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

HEARING

BEFORE THE

SUBCOMMITTEE ON ANTITRUST,
BUSINESS RIGHTS, AND COMPETITION

OF THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

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

TUESDAY, APRIL 30, 2002

UNITED STATES SENATE,
SUBCOMMITTEE ON ANTITRUST, BUSINESS RIGHTS,
AND COMPETITION,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The committee met, pursuant to notice, at 2:54 p.m., in room SD–226, Dirksen Senate Office Building, Hon. Herb Kohl, chairman of the subcommittee, presiding.

Present: Senators Kohl, Leahy, Schumer, and DeWine.

OPENING STATEMENT OF HON. HERB KOHL, A U.S. SENATOR FROM THE STATE OF WISCONSIN

Chairman KOHL. This hearing will come to order. I held it for Senator DeWine, who is unavoidably detained for just a few minutes and he 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 CAT 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 guying 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 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.

Gaining 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 injured, 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 cannot get it to patients because a GPO stands in your way.

With that kind of power comes responsibility. But too often, it seems that GPOs have failed to serve as honest brokers seeking to

serve the best interests of hospitals and patients. We are going to detail three major concerns.

First, conflicts of interest raise the specter of critical health care decisions being influenced by financial ties to suppliers. We have heard startling allegations of scandal and conflicts of interest that have infected the GPOs. Premier's chief executive 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 its $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 interest and in which many of Novation's senior executives hold 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 stock holdings 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 buying off the GPO contract. 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 position. Practices such as sole sourcing, high commitment levels, which require a hospital to purchase as much as 90 percent of a product from one company in order to get the maximum discount, and bundling, which gives hospitals 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.

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.

[The prepared statement of Senator Kohl follows:]

STATEMENT OF HON. HERB KOHL, A U.S. SENATOR FROM THE STATE OF WISCONSIN

Today our subcommittee turns its attention to an issue affecting the health and safety of every American who has ever, or ever will, need treatment at a hospital—in other words, all 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 CAT scanners to needles and Band-Aids—and how those groups affect the cost and quality of patient health and medical innovation.

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With that kind of power comes responsibility. But too often it seems GPOs have failed to serve as honest brokers seeking to serve the best interests of hospitals and patients.

We have three main concerns.

First: conflicts of interests raise the specter of critical health decisions being influenced by financial ties to suppliers. We have heard startling allegations of scandal and conflicts of interests that have infected the GPOs. Premier's chief executive 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 its initial $100 investment into a stake worth $46 million dollars 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 interest and in which many of Novation's senior executives hold personal stakes.

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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 or medical innovation. We thank our witnesses for testifying today and look forward to hearing their views.

Chairman KOHL. I call now on my colleague and the ranking member of this subcommittee, Senator Michael DeWine.

STATEMENT OF HON. MIKE DEWINE, A U.S. SENATOR FROM THE STATE OF OHIO

Senator DEWINE. Mr. Chairman, thank you very much. Let me begin by saying that I am also quite disturbed by some of what we have learned in our investigation of group purchasing organizations.

There is certainly some anecdotal evidence and 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 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. 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 a 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 interests 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 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 start-ups, 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. 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 costs 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 both 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 and 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.

[The prepared statement of Senator DeWine follows:]

STATEMENT OF HON. MIKE DEWINE, A U.S. SENATOR FROM THE STATE OF OHIO

Let me begin by saying that I am also quite disturbed by some of what we have learned in our investigation of group purchasing organizations. There is certainly some anecdotal evidence, and 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 we need to decide how to prevent them in the future.

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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. 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.

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Chairman KOHL. Now, to our witnesses. I will introduce the seven and then we will start with their testimony.

Mr. Richard Norling is Chairman and CEO of Premier, Incorporated. He joined Premier in 1997, first as Chief Operating Officer. 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 the 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 Materiel 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 co-founder and CEO of Masimo Corporation, a privately-held medical technology company. He is also an inventor on more than 30 patents related to signal processing sensors and patient monitoring.

Dr. Mitch Goldstein is a physician at the Citrus Valley Medical Center and 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.

STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM THE STATE OF VERMONT

Chairman LEAHY. Mr. Chairman, just hearing your comment about keeping it brief, I just want to compliment both you and Senator DeWine. As I have said on many occasions, the two of you, the subcommittee should be a model for the rest of the Senate in the way you handle it.

One, we all agree that we worry about escalating health care costs, whether you are a legislator or a provider or you are a consumer or anything else. I am concerned on this one issue: Do the GPO's contracts and other practices with 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 who act as go-betweens for the hospitals exceed statutory limits? Do some GPOs have officers and employees with inappropriate connections to large medical suppliers? Should they be funded by the suppliers at all, rather than by the member hospitals?

So these are the issues. I will, because of our other hearing, I will leave most of these for the record, but I do want to compliment you, Mr. Chairman and Senator DeWine, 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.

[The prepared statement of Senator Leahy follows:]

STATEMENT OF HON. PATRICK LEAHY, A U.S. SENATOR FROM THE STATE OF ARIZONA

Escalating health care costs are a source of concern to all of us, as legislators and as health care consumers. The struggle to keep health care costs as low as possible, while ensuring that the quality of care remains high, is the Herculean task confronting our nation's health care providers and hospital administrators. In recent years, the development of Group Purchasing Organizations, or GPOs, has been heralded as an effective tool to meet this pressing need. *The New York Times* reported today that the General Accounting Office has just released a study concluding that hospitals do not necessarily benefit from participating in GPOs.

GPOs allow hospitals to aggregate their buying power in making purchases from suppliers of medical equipment, pharmaceuticals, and the many ordinary products necessary for the daily functions of any hospital. By purchasing in bulk, the hospitals ostensibly would save money, and because the GPOs handle much of the administrative burden of dealing with the suppliers, the hospitals would then be relieved of those tasks.

However, recent media reports and industry commentaries suggest there are issues we need to address in the context of GPO purchasing. I see this hearing as an opportunity for the Judiciary Committee and for the public to learn more about how GPOs operate, how they benefit hospitals, and whether there are any changes that could improve their operations.

Serious questions on several topics should be answered, including:

• Do the fees paid by suppliers to the GPOs who act as the go-betweens with the hospitals exceed the statutory limits?

• Do some GPOs have officers and employees with inappropriate connections to large medical suppliers?

• Should the GPOs be funded by the suppliers at all, rather than by their member hospitals?

• Do the GPOs' contracts and other practices with large, established medical and pharmaceutical supply companies keep newer and smaller companies from bringing innovative and high-quality products into our nation's hospitals?

• In light of the new GAO report, do GPOs actually save hospitals money?

I look forward to exploring these questions with the panel today, and I thank Senators Kohl and DeWine for their laudable and bipartisan efforts to ensure that these questions—and other important antitrust issues—are considered in this forum. I commend the chairman and the ranking member of this subcommittee for their productive working relationship. This level of cooperation should be the rule and not the exception in the Senate.

Another significant effort to improve the quality and lower health care costs is the Drug Competition Act of 2001, S. 754, which was reported out of this Committee unanimously last October. Drafted in the wake of several Federal Trade Commission suits against large brand name drug makers who paid off their generic rivals to keep their lower cost drugs off the market, that bill would require that such deals be filed with the antitrust enforcement agencies. The FTC and the Justice Department would then have the tools they need—tools they have asked us for—to combat these pernicious practices which keep prescription drug costs unnecessarily high by blocking generic entry into the marketplace. But that bill has been awaiting Senate action for 6 months, the victim of a partisan anonymous hold. Such politically motivated efforts only hurt consumers, and I would hope that this body could focus on the best interests of the American people, rather than on short-term political gain.

I thank the witnesses for coming before us today and I look forward to hearing their testimony.

Chairman KOHL. We start with your testimony first, Mr. Norling.

STATEMENT OF RICHARD A. NORLING, CHIEF EXECUTIVE OFFICER, PREMIER, INC., SAN DIEGO, CALIFORNIA

Mr. 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 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 would like to talk to the subcommittee on 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 is the most significant health care database available in America 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 through all 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 processes. 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 breakthrough 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 is a very, very exciting technology. Within 30 days of learning that, we had a group contract with this 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 Needle Stick Safety Act, which I might note we very strongly supported, Premier reached out to the industry for new safety products in this arena. 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 hospitals. Once they, the committees, make their decisions, we negotiate the contracts. But Premier does not purchase products, hospitals do. Our group purchasing contracts do not 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 do not require up-front payments, and since 1997, 67.4 percent of all administrative fees we receive 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 have 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, Senators, 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.

Now from Novation, we have Mr. McKenna.

STATEMENT OF MARK MCKENNA, PRESIDENT, NOVATION, LLC, IRVING, TEXAS

Mr. 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. I am also 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 on us and the collective strength of their membership.

Group purchasing saves hospitals hundreds of millions of dollars annually. By our estimate, last year alone, we saved our members over $1 billion by aggregating their buying power and by consequently avoiding other costs. Many hospitals, especially those serving rural communities, could not realize these savings on their own. Here is 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 2 years through purchases made by Novation contracts, and they report that these savings have helped them fund a free clinic for indigent care patients in their community.

The benefits enjoyed by Community Memorial reflect a sound business model. It is a cooperative model, similar to others outside the health care sector, such as agriculture and electronics.

Now, I would like to take a moment to briefly comment on Novation's business practices. I am 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 and 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 the selection of high-quality, low-cost products. We use over 20 member advisory councils. Our councils include more than 450 individuals 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, cost.

Some suppliers may provide a single product. Others provide more. But each product is chosen on its own merits through this fair, objective, and inclusive process. In fact, all our bids are posted on our public website so they are all available to all suppliers. This methodology results in low best bid, which in our 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's definition of a small business. One example, Triad Disposables, a small Upper Midwest company that makes alcohol preps, which won a bid over much larger competitors, proves this out.

Our contracts are also flexible, allowing us to continually seek and offer new and alternative products and 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 freely 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 have 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 and serve their communities. Thank you for this opportunity to tell our story.

[The prepared statement of Mr. McKenna follows:]

STATEMENT OF MARK MCKENNA, PRESIDENT, NOVATION, LLC

Chairman Kohl, Ranking Member DeWine, and distinguished members of the Subcommittee, thank you for this opportunity to tell our story and share with you examples of the value we believe Novation delivers to the nation's patients and hospitals. My name is Mark McKenna. I am the president of Novation, the supply chain management company for VHA Inc. and University HealthSystem Consortium (UHC), two alliances comprised of community-owned not-for-profit hospitals and academic health systems throughout the United States.

Our focus at Novation is to help the hospital members of VHA and UHC realize efficiencies and cost savings in their purchasing functions. As I'm sure you know, the environment of health care has changed dramatically in the last 10 years—

through the Balanced Budget Act of 1997, staffing shortages, advances in technology, aging populations and managed care. Our nation's hospitals are facing these pressures and the rising costs of supplies, as well. At the same time, reimbursements from HMOs and Medicare continue shrinking, while many more patients are uninsured and are unable to pay at all. Hospitals are caught in the middle. Novation, as an extension of its owner alliances, works to lessen this financial pressure by helping those it serves create a more cost-efficient supply chain, while keeping quality the top priority.

For example, Community Memorial Hospital, a VHA member and not-for-profit health care organization in Menomonee Falls, Wisconsin, employs almost 1,300 people and provided care to more than 60,000 patients last year, including many indigent patients. By choosing to purchase quality products through Novation contracts they realized tangible costs savings of well over $700,000 in 2001, in addition to significant cost-avoidance. These savings went directly to their bottom-line and helped them maintain their community outreach and indigent care services to their community, such as their free clinic. This hospital's story is only one of many around the country.

At its very core, group purchasing benefits hospitals as well as the entire health care system. As it currently stands, group purchasing brings the most value to hospitals and maintains a fair market for suppliers. All of the hospitals Novation serves are under tight budget constraints. Thousands of free standing large, medium and small hospitals—especially smaller facilities in rural areas—would experience increased costs and struggle to survive if the system was changed.

Health care group purchasing was created by groups of hospitals that came together to gain efficiencies. History traces the concept of group purchasing in the health care industry to as far back as the late 1800's. However, it really didn't take hold until the late 1970's, when health care costs, specifically supply costs, were escalating at an alarming rate. Not-for-profit and academic hospitals, hurting financially, sought a way to aggregate purchasing strength to lower supply costs and to better compete with the for-profit hospital chains. By pooling their efforts, they were able to achieve more together than they could alone.

VHA and UHC are organized as cooperatives and as such, return 100 percent of their cooperative income to members in cash and equity. In 2001, VHA returned approximately 32 percent of its revenue to members in cash payments. UHC distributed almost 40 percent of its revenue to members in cash payments. Members indicate that the combination of VHA and UHC's cash and equity returns, pricing, and value beyond price for products and services are superior to other alternatives. These cooperative payments and the clinical services that the alliances offer help hospitals carry out their missions.

Fees also fund other services of the alliances and are utilized in board-approved initiatives such as information technology resources, research, benchmarking, educational programs, and other efforts to improve health care—things that would be too costly for hospitals to do on their own.

We continue this vision of slowing rising health care costs, helping hospitals fulfill their mission of healing and saving lives. Novation serves the purchasing needs of more than 2,300 health care organizations—the members of VHA and UHC. Our company was formed in January 1998 when these two alliances created a new joint venture firm that would efficiently serve the purchasing needs of both alliances. VHA, is a nationwide network of more than 2,200 leading community-owned health care organizations and their physicians. It comprises 26 percent of the nation's community hospitals. UHC, representing most of the academic medical centers in the United States, is an alliance of 87 academic medical centers and 110 associate members. In total, VHA and UHC represent health care organizations in all 50 states.

Cooperative group purchasing, as well as Novation's overall approach, are commonly recognized business models. Novation's relationships with suppliers are similar to business-to-business relationships in other industries where agents broker services such as real estate, financial services, travel and hospitality and other buying agents in the electronics and food industries.

Cooperatives have served this country well. They enable their members to reap the benefits of joint endeavors while still maintaining their independence. They allow the members to own and control the business and to operate it for their benefit. Our cooperative structure is similar to other cooperatives in the farming, building, hardware and restaurant industries. Supplier-paid fees are a means by which cooperatives operate. This is the most effective way to fund our operations, given the financial constraints that most hospitals operate under.

Novation receives fees from suppliers just as other cooperatives do. The amount of the fee offered is generally based upon the value placed on Novation's services

by the supplier and usually varies based upon the product category. Fees are paid based on a percentage of member purchases from the agreements accessed.

Our average overall fee is 2.1 percent. Of those fees that are above 3 percent, the vast majority are for NOVAPLUS agreements—our private label brand owned by VHA and UHC members. These slightly higher fees involve trademark and licensing fees. Novation, VHA and UHC are fully accountable for the fees they collect from suppliers and manufacturers and disclose all fee information to the member hospitals.

The Federal Government has previously reviewed the issue of administrative fees received by group purchasing organizations from suppliers and determined that based on the benefit of these organizations to the nation's health care system, the fees they generate on behalf of their memberships should be permitted. On April 17, 1985, Richard P. Kusserow, HHS Inspector General said:

> "We [HHS OIG] believe the current practice of reimbursement by vendors to group purchasing agents should be permitted . . . The use of volume purchasing through group purchasing agents clearly reduces the cost of purchases by hospitals. Therefore, we would encourage use of such arrangements regardless of the reimbursement methodology."

Novation works as an agent on behalf of VHA and UHC hospitals, ultimately answering to them. Whereas publicly held manufacturers ultimately answer to stockholders for their financial performance, we answer to hospitals for financial performance as well as by how well we help them fulfill their missions of healing. Member satisfaction is extremely important to Novation. Half of our yearly incentive plan for all employees is based on member satisfaction. As stewards of the members' finances, the other half is based on achieving operating income goals.

