most effective technology. We work closely with our hospitals to identify and evaluate promising new products and prophecies.

We have staff dedicated to tracking key medical developments to identify the very best products. Our technology assessment team's primary job is to evaluate promising new technologies with an eye towards bringing those advances into our hospitals.

Our contracts give us flexibility to add great to technologies regardless of the existence of existing contracts. If I can, a couple of examples with regard to our record on innovation. We regularly examine the marketplace and move rapidly to evaluate new technologies and make available under group contracts those that are real breakthrough advances.

In January, shortly after the cutting-edge Given Imaging "camera pill" was launched--I have an example of that right here. Our staff recognized the potential of this pill-sized device, which after being swallowed by the patient provides the most advanced images of the small intestine available. It's a very, very exciting technology. Within 30 days of learning that, we had a group contract with its company. The only group purchasing organization at this time with a contract of this revolutionary new product.

Second point. Even when a contract is already in place, we can add breakthrough products to our portfolio. In early 1999, well before Congress passed the Needlestick Safety Act, which I might note we very strongly supported, Premier reached out to the industry for new safety products in this agreement. Through our technology breakthroughs program, we added three new syringes and four blood drawing devices with safety features to expand our portfolio, all but one of these from small manufacturers. Currently, we have 96 sharps safety products categories on contract with 772 individual products available to our members. These are manufactured by 15 different companies.

The facts are clear. Our contracting process is open to all suppliers and we are always interested in and actively seek out more advanced and safer products. If this were not the case, there is no doubt our member hospitals would go elsewhere.

Let me emphasize how we engage those hospitals. All product selections are made with substantial clinical input by committees of people who work at our hospital. Once they, the committees, make their decision, we negotiate the contracts. Premier doesn't purchase products, hospitals do.

Our group purchasing contracts don't require our hospitals to use a contract for all of their needs in any product category. Our members can and do buy items to meet their unique needs and preferences while still getting a negotiated discount for products under group contracts.

Like all GPOs, we receive administrative fees in return for our services. Our fees average 2.1 percent, well within federal guidelines. We have no fees in excess of 3 percent involving medical products or pharmaceuticals. We don't require up front payments and since 1997, 67.4 of all administrative fees--percent, of all administrative fees we received through group

purchasing have been distributed as cash payments or credited to Premier hospitals as incremental equity in their retained earnings.

After Premier's creation in late 1995 through a three-way merger, we inherited from our predecessor organizations some practices that are figured in recent criticisms of our organization. As Premier has matured and evolved, many of those practices have been discontinued.

In conclusion, we are very proud of our accomplishments in pursuing excellence in health care. We are committed to operating openly, honestly, and transparently. We intend to cooperate with the Subcommittee and the health care community to explore every avenue to make our work even more effective. If there is an opportunity to improve, Senator, we will take it. And may I say that I applaud you for your proposal on the idea of an industry wide set of ethical practices and you have Premier's absolute full support in trying to seek that common ground that I think is so important. Thank you.

CHAIRMAN KOHL: We thank you, Mr. Norling.

And now from Novation, we have Mr. McKenna.

MR. MARK MCKENNA: Good afternoon, Chairman Kohl, Ranking Member DeWine, and Senator Leahy. It is my pleasure to be with you today representing over 2,300 health care organizations.

Most are compelled to relay this message from our members. The value, cost savings, and other benefits they receive through Novation are necessary and crucial to their survival and to their ability to provide quality patient care in their communities.

Novation was formed in 1998 by combining the group purchasing programs of VHA and the University Health System Consortium. Two national health care alliances with members in all 50 states. From major academic medical centers to rural 50-bed facilities, these hospitals share a common mission of community service. A vision of continually improving the quality of care and an imperative to operate more efficiently. These hospitals rely and the collective strength of their membership.

Group purchasing saves hospitals hundreds of million dollars annually. By our estimate last year alone we save our members over $1 billion by aggregating their buying power and by consequently avoid other costs. Many hospitals, especially those serving rural communities, could not realize these savings on their own. Here's just one result of how these savings can directly improve community health and why our members value what we do.

In Menomonee Falls, Wisconsin, Community memorial Hospital saved $1.5 million over the last two years through purchases made by Novation contracts. And they report that these savings have helped them fund a free clinic for indigent care patents in their community. The benefits enjoyed by Community memorial reflecting a sound business model. It's a cooperative model similar to others outside the health care sector such as agriculture and electronics.

Now, I'd like to take a moment to briefly comment on Novation's business practices. I'm proud of our organization and what we accomplish every day on behalf of our members. We are member-driven and rely heavily on member input in determining the needs, identifying the evaluating products, and by helping individuals share ideas and best practices. Novation provides many ways for physicians and other clinical professionals from our member organizations to guide us in administering an objective and open bid process resulting in this election of high quality low cost products.

We use over 20 member advisory counsels. Our counsels include more than 450 individual from 300 health care organizations. These represent both large and small hospitals. Our contract decisions are supported by a matrix evaluation that considers safety, quality, availability, support, customer service, education, and of course, costs.

Some suppliers may provide a single product. Others provide more. But each product is chosen on its own merits to the spare objective and inclusive profits. In fact, all our bids are posted on our public web site so they are all available to all suppliers. This methodology results in low best bids which in my definition means providing our members the highest quality products at the lowest possible costs.

I should point out that many suppliers can and do take advantage of opportunities to provide contracts through Novation. In fact, approximately 25 percent of our suppliers meet the Small Business Administration definition of a small business. One example, Triad Disposals, a small upper Midwest company that makes alcohol preps, which won a bid over a much larger competitor's, proves this out.

Our contracts are also flexible, allowing us to continual seek and offer new and alternative products in the latest technology. For example, our members told us that Possis Medical had an innovative device to more effectively treat blood clots. And after receiving input from members on our advisory councils, we promptly added it to our portfolio.

Finally, our members can really choose whether or not to purchase through Novation contracts and we believe that this voluntary approach has been key to our success and greatly enhances the satisfaction of our members. They retain the freedom to choose the products that best meet their specific needs.

In the time allotted I hope I've been able to give you a sense of how group purchasing benefits hospitals and how Novation adheres to a strong, fair and ethical process in contracting. As you know, hospitals across the country are under severe budget constraints and desperately need ways in which to reduce their costs to serve their communities. Thank you for this opportunity to tell our story.

CHAIRMAN KOHL: Before we proceed further, I would like to ask Senator Schumer who is on a very tight schedule to make his always very brief and concise statement.

SENATOR CHARLES SCHUMER (D-NY): Thank you, Mr. Chairman, and I want to thank you for squeezing me in right now and more importantly for your leadership, and I thank Ranking Member DeWine as well.

And what I wanna do is just ask that my statement be added into the record, my whole statement, to make the point, of course, that health care costs are out of control. We have to find solutions to this and I think it's very important that all of us keep in mind that GPOs in concept are not at all a bad thing. They perform a valuable service by permitting hospitals to buy supplies more effectively. And when hospitals can purchase quality equipment at cheaper prices consumers save money.

Now, health care bills are soaring. We know that. Savings can't come at the cost of the quality of care and so the balance we need to strike at this hearing today is important. We have to see--not throw out the baby with the bath water. Look at the concept of GPOs and understand why they are needed, see how business has been conducted and works. There have been some serious allegations that it hasn't. And, I look forward to, Mr. Chairman, not only to your hearing, but knowing your thoughtful diligence and persistence at these issues, to help you come up with whatever solutions might make things a little better. Thank you.

CHAIRMAN KOHL: Thank you, Senator Schumer.

SENATOR SCHUMER: Thank you, everybody. I apologize. We have--the Bankruptcy Committee always has a lot of things going. And we have the Bankruptcy conference as well. But I wanted to come in here and--.

CHAIRMAN KOHL: --Thank you for coming--.

SENATOR SCHUMER: --Appreciate it.

CHAIRMAN KOHL: Now we proceed to Ms. Trisha Barrett.

MS. TRISHA BARRETT: Chairman Kohl and Senator DeWine, it is a pleasure to be with you this afternoon to share my perception of how our hospital benefits from its association with Novation.

My name is Trisha Barrett. I am the Value Analysis Facilitator for the University of California San Francisco Medical Center, a member of UHC, where my responsibilities include the clinical coordination for--product selection and standardization.

I've been a nurse for 25 years. Previous to joining UCSF, I served in a similar capacity at a VHA facility. I have thus served on the Novation Nursing Council as both a VHA and a UHC member representative. I'm proud to serve an organization like UCSF Medical Center where our mission focuses on caring, healing, teaching, and discovering.

UCSF Medical Center is a 500-bed academic hospital. Annually, we perform over 20,000 surgical procedures and provide literally tens of thousands of days of care. To meet this demand,

we maintain a product and device inventory anywhere from 20,000 to 30,000 items. Recently, we were named one of the top ten hospitals by U.S. News and World Report.

Beyond the daily challenges of providing care and savings lives, America's hospitals face nursing shortages, constraints imposed by managed care, and important patient and healthcare worker safety issues. Overshadowing these challenges is financial pressure due to ever rising costs of pharmaceuticals, supplies, devices, and equipment.

While Medicare, Medicaid, and private payer reimbursements go down, the cost of health care continues to rise. Novation helps our organization remain financially viable, allowing us to place our energies where they belong, on patient care.

We spend about $120 million each year for supplies, 50 percent of that through Novation contracts. The remaining 50 percent is spent on products that are not on contract or on products that may compete with Novation contracts but our clinicians choose to use them.