With significant involvement from, and on behalf of, VHA and UHC members, Novation works with medical supply companies to offer contracts for products of the highest quality at the most cost-efficient price. When comparing Novation's product portfolio to member and prospective member hospitals' supply purchasing Novation has saved VHA and UHC member hospitals approximately $2.1 billion since its inception in 1998.

Dennis Barry, President and CEO of Moses Cone Health System in Greensboro, NC and chairman-elect for the board of the American Hospital Association, probably sums it up best:

> "[They] bring significant value to us as an organization: better pricing for consumables and equipment than we could arrange on our own; a range of other services . . . helpful to our organization; the ability to network with other similar sized organizations throughout the country on a whole range of questions or issues."

You will hear many benefits and aspects of group purchasing and Novation mentioned today, but the primary one to remember can be summed up in our mission statement: *In partnership with VHA and UHC, Novation will deliver industry-leading supply chain management solutions that assist community-based, not-for-profit and academic hospitals in improving financial, operational and clinical performance.*

Novation, and group purchasing as a whole, brings tremendous value to health care. In this regard, my testimony will focus on five topics:

- The philosophy and ethics of Novation's overall business practices
- The value created by Novation's competitive "low best bid" process
- The fair, open and competitive nature of Novation's bidding process for suppliers of all sizes
- The flexibility of participation in our product and program offerings
- The clinical & operational benefits beyond group purchasing of the VHA and UHC alliances

Now, I would like to tell you about the way Novation delivers value to member hospitals:

NOVATION'S OVERALL BUSINESS PHILOSOPHY

Our overall philosophy is to deliver the greatest possible value to hospitals, keeping both quality and cost squarely in focus. This is accomplished in large part through our open competitive bid process and through extensive member input.

On a more practical level, our day-to-day purpose is to offer and manage contracts with a variety of companies that provide VHA and UHC hospitals with the ability to access high quality products in a cost-efficient manner. Much of what we contract for is commodity-oriented products.

Our contracting objective is to provide members with the highest quality products at the lowest total delivered cost. Recognizing the diversity of the hospitals we serve, all participation in our product agreements is purely voluntary. We seek to provide additional value to hospitals based upon their purchasing volume, commitment and ability to drive purchasing efficiencies across their respective systems. To that end, considerable attention has been given to the following elements:

- Involvement of VHA and UHC member representatives in the process
- Development of a structured process with "high integrity" to accommodate the competitive bid requirements of public institutions
- Reliance upon the business acumen and facilitation skills of staff to guide the process

Because of our eight-step contract process—what we believe to be the most extensive in the industry—hospitals can have confidence that Novation ensures consistent, high-value agreements. This process is used across all departments and program areas of the company to achieve a consistent, high-value outcome.

Novation's contracting process includes the following steps:

1. Identifying VHA and UHC member contract needs
2. Conducting member and market research
3. Developing and analyzing bids with councils
4. Deciding awards
5. Resolving and clarifying contract issues
6. Finalizing the award
7. Launching the agreement
8. Retaining records

To determine contracting priorities, Novation relies on member input and member purchasing behavior. Through the direction of member councils, made up of clinical and procurement professionals, as well as surveys and other research, we distribute Invitations to Bid for specific product categories. These include specific questions related to member-determined specifications.

Additionally, we post and maintain a bid calendar of products that are up for bid on our public web site, inviting all suppliers, large and small, to request an invitation to bid. While many manufacturers offer multiple product lines, they must submit separate bids for each product category based upon the bid calendar. Novation's supplier agreements are generally 3-year agreements with two 1-year optional extension years, exercised at the discretion of Novation and the hospital members. Member councils also help determine if an agreement is sole (one supplier) or multi-sourced (multiple suppliers.) Generally, when there is little difference in the overall award decision criteria matrix results, a multi-source award is recommended to give members more choice.

"Low Best Bid" Contracting Process

Novation is proud of its innovative "low best bid" approach to contracting. In fact, it is one of the first things new Novation employees learn as they are oriented into the company. Understanding the low best bid process is the key to understanding Novation's overall strategy. The concept centers around the view that hospitals derive the most value from supply agreements when other qualitative (non-financial) factors are considered rather than just the lowest price. The product with the best value for hospital members is not necessarily the product with the lowest price. The low best bid takes into account both financial and non-financial criteria. All decision criteria are established by member councils and through research and vary from product category to product category. For example, non-financial requirements might include: patient and care provider safety, customer service, product quality, clinical knowledge of company representatives, educational offerings and cost in use. Financial criteria can include price, fees and other value measures such as free goods for trial, which are deducted from the cost of the product. These criteria are entered into a matrix—what we call a Decision Criteria Award Matrix—standardizing the way decisions are made. To calculate the low best bid, the financial scores are divided by the non-financial scores for each bidder. This fair and equitable process, created with significant member involvement, ensures a mix of both high quality and cost effectiveness.

Our contracting process is thorough and exhaustive. The average contract decision takes 9 months, and some take as long as 1½ years from start to finish. In addition to member-based criteria and input, the decisions take into account such things as: interviews, field trials and published literature, as well as the opinions of multiple member clinicians. Imagine the time, resources and cost associated with these activities if more than 2,000 hospitals did them individually.

The entire contracting process is member-driven. As the contracting arm for the members of VHA and UHC, Novation works with prestigious hospitals around the country that employ some of the most well-respected clinical professionals. Novation seeks member input in many ways including through surveys, councils, task forces and focus groups. In fact, Novation sponsors 23 standing member councils and several other ad hoc task forces, representing more than 300 hospitals, that help shape Novation's product portfolio.

Novation keeps its member-centered focus throughout its award selection process. Physicians, nurses, pharmacists, directors of operating rooms, other clinicians and materials managers from around the country are included on councils. These member councils help decide the bid criteria before the invitations to bid are even sent to suppliers.

It's also important to note that Novation's highly objective and fair contracting process makes the concept of "inherent conflicts" practically impossible. Fees are one small part of a host of quality, non-financial and pricing criteria, which is also set by members. Mathematically alone, fees alone never drive decisions. Quality plays too important a role—as it should.

WORKING WITH SUPPLIERS OF ALL SIZES

Novation's public competitive bid process allows all eligible suppliers to participate in a fair manner. Novation welcomes competition from manufacturers as it allows us to gain better value for the members we serve. The competitive bid process and our low best bid approach, provide a level playing field for manufacturers large and small. Our bid calendar is continuously posted on our public web site to ensure the bid is open to all interested parties and those interested in receiving a bid are encouraged to request one.

Of the approximately 500 suppliers contracted with Novation, 25 percent of them are small businesses, as defined by the Small Business Administration. A shining example of Novation working with a small company is our relationship with Triad Disposables, a small business based in Wisconsin. Through the contracting process, they were awarded the contract for alcohol wipes, a low-tech but vital supply for all hospitals. During the contract process, they won over other larger suppliers, including one of the largest in health care, simply because they brought the most value to the members per the decision criteria established by the members.

Innovative technology suppliers, in addition to small suppliers, are found throughout our portfolio of supplier contracts. One innovator, Possis Medical, is a leader in creating a significant new medical market for the mechanical removal of blood clots with a procedure known as "rheolytic thrombectomy." Soon after the FDA approved this new technology, Novation placed it on contract in September 1999, following input from members. The members involved in the decision consisted of interventional radiologists, radiology technologists, interventional cardiologists and cardiovascular administrators and nurses. Additional input was obtained through market research studies to VHA and UHC members.

It is important to note the distinction between "new" (something not available anywhere else) and "different" (something similar that accomplishes the same outcome) technology. Novation is committed to providing agreements containing the latest technology to members—the competitive bid process and provisions in our contracts ensure it.

Novation strives to be sensitive to continually evolving health care technology, to remain relevant to those we serve. Through our contracting process, we ensure that we contract for the technology that is most acceptable to VHA and UHC hospitals at the time of the bid award. Should technology change during the term of the agreement and the current supply partner not provide the latest technology, Novation can add other suppliers or terminate the existing agreement and put out a bid for a new agreement if the members find the technology change so substantive to deem the current agreement's offerings outdated. All agreements contain termination clauses that allow Novation to terminate the agreement with the existing supplier with 90 days written notice when necessary.

An example of a supplier with a new technology being added to the portfolio is Megadyne, a small company that makes an innovative product—reusable grounding pads—used to protect patients from electrical shock. Novation already had disposable grounding pads on contract with 3M and Valley Lab. Megadyne's reusable pads employed a new technology that VHA and UHC members wanted added to the portfolio. These reusable pads are and example of "new" technology.

An example of technology that is simply "different" is in the field of pulse oximetry. The selection of Nellcor over Masimo is a good example of how Novation's bid process works fairly. During the contracting process, which took almost 18

months to complete, we used enormous amounts of clinical input from members, including the active involvement of five separate member councils made up of more than 40 hospital professionals as well as survey results involving more than 850 member hospitals. Regarding the non-financial criteria, our process revealed that Masimo's technology is based on "rhythmic and repetitive" patient motion while Nellcor's technology is based on "random and chaotic" patient motion. Masimo's product was deemed to be a different technology, but not a new technology. Our clinicians gave us input that random and chaotic patient motion is a more realistic measure, especially when the patients are children and babies. Overall, in the non-financial categories, Nellcor received higher marks from clinicians than any other competitor in every single category. In the end, the results were overwhelmingly in favor of Nellcor, far above all other bid participants. Ultimately, the member councils recommended the bid award go to Nellcor.

Besides meeting member standards, suppliers with new technologies also face additional challenges. Some truly "new" technologies must wait for FDA approval.

Others are available, but must wait long periods for reimbursement approval, making them cost-prohibitive to many health care institutions. Finally, many companies with "new" technologies are not always interested in contracts with group purchasing organizations, believing that with no competition they can command higher pricing for their product on their own.

Possibly even more telling regarding clinical input in decisions, is the support of many clinicians at VHA and UHC member hospitals following bid awards. Because participation in our contracts is voluntary, hospitals often conduct their own clinical trials on some contracted products, even after the rigorous review the Novation contracting process gives to the products. By conducting their own clinical trials, members ensure they are choosing to access the products that best meet their needs. This not only underscores the clinical decision of our member councils, but also underscores the inherent freedom of choice that member hospitals enjoy in the Novation relationship.

In addition to relying on member input to keep us updated on health care technology changes, Novation's contracting staff—with significant input from Novation's field-based service delivery team—is responsible for monitoring their respective product's markets for technological advances. These staff members typically have a high degree of experience, training and expertise related to their area of responsibility—often having direct experience in these areas at provider organizations. Should a Novation staff member learn of changes in product technology, the staff member can review the impact of the technology changes with one of Novation's member councils.

As a member-driven organization, it is always in the members' best interest to make sure that our agreements meet the needs of the VHA and UHC members—clinically, financially and operationally.

Flexibility of Member Participation

Hospital participation in Novation agreements is totally voluntary. Novation strives to offer VHA and UHC hospitals the most competitive value on the highest quality products based upon members' purchase patterns and ability to deliver volume, commitment and purchasing efficiencies.

However, we also recognize that each hospital's ability to commit varies. In response, Novation offers a portfolio of agreements and programs in which organizations can freely choose to participate in, without disadvantaging those that cannot.

For example, Novation offers a committed purchasing program we call OPPORTUNITY. Novation's approach to commitment is a self-selecting philosophy in which members are free to choose whether they wish to participate. We believe the voluntary nature of OPPORTUNITY has helped make it the industry's leading and most successful committed purchasing program. In addition to offering best pricing, the program helps organizations focus their efforts on further improving efficiencies through standardization and utilization. OPPORTUNITY delivers cash rewards for commitment and the potential to increase VHA's and UHC's cooperative returns. OPPORTUNITY rewards VHA and UHC hospitals that voluntarily meet previously agreed-upon commitments in designated product categories. There are no Novation programs that require 100 percent participation.

Our contracts offer product coverage of about 75 percent of the total supplies the average hospital uses. So, there is 25 percent we don't have on contract at all—these products could represent fast-changing technology areas, local or regional products or large capital expenditures. Of the 75 percent product coverage we offer, VHA and UHC hospitals typically use our contracts for about 55 percent of their purchases. So, overall, VHA and UHC hospitals use Novation's services to purchase about 40

percent or less of their product needs, all of which is accessed on a voluntary basis. Hospitals choose what works best for them.

The significant involvement of the councils and hospitals as a whole, play an important role in the aggregated purchasing strength of the VHA and UHC facilities. We actually see ourselves as a champion for the small rural or community hospital that would have a difficult time providing these services on their own. Through our aggregated approach, small rural and community hospitals enjoy the buying strength of large health systems. More than 700 VHA and UHC member hospitals have fewer than 100 licensed beds. According to the March 2000 Muse & Associates study, *The Role of Group Purchasing Organization in the U.S. Health Care System*, without Novation to contract on their behalf, these small health institutions could be spending up to 15 percent more on hospital supplies. Additionally, of our 23 member councils and task forces, about 30 percent of the participants are representatives from small hospitals with 100 beds or less.

To better illustrate this, if I may quote Susan Park, Purchasing Agent of VHA member Sarah D. Culbertson Memorial Hospital in Rushville, IL, she says,

> "We have limited resources, as a 58-bed facility, and Novation is always willing to work with us to meet our needs. With Novation's help, we gain the benefits of a bigger hospital that we couldn't get on our own. Through Novation, we are not little, but mighty."

CLINICAL & OPERATIONAL BENEFITS OF THE VHA AND UHC ALLIANCES

It's important to note that health care organizations affiliate with VHA and UHC and gain access to Novation's services for a number of benefits beyond simply supply chain management. These include: nationwide collaboration on clinical improvement initiatives; high-quality educational opportunities; groundbreaking research on emerging technologies; consulting services that improve operational efficiencies; research on consumer trends; advocacy on public policy issues; and innovative services provided by VHA and UHC that might not otherwise be affordable for individual organizations or available from other sources. Alliances represent the coming together of their member organizations in areas other than purchasing. More can be done to improve the country's health through collaboration and scales of efficiency.

For example, VHA recently launched the nationwide program, Women's HeartAdvantage, as part of a national initiative to change how women are treated for heart disease and to educate women about their own risks for heart disease. VHA is collaborating with hospitals across the Nation to implement the first hospital-based program to address heart disease, which is the greatest health threat to women. To address this largely unrecognized health crisis, VHA conducted nationwide and market-specific benchmarking research on the attitudes and awareness among women about heart disease. Interval results from the Yale-New Haven Hospital demonstration program revealed that after 10 months of the Women's HeartAdvantage program, awareness significantly increased from 26 percent to 39 percent. In fact, already we know it's helped save at least one life. After experiencing chest pain, a patient mentioned to her doctor that she had read about Yale-New Haven's participation in Women's HeartAdvantage. The symptoms she read about reminded her of her own discomfort. She was sent to the hospital, where doctors performed an emergency balloon angioplasty, and she's doing fine.

Likewise, UHC helps members identify standards of excellence among academic health centers and community providers so that members can achieve optimal quality and productivity.

UHC's improvement and effectiveness services focus on enhancing practice management, improving members' clinical and operational performance, and providing the support and resources for effective clinical decisionmaking. UHC's benchmarking projects use data-driven processes to identify models of efficiency and best practice, share up-to-date information, and initiate effective, long-term clinical and operational improvements. A recent benchmarking study focused on ischemic strokes. Participating hospitals reported current patient care protocols for treating stroke victims. UHC compiled and reviewed the information and produced a report that identified best practices in patient care. The University of Utah Hospitals and Clinics was one of the stroke project participants. Using the findings from the UHC study, the hospital's staff formed a clinical "brain attack team" of physicians, nurses and pharmacists. The team reviewed the findings and modeled their response and treatment patterns on better performers' practices. Since implementing their new response protocols, they have experienced improved outcomes with many of their stroke patients.

Attention to safety is also a vital initiative. Novation's comprehensive safety initiative promotes and enhances patient, care provider and environmental safety.

Through this initiative, Novation increases member awareness of its safety-related contracted products; promotes and tracks supplier-sponsored safety initiatives; obtain member input on safety projects through councils; and incorporates safety specifications into the contract process. Our quality assurance/regulatory affairs team ensures the delivery of safe and effective products by conducting manufacturing inspections and audits of supply partners, monitoring customer complaints and enforcing all regulatory guidelines.

During 1999 and 2000, 25 VHA and UHC member organizations participated in the Novation Education in Anesthesia Techniques program. This program is an anesthesia clinical simulation training program offered by Novation's anesthesia business unit. The initiative was presented, reviewed and supported by the Novation Anesthesia Advisory Council which consists of clinicians such as nurses and pharmacists. This program allows organizations to receive a free, cutting-edge and accredited training program for anesthesiologists, nurses and pharmacists. Nine out of ten participants felt that their clinical staff gained enhanced clinical knowledge from the program. Multiple clinical participants wrote to us following the program. One letter from a physician and professor at the University of Minnesota said the program was "tremendously successful educationally for medical students, residents, fellows, anesthetists and staff."

Additionally a fourth-year medical student that attended the program wrote to us saying:

> "I attended a training session on the identification and treatment of a tension pneumothorax. The very next morning, one of our patients developed a tension pneumothorax in the PACU. After the incident, when the resident began asking questions about how to treat this condition, I was able to answer correctly."

Additionally, VHA and UHC, operational efficiency solutions are offered to hospitals through Marketplace@Novation, Novation's Internet information solution containing a members-only Web site and e-commerce services for hospitals and suppliers. Hospitals can access contract and program information, publications and other Novation supply chain tools. In the late 1990s, VHA and UHC members strongly indicated a need and a desire for electronic health care procurement. VHA and UHC's strategic investment in Neoforma to build Marketplace@Novation ensures that members have easier access to innovative technologies and reduces members' development costs for these services.

The health care industry is large, fragmented and surprisingly behind in the information arena. Easily accessible information available to all parties in the supply chain is non-existent. In 1995, the industry-wide study, "Efficient Healthcare Consumer Response" stated that by addressing current inefficiencies in the supply chain, $11 billion of additional savings could be realized by America's hospitals. Despite the industry's best efforts to try to address these issues, very little was accomplished. The evolution of the Internet and the 2001 study, "The Value of e-Commerce in the Healthcare Supply Chain" identified specific steps we can take to achieve potentially 2–10 percent savings and help hospitals accelerate the technology timeline to reach supply chain efficiencies enjoyed by other industries. Those steps are the guiding development principles behind the Marketplace@Novation.

Marketplace@Novation is an evolution of our core competency of aggregating purchases to reduce supply costs. The Internet makes it possible to streamline the process, create new efficiencies and connect existing information systems to perform productive new activities. Marketplace@Novation will enable members to purchase virtually all their supplies through our e-commerce services. In fact, any supplier—both those with and without Novation agreements—can post all of their product information on Marketplace@Novation—not just those products on contract—to allow greater visibility. These services will allow members and suppliers to automate current manual purchasing processes.

It will reduce administrative costs by aggregating purchasing information across all health care organization sites. Marketplace@Novation is a logical extension of what we already do for VHA and UHC members—deliver value.

As it grows and develops, Marketplace@Novation is proving to be successful. In just over a year since its first member hospital went online, Marketplace@Novation has seen dramatic increases in the transaction volume and rapid hospital and supplier adoption. Currently, more than 700 VHA and UHC hospitals and almost 240 supply and distribution companies have signed on to participate in Marketplace@Novation e-commerce services. This leading supply chain solution facilitates the efficient exchange of information with hospitals and their suppliers for the procurement of goods and services, resulting in streamlined processes, reductions in administrative costs and more efficient healthcare purchasing.

CONCLUSION

Safety, quality patient care and good stewardship of resources are the top priorities of the hospitals and health care professionals we serve. Their passion, commitment, and insight are transferred to us through their involvement in everything we do as a company. We are dedicated to helping hospitals around the country realize significant efficiencies and cost-savings—the underlying reason for the existence of group purchasing organizations. In today's health care environment of tight budgets, these savings are invaluable in allowing hospitals the breathing room to have resources for safe and quality patient care, providing indigent care, hiring practitioners, providing community outreach programs and offering the best services most effective to better the health of our nation.

On behalf of Novation, VHA, UHC, their hospitals and their patients, I deeply appreciate the opportunity to share with you of the value and benefits we bring to public and community-owned hospitals around the United States.

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.

[Laughter.]

OPENING STATEMENT OF HON. CHARLES E. SCHUMER, A U.S. SENATOR FROM THE STATE OF NEW YORK

Senator SCHUMER. 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.

What I want to 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. I think it is very important that all of us keep in mind that GPOs, in concept, are not 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 cannot come at the cost of the quality of care. So the balance we need to strike at this hearing today is important. We have to not throw out the baby with the bathwater, look at the concept of GPOs and understand why they are needed, see if how business has been conducted works—there have been some serious allegations that it has not—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.

Chairman KOHL. Thank you, Senator Schumer.

Senator SCHUMER. Thank you. I apologize. This committee always has a lot of things going and we have the bankruptcy conference, as well, but I wanted to come in here, so thank you. I appreciate it.

Chairman KOHL. Thank you for coming.

[The prepared statement of Senator Schumer follows:]

STATEMENT OF HON. CHARLES E. SCHUMER, A U.S. SENATOR FROM THE STATE OF NEW YORK

Mr. Chairman, thank you for squeezing me in to make a few brief remarks. As you know because of all the work you've done on the bill, we're trying to work out the final details in the bankruptcy legislation that's in conference. But I did want to take a couple of moments out of that process to say a few words here.

It's no secret that health care costs in this country are spiraling way out of control. An ever increasing percentage of Americans' monthly income is going to pay absurdly high health care bills. We need to find solutions to this problem that will only get more serious as the baby boomers move into their later years.

One area that I've been looking at is prescription drugs. Senator McCain and I have a bill that would make generic drugs more broadly available and reduce patients' reliance on high-priced drugs from the big pharmaceutical companies. Passing that bill would be a start, but only a start.

In the past few months there's been a lot of debate about the role of group purchasing organizations in the health care system. As you mentioned in your statement, the New York Times ran a front page article raising some serious questions about the practices of certain GPOs and I'm pleased to see that they're here today to give some answers to those questions.

As we examine the problems, it's important for all of us to keep in mind that GPOs, in and of themselves, are not a bad thing. They perform a valuable service by permitting hospitals to buy supplies more affordably. When hospitals can purchase quality equipment at cheaper prices, consumers save money.

Not to put too fine a point on it, but lower operating costs lead to lower-cost operations.

With health care bills soaring through the roof, every dollar counts. But savings can't come at the cost of quality care. That's the balance we need to strike and this hearing today is important because it will examine both the problems with and the advantages of using GPOs.

Government shouldn't jump in with fixes to problems that industry can clean up on its own. That's why I'm so pleased to hear that the GPOs have committed to creating their own code of conduct which, we trust, will resolve the concerns that have been raised about the ways GPOs operate.

Mr. Chairman, I know that you share my view on that issue and I believe that holding this hearing, focusing attention on these issues, and taking a constructive approach to solving the problems you're highlighting here is just the kind of limited government intervention that serves our constituents well.

I look forward to reading the testimony of everyone here and to reviewing your answers to the questions posed. I apologize for not being able to stay to participate, but duty on the bankruptcy bill calls.

Chairman KOHL. Now, we proceed to Ms. Trisha Barrett.

STATEMENT OF TRISHA BARRETT, BSN, ASSISTANT DIRECTOR, MATERIEL SERVICES, VALUE ANALYSIS FACILITATOR, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO MEDICAL CENTER, SAN FRANCISCO, CALIFORNIA

Ms. 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 have 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 am 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 saving lives, America's hospitals face nursing shortages, constraints imposed by managed care, and important patient and health care worker safety issues. Overshadowing these challenges is financial pressure due to ever-rising costs of pharamceuticals, 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 is 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 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 our 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 national nursing shortage or 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, seven-day-a-week training during conversion from old product to new. These discussions lead to consensus and advice 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 patients makes it all worthwhile. 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 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 passive 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.

Chairman KOHL. Thank you for your statement, Ms. Barrett.

[The prepared statement of Ms. Barrett follows:]

STATEMENT OF TRISHA BARRETT, VALUE ANALYSIS FACILITATOR, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO MEDICAL CENTER

Chairman Kohl, Senator DeWine, and distinguished members of the Subcommittee, it is a pleasure to be with you this afternoon to share my perspective of how our health care organization benefits from its association with Novation.

My name is Trisha Barrett and I am the Value Analysis Facilitator for the University of California, San Francisco Medical Center—a member of University HealthSystem Consortium (UHC)—where my responsibilities include the clinical coordination for product selection and standardization. I have been a nurse for 25 years. Previous to joining UCSF, I served in similar capacity for Alta Bates Summit Medical Center in Berkeley and Oakland California, a member of VHA. I have thus served on the Novation Nursing and Clinical Practice Council as both a VHA and UHC member representative.

I am proud to serve in 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, located in northern California that employs 5,500 health care professionals. Annually, we perform 20,000 surgical procedures, and provide tens of thousands of inpatient and outpatient days of care. To meet this demand, we maintain a product and device inventory of anywhere from 20,000 to 30,000 different items. Recently, we were named one of the top ten hospitals in the Nation by *U.S. News and World Report*.

Beyond the daily challenges of providing care and saving lives, America's healthcare organizations face shortages of nurses, constraints imposed by managed care, patient and healthcare worker safety issues, the aging of the baby boomer generation and more. Overshadowing these challenges is financial pressure due to the 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. We at UCSF choose to access just over 50 percent of the Novation contracts available to UHC hospitals. The remaining 50 percent is spent on products that are not on contract, or on products that may compete with Novation's contracts that our clinicians choose to use instead. 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 on councils and task forces because it provides a forum where I am able to provide clinical expertise and experience in the formation and analysis of Novation contracts. Clinicians like me from hospitals 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 staff.

For example, I am currently working with fellow clinicians throughout the country to establish quality criteria for the IV catheters bid. Clinical council members share our experiences and opinions during meetings and conference calls where we discuss IV catheter quality criteria and supplier service criteria. We recently discussed the need for the supplier to support hospitals with education and training.

Many hospitals have lost onsite nurse educators either to the national nursing shortage or to financial constraints. Educational support is a high priority for the supplier we choose—that they be able to provide training 24 hours a day 7 days a week during conversion from old product to new. These meetings and discussions lead to consensus and advice that makes the final bid a good one and also makes it satisfying to participate on the councils and task forces.

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 decisions. I take my role as a health care professional very seriously, so when I was invited to become a part of Novation's Nursing and Clinical Practice Council in 1999, I welcomed the opportunity. Being a member of a council is something I do above and beyond my current responsibilities at UCSF and involves being away from my family periodically. However, having the opportunity to assist Novation in contracting for the highest quality, most clinically acceptable products available on behalf of patients makes it all worth it. More importantly I can trust in other contracts because I know there are hundreds of others like myself working on the other member councils.

I have the privilege of assisting some of the best doctors, nurses and other healthcare professionals in the country. With that privilege comes the moral and legal responsibility to invest the organization's funds wisely. I ask fellow clinicians to think of these funds as they would their own family budget. When possible, we use Novation contracts. Beyond that, we concentrate our own hospital resources at searching and bidding for those items our care providers need that are not on contracts or offered by suppliers who choose not to participate in Novation bids.

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 health care organizations, and ultimately patients, would pay more for health care. In addition, we would be forced to dedicate significant additional resources toward contracting, diverting precious resources away from the delivery of care.

Thank you.

Chairman KOHL. Now, we are going to hear from Joe Kiani, who is a co-founder and CEO of a privately-held medical technology company. Thank you for being here.

STATEMENT OF JOE E. KIANI, PRESIDENT AND CHIEF EXECUTIVE OFFICER, MASIMO CORPORATION, IRVINE, CALIFORNIA

Mr. KIANI. Thank you, Chairman Kohl and Ranking Member DeWine. Good afternoon. We are happy to be here to testify. We thank you.

Masimo is a typical American start-up company. Our goal was to make a contribution to humanity by improving care and reducing cost of care. We also wanted to become financially independent and reward 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 do not know—we have lived this for 14 years—is the non-invasive monitor to measure oxygen in the blood, and it is important, because if your blood oxygen drops below normal, within three minutes, you can get brain damage, and within five minutes, you can die. On neonates, there is an additional problem. If they get too much oxygen, they can get eye damage.

Masimo is the innovator in the industry. The problems that were thought to be inherent limitations with pulse oximetry, we solved. These were problems of motion artifact, like you would see with ba-

bies moving or agitated patients in the intensive care unit or recovery room, and maybe just as importantly, very sick patients have very low perfusion, which means very low blood flow.

In fact, there have been over 50 clinical studies over the last several years by independent researchers across the country that have proved that Masimo SET is indeed superior and it has improved care and reduced costs. But you gentlemen do not 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 us compete in a free market.

We believe there needs to be reform because there is a system here that precludes innovative devices to get to the hands of the clinicians who are the best to know what is best for the patients, and this is happening at the expense of not only manufacturers like ours, but 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 is not good for Masimo and it is 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 that GPOs are saving money. I do not 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, those are not called kickbacks, they are called administration fees, marketing fees, other types of fees.

GPOs, and when I mean GPOs, I am 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 maximize 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 expenditures.

Why have we concluded this? For 4 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 sole-source contracting, by bundling, by questionable tactics, which include threatening manufacturers of Masimo-type devices, the same manufacturers that actually are current, or some of them are still current GPO contractees, with expulsion if they show Masimo technology to their member hospitals. We 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.

Is this all sour grapes? There is an exhibit I would like to show you. I think it is important, if you will allow us, Chairman Kohl, to show it.

Let us look at this exhibit. Masimo has 100 percent success rate in the free markets. In the magenta, you see the sole-source GPOs. In the 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. AmeriNet 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. Then also, independent hospitals, zero. I did not expect to see the statistics, Chairman Kohl, but we lost zero.

At the same time, we lost 48 contracts, 22 at Premier, 24 at Novation, and 22 at Consorta. These are all sole-source contractees with Tyco–Nellcor, who is the 90 percent market share competitor of ours. As you can see, in hospital-wide conversions, what that means, these are hospitals that chose that every one of their patients should have access to Masimo SET, in the free markets, over 50 percent of those hospitals chose to have every patient there be monitored with our technology. As you can see, the sole-source environment, in Novation, we did have some success, 10 percent, but those happen to be the most famous institutions, like Massachusetts 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, just 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 for group purchasing organizations like Premier and Novation sell markets and exclusivity to group selling organizations, these big companies I big call them, has 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. Today, it is the best pulse oximetry, the best pacemaker, the best safety needle, but tomorrow, it could be the best cancer treating medication that is kept out.

We need a solution. The solution should restore free market. I have my own. I would be happy to share with you what my recommendations for those 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 your questions and I thank you for this opportunity.

Chairman KOHL. Thank you for your testimony today, Mr. Kiani.

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

Dr. Goldstein.