That's one of the good things about Novation. Use of their services and product contracts are voluntary. However, we do use Novation agreements whenever we can because they bring value to UCSF Medical Center. The Medical Center benefits from my participation in councils and task forces because it provides a forum where I am able to provide clinical expertise and product experience in the formation and analysis of Novation contracts.

Clinicians like me from across the--across the country, gather and collaborate to share our experience, reach consensus, and advise Novation in structuring and awarding contracts that we know will best meet the needs of our patients and out staff. For example, I am currently working with fellow clinicians throughout the country to establish quality criteria for the upcoming IV catheter bid. We clinicians share our experiences and opinions to formulate catheter quality and supplier service criteria.

For instance, many hospitals have lost on-site nurse educators either to the national nursing shortage of to financial constraints. Therefore, educational support will be a high priority for the supplier we choose. That the supplier will be able to provide 24-hour a day, 7-day a week training during conversion from old product to new. These discussions lead to consensus and advise that make the final bid award a good one.

It is important to note that as clinicians who actually use medical products to treat, heal, and save lives, we place a high priority on product quality and performance in our discussions and our decisions. I take my role as a health care professional very seriously.

So when I was invited to participate on the Novation Nursing Council in 1999 I welcomed the opportunity. Being a council member is something I do above and beyond my day to day responsibilities at UCSF, and often involves being away from my family.

However, having the opportunity to assist Novation in contracting for the highest quality, most clinically acceptable products available on behalf of our patient makes it all worth while. More importantly, I can trust in other Novation contracts because I know there are hundreds of others

like myself working on other member councils. I have--I have the privilege of assisting some of the best doctors and nurses in the country at UCSF. With that privilege comes the moral and legal responsibility to invest the hospital's funds wisely.

When selecting products, I ask my fellow clinicians to think of these funds as they would their own family budget. There has been a perception that member hospitals are a captive third party when these awards are made. Nothing could be further from the truth. At each individual facility, the hospital must evaluate Novation's offering, committed or not, on its clinical and financial merits.

In closing, I would suggest that the members of the Committee proceed very carefully in considering any new laws that could potentially place additional financial pressure on an already fragile health care system. Without companies like Novation, I am concerned that hospitals, and ultimately patients, would pay more for health care. In addition, we in hospitals would be forced to dedicate significant additional resources to contracting, diverting those precious resources away from care at the bedside. Thank you.

CONGRESSMAN KOHL: Thank you for your statement, Ms. Barrett.

And now we are going to hear from Mr. Joe Kiani who is the cofounder and CEO of a privately held medical technology company. Thank you for being here.

MR. JOE KIANI: Thank you--Chairman Kohl, and Ranking Member DeWine. And, it's good afternoon and we're happy to be here to testify. We thank you.

Masimo was a typical American startup company. Our goal was to make a contribution--our goal is to make a contribution to humanity by improving care and reducing cost of care. We also wanted to become financially independent and we were the investors who invested in our dream. Masimo actually started very humbly in our garage. I took a loan, a second loan on my home, and since then $90 million has been invested in Masimo by some of the leading health care investors in this country.

Masimo has developed the next generation pulse oximetry. Pulse oximetry, in case you don't know, we've lived this for 14 years, is the non-invasive monitor to measure oxygen in the blood and its important because if your blood oxygen drops below normal, within three minutes you can get brain damage and within five minutes you can die. And, on neonates there is an additional problem. If they get too much oxygen they can get eye damage. Masimo is the innovator in this industry.

The problems that were thought to be inherent limitation to pulse oximetry we solved. These were problems of motion artifact, like you would see with babies moving, or agitated patients in the intensive care unit or recovery room. And maybe just as importantly, very sick patients have very low profusion, or--which means very low blood flow.

The fact is there has been over 50 clinical studies over the last several years by independent researchers across the country that have proved that Masimo's set is indeed superior, it has improved care, and reduced costs. But you gentlemen don't need to decide that here.

We understand your role as policy makers is to not favor any company but to foster a free market. We are not asking for special treatment. We are just asking for you to show oversight on this and help u us compete in a free market.

We believe there needs to be reform because there's a system here that precludes innovative devices to get to the hands of the clinicians who are the best to know what's best for their patients. And this is happening at the expense of not only manufacturers like ours, but the expense of clinicians, patients, and payers.

The fact that our primary competitor who owns more than 90 percent of the pulse oximetry market can pay group purchasing organizations to exclude Masimo from the market is dead wrong. It's not good for Masimo and it's not good for the society. The title of the hearing is "Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Improvements."

I presume this title assumes the GPOs are saving money. I don't understand how they can save money when they exclude competition in most instances. My dad used to say to me to keep your honest neighbors honest, lock your front door. Well, with very good intentions Congress left the door open in 1986 and allowed kickbacks to be paid by suppliers to group purchasing organizations. I guess, in a polite world they are not called kickbacks, they are called administration fees, marketing fees, other types of fees.

GPOs, and when I mean GPOs I'm talking about the most powerful group purchasing organizations like Novation and Premier, are using this policy to enrich themselves and a few companies. By selling them exclusivity and market share to these powerful companies. Their strategy is to maximum the group purchasing organizations and these companies revenues at the expense of vendors, hospitals, patients, and payers. And as you very well know, government is one of those payers, and pays over 40 percent of health care expenditure.

Why have we concluded this? For four years we have had direct experience dealing with Premier and Novation who we believe actually control over 70 percent of U.S. hospitals' purchasing. There has been a systematic pattern of exclusion, of competition, by source of contracting, by bundling, by questionable tactics, which include threatening manufacturers of Masimo type devices -- the same manufacturers that are actually all current, well, some of them are still current, GPO contractees -- with expulsion if they Masimo technology to their member hospitals.

And we've discovered the hard way that the breakthrough process, the breakthrough technology process, or the technology assessment process, is a sham. I have specific examples that I will be happy to share with you here today and I welcome your questions on that.

If it was all sour grapes--there is an exhibit I would like to show you. I think it's important if you will allow us, Chairman Kohl, to show it. Thank you.

Let's look at this exhibit. Masimo has 100 percent success rate in the free market. In the magenta, you see the sole source GPOs, and in yellow you see the free markets. Last year, we did not lose one deal. We did not lose one opportunity at a hospital that was in a free market. Amerimed is actually one GPO who has allowed Masimo in contract and we are grateful of that. They are acting differently. They do believe members should have choice and voice and they do believe in bringing value. And then also independent hospitals, zero. I didn't expect to see this statistic, Chairman Kohl, but we lost zero.

At the same time, look at it, we lost 48 contracts, 22 at Premier, 24 at Novation and two at Consorta. These are all sole source contractees where Tyco-Nellcor who is the 90 percent market share competitor of ours. And as you can see, in hospital like conversations--what that means, these are hospitals that chose that every one of their patients should have access to Masimo set.

In the free market, over 50 percent of those hospitals chose to have every patient there be monitored with our technology. And as you can see, the sole source environment--in Novation we did have some success, 10 percent. But this happened to be the most safest institutions like Mass General Hospital where they are not easily bullied by such tactics. Thank you.

We are not just an anecdote. I know some would like you to believe that, but Masimo's story is just one of many, one example. Chairman Kohl, there are numerous other companies, I can go from A to Z. Companies like Applied Medical, Biotronics, Retractable Technologies, St. Jude Medical and Utah Medical that suffer the same problems that I am talking about today.

The current system where group purchasing organizations like Premier and Novation sell market and exclusivity to group selling organizations, these big companies I call them, have a negative impact on health care. Many companies are exploiting the system to exclude competition. Competition and innovation is therefore stifled. Prices are artificially kept high. Patient care is being harmed, and today it's the best pulse oximeter, the best pacemaker, the best safety needles. But tomorrow it could be the best cancer treating medication that's kept out.

We need a solution. The solution should restore free market. I have my own--I'd be happy to share with you what my recommendations for their solutions are. But we believe competition is not only the key to innovation and improved health care, but as one hospital purchasing manager has put on his walls, he put Competition is the Mother of Lower Prices.

So I would be happy to answer all your questions and I thank you for this opportunity.

CHAIRMAN KOHL: Thank you for your testimony today, Mr. Kiani.

And now we move on to Mr. Mitchell Goldstein, a physician at the Citrus Valley Medical Center and the University of California Irvine Medical Center. He specializes in neonatal medicine. Dr. Goldstein?

DR. MITCHELL GOLDSTEIN: Good afternoon. Thank you for inviting me to testify today.

I'm Dr. Mitchell Goldstein. I am practicing neonatologist and clinical research in Southern California. I am here because I have become concerned that products offering improved care and potentially decreased costs are being kept from reaching patients due to purchase constraints. GPOs operate in the middle group, selectively contracting with manufacturers and supposedly providing discounted pricing to hospitals.

Pulse oximeters, excessive beeping and alarming were more of a distraction than a useful clinical tool when I started practice. During one outbreak of retinopathy of prematurity, a disease 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. The devices were the cause of inappropriate oxygen administration. This was the beginning of my interest in improving this technology.

Since 1994, I have conducted several studies on pulse oximetry. I found a 90 percent reduction in false alarms in neonatal patients using Masimo technology. Looking at the independent studies, Masimo set has been shown to be overwhelmingly superior to its competition.