STATEMENT OF MITCHELL GOLDSTEIN, M.D., NEONATOLOGIST, CITRUS VALLEY MEDICAL CENTER, WEST COVINA, CALIFORNIA

Dr. GOLDSTEIN. Good afternoon. Thank you for inviting me to testify today. I am Dr. Mitchell Goldstein. I am a practicing neonatologist and clinical researcher 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 purchasing constraints. GPOs operate in the middle ground, selectively contracting with manufacturers and supposedly providing discounted pricing to hospitals.

Pulse oximeters' incessant beeping and alarming were more of a distraction than a useful clinical tool when I started practice. During one outbreak of retinopathy 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 GPO's availability list. Those of us physicians who have tried to lobby for purchase of Masimo SET in GPO-dominated hospitals have dealt with the incessant smoke and mirrors techniques. One former associate of mine in 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. His 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 the emergency room in extreme condition. 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. Another oximeter's failure 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 clinical use in this particular hospital. Why? Because despite the manufacturer's admission that the oximeter was not designed to work in this type of situation, a GPO-mandated contract stipulates that

this hospital cannot engage in contracting to purchase another manufacturer's pulse oximeters.

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 been 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, ventilators, catheters, and other equipment, develop only for the highly profitable product lines, cater to the lowest common denominator, and patient care will be compromised, 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 weigh thoroughly our choices for care and medical therapeutics. Where medical care has become subservient to contracting demands, our ability to practice medicine is curtailed. Innovation deferred, health care denied. Give us the option, the freedom of choice to select the medical equipment that will most adequately meet our patients' needs at the best possible price. Thank you very much.

Chairman KOHL. We thank you very much, Dr. Goldstein.

[The prepared statement of Dr. Goldstein follows:]

STATEMENT OF MITCHELL GOLDSTEIN, M.D., NEONATOLOGIST, CITRUS VALLEY MEDICAL CENTER

Patient care is dependent on the availability of equipment designed specifically to meet patient needs. The individual needs of patient care are often subservient to the contracting demands of institutions. Without doubt, the need to decrease cost is a powerful drive to achieving better access to health care. A better balance sheet allows a hospital to more efficiently meet its needs. Group Purchasing Organizations operate in the middle ground selectively contracting with manufacturers and supposedly providing discounted pricing to hospitals. However if the equipment avail-

able doesn't provide for the individual needs of the patient, at what price is cost savings achieved?

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

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

Other groups have looked critically at the emerging pulse oximeter technologies. Dr. Barker has shown significantly fewer missed true events and false alarms using Masimo SET technology in adults. He has demonstrated that Masimo SET is on the top of the curve relative to performance when compared to other oximeter technologies using a model of motion and low perfusion. Dr. Torres's group has shown the failure rate of the Nellcor 395 to be four times that of Masimo SET. Dr. Brouillete has shown that Masimo SET is more accurate for monitoring breathing obstruction during sleep in children and that the Nellcor 395 is not adequate for a sleep laboratory setting. Dr. Hay has shown decreased false alarms, missed true events, and measurement failures by Masimo SET relative to other technologies. Dr. Sola has demonstrated a significant decrease in retinopathy of prematurity. Overall looking at major independent studies, Masimo SET has been shown to be overwhelmingly superior to its competition.

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

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

baby, who was subsequently diagnosed with a complex heart defect, would have died instead of receiving a life sustaining heart transplantation. At this hospital, the same pulse oximeters that failed to measure this baby's vital signs are still in use despite my years of research demonstrating the superiority of Masimo's technology. GPO related incentives prevented the introduction of a better product.

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

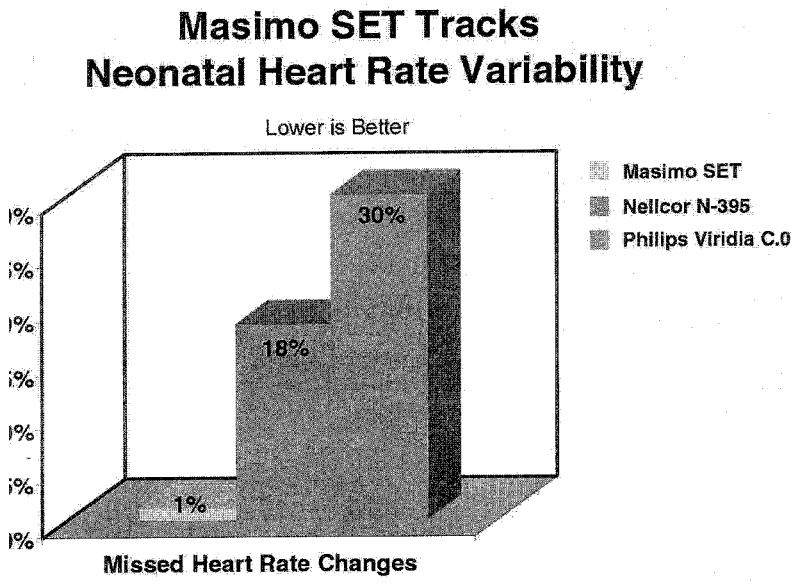
There are additional examples. In the area of assisted ventilation, GPO mandated contracts have restricted innovation. Bunnel Incorporated has for many years produced a State of the art newborn ventilator that helps prevent chronic lung disease by delivering very fast but very small ventilator breaths.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

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

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

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

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



ldstein MR, Furman GI, Pernia LM, Lawas-Alejo P, Yang LL, Sindel BD, Ochikubo CG, Martin GI. *esthesia and Analgesia 2002*;94(S1):S102,A5

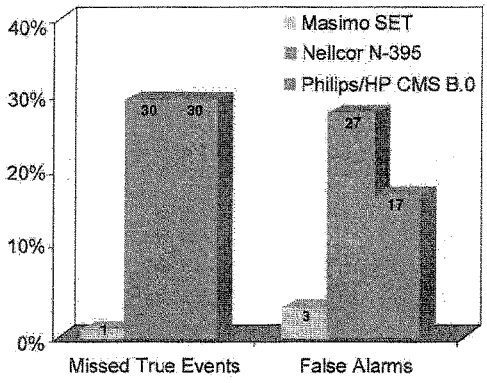
Viability of Unsubstantiated Product Features: Nellcor SatSeconds

"As desaturation progresses, SatSeconds becomes progressively less sensitive to small changes in saturation.

. . . Despite the promise of better alarm management, SatSeconds efficacy cannot be substantiated."

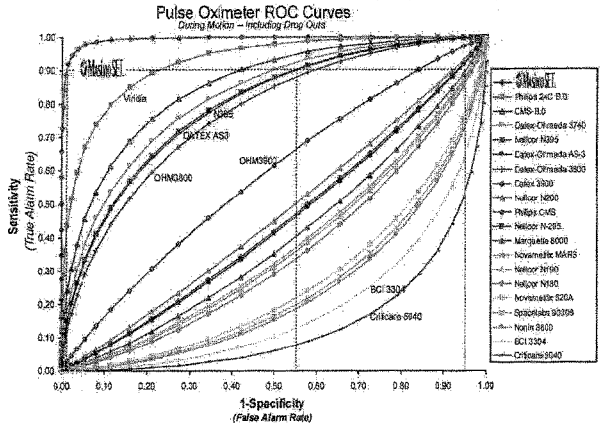
Goldstein MR, Furman GI, Sindel BD, Yang LL, Ochikubo C, Pernia ML, Lawas-Alejo P, Martin GI. SatSecond alarm management misses short desaturations common to periodic breathing and infantile apnea *Pediatric Research 2001*;49(4):400A,2296.

Masimo SET's Proven Performance on Adults



Barker SJ. *Anesthesiology.* 2001; 95:A587

Masimo SET's Performance Substantially Better than Other Pulse Oximeters Tested During Motion and Low Perfusion



Barker S.J. *Anesthesia and Analgesia* 2002;94(S1):S17-A20

Masimo SET's Proven Performance in the Pediatric ICU

	Masimo SET	N-395
Failure Rate (no SpO_2 value)	9.8%	41.0%

Torres A, Skender K, Wohrley J, Aldag J, Raff G, Geiss D.
Critical Care Medicine 2002; 29(12): A117

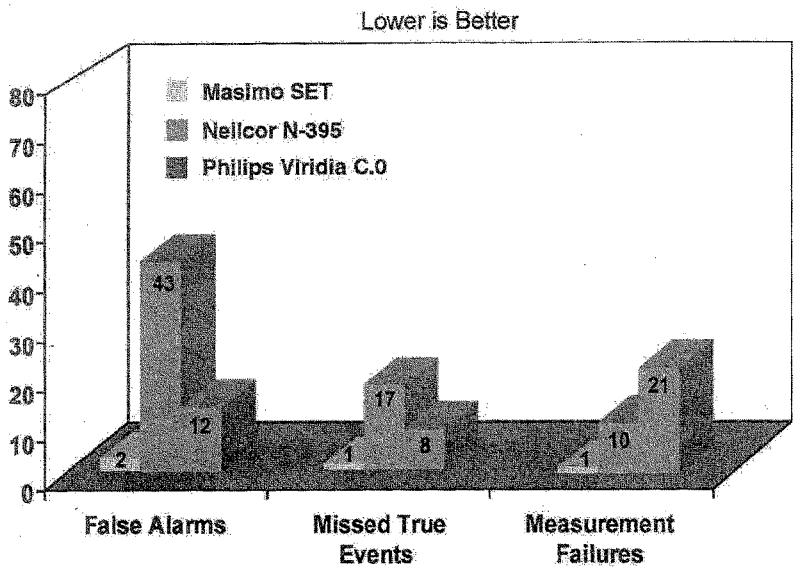
Masimo More Accurate for Monitoring Breathing Obstruction During Sleep in Children

"The sensitivity and motion artifact rejection characteristics of the Nellcor N-395 oximeter are not adequate for a pediatric sleep laboratory setting."

	Masimo SET	Nellcor N-395
True Events Missed	1%	55%

Brouillette RT, Lavergne J, Leimanis A, Nixon GM, Laden S, McGregor CD. *Anesthesia and Analgesia 2002*; 94(S1): S47-53.

Masimo SET's Proven Accuracy in the Neonatal ICU



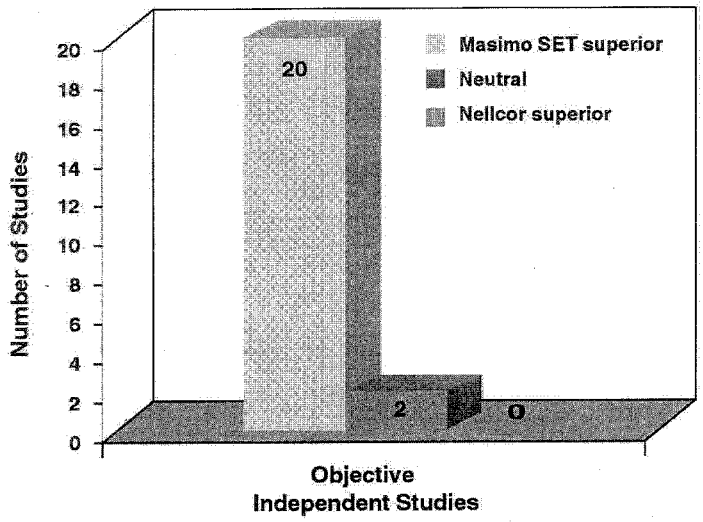
Hay WW, et al. *Hot Topics in Neonatology 2001*, Washington DC, 12

Cedars Sinai Medical Center Severe Infant Eye Damage (ROP) Drops to Zero with Masimo SET

	Eye Damage with Babies over 750 grams	Babies Requiring Eye Surgery
Nellcor	12%	5%
Post Masimo	0%	0%

Letter from Augusto Sola, MD, Professor of Pediatrics, Director of Neonatology, to Senator Kohl

Studies Overwhelmingly Conclude Masimo is Superior to Nellcor



Source: Data from Survey of Published Clinical Studies

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

STATEMENT OF LYNN R. DETLOR, PRINCIPAL, GPO CONCEPTS, INC., SAN DIEGO, CALIFORNIA

Mr. DETLOR. Senator Kohl, thank you, Senator DeWine. My professional career in health care began in 1972. Group purchasing in health care at that time was in its infancy. Hospital medical supply costs averaged 6 to 7 percent of our annual expense budget, as compared to today in a hospital, where the expense for medical supplies could range anywhere between 23 to 28 percent, depending on the acuity of care delivered. The growth in new technology has helped to expand the growth in the supply cost arena.

The political impact of Medicare legislation in the mid–1970s on operating expenses had a direct impact on hospital executives targeting areas to lower expenses. Salary impact as a potential target caused adjustments in nurse staff-patient ratios, and supply cost reductions through materials management was the major targets. This drove the rapid growth of State and local group purchasing organizations.

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 shortly led to the expansion of the program to all 84 Adventist institutions in North America.

In 1986, I was hired by American Healthcare Systems 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 in select markets throughout North America, American Healthcare Systems operated with approximately 60 employees and an annual operating budget of $10 to $12 million.

Income was derived from annual dues from its members. Over time, dues were 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 costs 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 from 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. Two, Novation and Premier, represent over 60 percent of the nation's institutions.

In 1995, American Healthcare 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 the University Hospital Consortium and the Voluntary Hospitals of America.

The outcome of mergers has led to large organizations with operating budgets in excess of $300 to $400 million. Diversity to be more than just a group purchasing organization has led to program expansions in e-commerce, data mining, business development, physician practice management, et cetera.

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 is 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 their costs.

Probably the remaining question in today's marketplace, are hospitals not competing for the same dollars that today go to the GPOs? It is a question the committees and GPOs have to face in the future. The solution rests 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.

[The prepared statement of Mr. Detlor follows:]

STATEMENT OF LYNN R. DETLOR, PRINCIPAL, GPO CONCEPTS, INC.

My professional career in health care began in 1972. Group purchasing in hospital health care was in its infancy.

Hospital medical supply costs averaged 6 to 7 percent of annual expense budget as compared to today in a hospital where the expense for medical supplies could range anywhere between 23 to 28 percent depending on the acuity of care delivered. The growth in new technology has helped to expand the growth in supply costs.

The political impact of Medicare legislation in the mid-70's on operating expenses had a direct impact on hospital executives targeting areas to lower expenses. Salary impact as a potential target caused adjustments in nurse-patient staffing ratios and supply costs reduction through material management were the major targets. This drove the rapid growth of State and local group purchasing organizations to emerge.

In 1974 I was hired by Adventist Health System West to organize and establish a collective purchasing program for 17 Adventist hospitals in the Western United States. This shortly led to the expansion of the program to all 84 Adventists throughout North America. In 1986 I was hired by American Healthcare Systems to organize and develop a national group purchasing organization which ultimately grew to 40 multi-hospital systems representing approximately 1400 hospitals. This growth and expansion was directly related to the continued pressure to lower operating costs. Also in response to competition from the for-profit health systems in select markets through North America, American Healthcare Systems operated with approximately 60 employees and annual operating budget of 10–12 million dollars. Income was derived from dollars. Income was derived from annual dues. Over time dues were replaced by fees charged to select group of manufacturers called corporate partners. Fees were not taken on all contracts. Instead, management's time was spent on helping the selected manufacturers reduce their costs 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 from the medical manufacture industry.

Pricing of products was implied by medical manufacturers to be linked to the largest compliant customers. This in turn led to consolidation of the market place. Local and State group purchasing organizations began consolidating 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 nations hospitals. Two, Novation and Premier represent over 60 percent of the nations hospitals.

In 1995 American Healthcare Systems and Premier (A group purchasing organization out of Chicago) merged and 6 months later Sun Health merged to form what today is the new Premier. Novation was formed by a linking of the University Hospital Consortium and the Voluntary Hospitals of America.

The outcome of the mergers has led to larger organizations with operating budgets in excess of $300–$400 million dollars. Diversity, to be more than just a group purchasing organization, has led to program expansions in e-commerce and data mining, business development, physician practice management, etc.