Masimo set has not been placed on the GPOs availability list. Those of us physicians who have tried to lobby for purchase of Masimo set in GPO-dominated hospitals have dealt with the excessive smoke and mirrors techniques. One former associate of mine at an area children's hospital has indicated in a national neonatal forum that his hospital's GPO contract prevents them from acquiring more than a certain percentage of Masimo pulse oximeters. This hospital has also requested that he not speak publicly about these constraints.

Several years ago, I was involved in the care of a newborn several weeks of age. The baby came to emergency room in extreme conditions. The skin was blue. Resuscitation was begun. The conventional monitors gave no indication of improvement. The pulse oximeter could not measure the infant's oxygen saturation. No amount of effort appeared to improve the situation. The nurses and respiratory therapists questioned the wisdom of continuing the resuscitation. I attached a novel new oximeter that we had only because of our research. We finally had a number to work with.

If not for the presence of the Masimo pulse oximeter, life-sustaining efforts would have been discontinued. At this hospital, the same pulse oximeters that did not work are still in use. GPO related incentives prevented the introduction of a better product, and other familiar oximeters nearly cost several small premature babies' lives. In one case, this device reported a near perfect saturation when the baby had no oxygen in the blood at all.

While these occurrences have been reported to the manufacturer and subsequently to the FDA, these oximeters are still in critical 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.

Bunnel, Incorporated produces a state-of-the-art newborn ventilator that prevents chronic lung disease by delivering very fast but very small ventilator breaths. An innovative device with improved ventilation and better monitoring has put on the shelf because of 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 an existing relationship with any of the GPOs. Efforts to produce a ventilator for adults have met with similar outcome. The GPOs have not only restricted market access, but have discouraged and prevented research and development of newer innovative technologies.

Another ventilator company, Infrasonics Corporation, with an innovative line of ventilators with promising clinical results was unable to capture sufficient market share to remain viable due to GPO contracting. Utah Medical Products makes special newborn central line catheters designed to reduce complications. In some hospitals, these catheters are smuggled in or kept under lock and key because they are prohibited under the GPO contract. Physicians are discouraged from officially approaching the vendor for in-hospital competitive trials.

Who is it, after all, that decides which equipment is covered by the GPO contracts? 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 my field, the answer is clear. Take away the incentive to develop newborn appropriate devices, pulse oximeters, ventilator, catheters and other equipment. Develop only for the highly profitable line, cater to the lowest common denominator, 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 weight thoroughly our choices for care and medical therapeutics. Where medical care has become subservient to contracting demands, our ability to practice medicine is curtailed. Innovation deferred, health care denied. 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. Thank you very much.

CHAIRMAN KOHL: We thank you very much, Dr. Goldstein.

Now, we turn to Mr. Lynn Detlor. He is the principal of GPO Concepts, Inc.

MR. LYNN DETLOR: Senator Kohl, Senator DeWine.

My professional career in health career began in 1972. Group purchasing in health care at that time was in its infancy. Hospital medical supply costs averaged 67 percent of our annual expense budget as compared today in a hospital where the expense for medical supplies can range anywhere between 23 to 28 percent, depending on the acuity of care delivered.

The growth and new technology has helped to expand the growth in the supply cost arena. The political impact of Medicare legislation in the mid-'70's on operating expense had a direct impact

on hospital executives targeting areas to lower expenses. Impact as a potential target, cost adjustments in nurse staff, patient ratios, and supply cost reductions in material management was the major targets. They started the rapid growth of state and local group purchasing organization.

In 1974, I was hired by the Adventist Health System to organize and establish a collective purchasing program for 17 hospitals in the Western United States. This certainly led to the expansion of programs for all 84 Adventist institutions in North America. In 1986, I was hired by American Health Care System to organize and develop a national group purchasing organization, which ultimately grew to 40 multi-hospital systems representing approximately 1,400 institutions.

This growth and expansion was directly related to the continued pressure to lower operating costs. Also, in response to competition from for-profit health systems and select markets throughout North America, American systems operated with approximately 16 employees and an annual operating budget of $10 -$12 million.

The income was derived from annual dues from its members. Over time, dues are replaced by fees charged to a select group of manufacturers at that time which we called corporate partners. Fees were not taken on all contracts. Instead, management time was spent on helping the select manufacturers reduce their cost of selling and passing it along to the hospitals.

The elimination of dues was seen as an additional cost cutting strategy. Other group purchasing organizations were already solely fee funded for the medical manufacturing industry. Pricing of products was implied by medical manufacturers to be linked to the largest compliant customers. This in turn led to the consolidation of the marketplace.

Local and state group purchasing organizations began to consolidate with larger national organizations in the quest for lower prices for their members. Today, less than a dozen group purchasing organizations represent the majority of the nation's hospitals. Novation and Premier represent over 60 percent of the nation's institutions.

In 1995, American Health Care Systems and Premier, a group purchasing organization out of Chicago, merged and six months later Sun Health merged to form what today is the new Premier. Novation was formed by the linking of University Hospital Consortium and the Voluntary Hospitals of America. The outcome of mergers has led to large organizations with operating budgets in excess of three to four hundred million dollars. Diversity, to be more than just a group purchasing organization has led to program expansions in e-commerce, a data mining, business development, physician practice management, etc.

Today, working as a consultant in GPO Concepts, we hear the same question from two sides of the marketplace, the medical manufacturers and the hospitals. The medical manufacturers are concerned about the value they receive from the fees paid. How much of it makes its way down to the hospitals are a also a major concern.

The hospitals are questioning where and how the fees are spent and yet hospitals face even more pressure to continue to lower the costs. Probably the remaining question in today's marketplace, are hospitals not competing for the same dollars that today go to the GPOs? It's a question, you know, the Committee and GPOs have to face in the future. The solution rests, you know, in their management and with the marketplace demands upon how they function and how they behave. Thank you.

CHAIRMAN KOHL: We thank you, Mr. Detlor.

And finally we come to Elizabeth Weatherman, who is the Managing Director of Warburg Pincus, where she has been a member of the health care group since 1988.

MS. ELIZABETH WEATHERMAN: Thank you Senator Kohl, Senator DeWine.

Yes, Warburg Pincus is one of the largest venture capital firms in the United States and therefore in the world because the United States is the most vital community for venture capital. We are also--we've been a leader in health care investing for over 30 years. I've been with the firm for 14 years and for the last 13 of those have been actively investing in medical technology companies.

I am also the Vice Chair of the Medical Group within the National Venture Capital Association, and I am here today on behalf of the more than 475 professional venture capital firms dedicated to stimulating the flow of equity capital to emerging growth and developing companies.

Our members currently invest more than $36 billion per year in such companies and--have invested nearly $210 billion in aggregate over the past 20 years, forming any of the most important technological and medical breakthroughs of that period across the fields of biotechnology, drug development, medical devices, and health care services.

First, I'd like to thank you, Senator Kohl, and your Committee and your staff for bringing forth and taking the initiative to examine this very critical issue to the venture capital medical device industry and the medical community at large and patients and Americans at large.

During the past 30 years, the venture community has financed over 1,300 innovative medical companies with more than $20 billion in startup capital including more than $4.2 billion in last year alone. These companies now have sales of tens of billions of dollars and employ more than two million people and most importantly have revolutionized medical care for nearly all Americans.

In fact, it is fair to say that virtually every U.S. citizen born during the last 30 years will benefit personally and significantly from one of more of the drugs or medical devices developed with venture capital. These include MR imaging, ultrasound, coronary angioplasty, and cardiac defibrillators, spinal implants, pulse oximetry and drugs for cancer, heart attacks and anemia, to name a very few.

Currently, what these companies do is critically important to the well being of the American public and the world at large.

My second point is that bringing medical innovation to market is very hard. It entails taking enormous risks. These include the funding and perfecting of the technology itself, proving the safety and efficacy via well conceived and executed human clinical trials, obtaining the FDA approval to market the technology, developing the means to ensure high quality manufacturing of the technology, and obtaining an efficient means to sell and distribute it to the market.

And like any market it also entails for new entrants contending with established competitors who already have significant share with the customer base. Any one of these risks alone may lead to a venture-backed company's failure. And many companies focused on medical innovation actually do fail. Venture capitalists accept these legitimate risks everyday, while traditional financial institutions and government supported programs cannot. It is a function of the venture capital community to take risks like this.

However, it is our view that the anti-competitive practices of the GPO community as currently configured disrupts the already highly fragile and risk process of bringing medical innovation to market. The new reality is that GPOs are not financed and therefore too controlled by large medical products companies rather than by the hospitals they are intended to represent.

GPO practices such as long-term contract exclusivity, substantial fee structures, and product bundling, if allowed to continue, will so constrict potential markets that product segments where these practices are widely adopted will simply not be considered for venture capital backing. This investment drain will result in a stagnation of product innovation and finely improved patient care in these product segments.

It is hard enough for a small company to overcome the power of a large entrenched competitor even in the open and competitive marketplace. It is nearly impossible for monopolistic producers to collude with monopolistic buyers such as GPOs to suppress competition.

While the government did not tolerate such practices in any other sector of the economy, for it to tolerate or even encourage the situation in medicine is very distributing. Because one of the clear effects it to impede innovation, certainly not the government's intent. In medicine, as much if not more than any other sector, in contrast, this is to reduce innovation ultimately affects patients' lives and health. And there is no doubt that patients' health has suffered as a result of GPO activities. In light of this, the anti-competitive activities of GPOs should be viewed with even more not less skepticism.

Finally, the idea that GPOs save money for hospital by extracting larger price discounts from manufacturers than could achieve--than manufacturers could achieve themselves is unprovable and most likely wrong. Unprovable because no one knows what the real market price would be in a truly competitive market among producers in the absence of GPO gate keeping. In fact, the product areas where GPOs collude with producers who already have virtual monopolies, the "discount price" that the GPOs claim to achieve is almost certainly well above what the market price would be in an open and competitive marketplace.

In summary, the venture capital community believes there are enormous opportunities to continue to improve the health of the American public through the development and application of new technologies. These efforts are already very expensive and risky. Despite this, my community is committed to further investments in U.S. health care and technology. However, the increasing powers of GPOs and their collusive and anti-competitive activities with larger entrenched medical companies threatens to undermine the open and competitive markets that have served the American public well by stimulating fair prices and vast technological innovation.

We would strongly encourage the Committee to correct these abuses and again open these markets to fair and vigorous competition.

CHAIRMAN KOHL: We thank you, Mr. Weatherman.

Before we begin questioning, Senator DeWine, who has to leave for another unavoidable commitment has asked to make a comment.

SENATOR DEWINE: Well, thank you, Mr. Chairman. I do apologize to the panel and to you for having to leave. Our voting schedule has thrown off my schedule a little bit today, but I look forward to hearing your comments and reading your comments. And I will, Mr. Chairman, be submitting questions for the record for the different panelists.

I have found, Mr. Chairman, that the testimony of Mr. Kiani, Dr. Goldstein, Ms. Weatherman to be extremely troubling. And I am anxious for Mr. Norling and Mr. McKenna's--to hear their answers because each one of us has benefited from technology--medical technology. There isn't a person in this room who has not. And the older we get the more we benefit. But we also see it in our children and our grandchildren.

And so, I am always alarmed if there is any possibility that any kind of practice that this Congress has permitted, which we have with the law that we passed a few years ago, that might impede that kind of research, might impede people taking chances, might--with their money, might impede smaller startup businesses that have an idea from getting a fair hearing. And more importantly than to get a fair hearing, to get the opportunity to make that sale.

And so, again, I apologize to you, Mr. Chairman, and the members of the Committee. I think the testimony has been very good. I will--I will take a look at the answers to your questions and the rest of the hearing and I will be submitting questions for the record. Thank you.

CHAIRMAN KOHL: We thank you very much, Senator DeWine.

And, ladies and gentlemen, it's good to have you here. We think there's an opportunity to accomplish some significant things, not just today, but tomorrow, next week, and next month. And this whole area of the GPOs and their impact on health care in our country.

I was interested and satisfied, very pleased to hear you, Mr. Norling, say that you are willing and more than willing to be part of a group that's put together to study how we can improve, if possible, improve the practices of GPOs.

I assume, or I'd like to hope, Mr. McKenna, that you would be equally willing to be part of a group that would include not only your two companies, but perhaps manufacturers, device manufacturers, some hospitals. A small group, but a representative group of this entire industry to do what we can collectively do to improve something, and that you would like to improve yourself if possible. Is that a--is that correct?

MR. MCKENNA: That's more than a fair statement, Senator. As a matter of fact, if you looked at my chicken scratch notes, it said add something at the end to acknowledge that and in the press of the schedule, I did not do that. But I overwhelmingly would be in favor of principles of operation, things that would make us better. We're always--benefit from improvement.

CHAIRMAN KOHL: Mr. Norling?

MR. NORLING: I reiterate my comments, Senator. Anything that is ultimately gonna benefit patients you are going to find us thoroughly supportive of.

CHAIRMAN KOHL: So, we will be able to discuss whatever the law permits us to discuss. I think that would be significant and I believe that that will result--and I say this not just optimistically. But I believe that it is your intention and your sincerity in wanting to run a business as well as you can, as clean as you can, and as efficiently and effectively as you can, and you'd be happy to discuss it. So I think that's a--that's a good start.

Now we'd like to ask the two of you this question of financial interest in companies, either individually or corporately, that you do business with. I'm sure you can understand how at least on the surface if not far deeper there is a concern on how theoretically or in fact you serve more than one master. So, in advance of asking you to desist, we'd like you to respond to our concern about financial interests either as individuals or corporately in companies in which--with which you do business. Mr. McKenna, would you like to speak first, then Mr. Norling?

MR. MCKENNA: Certainly, Senator. Thank you. We have a very specific conflict of interest policy and a code of ethics that we have provided and put into the testimony. And so, we have employees in our company that like many companies can own up to 1 percent of our public company.

In regard to that matter, and what I personally own as the only member of the senior management team that has individual stockholdings--sorry about that, I own at this point in time five stocks that would be medically related. Actually, four medically related and one other. And the total holdings are 1,371 shares with the highest holding being 249 shares.

And so what I would suggest in that regard, Senator, is that with good clinicians like Ms. Barrett next to me, and the over 23 advisory councils that we have, they have no knowledge of my holding nor would they have a need to. But they do not come into play relative to the decisions

that clinicians and others make relative to our contract process, which separates both the non-financial or quality criteria from the financial criteria.

CHAIRMAN KOHL: Wait--you are saying you do hold stock in companies with which your company does business?

MR. MCKENNA: Yes sir.

CHAIRMAN KOHL: You are saying this is okay?

MR. MCKENNA: We have a code of conduct and an ethics policy for our company and that policy allows for ownership in public companies of up to 1 percent.

CHAIRMAN KOHL: Well, that may be your company's policy--that's what we're discussing.

MR. MCKENNA: Yes, sir.

CHAIRMAN KOHL: And I'd like to hope you can understand how people like myself and others would be skeptical about such ownership. That in fact, if you want to be as clean as clean can be, then you might consider having a policy--after all, there are many stocks to own in this world. I mean you could own a plethora of bad stocks or good stocks.

MR. MCKENNA: That's true.

CHAIRMAN KOHL: So, why not just say look, it's a bad idea. Some people who are reputable consider it to be questionable, so I and all those with whom I am associated with in my company will not do business stock-wise with companies that we buy from or who buy from us?

MR. MCKENNA: Certainly, sir, I think it's worthy of review. We are in the process of looking at our code of conduct. It has served us well, we believe, up to now. We don't believe there has been any conflict of interest. Even our advisors are asked to abide by the same conflict of interest as they make decisions for us. But I think taking a look at it certainly would be in order.

CHAIRMAN KOHL: Okay.

Mr. Norling?

MR. NORLING: Senator, we also have a code of conduct conflict of interest policy. It speaks to individuals and we also have a practice with regard to corporate conflict of interest. IN regard to individuals, first of all to clarify that policy, in any cases where an individual is appointed by Premier to any kind of an outside board, it is against our policy for those individuals to financially benefit. Very specifically, the policy suggests that any income earned through that sort of process by they director's options, director's fees or anything else, would accrue to Premier and thus accrue to Premier's hospitals.

So, we are very specific on that. Cases have been reported in the media that suggest that practices have occurred otherwise. That dates back to the early history of the new Premier. There are no such cases at this time. Those cases that were reported are under investigation by our outside counsel. We are awaiting a comprehensive recommendation case by case as to what we ought to do in the four specifics that were noted.

We have also been advised to retain confidentiality of the individuals involved until we conclude our action. So, specifically in that regard, as regards holdings by members of management in this area, our policy is clear. Some exceptions have now been noticed. They are historic, but that doesn't mean they are not significant. They are being dealt with I think in an appropriate way that once we learn about the conflict or the inconsistency of disclosure, we in turn pursue it. So, with regard to that point, I think it's pretty clear.

Regarding investments by employees in companies that we do business with or might do business with, our policy currently calls for disclosure number one, and recusal, number two. And, I get a sense of where you're going here and we are in the process of reviewing this policy. And I can tell you that I personally as regards employees in our company and having shares in companies we do business with, I am in personal support of a prohibition of that. And so as we review our policies we indeed will do that.

Regarding board members, for example, who may have a relationship with a company in the medical area, our policy also calls for disclosure and recusal and I happened to believe that's appropriate. Board members serve a defined time period. More often than not they come to the board with a set of experience, etc. and to say that to join this board you must change your retirement account that might perhaps have X shares of some medical products company, does not to me make sense.

We think the policy of disclosure, and we do have a conflict of policy that requires full disclosure and the policy related recusal should any issue come to the board regarding that is an appropriate one. But as in all things, we are open to improving and we are open for dialogues in that arena.

CHAIRMAN KOHL: Great. I think that's great. All right.

Gentlemen, Mr. Kiani, I'm sure you would say, made some very strong testimony here today. He said that he has an outstanding product. He says that he can--he has sold that product to independent hospitals all across this country very successfully and the product is recognized as a legitimate, legitimate, very legitimate tool.

Now, why would you not have him on your list? I mean, the man has tried to get on your list. He's clearly got a product that is on the list of many hospitals. He is not able to do business with you fellows. I would think that one of your sensitivities in your job is to recognize as has been pointed out by people on this panel how important innovation is.

That one of your proclivities should be to bend over backwards to find ways to encourage innovation which really means to get on your list. If they can't get on your list, as they have pointed out, they are out of business.

So, here's one example of a man who has go a product which we'd like you to comment on and perhaps tell us why, in your esteemed judgment, he doesn't belong on your list. Who wants to be first?