Today, working as a consultant at "GPO Concepts" we hear the same questions from two sides of the market place, the medical manufacturers and the hospitals.

The medical manufacturers are concerned about the value they receive from the fees paid. How much makes its way down to the hospitals is 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 costs. Are the hospitals now competing for the same dollars that today goes to the group purchasing organizations?

Chairman KOHL. 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.

STATEMENT OF ELIZABETH A. WEATHERMAN, VICE CHAIR, MEDICAL GROUP, NATIONAL VENTURE CAPITAL ASSOCIATION AND MANAGING DIRECTOR, WARBURG PINCUS, LLC, NEW YORK, NEW YORK

Ms. 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, since the United States is the most vital community for venture capital. We have also been a leader in health care investing for over 30 years. I have 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 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, funding many 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 would 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 start-up capital, including more than $4.2 billion 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 or more of the drugs or medical devices developed with venture capital. These include MR imaging, ultrasound, coronary angioplasty and stints, implantable cardiac defibrillators, spinal implants, pulse oximetry, and drugs for cancer, heart attacks, and

anemia, to name a very few. Clearly, what these companies do is critically important to the well-being of the American public and the world at large.

A second point is that bringing medical innovation to market is very hard. It entails taking enormous risks. These include refining and perfecting 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 assure high-quality manufacture of the technology, and obtaining an efficient means to sell and distribute it to the market. 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 every day, while traditional financial institutions and government-supported programs cannot. It is the 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 risky process of bringing medical innovation to market. The new reality is that GPOs are now 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 stymie 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 an open and competitive marketplace. It is nearly impossible when monopolistic producers collude with monopsonistic buyers, such as GPOs to suppress competition.

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

Finally, the idea that GPOs save money for hospitals by extracting larger price discounts from manufacturers 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 gatekeeping. In fact, the product areas where GPOs collude with producers who already have virtual monopolies, the

"discounted" price, quote-unquote, 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 technology. These efforts are already very expensive and risky. Despite this, my community is committed to further investments in U.S. health care 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, Ms. Weatherman.

[The prepared statement of Ms. Weatherman follows:]

STATEMENT OF ELIZABETH A. WEATHERMAN, VICE CHAIR, MEDICAL GROUP, NATIONAL VENTURE CAPITAL ASSOCIATION AND MANAGING DIRECTOR, WARBURG PINCUS, LLC

Good Morning. My name is Bess Weatherman and I am Vice Chair of the Medical Group of the National Venture Capital Association. I am here today on behalf of the more than 475 professional venture capital and private equity 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, funding nearly all of the most important technological breakthroughs of that period. A substantial number of these firms invest heavily in the life sciences field that includes biotechnology, drug development, medical devices and therapeutics and health care services. In 2001, the venture capital community invested more than $4.2 billion, or more than 10 percent of all venture investing last year, in these medical industries.

Venture investment in the life sciences has given new hope to people who suffer maladies across virtually the entire spectrum of diseases and afflictions. In fact, without patient investment from venture capitalists, the biotechnology and medical technology industry, for example, would be virtually nonexistent. Almost every biotechnology product that has been approved for sale by the Food and Drug Administration has been financed by the venture capital community. The venture community also provided financing for many of the medical devices and therapeutics we take for granted today, including the entire interventional cardiology or stent industry. These now standard medical treatments allow patients to lead longer and healthier lives. The venture community's dedication to the medical technology industry exists despite heavy government regulation and the longer-term investing strategy required for successful development of new medical technology, even when compared to other emerging market investments.

Few can argue that what these companies do is critically important to the well being of the American public and the world at large. However, the results of the debate we are holding today on reforming group purchasing organizations to ensure a competitive and open market for all medical industry producers will directly affect the future of emerging life science companies and in turn impact the availability of the important medical products these companies are developing.

Let me be clear, companies subject to, or potentially subject to, anti-competitive practices by GPOs will not be funded by venture capital. As a result, many of these companies and their innovations will die, even if they offer a dramatic improvement over an existing solution. Permitting this innovation stifling practice is unnecessary and counter to what we believe should be a fundamental role of the government: enhancing health by making new or improved products widely available as quickly and efficiently as possible.

THE ROLE OF VENTURE CAPITAL IN IMPROVING AMERICA'S HEALTH

Venture capital plays an integral, often-unsung role in the development of medical technology. In fact, venture capital is the single most important source of early

stage financing to new and emerging health-focused companies. During the past 30 years, the venture community financed 1,324 innovative medical companies with more than $20 billion in startup capital. These companies now have sales of tens of billions of dollars, employ more than 2 million people and most importantly, have revolutionized medical care for nearly all Americans. It is fair to say that virtually every U.S. citizen born during the last thirty years has benefited or will benefit, in his or her lifetime, personally and significantly from one or more of the drugs or medical devices developed with U.S. venture capital. These include MR imaging, ultrasound, angioplasty/stents, implantable defibrillators, spinal implants, pulse oximetry and drugs for cancer, heart attacks, and anemia, to name a very few. It is also important to note that the real medical impact of venture investments is also significantly greater than even these numbers would suggest, since our investments are normally focused only on ground breaking or revolutionary technology by the very nature of our investment selection process. Many of these companies' names are now synonymous with progressive medical technology including Guidant, Amgen, and Genentech.

WHY MEDICAL DEVICE AND BIOTECHNOLOGY COMPANIES NEED VENTURE CAPITAL

Medical device and biotechnology companies need venture capital because their capital needs are so large, their time to market so long—due in large part to regulatory compliance—and their risks so high. There are enormous entrepreneurial risks in bringing medical products to market—risks that include proving product safety and efficacy, securing patent protection, securing a good distribution channel, facing entrenched competition, and possibly running out of money before the product can reach a significant portion of the market—to name just a few. Such characteristics make these young companies ineligible for bank financing or other sources of private capital.

It is important to note that venture capitalists will accept these legitimate risks that traditional financial institutions and government supported programs cannot—it's part of our function. But, VCs do not, cannot, and will not accept unnecessary and unfair risks. We need to provide our investors with justification that substantial capital investment can result in successful product development and financial gain. Thus, we have no interest in products that can be blocked from fairly competing for a share of a market, even after a long, expensive and risky product development cycle. Simply put, venture capitalists will increasingly stay away from many investments in long-term, high-risk medical breakthroughs if the government continues to allow anticompetitive business practices to artificially limit access to medical market.

STANDARD BUSINESS PRACTICES BY GROUP PURCHASING ORGANIZATIONS AFFECT VENTURE CAPITAL INVESTMENT EMERGING MEDICAL COMPANIES, AND PATIENT CARE

GPO roadblocks have greatly diminished the attractiveness of medical device and biotechnology investments because they reduce the confidence of venture capitalists that they will have fair access to medical markets and thereby will achieve a return on very risky investments. To put this in perspective, between 1990 and 1994 at least 22 percent of all companies financed by venture capitalists were medical device or biotechnology companies, with medical device companies accounting for approximately 9 percent and biotechnology companies accounting for 13 percent of the 22 percent. By comparison, during the period 1999 to 2001 these companies made up only 8.9 percent of all companies receiving venture capital financing. Of this 8.9 percent, device companies received 5.0 percent and biotechnology companies receive 3.9 percent.

These numbers dropped dramatically from 1999—2001 when 9.8 percent, 7.1 percent and 11 percent respectively of the companies funded were medical device or biotechnology companies. For these years, medical device companies dropped more, making up only 5.5 percent, 3.9 percent and 6.2 percent of the combined totals.

One of the reasons for this relative decline new investment is a lack of market access brought about by the business practices and the increasing power of GPOs. GPO practices such as 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 stymie improved patient care across these product sectors.

The arguments made by GPOs about the "administrative" savings they provide to members could be applied to every single sector of the economy and are virtually identical to the arguments made by the anticompetitive "trusts" of the early 1900's, which led to the landmark Sherman Antitrust laws. The idea that the GPOs "save"

money for hospitals by extracting larger price discounts from producers than they could achieve by 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 gatekeeping). In fact, in product areas where GPOs collude with producers who already have virtual monopolies, the "discounted" price that the GPOs claim to achieve is almost certainly well above what the market price would be in an open and competitive marketplace. The impact of the GPOs in healthcare is equally anticompetitive and stifling of innovation, and there is no special reason why the healthcare system should be the only sector of the economy where such practices are tolerated.

The venture capital industry exists, in part, because the antitrust philosophy of the United States prevents entrenched, unmoveable competitors from abusing their market power to unfairly restrain competition. By their very nature, virtually every company we finance is a "revolutionary" and a threat to the established order. The technological innovations they develop, whether in computers, electronics, software, telecommunications or medicine, are inevitably threats to some existing larger competitor who will use all means at its disposal to defend itself. It is hard enough to overcome that kind of power in an open and competitive market place. It is nearly impossible when monopolistic producers collude with monopsonistic buyers such as GPO to suppress competition. This is precisely what is now happening in healthcare.

As the GPOs become more powerful and add more technologically sophisticated products to their portfolios (instead of the more commodity-like products such as rubber gloves, syringes and cotton swabs that they originally focused on) the adverse impact on innovation will increase. There will be fewer and fewer areas in which venture capital will invest. The current trend is not encouraging.

The venture capital community believes that collusion between GPOs and providers of medical products to limit market access to competitors is extremely anticompetitive and not justified by any peculiarities of the medical sector. On the contrary, while the government would not tolerate such practices in any other sector of the economy, for it to tolerate (and even encourage) this situation in medicine is disturbing, because one of the clear effects of these practices is to impede innovation. In medicine, in contrast to any other sector, reduced innovation ultimately affects patients' lives and health. There is no doubt that patients' lives have been lost and other harm done as a result of GPO's activities. In light of this, the special exemptions from the normal operation of the antitrust laws granted to the GPOs should be viewed with even greater, not less skepticism.

CONCLUSION

The venture capital community believes that there are enormous opportunities to continue to improve the health of the American public through the development and application of new technology. These efforts are already very time consuming, expensive and risky, particularly given recent increases and uncertainties in the U.S. regulatory environment.

Despite this, the venture capital community is committed to further investment in U.S. healthcare technology. We welcome open and competitive marketplaces, and we believe that competition has served the American public well by stimulating fair prices and vast technological innovation. The increasing power of GPOs, and their collusive and anticompetitive activities with larger medical companies, threatens to undermine the open and competitive markets that have produced such obvious benefits for the American public, not only in healthcare, but also across the entire economy. We would strongly encourage the committee to consider legislation to correct these abuses and again open these markets to fair and vigorous competition.

Thank you.

Number of Deals by Year

Year	Number of Deals - All VC	Number of Device Deals	% of Deals in Devices	Number of Biotech Deals	% of Deals in Biotech
1990	1,402	197	14.1%	120	8.6%
1991	1,207	158	13.1%	117	9.7%
1992	1,323	193	14.6%	132	10.0%
1993	1,123	139	12.4%	114	10.2%
1994	1,167	130	11.1%	118	10.1%
1995	1,851	192	10.4%	153	8.3%
1996	2,593	239	9.2%	197	7.6%
1997	3,194	274	8.6%	211	6.6%
1998	3,737	305	8.2%	230	6.2%
1999	5,605	308	5.5%	218	3.9%
2000	8,053	314	3.9%	246	3.1%
2001	4,651	290	6.2%	233	5.0%

Number of Companies Financed by Year

Year	Number of Companies Financed by VC	Number of Device Companies	% of Companies in Devices	Number of Companies in Biotech	% of Companies in Biotech
1990	1,021	139	13.6%	90	8.8%
1991	877	109	12.4%	82	9.4%
1992	974	136	14.0%	91	9.3%
1993	866	107	12.4%	84	9.7%
1994	915	103	11.3%	88	9.6%
1995	1,523	150	9.8%	125	8.2%
1996	2,076	188	9.1%	154	7.4%
1997	2,548	214	8.4%	164	6.4%
1998	3,000	240	8.0%	187	6.2%
1999	4,400	253	5.8%	175	4.0%
2000	6,245	245	3.9%	200	3.2%
2001	3,734	225	6.0%	186	5.0%

Information provided by: PricewaterhouseCoopers/ Thompson Financial Venture Economics/ National Venture Capital Association MoneyTreetm Survey

Total Venture Capital Dollars Invested by Year

Year	Total VC Investment ($M)	VC Investment in Device Companies ($M)	% Investment in Devices	VC Investment in Biotech Companies ($M)	% Investment in Biotech
1990	2,799	348	12.4%	282	10.1%
1991	2,246	242	10.8%	251	11.2%
1992	3,408	513	15.1%	397	11.6%
1993	4,367	391	9.0%	390	8.9%
1994	3,920	439	11.2%	445	11.4%
1995	7,399	685	9.3%	718	9.7%
1996	13,197	695	5.3%	1,312	9.9%
1997	16,084	1,034	6.4%	1,912	11.9%
1998	21,941	1,247	5.7%	1,282	5.8%
1999	55,363	1,576	2.8%	1,699	3.1%
2000	110,418	2,704	2.4%	3,214	2.9%
2001	42,264	1,999	4.7%	2,249	5.3%

Information provided by: PricewaterhouseCoopers/ Thompson Financial Venture Economics/ National Vent Capital Association MoneyTreetm Survey

Chairman KOHL. Before I begin my questioning, Senator DeWine, who has to leave for another unavoidable commitment, has asked to make a comment.

Senator DEWINE. 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, and Ms. Weatherman to be extremely troubling, and I am anxious for Mr. Norling and Mr. McKenna, to hear their answers, because each one of us has benefitted from technology, medical technology. There is not 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.

So I am always alarmed if there is any possibility that any kind of practice that this Congress is permitting, which we have with the law that we passed a few years ago, that might impede that kind of research, might impede people taking changes with their money, might impede smaller start-up businesses that have an idea from getting a fair hearing, and more importantly to get a fair hearing, to get the opportunity to make that sale.

So, again, I apologize to you, Mr. Chairman and the members of the committee. I think the testimony has been very good and 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.

Ladies and gentlemen, it is good to have you here. We think there is some opportunity to accomplish some significant things, not just today, but tomorrow, next week, and next month, and this whole area of 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 were willing and more than willing to be part of a group that is put together to study how we can improve, if possible, improve the practices of GPOs. I assume, or I would 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 some manufacturers, device manufacturers from hospitals, a small group, but a representative group of this entire industry, to do what we can collectively do to improve something that you would like to improve yourself, if possible, is that correct?

Mr. MCKENNA. That is more than a fair statement, Senator. In fact, if you looked at my chicken-scratched notes, it said to add something at the end to acknowledge that——

Chairman KOHL. Right.

Mr. MCKENNA [continuing]. In the crush 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 always have room for improvement.

Chairman KOHL. Mr. Norling.

Mr. NORLING. I reiterate my comments, Senator. Anything that is ultimately going to 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 would be happy to discuss it. So I think that is a good start.

Now, we would like to ask the two of you this question of financial interest in companies, either individually or corporately, that you do business with. I am sure you could 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 would like you to respond to our concern about financial interests, either as individuals or corporately, in companies with which you do business.

Mr. McKenna, would you like to speak first, and 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. So we have employees in our company that, like many companies, can own up to 1 percent of a public company. In regard to that matter, and what I personally own, as the only member of the senior management team that has individual stock holdings, 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.

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 holdings nor would they have a need to. But they do not come into play relative to the decisions that our 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, wait, 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 OK?

Mr. MCKENNA. We have a code of conduct, 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 is what we are discussing.

Mr. MCKENNA. Yes, sir.

Chairman KOHL. I would like to hope you could understand how people like myself and others would be skeptical about such ownership. 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——

Mr. MCKENNA. Certainly.