MR. MCKENNA: In our case, Senator, Mr. Kiani's company did participate in our process, as I mentioned, at the opening fair and he went through the entire process along with two other companies that went through the bid process. This process involved an 18-month period where we utilized over 40 hospital professionals from five of our advisory councils and also got research returned to us from 850 of our member organizations.

Utilizing the process that our members have helped develop which is called lowest bid, we separate out the non-financial criteria, very important things to do--quality, safety, availability, education, service, from the cost factors. And taking the entire submissions through that process, our clinicians overwhelmingly endorsed the company that we made an award to.

Now, I would point out that 30 percent of our portfolio is offered on a dual or a multi-source basis. And so directly to your question, in this case, we found that this technology was different from the other technology that we selected. We did not find it at the time to be new or innovative. And therefore, we looked at what value would be put on the table relative to the decision process. And, once again, the task force that drove this decision, over 40 individuals strong, overwhelmingly came in favor of the company that we selected.

And we would, if we have not already submitted it into the record, would be happy to give a detailed report to you, Senator Kohl, and all of the Committee members, to review our process of cost divided by quality resulting in low best bid.

CHAIRMAN KOHL: And before we ask Mr. Kiani and maybe Mr. Goldstein to respond, Mr. Norling, would you like to respond?

MR. NORLING: Yes indeed. Thank you. First of all, I am not a clinician, so obviously I listened to the presentation both from Mr. Kiani and by Dr. Goldstein and it sounds very, very compelling. And I'll tell you very frankly, in the role I'm in I get the benefit of multiple inputs from multiple manufacturers, frankly, all of whom suggest their product is unique and differentiated. And I'm not one to make that determination. My role is to see that there is a fair and effective process, so let me speak to that.

First of all, Premier facilities are free to choose Masimo's product. Now, I would acknowledge that we do have a contract that has a target commitment percentage. But there is plenty of room for the use of Masimo's product, and if I could, Senator, I have a couple of letters from some very key institutions that speak directly to this and I wonder if I might be allowed to quote from those letters.

First of all, from St. Vincent Catholic Medical Center in downtown Manhattan, an organization that really distinguished itself during the 9/11 tragedy. David Campbell is the President and CEO of that organization. He writes in a letter to the editor of the New York Times in response to a New York Times article. He wanted to highlight the positive relationship he had with Premier. He indicated that they internally estimate that they have saved 7 to 10 percent through that relationship.

He highlights the flexibility within Premier's contracts also allow us to choose those products that physicians require whether or not Premier has arranged a group contract. There are instances when we have chosen to use products not on contract such as Masimo's pulse oximeter to support our caregivers' preference with no penalty from Premier. We currently, as Mr. Campbell says, use Masimo's technology in our hospitals, although--and the rest speaks to the Times and their article.

Likewise, I have a similar letter here from the Henry Ford Health System in Detroit, a large organization serving all of southeast Michigan. I frankly could come up with additional letters, but there is certainly the opportunity for the Masimo product to enter Premier hospitals. And so I would take exception to the suggestion that that's not the case. I have two letters here and frankly could produce others over time.

If you are willing, sir, I'd submit these for your consideration in the record and--.

CHAIRMAN KOHL: --All right.

So now, I'd like to go to Mr. Kiani. I think I'm hearing at least Mr. McKenna say that your product is not all that good in comparison to its competitor and that it doesn't belong on their--on their list. Incidentally, Mr. McKenna, is the other product sole source?

MR. MCKENNA: In this case it is a sole source contract.

CHAIRMAN KOHL: Sole source.

MR. MCKENNA: So, it may have been as good, but it's just not--we didn't find it to be--clinicians did not find it to be innovative, but just different technology.

CHAIRMAN KOHL: Then the question I would also like to keep on the table here is recognizing your responsibility to be sensitive to innovation. I still wonder why the pulse oximeter should be a one sole source commodity unless you can make the case, not only with respect to this product, but many other products, that the alternative doesn't belong on anybody's list.

MR. MCKENNA: Not at all, Senator.

CHAIRMAN KOHL: Then, why sole source? Before I get to Mr. Kiani, why sole source?

MR. MCKENNA: In this case, the differential in value is such offered both in pricing as well as the most--more importantly non-financial criteria. The clinicians overwhelmingly endorsed this product and found it to be the technologies to be different but not new and innovative. So, when looking at then making an award, we went through our low best bid process, and the greater value accrued to our membership by the decision that we had made.

Mr. Kiani has a fine product and as Mr. Norling has stated, in our organization, our members are free to choose. We have members that use us to a great degree. We have members that use us very little. Of the 70 percent of the products that we cover that numbers use, that means 30 percent we don't have contracts for, we probably have in the vicinity of a little over 50 percent--50 or 60 percent of their business.

So, about 60 percent bought off contract to begin with, and 40 percent has bought on contract and the net level will vary. If I could, I sense that Ms. Barrett has some information that could be helpful relative to--.

CHAIRMAN KOHL: All right. Then we will hear from Mr. Kiani and Mr. Goldstein.

MS. BARRETT: If I could, I'd like to take Mr. McKenna off the hot seat a little bit in that we who participate on the panels often discuss that issue as we see a marketplace of items. And I'd have to again ask the Committee to consider the fact that we as individual professionals who serve on these councils take that duty to look at innovation, look at the marketplace, consider patient safety, very heavily in our deliberation.

In many cases, we will be advising the Novation staff whether we think what we've seen and reviewed warrants a sole source, a dual source, or in some cases triple source. We as individual members have to realize that when we make that advice to Novation, we probably will be giving up on some financial value. But those are decisions that we are clinicians on panels and councils take very seriously.

CHAIRMAN KOHL: Okay. Mr. Kiani, then Mr. Goldstein, and Ms. Weatherman.

MR. KIANI: Well, Senator Kohl, if you don't mind, I'd like to make just a few points. Number one, we don't disagree with Ms. Trisha Barrett that the advisory groups that Novation has put together does meet and does diligently try to come up with the best solution. But we have reasons to believe that the advisory groups, when the votes are taken, they are not listened to, and they are taken in not a way or format where people really know what all the people in the advisory group really want to do.

Now that I've made that point, could I--I do respect the advisory groups and the members. I'm not denying they are very good people. It's just not being listened to.

I would like to address both Premier and Novation, if I may, of what's happened in this particular situation. First of all, Premier's technology assessment team, which supposedly does technical evaluations for Premier and the hospitals, did come out with a report that said that Masimo is a breakthrough and should be allowed and if necessary for certain types of patients.

After completing this report, Premier stalled us for two years. In the meantime, Premier extended the contract with Tyco-Nellcor to 2007 without even asking us for a price. Now, I don't understand how they could be saving their members--.

CHAIRMAN KOHL: Say that again because I want to be sure. You are saying they came up with a conclusion that your product does represent a breakthrough technology?

MR. KIANI: Yes, sir.

CHAIRMAN KOHL: And then at the same time they extended the contract with their other supplier, sole source?

MR. KIANI: Yes, sir.

CHAIRMAN KOHL: To 2007?

MR. KIANI: To 2007. This contract has been in place since 1996 and it was extended to 2007, and not once did they even ask us what is your competitive bid so they could use that to hopefully get a better price from Tyco-Nellcor. In fact, I have a chart that's in the back of your book that I could also put up. That price has been constant since 1996.

CHAIRMAN KOHL: You talk about independent hospitals where you are--you have made a sale. How many hospitals are there--I think you said 44 percent, but I didn't get the number. Did I miss the number of independent hospitals where your pulse oximeter is--.

MR. KIANI: Yes, I do have the exact number. It's probably in the area of about 60 to 70 hospitals that we did--were able to make sales. And the testimony that Premier and Novation hospitals wish to have our product is that they buy our product but they stayed below the 5 percent compliance level, well, in fact, the exclusion level that Novation has, and the 10 percent level that Premier has.

But if I may just take you through the Premier process. Well, despite--once they renewed it, then later Premier pronounced that because Tyco-Nellcor had purportedly a competitive product, they would not further consider Masimo as a breakthrough technology. Now, I don't want to take you through 50 clinical studies. I have charts. I don't think it's your--you are not here to decide if we are better or not. You know, they're not capable of deciding that. It should be clinicians that decide what's best for their patient.

Well, I also mentioned that they also say we can get it to hospitals. We know that Premier Hospitals continue to petition Premier for exemptions to permit them to purchase Masimo technology. to date all of these have been denied or not responded to.

And then, in the same period at least two of our license fees from manufacturers who use our technology were threatened by Premier to not even show Masimo to Premier hospitals. In fact, one of them refused and then coincidentally their contract was not renewed. Now, Senator Kohl,

over 40 companies -- companies like GE Medical Systems, Data School (?), Zoell (sp) -- they did their own evaluation. They decided Masimo was a breakthrough and they made it a standard product. But they can't sell it into Premier and Novation hospitals because of these competitors.

I'd like to just briefly tell you about the Novation experience. Novation initially said it is not going to grant a source of contract for pulse oximetry. They said they were going to do their dual source. Masimo was told that many Novation hospitals wanted our technology and had listed accuracy, motion performance, which is what we pioneered, and price that's key to any decision.

Now, not only did our product beat Tyco-Nellcor's respectfully, even though Mr. McKenna says they are just different, on accuracy and motion performance by 2 to 10 to 24 to 34, depending on which study you look at--independent studies, not ours. But, we have since learned that our bid price to Novation was 30 percent lower than Tyco-Nellcor, who got the contract. Now, here is a group purchasing organization that granted the sole source contract, frankly, Senator Kohl, we assumed Tyco must have given them a better price. But we gave a price of 30 percent lower and I have a chart that I could show you if you'd like me to.