Chairman KOHL [continuing]. You could own a plethora of bad stocks or good stocks.

Mr. MCKENNA. That is true.

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

Mr. MCKENNA. Certainly, Senator. I think it is worth a review. We are in the process of looking at our code of conduct. It has served us well, we believe, up to now. We do not believe there is 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. OK. 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.

As regards 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, be 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 maintain 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 to that have been noticed. They are historic, but that does not mean that they are not significant. They are being dealt with in, I think, 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 is 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. I get a sense of where you are going here, and we are in the process of reviewing this policy. 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. So as we review our policies, we, indeed, will do that.

Now, 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 happen to believe that is appropriate. Board members serve a defined time period. More often than not, they come to the board with a set of experience, et cetera, 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 interest 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 dialogue in that arena.

Chairman KOHL. Great. I think that is great. All right.

Mr. Kiani, I am sure you would say, made some very strong testimony here today. He says he has an outstanding product. He says that 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 has 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 cannot get on your list, as they have pointed out, they are out of business.

So here is one example of a man who has got a product which we would 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?

[Laughter.]

Mr. MCKENNA. In our case, Senator, Mr. Kiani's company did participate in our process. As I mentioned, it is open and 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 us develop, which is called low best bid, we separate out the non-financial criteria, very important, things to do with quality, safety, availability, education, and 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 we 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.

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. Before we ask Mr. Kiani and maybe Mr. Goldstein to respond to you, Mr. Norling, would you like to respond?

Mr. NORLING. Yes, indeed. Thank you. First of all, I am not a clinician, so obviously I listen to a presentation both by Mr. Kiani and by Dr. Goldstein and it sounds very, very compelling. I will tell you very frankly, in the role I am in, I get the benefit of multiple inputs from multiple manufacturers, frankly, all of whom suggest their product is unique and differentiated and I am 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. It 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 able to quote from those letters.

Chairman KOHL. Sure. Go ahead.

Mr. NORLING. Thank you very much. First of all, from St. Vincent Catholic Medical Centers 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 caregiver's 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 suggestions that that is not the case. I have two letters here and, frankly, could produce others over time.

If you are willing, sir, I would submit these for your consideration in the record, and that is up to you, if you would like to do so.

Chairman KOHL. All right.

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

Mr. MCKENNA. In this case, it is a sole-source contract, Senator——

Chairman KOHL. Sole source, all right.

Mr. MCKENNA [continuing]. It may have been as good, but just not—we did not find it to be—clinicians did not find it to be innovative, but just different technology.

Chairman KOHL. Then the question that 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, is that what it is?

Mr. MCKENNA. Yes, sir.

Chairman KOHL [continuing]. Should be a sole-source commodity, unless you can make the case, not only with respect to this product but many other products, that the alternative does not 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, more importantly, non-financial criteria, the clinicians overwhelmingly endorsed this product and found 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 members use, that means 30 percent we do not have contracts for, we probably have in the vicinity of a little over 50 percent, 50 to 60 percent of their business. So about 60 percent is bought off-contract to begin with and 40 percent is bought on-contract, and then that level will vary.

If I could, I sense Ms. Barrett has some information that could be helpful relative to——

Chairman KOHL. All right, and then we will hear from Mr. Kiani and Mr. Goldstein.

Ms. BARRETT. If I could, I would 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. I 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 deliberations.

In many cases, we will be advising the Novation staff whether we think what we have seen and reviewed warrants a sole source or 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, as clinicians on these panels and councils, take very seriously.

Chairman KOHL. OK. Mr. Kiani, then Dr. Goldstein and Ms. Weatherman?

Mr. KIANI. Senator Kohl, if you do not mind, I would like to just make a few points. Number one, we do not disagree with Ms. Trisha Barrett that the advisory group that Novation has put to-

gether 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 taking another way or format where people really know what all the people on the advisory group really want to do.

Now that I have made that point, because I do respect UCSF, I do respect the advisory groups and the members. I have met with a lot of them. They are very good people. It is just not being listened to.

I would like to address both Premier and Novation, if I may, of what has happened in those particular situations. 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 Masimo is a breakthrough and should be allowed and is necessary for certain types of patients. After completing this report, Premier stalled us for 2 years. In the meantime, Premier extended the sole-source contract with Tyco–Nellcor to 2007 without even asking us for a price. Now, I do not understand how they could be saving their members——

Chairman KOHL. Let me say this 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. Yet, 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 our competitive bid, so they could use that to hopefully get a better price from Tyco–Nellcor. In fact, I have a chart that is in the back of your book that I could also put up. That price has been constant since 1996.

Chairman KOHL. You are talking about independent hospitals where you have made a sale. How many hospitals are there? I think you said 44 percent, but I did not 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 is probably in the area of about 60 to 70 hospitals where we were able to make sales, and the testament that Premier and Novation hospitals wish to have our product is that they buy our product, but they stay below the 5 percent compliance level, or the 5 percent exclusion level that Novation has and the 10 percent level that Premier has.

Chairman KOHL. OK.

Mr. KIANI. But if I may just take you through the Premier process, once they renewed it, then later Premier pronounced that because Tyco–Nellcor had purportedly a competitive product, it would not further consider Masimo as a breakthrough technology. Now, I do not want to take you through 50 clinical studies. I have charts. I do not think it is your—you are not here to decide if we are better or not. They are not capable of deciding that. It should be clinicians that decide what is best for the patient.

I also mentioned that they also said we can get into hospitals. We know the 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. During the same period, at least two of our licensees who manufacture patient monitors with our technology were threatened by Premier to not even show Masimo to Premier hospitals. In fact, one of them refused and, maybe coincidentally, their contract was not renewed.

Now, Senator Kohl, over 40 companies, companies like GE Medical Systems, Dataskove, Zoehl, they did their own evaluation. They decided Masimo SET was a breakthrough and they made it their standard product, but they cannot sell it into Premier and Novation hospitals because of these impediments.

I would like to just briefly tell you about the Novation experience. Novation initially said it was not going to grant a sole-source contract for pulse oximetry. They said they were going to do a dual source. Masimo was told that many of Novation's hospitals wanted our technology and had listed accuracy, motion performance, which is what we pioneered, and price as key to any decision. Now, not only did our product beat Tyco–Nellcor's, respectfully, even though Mr. McKenna says we are just different, on accuracy and motion performance by 2- to 10-fold to 20-fold to 30-fold, 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 a sole-source contract, so frankly, Senator Kohl, we assumed Nellcor must have given a better price, but we gave a price that was 30 percent lower, and I have a chart that I could show you if you would like me to.

Chairman KOHL. All right.

Mr. KIANI. One last thing. I am sorry. You asked a very important question. You asked, why was Masimo excluded?

Chairman KOHL. Yes.

Mr. KIANI. You asked 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 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 is because of the payments that are being paid by these big suppliers who have learned how to manipulate the system to keep their 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 would like, I even have letters from UCSF, I have letters from St. Francis Hospitals, and I would just like to read maybe even UCSF's letter.

"Dear Mr. Wilson."

Mr. Wilson is one of our clinical specialists,

"We have evaluated the new Masimo Corporation pulse oximetry and found them superior to existing Nellcor monitors. I strongly recommend them for the pediatric intensive care unit as well as the operating room."

This is by Dr. Mohan Reddy from UCSF, which Ms. Trisha Barrett is at.

Another letter from UCSF, Dr. Scott Soifer, who is the Professor of Pediatrics and Vice Chair of Clinical Affairs. He writes,

> "Dear Mr. Wilson, I would like to thank you"

and this is October 12, 2001.

> "for the support Masimo provided during our evaluation of pulse oximetry and inquire about when we might be receiving new oximeters. After comparing the Masimo to the new Nellcor"

this is the device they say is as good as ours and 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 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 assess 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 did not 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 into 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.

To that extent, that is still under consideration at our institution at this very moment. I think it speaks to the opportunity that we can 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 as I think one thing the committee has to consider in looking at what we are facing every single day in constrained costs, and that is considerable capital equipment to balance with rewiring the whole place. We had 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.

I would 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 new innovation every year of my nursing career, and so I am excited about innovation. I am worried about innovation and it getting to our patients for a lot of reasons.

But I also have to consider the constant churn of new product and 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 is 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. I want to just pose this question and maybe 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 this commitment, as you know, is as high as 90 percent. In fact, it may be in Mr. Kiani's case. Why not give the hospital a choice?

I do not understand this 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, it almost never occurs, it only occurs where there clearly is no alternative. We are very sensitive to innovation. We bend over backwards to encourage innovation. That is why sole source never occurs or rarely occurs.

But that is not our understanding here, that sole source is not an extremely rare occurrence. You hear all the other people on the panel say you have got to have, they have got to have access to you fellows or they are out of business or they are not even in business. Recognizing that, what is with this sole source?

Mr. MCKENNA. First of all, Senator, all of these gentlemen do have access. I 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 would 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 do not think my staff does, either.

In regard to your direct question about sole source versus dual source, we have many multi source, which is more than two, and dual source arrangements where the value and the innovation, or the 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 clinician 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 a sole-source product 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 a sole source.

So we have a blend of 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 want to make a comment?

Ms. WEATHERMAN. Yes, I would make a couple comments. I think it is very important, as I have highlighted here, and I think everyone in this room would agree that medical innovation is important. But I think it is also important that innovation for innovation's

sake is not what we should be focused on. What we need to focus on is, is a new product or an existing product truly serving a clinical need? Is it delivering value to the marketplace? Maybe it is because it is cheaper. Maybe it is because it is better, it is more accurate, it is easier to use. I mean, there are a lot of criteria for value that hospitals would perceive in a new or existing product.

I think it is 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-Mallinckrodt-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 has said it is worse in terms of delivering or serving a clinical need—I think it is very important to look at the context of how big is Nellcor-Tyco's position and what are their total fees that they have been paying over the years to Premier and Novation. It is a very important fact that needs to be looked at.

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. 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 an unmet clinical need? I do not think you are going to find nearly the outcry or the market potential that you will see that Nellcor's sensors currently enjoy in the U.S. market.

Chairman KOHL. OK.

Mr. Detlor.

Mr. DETLOR. Yes. One of the things that several parties have said here, and it is one of the things that is a challenge to a GPO in general, the first thing is that incumbent clinicians in the sense of their historical experience deal with 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 have got a segmented market that has developed in the pulse oximetry issue. So the demands of what was used in an adult marketplace, there was very little product available that had any sense of accuracy in the neonatal arena. Masimo's product bridges that type of issue, the change in technology.

So if you go and survey in committees, which we used to spend months and hours with, what you would normally get out of a committee's feedback, unless they are focused solely on new technology, is their historical experience with the existing market incumbents, their satisfaction, the shortcomings, the things they like, et cetera.

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

So all things being equal, from a process perspective, it does not surprise me that you wind up with these types of scenarios. People

who sit on committees donate their time, et cetera. So many days out of a given year is all they can put in, at best. A good portion of that is going to be the historical experience, not the issue on future technology. They have not seen a salesperson. The companies do not have the kind of resources to make that type of intro and, therefore, it is very hard to have that be a 50/50 proposition, an equal footing, and I think you heard 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 is 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 is lumped into one contract, and historically, the GPOs would do that, not because they meant to do any harm to anybody, but because of the commission input they have had historically, based on what they have used over years in the past. It has a tendency to favor the incumbent manufacturers.

It is a process adjustment that has to take place. It is 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, et cetera, has to constantly challenge them not to take the shortcut, not to talk about what they have historically done, but take a look at what is new and current on the marketplace. It is not the clinicians are not willing, but they are also competing for their own day-to-day jobs and time and what they can give to the GPO.

So, hopefully, out of this process, maybe both GPOs, and I have heard the comments and the commitments, which is understandable, you know, you have to go back and reengineer your processes to make sure these things do not happen in the future as you move forward.

Chairman KOHL. All right. Dr. Goldstein, do you want to make a comment?

Dr. GOLDSTEIN. Thank you. I certain can appreciate cost and cost savings incentives and I understand what GPOs are all about and I can appreciate efforts involved to save money, but I would really at this point like to let some of the clinical studies talk. If you would not mind, I would like to bring out some of the placards that we have 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 a neonatal intensive care unit, 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 would like to bring up specifically looks at one institution's experience with the Masimo SET oximeter with respect to retinopathy of prematurity, and in this, Dr. Sola, in a letter to Masimo, detailed his experiences with and without Masimo technology, looking at eye damage, that is, retinopathy of prematurity, as I alluded to in my statement, in this target presen-

tation. As you can see, in the group that received pulse oximetry through Masimo SET, there was no evidence of retinopathy of prematurity, and this is a very significant finding.

The next study I would like to refer to is one—the Barker study. This is a study that I performed, as well, in 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 had problems with respect to heart rate variability tracking. Now, granted, this is in a target population, neonates, where you have a great deal of heart rate variability and, in general, in adults, you do not see as much. But again, it points out my focus, that the target population here is being ignored.

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.

To that, I would 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 5 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 5 years?

Mr. MCKENNA. The clinicians that make our decisions certainly have.

Dr. GOLDSTEIN. Personally, I am asking if you have been in the NICU for more than an hour in the past 5 years.

Mr. MCKENNA. No, I have not.

Dr. GOLDSTEIN. You at the end, as well?

Mr. NORLING. I have not.

Dr. GOLDSTEIN. OK. 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 of 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 I just now saw before us were published, I think, in the peer reviewed literature either late 2001 or one said 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-reviewed literature database, which admittedly it takes a long time for the studies to work their way through, peer-reviewed studies, but we do try to have that guide us wherever that is possible and where we can.

If I am not mistaken, the studies that are presented here may not have been available in a peer-reviewed manner at the time that this particular decision was made. I was not on that council.

The other question that I have has to do with the fact that we were trying to relook at—many of your studies talk about a neo-

natal patient population. We also, in reconsidering this technology, wanted to see, was it applicable in adult population for the reasons that I am sure you are aware of. In hospitals, we do our best to standardize out of patient safety, because we have a cross-training that goes on for many of our physicians as well as our therapists, and having one standardized system they can use can become a patient safety issue.

So my question is, to what extent do you think this technology is applicable to the adult ICUs, where it was also recently reconsidered by our adult therapists in that regard?

Dr. GOLDSTEIN. With respect to the adult ICUs?

Ms. BARRETT. Yes.

Dr. GOLDSTEIN. Again, 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 is better, 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 the, excuse the expression, almighty dollar to get large GPOs like Premier and Novation to exclude their competition. That is the problem, and we are just one example. There are adult examples right in the back of your hospitals you guys usually go to, unfortunately, where patients are being saved because of our technology and other stuff did not work, but that is not what it is 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 going to cause delay and delay means harm to patients and there needs to be something quick. It is not just about Masimo and this situation.

Chairman KOHL. As you know, what we have concluded here this afternoon is that we are going to have an immediate forum composed of these two companies plus people like yourselves and we are going to get together on opening up this system, if we can, on 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 is 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, as so often on Capitol Hill hearings, there are hearings and then they vanish into history. I am very hopeful that this hearing will result in something that is a new and improved GPO system, and I do not find the principals who are here today, the two major principals in the industry, unwilling to engage in that process to see what improvements can be made.

Mr. NORLING. Senator, can I speak to the question you asked, as I believe it has not 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. I would also like to, if I could, speak to a few of the other points that have been raised. Specifically, I think I 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 a clinical use and, 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 do not have a commodity, in effect, you have got something where there are some of the agreements that, frankly, have surfaced here. So I think it is important to get at this issue, and I think Mr. Detlor, in some ways, was trying to get at that also, this issue of high clinical preference and what is 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 have looked at this process and as we have 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, the idea of sole-source contracts in high clinical preference areas do not make a lot of sense.

So in terms of a practice going forward from Premier, I expect what you will see in these areas is as existing in-force contracts reach their expiration date, and prior to that, as we begin to renegotiate 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 in high clinical preference to dual source or, in some cases, not even a commitment target of any kind but a preferred contract. So that is 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 2004. I do not believe that is 7 years from now, nor was it 7 years from the time that was quoted.

Premier's administrative fee with regard to this is 3 percent, no more. Very frankly, since there is some inference of decision making based on fees, we get greater administrative fees, because I do not believe the Nellcor 3 percent fee would change, if we contracted with Masimo, and if product flowed through that contract, we would actually get more administrative fees than we do now, and that is 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 have had no reports of that. If that were possibly true, I would agree that it was 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 would also like to deal with this issue of the inference that Premier delayed the process for 2 years, and if I can, I would like to share with you a time line as I understand it. I have 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 hos-

pital administrator about four-and-a-half years ago, but I used to spend quite a bit of time prior to that.

The time line, 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 has been explained to me, and again, this is secondary, but again, I think it is 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. Our technology assessment group said that this was an exciting looking technology and actually encouraged them to work with other manufacturers who have stand-alone products and encourage them to make that technology available to them, and it sounds like Masimo has been very successful in doing that, not with Nellcor, but certainly with others. As regards the time frame, that was the interaction with our technology assessment group.

In January 2000, Premier received and was made aware of the Nellcor 395 pulse oximeter and contracted in January 2000 for that item. As I said, the contract goes with a term through 2004.

In March 2000, Nellcor approached Premier, indicating that they would—excuse me, Masimo approached Premier, indicating that they did have a product, a stand-alone product that they intended to bring to the market and data from Masimo suggests that product was first commercially available in August 2000. So in March 2000, we began the technology breakthrough process and the initial panel review suggested that this was worth 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 that was available to our group and based on the comparison to the existing contract, namely the Nellcor 395, Premier made the distinction that this was not a significant breakthrough. Now, that does not mean that this is not a great product. I am sure it is. It does not mean that it is not 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, indeed, want to explore its relevance elsewhere, that I would invite a resubmissions under 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 on earth that we would not want to have that kind of a product available for patients.

Chairman KOHL. OK. We are going to 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 is a fairly complex question. The answer is, often, that is true. The question is whether they can do it consistently and sustained and create value.

Chairman KOHL. So you have suppliers who will give a hospital of some size a better deal than they are giving you?

Mr. NORLING. In general, it would not be suppliers who work with us. It would be a situation where we would have a contract in place and a supplier who did not participate in that contract would come in and suggest that they would undercut the contract price.

Chairman KOHL. So it——

Mr. NORLING. That, frankly, is the marketplace at work in a very productive way.

Chairman KOHL. It is not the same product? It is 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 the same manufacturer doing some of that. It is 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 cover, such as the recent Lewin study that was submitted as part of the Health Industry Purchasing Group Association submission, studies out of Arizona State University, a study by Mr. Muse that suggests pretty significant benefits from GPO contracting, to the tune of 10 percent.

Senator, just to give you one good example of—again, I have 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 have 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 that 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 is a very significant amount of money, we have found consistently over 2 years in more than 200 hospitals that they are leaving 9.5 percent on the table by using contracts, or by buying product 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 is a very large number of hospitals and it is a very large number of dollars.

Chairman KOHL. You are estimating to the tune of maybe nine to ten percent?

Mr. NORLING. Yes, I am.

Chairman KOHL. 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. My answer is sometimes.

Chairman KOHL. So that can happen and probably does? How can it happen?

Ms. BARRETT. I could shed some 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 is 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 materiel 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 want it to be just raw in my question. I am going to take Johnson and Johnson band-aids, which I do not know if it is on your list, but maybe it is.

Mr. NORLING. Probably.

Chairman KOHL. Is it possible for a hospital to get a better price on that item than is on your list?

Mr. MCKENNA. I think it is possible. In our industry, there is a practice that we would call cherry-picking, maybe it is 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 is 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 a supplier, there may be a supplier that will buckle and provide a better deal.

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

Chairman KOHL. OK, last question. In the past, we have 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. It retained about 63 percent of the fee it collected from medical equipment suppliers, which was over $213 million.

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

Mr. NORLING. Thank you for your question, Senator. I think that I will do my best to simplify this, because this has been sort of an ongoing dialogue, both with your staff and with the media.

There are two sets of points that have been made. First of all, Premier is not just a GPO. We are an enterprise that is 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 is 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 is, 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 administrative 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 administrative fee dollar back to our members.

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

Chairman KOHL. OK. Mr. McKenna?

Mr. MCKENNA. Ours is a bit complex, but I will 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 local communities to reduce the risk of heart damage or stroke damage, and other services. After investing in those programs, which are board approved, they return—I am 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. OK. What I hope we have accomplished today is that we have 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.

If we can move forward on that, then I think we have 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 have made a real contribution.

Before adjourning, I would like to insert in the record a number of documents. First, I would include statements from Senator Orrin Hatch and Senator Strom Thurmond.

[The prepared statement of Senator Hatch follows:]

STATEMENT OF HON. ORRIN HATCH, A U.S. SENATOR FROM THE STATE OF UTAH

Thank you, Mr. Chairman. I commend you and Senator DeWine for holding this hearing, as well as for your continuing efforts to get to the bottom of the important—and extremely complex—set of issues that we are addressing here today.

I believe we need to examine how Group Purchasing Organizations—or "GPOs"—affect the cost and quality of health care in America. Recent studies and media reports have called into question whether the GPO system has been effective in reducing costs without sacrificing the quality of products available to hospitals. However, GPOs, various academics, and certain industry participants continue to argue that GPOs offer high quality products at significant savings.

I have received and considered numerous opinions from parties on both sides of the GPO debate, including health care specialists, academics, and industry participants both from my home State of Utah and around the nation. To say that there is widespread disagreement among the participants of this debate would be a considerable understatement. News sources, commentators, and industry analysts offer diverse opinions regarding whether the GPO system helps or harms hospitals, consumers, and competition. Well respected academics similarly disagree.

Although I believe that the concerns raised by those who are critical of GPOs certainly warrant further analysis and consideration, I do not feel that we have sufficient information to reach any solid conclusions on the issues that have been raised. Despite the need for further investigation, I want to emphasize that—based on the information and analysis currently available—I have several serious concerns regarding certain actions and practices of specific GPOs, as well as the structure of the GPO system in general. Without going into detail, I would like to summarize some of these in the hope that we might address them as we go forward on this issue.

I am deeply disturbed by allegations that GPOs may prevent superior technologies and products from being adopted by the hospitals they serve.

These claims have arisen in several distinct sets of circumstances, all of which raise significant questions. I am concerned about recent press reports that senior executives have received or obtained stock or stock options from product suppliers, creating serious conflicts of interest that may have improperly affected GPOs' purchasing decisions. Similarly, reports that large GPOs have favored products produced or supplied by entities in which they have invested raise serious questions as to conflicts of interest.

I am also concerned about certain practices that may limit competition among small medical device manufacturers, leading to decreased competition and innovation. Allegations that large suppliers have effectively "bought" access to GPOs warrant further investigation to ascertain how widespread such activities are. Similarly worrisome are assertions that the products of favored suppliers are included in "bundled" or "sole source" contracts that create strong disincentives for hospitals to purchase competing products, effectively shutting smaller competitors out of the market.

Finally, I note that many—perhaps even most—of the alleged harms and abuses raised by GPO critics have pertained disproportionately to the nation's two largest GPOs: Novation and Premier. The market shares of these two "super GPOs" dwarf those of the next eight largest GPOs. In fact, excluding Premier, Novation's estimated market share is roughly equal to the combined market shares of its four largest competitors. With the obvious exception of Novation, Premier's market share is almost three times that of its largest competitor. The enormous relative purchasing power of these two "super GPOs"—especially when coupled with allegations that this power has been used anticompetitively—raises obvious concerns. At this point, although it is unclear whether and to what extent the market power possessed by Novation and Premier has enabled allegedly anticompetitive practices, this question warrants further consideration.

I look forward to hearing from the witnesses testifying here today, and hope that they will address these important issues. I commend the members of this committee for their efforts to date, and hope that—in conjunction with the appropriate govern-

ment agencies and with the help of industry participants—this committee will continue its attempt to get to the bottom of these important issues.

[The prepared statement of Senator Thurmond follows:]

STATEMENT OF HON. STROM THURMOND, A U.S. SENATOR FROM THE STATE OF SOUTH CAROLINA

Mr. Chairman: Thank you for holding this important hearing today on hospital group purchasing and its effects on patient health and medical innovation. In particular, this committee should carefully examine the role that Group Purchasing Organizations (GPOs) play in bringing medical products to market. GPOs deserve antitrust scrutiny for two significant reasons.

First, the organizations themselves are the result of hospitals banding together in order to increase buying power. Second, GPOs have merged and consolidated the industry significantly. The result is that two large corporations, Premier and Novation, control purchasing for approximately 60 percent of the Nation's hospitals. With these two concerns in mind, we must determine whether the consumers of medical care, the patients, are being well-served by GPOs.

The fundamental premise of a GPO is to allow hospitals to aggregate their purchases and thereby negotiate lower prices. GPOs are generally immune from antitrust scrutiny for an array of policy reasons. When hospitals band together, they are better able to counteract the significant market power of large manufacturers of medical supplies and equipment. Additionally, the lower prices procured by the hospitals enable them to maintain financial stability in the Medicare prospective payment system. This prospective payment system replaced fee for service plans and essentially resulted in caps on Medicare payments, limiting what the Federal Government would pay hospitals for medical services.

In addition to the relaxed antitrust scrutiny, GPOs have another useful tool in procuring lower costs for hospitals. They are immune from anti-kickback laws. This allows the payments for services provided by the GPOs to be shifted from the hospitals, the buyers of the goods, to the manufacturers of the goods. Therefore, manufacturers of goods pay kickbacks, often called administrative fees, to the GPOs. Administrative fees are commonly 3 percent of the value of goods sold to the hospitals, and may be higher if disclosed in writing. These fees go the GPO itself, and portions are remitted to the hospitals. Due to this arrangement, hospitals realize lower costs.

At first glance, the lower costs attributed to group purchasing power may appear to benefit patients. Indeed, group purchasing keeps prices low, and that is certainly desirable in the medical marketplace. However, a closer look at current policies reveals some disturbing consequences.

Many smaller device manufacturers have voiced concerns that they cannot break into the marketplace due to the power of GPOs. For example, GPOs negotiate long term contracts, thereby making it more difficult to bring new and innovative products to market. Long-term contracts themselves would not generally be a cause for concern. Two business entities may enter into these contracts if they wish. However, due to the fact that hospitals have all joined together in the GPOs, large numbers of hospitals are committed to these long-term contracts. This scenario warrants antitrust scrutiny.

Smaller manufacturers may also have a more difficult time paying the kickbacks, or administrative fees, required to sell their products to the GPOs. Furthermore, the anti-kickback exception invites the kind of abuse that anti-kickback laws were designed to stop. Larger manufacturers have an incentive to pay higher administrative fees in order to dissuade the GPOs from purchasing the products of smaller competitors.

It is my hope that this committee will closely examine the antitrust immunity and anti-kickback exception that GPOs enjoy. We should not support policies that inhibit the abilities of smaller manufacturers to introduce innovative products into the marketplace. If patients are not benefiting from current practices, we should seek to implement reforms that free the marketplace to function unhindered by anti-competitive practices.

Another concern associated with the GPO system is the consolidation of the industry. In many areas, one of the two dominant GPOs, Premier or Novation, serves all of the hospitals while the other is almost nonexistent. The result is a dominant buyer in the market, which has been referred to as a monopsony, or a buyer monopoly. For antitrust purposes, a monopsony may be just as troubling as a monopoly due to the distortions that it creates in the market.

The buying power of the GPOs raises questions about the common practice of "bundling" in contracts with medical manufacturers. A bundled contract provides for

numerous products to be purchased in one order, benefiting the seller, who can sell more products, and allowing the GPO to negotiate lower prices. While this practice may lower hospital costs, it may also have the effect of keeping other manufacturers out of the market. Because hospitals must usually purchase a high percentage of their products through the GPO to take advantage of discounts, there is less of an incentive for hospitals to bypass the GPOs and negotiate with the manufacturers directly.

Additionally, recent media reports have indicated that Premier invested in medical supplier companies, and then made contracts with them to provide supplies to Premier hospitals. I am greatly concerned about these allegations, and this committee should thoroughly study these potential conflicts of interest. If Premier has engaged in such activity, it has leveraged its buyer monopoly to procure goods from a company in which it has an interest, effectively blocking out legitimate competitors.

Mr. Chairman, I appreciate your work on this matter, and I hope that we will learn more today about the role of GPOs in the health care industry. While GPOs have almost certainly led to decreased costs for hospitals, we should carefully examine whether patients benefit from the current system of group purchasing. If innovative and crucial technology is not reaching our Nation's hospitals, we should consider reforming current practices. We should ask whether GPO immunity from general principles of antitrust law and anti-kickback law best serves those in need of medical care. I hope that our witnesses will address these important questions, and I look forward to hearing from them today.

Chairman KOHL. I would like to insert the GAO report that has been referred to several times during this hearing, entitled "Group Purchasing Organizations: Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices."

I would also like to insert a number of statements that have been submitted for the record. These are from Thomas J. Shaw, President and CEO of Retractable Technologies, Inc.; Larry Holden, President, Medical Device Manufacturers Association; Thomas V. Brown, Executive Vice President of Biotronik; Robert Betz, President and CEO of the Health Industry Group Purchasing Association; Paul Hazen, President and CEO of the National Cooperative Business Association; Einer Elhauge, Professor of Law at Harvard Law School; Jeffrey C. Lerner, President and Chief Executive Officer of ECRI; Dr. Augusto Sola, Professor of Pediatrics and Obstetrics and Gynecology, and Director, Division of Neonatal–Perinatal Medicine at Emory University School of Medicine; Frederick M. Valerino, Jr., President, Pevco Systems International, Inc.; and Julia Naunheim Hipps, a registered nurse from St. Louis, Missouri.

This hearing is now adjourned.

[Whereupon, at 5:00 p.m., the subcommittee was adjourned.]

[Questions and Answers and Submissions for the record follow.]

[Additional material is being retained in the Committee files.]

QUESTIONS AND ANSWERS

Questions for Richard Norling and Mark McKenna from Senator Leahy

1. **Today's *New York Times* story raises a very basic and troubling question about GPOs: do they actually save hospitals money? The preliminary answer seems to be "no." If GPOs do not perform the function they were designed for, and for which they receive special antitrust treatment as well as "safe harbors" in the kickback laws, why should they be permitted to continue?**

Novation does save the hospital members of UHC and VHA money. Indeed, Novation has team of employees whose sole responsibility is to conduct comparative pricing analysis studies for hospital members (and prospective members). These comprehensive analyses demonstrate that Novation contract prices are well below those of individual hospitals and our competitors. In fact, in 2001, we documented a 5.9 percent price savings in studies conducted for 50 hospitals that covered $136 million in purchases. The methodology and results of these studies are included in Appendix No. 2.

With respect to the article at issue, it fails to quote or mention any of the many hospitals that find tremendous value in their relationship with Novation. Moreover, the "pilot" GAO study referenced in the article does not accurately reflect the true value group purchasing brings to the health care industry. For example, the study looked at only two products that account for less than one percent of hospital purchases. Further, the study was conducted in only one market. In addition, there are a large number of factors impacting price that were not taken into account (e.g., cooperative distributions and cost avoidance services performed by GPOs). (On the other hand, the GAO study did demonstrate one important fact: participation in GPOs is purely voluntary and hospitals are free to — and, in fact, do — purchase products on their own.)