CHAIRMAN KOHL: All right.

MR. KIANI: Now, one last thing. I'm sorry. You asked a very important question. You asked why was Masimo excluded? You ask why Masimo was excluded. We have been told that up until the sixth week of the 18-month process this was going to be a dual source. And Tyco-Nellcor went in the 11th hour and offered a kicker. More than $6 million more per year to Novation through an extra 10 percent fee for Novation to put their brand name on Nellcor Tyco sensors and sell it.

So, if you ask why we get excluded, it's because of the payments that are being paid by suppliers who have learned how to manipulate the system to keep the competitors out. In fact, we actually believe they are paying between 12 to 23 percent kickbacks to Novation in order to get this exclusion. And, if you like, I even have letters from UCSF, I have letters from St. Francis Hospital. And I'd just like to read, you know, even UCSF's letter.

“Dear Mr. Wilson” -- Mr. Wilson is one of our clinical specialists -- “We have valued the new (inaudible) pulse oximetry and found them superior to existing Nellcor monitors. I strongly recommend them for pediatric intensive care units as well as the operating room.” This is by Dr. Mohan Reddy (sp) from UCSF, which Mr. (inaudible) is at.

Another letter from UCSF. Dr. Scott Soifer who is a Professor of Pediatrics, Vice Chair of Clinical Affairs. He writes, “Dear Mr. Wilson, I would to thank you” -- and this is October 12, 2001 -- “I would like to thank you for the support Masimo provided during our evaluation of pulse oximetry and inquire about when we might be receiving the oximeters. After comparing the Masimo to the new Nellcor” -- this is the device they say that we are just different -- “and HP on dozens of patients, I am eager to see a Masimo at every bedside in the pediatric intensive care unit. I am impressed--I was impressed with the performance of your monitor on patients that presented challenges for the other monitors and feel that Masimo will help improve our ability to

asses and treat our patients. Please provide me with an update on your progress toward supplying the pediatric intensive care unit at UCSF with Masimo monitors. If I can help the process please tell me what is needed to move this along."

MS. BARRETT: May I respond to that? I didn't know that was going to be coming up today. As a result of some of the new technology coming our way, regardless of our contract situation, we invited both Nellcor and Masimo back in to the institution just recently as Mr. Kiani suggests. Both the pediatric intensivists as well as the adult intensivists as well as all of our respiratory therapists who have a stake in this hearing were invited to those presentations. There was about an hour and 45 minutes allotted.

Both manufacturers were provided the opportunity to make another presentation and come back for questions and answers. And to that extent that consideration--that is still under consideration at our institution at this very--at this very moment. I think it speaks to the opportunity that we could make an individual decision should all of the stakeholders, not just the two that were mentioned, reach a consensus, we can do that.

And, if we choose to do that, we will take into account whatever value we are giving up in doing that as well. I think one thing the Committee has to consider is looking at what we are facing every single day in constrained costs, and that's a considerable capital equipment to balance with rewiring the whole place.

We have just instituted all new critical care units for the adult side. So that is not an inconsequential consideration for us as we move forward to try to standardize. And I'd also like to take this opportunity to make the point about standardization. A lot has been discussed here about innovation and again, I am a health care provider who has worked in no other industry waiting for innovation every year of my nursing career.

And so I am excited about innovation. I'm worried about innovation and it getting to our patients for a lot of reasons. But I also have to consider the constant turn of new product in that technology as it faces our clinicians. Because with every new device, especially more complex devices, we face an enormous education, patient safety, and in some cases, health care worker safety, and we have to make that balance.

You, Senator Kohl, spoke very eloquently about some balance in decisions. And that's a balance that we are looking at continually as we meet that innovative part of our mission and discovery as well as trying to standardize and make care for our providers as quick and efficient as possible in the safest possible manner.

CHAIRMAN KOHL: Well, I wanna just pose this question and maybe we can get some input from some of the other panelists, which hits on what we are talking about here. Why do we have so many GPO contracts that require hospitals to purchase the vast majority of their supplies in a product category from the manufacturer with the GPO contract in order to gain the GPO negotiated discount price sometimes, and as you know, as high as 90 percent. In fact, it may be in Mr. Kiani's case.

Why not give the hospital a choice? We--I don't understand the sole source. Unless there is so little innovation, so few products that compare to the one you choose. I do not understand this business of sole source unless it is very rare, almost never occurs, it only occurs where there clearly is no alternative. You know, we are very sensitive to innovation. We bend over backwards to encourage innovation. That's why sole source never occurs or rarely occurs. I mean, that's not our understanding here. That sole source is not an extremely rare occurrence.

And you hear all the other people panel say you've got to have--they've got to have access to you fellows or they are out of business or they are not even in business, recognizing that. What's with the sole source?

MR. MCKENNA: First of all, Mr. Senator, all of these gentlemen do have access. Just would comment--the last meeting I had with Mr. Kiani was on an invite to come in when he did not get the contract award. We sat down and reviewed the process. Since that time I have not heard from Mr. Kiani. And so, I'd be always open minded in our business practice to sit and meet with innovative companies. Seldom, if ever, do I ever get a call from a venture capitalist. I don't think my staff does either.

In regard to your direct question about sole source versus dual source, we have many multi-source with one, two and dual source arrangements where the value and the innovation or a combination of both is perceived, and in fact, laid out by our clinicians and others that evaluate our products to bring them the best value.

But in many of our contracts, after evaluation of the submitted bids on criteria that the clinicians set prior to the bid going out and putting a weighting on it, in the evaluation coming back looking at cost factors and quality factors, and dividing cost by quality. And looking at the differential that would be left from one decision to standardize on our sole source products that more than meets the clinical requirements. And going to two sources of supply which would leave value on the table that would not be able to inure to people like Ms. Barrett and her organization. We go with the sole source. So we have a blend with both our members who we are here to serve and whose bidding that we do, really drive those decisions.

CHAIRMAN KOHL: Ms. Weatherman, do you have any comments?

MS. WEATHERMAN: Yeah, I'd make a couple of comments. I think it's highlighted here and I think everyone in this room would agree that medical innovation is important. But I think it's also important that innovation for innovation's sake is not what we should be focused on. What we need to focus on is the new product or an existing product serving a clinical need. Is it delivering value to the marketplace. Maybe it's because it's cheaper. Maybe it's because it's better, it's more accurate, it's more--easier to use. There are a lot of criteria for value that hospitals could--would perceive in a newly existing product.

And I think it's important for the Committee and my suggestion would be: to investigate or gather the information to try to understand what the total revenues are and the prices that Tyco-Nellcor charge for their sensors. How significant is that market and how much of a share do they

own? And really look at regardless of whether Mr. Kiani's technology is the same or better, I think no one out here has said it's worse in terms of delivering you know, serving a clinical need.

I think it's very important to look at the context of how big is Nellcor Tyco's position, and what are their total fees that they've been paying over the years to Premier and Novation? That is a very important fact that needs to be looked at. And I would contrast that, if you also wanted to investigate the situation with the given technology, that was also highlighted, that in that particular situation there is no significant incumbent that is being threatened by the entrance of that new technology.

And in fact, I would even ask you to look at what the true market potential is for that product. Where are the clinicians out there crying out for that technology to solve that clinical need? I don't think you are going to find nearly the outcry or the market potential that you will see that Nellcor sensors currently enjoy in the U.S. market.

CHAIRMAN KOHL: Okay, Mr. Detlor.

MR. DETLOR: Yeah, one of the things that several parties have said here. It's one of the things that is the challenge to a GPO in general. The first thing is that, you know, incumbent clinicians in the sense of the historical experience gilds adult products. The products in this pulse oximetry were not. To Dr. Goldstein's conversation, were not originally focused nor did they have the sensitivity or the capability to deal with the neonatal. So, you've got a segmented market that's developed in pulse oximetry issue.

So, the demands of what was used in the adult marketplace, there was very little product available that had any sense of accuracy in the neonatal arena. Masimo's product, you know, bridges that kind of issue, the change of technology. So, if you go and survey in committees, which we used to spend months and hours with, you should normally get out of the committees feedback unless they are focused solely on new technology. Is there historical experience with the existing marketing incumbents? Their satisfaction, shortcoming, things they like, etc.

It takes an extremely proposition for a startup company to put in a sales force that's gonna equal what a Nellcor has established over decades. So, to develop the same clinician exposure to new technology, which means that somebody as a clinician has to stop what they are doing in patient care and spend a certain amount of time with new technology, is a very difficult task in today's health care environment.

So, all things being equal from a process perspective, it doesn't surprise me that you wind up with these types of scenarios. People who sit on committees, donate their time, etc. So many days out of a given year is all they can put in it at best. A good portion of that is going to be the historical experience not the issue on future technology. They've not seen a sales person. The companies don't have the kind of resources to make that type of intro and, therefore, it's very hard to have that--be a 50/50 proposition, an equal footing.

And I think you heard, you know, Dr. Goldstein kind of refer to that. The changes that are going to have to take place is the fact that in the breakout, if there is a neonatal niche for this

technology which has an undefined market, who knows the size of it, I think that's still one of the issues in the marketplace. Then that has to be treated separately than the issue of what we do with adult pulse oximetry.

Right now, it's lumped into one contract and historically the GPOs, you know, would do that. Not because, you know, they meant to do any harm to anybody, but because of the commissioned input they had historically based on what they've used over years in the past, have a tendency to favor the incumbent manufacturers. It's a process adjustment that has to take place. You know, it's an issue that if we are going to look at more and more future technology, everyone has to guard against the management team that chairs those committees of clinicians, etc. and has to constantly challenge them not to take the short cut, not to talk about what they've historically done, but take a look at what's new and current on the marketplace. And it's not that clinicians aren't willing but they are also competing for their own day to day jobs in time and what they can give to the GPO.

So, hopefully, out of this process, maybe, you know, most GPOs and I've heard, you know, the comments and commitments, which is understandable. You know, you have to go back and re-engineer your processes to make sure these things don't happen in the future as you move forward.

CHAIRMAN KOHL: Okay. All right.

Dr. Goldstein, you wanna make a comment? Get the microphone close as you can folks.

DR. GOLDSTEIN: Okay. Thank you. I certainly can appreciate the costs and cost savings and incentives and I understand what GPOs are all about and I can appreciate efforts involved to save money, but I'd really at this point like to let some of the clinical studies talk. If you wouldn't mind I'd like to bring out some of the placards that we've prepared.

This first one shows a study that was done in an NICU, looking at false alarms, missed true events that is where the saturation, the amount of oxygen in the blood went down and the oximeter did not appreciate it, and measurement failures of the oximeter. As I mentioned, this took place in neonatal intensive care units which is certainly my focus population. But you can see clearly the demonstrable improvement that Masimo SET has relative to its competition in these particular areas.

The next example I'd like to bring up specifically looks at one institution's experience with the Masimo SET oximeter with respect to retinopathy and prematurity. And in this, Dr. Sola, in a letter to Masimo, details his experiences with and without Masimo technology, looking at eye damage that is retinopathy prematurity as I alluded to in my statement, in this target presentation.

As you can see, in the group that received pulse oximetry through Masimo set, there was no evidence of retinopathy prematurity and this is a very significant finding. The next study I'd like to refer to is one--no the Barker Study. The Barker Study. Okay. This is a study that I performed as well at my institution, again looking at Masimo SET specifically with respect to

heart rate variability and heart rate changes. In this we found that at no point more than 1 percent of the time, Masimo h ad problems with respect to heart rate variability tracking.

And granted, this is in a target population of neonates where you have a great deal of heart rate variability and in general in adults you don't see as much. But again, it points out my focus that the target population here is being ignored.

Next slide, please. Looking at the objective studies that have been done heretofore, notwithstanding studies that have been supported outright by grants from either Nellcor or Masimo, overwhelmingly, Masimo SET is superior to its competition. And to that I'd like to kind of ask, I mean, in terms of talking to people who make these decisions, to the GPOs. Which of you have been in an NICU for more than an hour within the past five years?

MS. BARRETT: I have.

DR. GOLDSTEIN: You have?

MS. BARRETT: Yes.

DR. GOLDSTEIN: Have either of you been in the NICU for more than an hour within the past five years?

UNIDENTIFIED MAN: The clinicians that make our decisions certainly have.

DR. GOLDSTEIN: But personally, I am asking if you've been in the NICU for more than an hour in the past five years?

UNIDENTIFIED MAN: No, I have not.

DR. GOLDSTEIN: And you as well?

UNIDENTIFIED MAN: I have not.

DR. GOLDSTEIN: Well, this is an important question because in the interest of looking at cost and cost containment, we have to ask the question what is the cost of a dead baby? What is the cost of a baby who has gone blind from retinopathy prematurity? How do you explain this? What do you say to the parents in defense of this action? After all, we do have these overwhelming studies.

MS. BARRETT: Could I take the opportunity here to make an observation and ask a question to capitalize on your expertise in the field? One is that the studies that are just now--before us were published I think in the peer review literature you k now late 2001 or once in 2002. So, what we are aiming to do on many of the councils that I am involved with, is look at evidence-based decision making. And in that our best way of doing that is looking to the peer review literature database which admittedly takes a long time for the studies to work their way through peer review studies.

But we do have--try to have that guide us wherever that's possible and where we can. And, if I am not mistaken the studies that are presented here, may not have been available in a peer review--in a peer reviewed manner at the time that this particular decision was made. I wasn't on that council.

The other question that I have has to do with the fact that we were trying to re-look at you--you--many of your studies talk about a neonatal patient population. We also in reconsidering this technology wanted to see was it applicable in adult populations for the reasons that I am sure you are aware of. In hospitals, we do our best to standardize patient safety because we have a cross training that goes on for many of our physicians, as well are our therapists, and having one standardized system they can use can become a patient safety issue.

So, I'm just--my question is, to what extent do you think this technology is applicable to the adult ICU's where it was also recently reconsidered by our adult therapists in that regard?

DR. GOLDSTEIN: With respect to the adult ICU's?

MS. BARRETT: Yes.

DR. GOLDSTEIN: I am a neonatologist and I do not profess to practice adult medicine. I am addressing a segment of the population that is often ignored and often not, I guess you could say, recognized in terms of the significance that newer technologies bring to care of these individual patients.

MR. KIANI: Senator Kohl, if I could say something. Although as the CEO of Masimo, and the person who founded it, I am enjoying all this conversation about Masimo pulse oximetry, how it's better. But this is not what this meeting is about of course. We have a systematic problem where large companies like Tyco-Nellcor have figured out how to use their, excuse the expression, almighty dollar, to get GPOs like Premier and Novation to exclude the competition.

That's the problem and we are just one example. And, there's adult examples right in the back of your hospital you guys usually go to and fortunately where patients are being saved because of technology and other stuff that works. But, that's not what it's about. I hope that there can be changes by the two groups sitting down and solving it. But, I have to say that this is gonna cause delay and delay means harm to patients and there needs to be something quick. I hope it's not just about Masimo--.

CHAIRMAN KOHL: --Well, as you know, what we have concluded here this afternoon is that we're gonna have an immediate forum composed of these two companies plus people like yourselves. And we're gonna get together on opening up this system if we can, eliminating all conflicts of interest, if we can, on trying to eliminate--if it is true as you are suggesting, companies buying market share. They deny it, but if it's there, they are prepared to work on that problem.

And getting this done in three months and reporting back in a public manner as to what we accomplish. So this, I hope, is not a hearing, which is so often on Capitol Hill, hearings that are hearings and then they vanish into history.

I'm very hopeful that this hearing will result in something that is a new and improved GPO system. And I don't find the principals who are here today, the two major principals in the industry, who are unwilling to engage in that process to see what improvements can be made.

MR. NORLING: Senator, can I speak to the question you asked since I don't really believe it has been answered yet? You were speaking about sole source contracts and I do have some data for you that might be useful.

CHAIRMAN KOHL: All right.

MR. NORLING: And I'd also like to, if I could, speak to a few of the other points that have been raised. Specifically, I think I've mentioned earlier, that Premier has contracts with about 450 different manufacturers and a total of 750 contracts. Of them, 377 are what you would call clinical. They essentially relate to products where there are clinical uses in effect where physicians may have various degrees of preference.

I think the issues we are talking about here are specifically in areas of high physician preference where you don't have a commodity in effect. You've got something where there are some of the disagreements that, frankly, have surfaced here. So, I think it's important to get at this issue. I think Mr. Detlor in some ways was trying to get at that also, this issue of high clinical preference and what's to be done.

Premier's data is as follows. Of 377 clinical contracts, we have 20 sole source contracts. I can tell you that as we've looked at this process, and as we've--as we've come to think about it more fully, and frankly, as the terms of some of our longer term contracts have now reached the expiration dates, our conclusion is that in some of these areas that the idea of sole source contracts in high clinical preference areas don't make a lot of sense.

So, in terms of a practice going forward from Premier, I expect what you'll see in these areas is as existing in force contracts reach their expiration date, and prior to that as we begin to re-negotiate them, and even prior to that as successful applications of our breakthrough technology clause are pursued, what you are going to see is a movement away from any sole source and high clinical preference to dual source. Or in some cases, not even a commitment target of any kind, but preferred contracts.

So that's a leaning in a direction that I think makes sense and is a good solid learning here. I would make a couple of points, and just for factual accuracy. Premier's Nellcor contract expires in December of '04. I do not believe that's seven years from now, or nor was it seven years from the time it was quoted. Premier's administrative fee with regard to this is 3 percent, no more.

And very frankly, since there is some inference of decision making based on fees, we'd get greater administrative fees because I don't believe the Nellcor 3 percent fee would change, if we

contracted with Masimo and if product flowed through that contract. We'd actually get more administrative fees than we do now. And that's just a true economic fact of how this all works.

Specific to the comment of being threatened by Premier members, I frankly have no knowledge of that. I've had no reports of that. If that were possibly true, I would agree that it is totally inappropriate. I seriously question whether it is true, but I will tell you that if, indeed, there is any inference of that, it would be totally inappropriate.

I'd also like to deal with this issue of the inference that Premier delayed the process for two years. And, if I can, I'd like to share with you a time line as I understand it. I told you again, and I would acknowledge, Senator, that I have not been in a neonatal intensive care unit since I left active practicing as a hospital administrator about four and a half years ago, but I used to spend quite a bit of time prior to that.

The timeline as I understand it is this: in 1999, Masimo approached Premier and our technology assessment group with regard to the technology that they had in place. As it's been explained to me, and again, this is--this is secondary, but again, I think it's accurate, is that what they had then was an algorithm, a calculation if you will, and the related software. They did not have a stand-alone product at that time.

And our tech assessment group said that this was an exciting looking technology and actually encouraged them to work with other manufacturers who have standalone products and encourage them to make that technology available to them. And it sounds like Masimo's been very successful in doing that, not with Nellcor, but certainly with others. So, as regards the time frame, that was the interaction with our technology assessment group.

In January of 2000, Premier received and was made aware of the Nellcor 395 pulse oximeter and contracted in January of 2000 for that item. As I said, the contract goes with the term through '04. In March of 2000, just to be very sure, in March of 2000, Nellcor approached Premier indicating that they would--excuse me, Masimo approached Premier indicating that they did have a product, a standalone product, that they intended to bring to the market. And data from Masimo suggested their product was first commercially available in August of 2000.

So in March of 2000, we began the technology breakthrough process. And the initial panel reviews suggested that this was worth a further look, which is obviously--you have to sort through all these requests to get to the absolute answer. We did bring together a panel, and at that time, based on the data, was available to our group, and based on the comparison to the existing contract, namely the Nellcor N-395, Premier made the distinction that this was not a significant breakthrough.

Now, it does not mean that this isn't a great product. I'm sure it is. It does not mean that it isn't particularly relevant in neonatology. Certainly, an expert here has suggested that it is. Our belief is that our contract leaves room for its use in that setting and our other belief is, very frankly, that if indeed these additional studies suggest this kind of power as regards this particular product, particularly in neonatology, although I would indeed want to explore its relevance elsewhere.

Then I would invite a resubmission into the breakthrough technology program with that data. And I would tell Mr. Kiani that I personally will pay attention to this and make sure that process is expedited. Because if indeed there is that kind of differential, there is no reason under this--no reason on earth that we wouldn't wanna have that kind of a product available for patients.

CHAIRMAN KOHL: Okay. We're gonna wrap this up in a couple of minutes. I would like to just touch on two other areas. Is it true that some hospitals can go outside the GPO and get a better price on a particular commodity?

MR. NORLING: That's a fairly complex question. The answer is often that is true. The question is whether they can do it consistently and sustain and create value.

CHAIRMAN KOHL: So you have suppliers who will give a hospital of some size a better deal than they're giving you?

MR. NORLING: In general, it would be suppliers who work with us. It would be a situation where we would have a contract in place and a supplier who didn't purchase or pay into that contract would come in and suggest that they would undercut the contract price. That leaves the marketplace at work in a very productive.

CHAIRMAN KOHL: It's not the same product. It's not the same commodity.

MR. NORLING: It may be the same product essentially, but it may be different manufacturers. Now, in some cases, you may get some same manufacturer doing some of that. It's pretty infrequent in our experience. But in general, and specific to the GAO report, there are a number of other reports that I believe were much more thorough and comprehensive in what they covered. Such as the recent Wooen (sp) study that was submitted as part of the Health Industry Purchasing Group Association submission, studies out of Arizona State University, a study by Mr. Mews (sp) that suggests pretty significant benefits from GPO contracting to the tune of 10 percent.

And, Senator, just to give you one good example of, again, I've been trying to stick to factual data here, we have a process we call portfolio analysis. We have a team of supply chain folks who go out into the hospitals and collaboratively with them ask them for a computer dump of everything they've bought for a year.

Now, we do about 200 of these assessments every single year. And we get a sense of here is everything that ultimately was purchased. We go through them and particularly highlight purchases for items in areas where we have a contract. But they were not purchased through our contracts. We look at those, not to penalize, but to suggest what the benefit might have been for using our contracts.

When we itemize these routinely, and it's a very significant amount of money, we have found consistently over two years in more than 200 hospitals, that they are leaving 9.5 percent on the table by using contracts, or by using--buying products outside of our contracts in areas where a

comparable product is under contract. That tells me that the marketplace in general out there is certainly not as competitive as the group purchasing prices that we have in place. And it's a very large number of hospitals, and it's a very large number of dollars.

CHAIRMAN KOHL: You are estimating to the tune of maybe 9 to 10 percent?

MR. NORLING: Yes, I am.

CHAIRMAN KOHL: Well, again, I want to ask this question. Is it possible that some hospitals go outside of the GPO and buy the same product with the same label for less?

MR. NORLING: The answer is sometimes.

CHAIRMAN KOHL: So, that can happen and probably does? How can it happen?

MS. BARRETT: To shed light on that, you are speaking about price. What we are looking for is a contract that offers us not just price but some other value and quality criteria. So, it's quite possible that a vendor may come in and give us a very low price and yet when we ask will they provide some educational support, will they provide some conversion support, then the price alone is not the only feature. So, it is indeed possible for them to undercut us on item by item pricing. But indeed, we as the individual department material services managers have to look at the whole package that they might be offering, where price alone may not be the only thing that we need to look at.

CHAIRMAN KOHL: Well, I wanted to be just raw in my question, I'm going to say Johnson & Johnson Band-Aid, which I don't know if it's on your list, but maybe it is. Is it possible for a hospital to get a better price on that item than is on your list?

MR. MCKENNA: I think it's possible. In our industry there is a practice that we would call cherry picking, maybe it's used in other industries where for the work that we do, and I think our numbers would be consistent with what Mr. Norling has pointed out for what's being left on the table. But if a member of one of our organizations chooses to leverage what we have already done, and apply pressure on the supplier, there may be a supplier that will buckle and provide a better deal.

But in the majority of instances it's usually one of our members that perhaps would leverage our contract price and go with the company that did not get the contract award, which I think proves the point relative to, you know, it's an open system and the hospitals will make the decisions on their own.

CHAIRMAN KOHL: Okay.

Last question. In the past, we've been informed that GPOs return about 80 percent of their administrative fees to their member hospitals, keeping the remaining 20 percent to cover their expenses. Data that Premier has provided to our Subcommittee shows that for Premier's most recent fiscal year, Premier retained 63 percent of the administrative fee instead of what we had

understood to be about 20--retained about 63 percent of the fees collected from medical equipment suppliers which was over $213 million.

So, we understand that GPOs--we assume, and you know, we are presuming GPOs are supposed to be merely non-profit buying agents for hospitals and that they are supposed to return their member hospitals the fees paid by suppliers less expenses. So where did all that money go, Mr. Norling?

MR. NORLING: Thank you for the question, Senator. I think that I'll do my best to simplify this because this has been sort of an ongoing dialogue both with your staff and with the media. There's two sets of points that have been made. First of all, Premier is not just a GPO. We are an enterprise, about a $500 million a year enterprise. About $300 million of that relates to GPO administrative fees. We are also in the business of comparative clinical data, which charges fees. We have a business of well over $100 million that repairs and maintains clinical equipment.

We also have a business that helps underwrite excess layer professional liability, professional and general liability. So, we have a series of other businesses that comprise Premier the enterprise. That's the organization that I run. The piece of it called Premier Group Purchasing Services is actually run by this gentleman here, Howard Sanders, who is Senior Vice President of Premier for Group Purchasing.

So, to the degree that I may not have had all the exact clinical data, that's in part because I am running the larger aggregate enterprise. The numbers are as follows. We have returned historically since Premier began 80 percent of the net income of Premier back to our hospital owners. So, 80 percent of the net income generated across all of those businesses, cumulatively since Premier started, has gone back to those hospitals.

Now, if you will take the admin fee portion of our revenues, which last year were about $300 million. And if you look at a combination of the dollars that we send back to all of our members, the dollars that go back to our hospitals and our affiliates, and the incremental value of the equity, just the incremental value, not the in place value, but the incremental value earned per year. We have returned last year 67.4 percent of the admin fee dollar back to our members.

So, it's two different numbers. One is a percentage of net revenue in the aggregate, and the other is a percentage of administrative fee revenue, which is a subset. I'd be more than happy to document this clearly to show you in our--in our submissions to the committee exactly where those numbers come from and those are indeed the numbers.

CHAIRMAN KOHL: Okay. Mr. McKenna?

MR. MCKENNA: Ours is a bit complex but I'll try to simplify it, Senator Kohl. We are owned by both VHA and UHC. After our expenses, everything that we have left goes to those organizations based on the way their members purchase since they are set up as cooperatives. They, like as Mr. Norling has outlined, invest in other programs. There are benchmarking programs, clinical programs to assist in local communities to reduce the risk of heart damage or stroke damage, and other services.

And after investing in those programs which are board approved, they return--I'm pretty sure this number is accurate for both alliances, 100 percent of their net income. If you were to translate that into going back to the GPO, I believe the numbers are respectively 32 cents and 40 cents on the dollar for both VHA and UHC respectively.

CHAIRMAN KOHL: Okay. All right.

Well, what I think I'd--hope I think we've accomplished today is that we've seen on the part of the head of the two major GPOs, a desire for a fairly extensive transparency with respect to your companies and how they function. A willingness to accept suggestions and comments from interested and sincere people who are here only to effect an improvement in the delivery of product and price and quality.

And that we will get to work immediately on putting together this group of individuals, along with you all, who will work on achieving this end and expect to have a report with, hopefully, some positive results inside of three months.

And if we achieve that, if we can move forward on that, then I think we've achieved a lot and you will have demonstrated a sincere interest and willingness to work in the public interest which is what this hearing was all about. So, we thank you all for being here. You've made a real contribution and this hearing is now adjourned.

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