For a more detailed discussion of our observations and concerns relating to the study, see *Novation's Observations Regarding the GAO Report on GPO Price Savings*, a copy of which is included at Appendix No. 1. We have shared our observations and concerns with the GAO and have offered our assistance in helping it to develop a subsequent study.

Can you address the contention that, in general, GPOs are not saving the hospitals the significant sums that they might, and can you tell us how you calculate the savings you claim for your participating members?

Novation is saving UHC and VHA member hospitals significant sums of money, and it is not only Novation that is making this claim, it is also the members themselves. As discussed above, Novation has a team that conducts comprehensive, comparative pricing analyses, and these analyses demonstrate that Novation contract prices are well below those of individual hospitals and our competitors. Moreover, of course, if Novation did not save UHC and VHA member hospitals money, it would rapidly become obsolete.

2. **We have also heard a great deal about the difficulties that small and start-up manufacturers are experiencing in trying to get their products into clinicians' hands. The basic claim seems to be that the GPOs, especially the large ones, enter into contracts with the largest suppliers of medical devices and products, thereby cutting out the smaller vendors from the possibility of selling their products – products they say are often more innovative and cost-effective – to the GPO member hospitals. These small manufacturers also report that the processes that GPOs have for evaluating new products tend to be very long, very costly, and very burdensome. How do you respond to those claims?**

Novation uses a fair and open public competitive bidding process to award agreements to suppliers that provide the best quality products and demonstrate broad-based clinical acceptability at the lowest total cost. Hospital members guide bidding and decision guidelines throughout the process. Furthermore, as discussed above, Novation is proud of its relationships with small manufacturers, with whom we have 25 percent of our contracts.

3. **It seems odd to me that the manufacturers of medical products pay the GPOs for including them in the contracts with the hospital, rather than having the hospitals pay fees to the GPOs for the services they provide. Why are GPOs set up this way, and how does that structure affect their incentives to provide hospitals with the best products?**

Our response to your question is several-fold. As an initial matter, although UHC and VHA are not public entities, they are legal cooperatives that were created by hospitals in response to certain market realities — most notably, the high and rising cost of equipment, supplies and services. GPOs not only were created by hospitals; they are owned by hospitals, are controlled by hospitals, and have one primary objective: bidding contracts on behalf of their hospital members for high quality items and services at a low cost. This objective is accomplished in several ways.

First, GPOs represent hundreds of hospitals. As such, GPOs typically are able to obtain better prices with a given supplier for a particular product than any individual hospital, acting on its own, could obtain. Moreover, the complex process of (1) getting suppliers to submit bids for GPO contracts, (2) analyzing these bids to determine which offer the best combination of clinical value and price, and (3) establishing contract terms, requires specialized personnel, is time consuming and is costly. Hospitals avoid these costs by having GPOs furnish these procurement services on their behalf.

Hospitals are able to avoid these costs, in turn, because GPOs are funded, in large part, through the administrative fees that suppliers pay under GPO-supplier contracts. These fees, which usually are based on a percentage of the value of GPO member hospital purchases, cover GPO clinical evaluation and contract bidding costs — costs, once again, that GPO member hospitals would otherwise be forced to incur. Thus, the existing fee structure enables hospitals to apply precious resources — resources that would otherwise be diverted to cover these evaluation and bidding costs — toward patient care.

Importantly, these fees have no adverse financial impact on federal health care programs. Indeed, upon examining the role of GPOs, the OIG observed that because hospitals generally are reimbursed a predetermined amount (based on a patient's diagnosis), the manner in which GPOs are funded — through vendor fees or member dues — is a "private matter" for the GPOs, their hospitals and suppliers. In essence, the OIG (correctly) concluded, the existence and amount of vendor fees does not trigger the principal policy objective of the anti-kickback law, which is preventing the overutilization of items or services paid for by the government and the concomitant expenditure of unnecessary government funds.

We should also note that in addition to the product evaluation and contract bidding services discussed above, Novation field-based personnel act as facilitators, assisting hospital members in identifying cost saving options. Moreover, GPOs like UHC and VHA offer their hospital members many educational, clinical and research-related services (such as the development of best practice protocols) that are currently unavailable through trade or professional associations.

Further, as noted above, many GPOs (including UHC and VHA) are cooperatives. It is common for cooperatives (1) to be funded by fees paid by vendors wishing to do business with coop members and (2) to return substantial portions of their net revenue to their members (a further source of cost reduction that has been overlooked by many including, the General Accounting Office in its recently released "pilot" study).

In sum, as long recognized by the HHS OIG (and many other government entities, such as the Department of Veteran Affairs) the use of volume purchasing generally results in substantial cost savings in the procurement of medical supplies. These cost savings are augmented through the payment of fees by vendors because (1) these fees cover costs that would otherwise be incurred by the hospitals and (2) portions of the fees are returned to the hospital members through cooperative distributions. Further, given the ubiquity of prospective payment reimbursement methodologies, the OIG has informed the Department of Justice (and the public) that it has "no policy objection to these [payment] arrangements," and the statutory GPO exception and regulatory GPO safe harbor reflect that policy determination.

We have been told that some GPOs offer their hospitals a list of products for which the GPO has negotiated contracts, but that some GPOs offer their hospitals a list of suppliers instead. Is this the case? If it is, can you explain how the "list of suppliers" approach brings hospitals the best products at the best prices?

Novation offers hospitals a list of contracted products only. We believe the "list of suppliers" business model brings less economic value to hospitals. However, hospitals have a choice in the GPOs they use and are free to align themselves with other GPOs that offer this type of approach.

My most basic concern is with the quality and cost of health care provided in our hospitals. Concerns have been raised about the cost aspect of this issue, but what can you tell me about how participation in a GPO affects the quality of care that hospitals can provide their patients?

Product quality specifications and clinical acceptability drive our decision-making process. Multiple member hospital representatives, who provide the bid and decision rationale, have significant input into award decisions. These individuals are more concerned with awarding agreements that provide the most clinically acceptable product than the one with the lowest price. Indeed, it is not uncommon for contracts to be awarded to the supplier with a higher price in order to provide hospital members with the most clinically acceptable product.

Moreover, participation in group purchasing aids hospitals' standardization efforts, contributing to patient and provider safety by reducing product variability. Again, please note that a GPO member hospital is always free to purchase from a vendor that is not under contract if it decides that doing so is in the best interest of its patients.

Finally, as discussed above, participation in GPOs allows hospitals to access many other services that improve quality of care, such as educational opportunities, joint research, and best practice programs.

Questions for Joe Kiani from Senator Leahy

1. **I understand that small medical device manufacturers are concerned that GPO contracts with large manufacturers limit the smaller companies' access to hospitals and clinicians. My wife is a nurse, so my concern that safe and effective medical equipment be readily available has a personal as well as a professional aspect to it. But how do you respond to the assertion of the GPOs that clinicians and hospitals that really want your products will be able to buy them? As I understand it, no GPO requires a hospital to buy all of its supplies from the contract list, so why is it not the case that a truly superior or innovative new product cannot be accepted by lots of health care providers? And if the response is that it is technically possible, but economically ill advised, for a hospital to buy "off-contract", could you please explain how we should try to quantify that economic disincentive?**

   Novation elects not to respond to this question.

2. **Of particular concern to me, given that my wife is a nurse, is the issue of safety needles. I know that this is a product that has also received a lot of press, as well it might, given the danger that needle sticks present to health care workers as well as patients. But we have been told that RTI, the much-publicized "little guy" in this market, actually has a contract with Abbott, one of the market's biggest players, to sell its safety needles. Is this true? And if so, how does that arrangement work? How many other small manufacturers are engaged in such ventures with their bigger rivals?**

   Novation elects not to respond to this question.

Senator DeWine
Group Purchasing Organization Follow-Up Questions
to Mr. Mark McKenna, President, Novation

1) Many of the programs and services listed in your testimony seem like useful and valuable services, but they seem to be more appropriate for an industry trade association or professional association than for a private buying organization. What is the public policy reason for allowing money generated through an anti-kickback exemption to be used for these purposes?

Our response to your question is several-fold. As an initial matter, although UHC and VHA are not public entities, they are legal cooperatives that were created by hospitals in response to certain market realities — most notably, the high and rising cost of equipment, supplies and services. GPOs not only were created by hospitals; they are owned by hospitals, are controlled by hospitals, and have one primary objective: bidding and managing contracts on behalf of their hospital members for high quality items and services at a low cost. This objective is accomplished in several ways.

First, GPOs represent hundreds of hospitals. As such, GPOs typically are able to obtain better prices from a given supplier for a particular product than any individual hospital, acting on its own, could obtain. In addition, the complex process of (1) getting suppliers to submit contract bids, (2) analyzing these bids to determine which offer the best combination of clinical value and price, and (3) establishing contract terms, requires specialized personnel, is time consuming and is costly. Hospitals avoid these costs by having GPOs perform furnish these complex procurement services on their behalf.

Hospitals are able to avoid these costs, in turn, because GPOs are funded, in large part, through the fees that suppliers pay to GPOs under GPO-supplier contracts. These fees, which usually are based on a percentage of the value of GPO member hospital purchases, cover GPO clinical evaluation and contract bidding, analysis and negotiation costs — costs, once again, that GPO member hospitals would otherwise be forced to incur. Thus, the existing fee structure enables hospitals to apply precious resources — resources that would otherwise be diverted to cover these evaluation and bidding costs — to patient care.

Importantly, these fees have no adverse financial impact on federal health care programs. Indeed, upon examining the role of GPOs, the OIG observed that because hospitals generally are reimbursed a predetermined amount (based on a patient's diagnosis), the manner in which GPOs are funded — through vendor fees and/or member dues — is a "private matter" for the GPOs, their hospitals and suppliers. In essence, the OIG (correctly) concluded, the existence and amount of vendor fees does not trigger the principal policy objective of the anti-kickback law, which is preventing the overutilization of items or services paid for by the government and the concomitant expenditure of government funds.

We should also note that in addition to the product evaluation and contract bidding services discussed above, Novation field-based personnel act as facilitators, assisting hospital members in identifying cost saving options. Moreover, UHC and VHA offer their hospital members many educational, clinical and research-related services (such as the development of best practice protocols) that currently are unavailable through trade or professional associations. These products and services, the need for which is determined by UHC and VHA members, lower health care costs and improve quality of care. In addition, Novation helps lower the costs of suppliers, large and small, by reducing marketing and selling expenses.

Further, as noted above, many GPOs (including UHC and VHA) are cooperatives. It is common for cooperatives (1) to be funded by fees paid by vendors wishing to do business with coop members and (2) to return substantial portions of their net revenue to these members (a form of cost reduction for hospitals that has been overlooked by many, including the General Accounting Office in its recently released "pilot" study).

In sum, as long recognized by the HHS OIG (and many other government entities such as the Department of Veteran Affairs) the use of volume purchasing generally results in substantial cost savings in the procurement of medical supplies. These cost savings for GPO hospital members are augmented through the payment of fees by vendors because (1) these fees cover costs that would otherwise be incurred by the hospitals and (2) portions of the fees are returned to the hospital members through cooperative distributions. Further, given the ubiquity of prospective payment reimbursement methodologies, the OIG has informed the Department of Justice (and the public) that it has "no policy objection to these [payment] arrangements," and the statutory GPO exception and regulatory GPO safe harbor reflect that policy determination.

On a final note, we should emphasize that GPOs such as UHC and VHA offer their hospital members many additional educational, clinical and research-related services (such as the development of best practice protocols) that currently are unavailable through trade or professional associations. These products and services, determined by the UHA and VHA members, lower health care costs and improve quality of care.

2) You mention that supplier-paid fees are not unusual. Describe other industries where supplier-paid fees are the norm.

Supplier-paid fees are a source of funding for many of the nation's cooperatives. Cooperatives are common, for example, in the farming, credit union, housing, childcare, health care, local food, mutual insurance, and rural electrical industries, among others. The commercial and residential real estate industries also are funded by seller-paid fees.

3) GPOs have been given legal authority to charge "administrative fees" to medical supply companies based on a percentage of sales. The payment of administrative fees is permissible because GPOs currently enjoy an exemption or "safe-harbor" from the Medicare/Medicaid anti-kickback statute. This allows the GPOs to be funded via fees from suppliers, but it has also led to a great deal of controversy about whether GPOs are working in the best interests of their member hospitals or whether they are instead focused on obtaining higher fees for themselves. What impact would there be on the GPO system if GPOs were no longer allowed to charge medical suppliers administrative fees, but instead had to be funded directly by the hospitals?

The impact of eliminating a tried and tested business model that evolved in the open market in response to surging medical supply costs could be drastic and disastrous, especially for community-based, not-for-profit rural hospitals and academic medical centers. A fundamental change of this kind is unnecessary; in fact, it should not even be considered without an extensive and rigorous economic and policy analysis.

As discussed above, the OIG has examined vendor payments to GPOs and concluded that these arrangements should be permitted because they reduce costs and do not harm federal health care programs. Further, the elimination of these payments would have two immediate and deleterious effects.

First, hospitals would have to fund GPO activities. Although this may be possible for some hospital systems, it will present a severe economic challenge to many of the community-based, rural and state-owned academic providers represented by UHC and VHA. According to preliminary information gathered by UHC, for example, a substantial number of its member academic medical centers (which are where the vast majority of future physicians are trained) are operating in the red. In a nutshell, many hospitals may not have the wherewithal to fund a GPO. Nor, importantly, do these hospitals — acting on their own — have the human or financial resources to effectively (1) assess the clinical quality of the hundreds of competing medical products or (2) obtain favorable terms with product manufacturers.

Second, because many GPOs are cooperatives that return fee income to their hospital members in the form of annual distributions, the elimination of vendor fees will eliminate another (important) source of hospital cost savings.

In sum, prohibiting GPOs from charging vendor fees could cause the collapse of group purchasing and, as a direct result, higher healthcare costs for hospitals, Medicare, other payers and consumers.

If the hospitals are truly receiving value from the GPOs in the form of lower supply costs, won't they be willing to pay for the cost of the GPOs themselves?

As discussed above, UHC and VHA were created, and are owned and controlled, by their member hospitals. If these GPOs do not provide valuable services — or otherwise fail in their mission — the hospitals members will affect the necessary changes or withdraw. Simply put, GPOs will become obsolete in the open market if they are not of "value" to their members.

Moreover, for the reasons discussed above, we do not believe that most hospitals are in a position to pay for the GPO services that they receive under the existing business model. (As an aside, we should note that we are skeptical that the elimination of vendor fees will prompt vendors to reduce their prices accordingly. Although the vendors you have heard from tout the best interests of our members, ultimately, these vendors owe fiduciary duties to their shareholders and do their utmost to maximize their own revenues.)

4) *The New York Times* recently reported that some GPOs have an ownership interest in companies that supply products to hospitals. This is also demonstrated in information supplied to the Subcommittee. This arrangement raises concerns because it provides the GPO with a financial interest in granting these companies a contract, even if the company doesn't necessarily have the best product or the lowest price. What is the justification for GPOs having an ownership interest in companies that supply products to hospitals?

Neither UHC nor VHA has any ownership interest in any company that supplies medical products or pharmaceuticals to its hospital members. Nor does Novation have any such ownership interest.

For the record, and in the interest of full disclosure, Novation has no ownership interest in any other company; UHC has a minority interest in Neoforma, Inc. (the company that operates Marketplace@Novation, Novation's e-commerce platform); and VHA owns a minority interest in Neoforma and two other companies that offer information technology solutions for hospitals (Healthvision and Solucient, which help ensure that hospital members have cost-effective access to innovative administrative technologies). Again, none of these investments are in companies that sell medical or pharmaceutical products to our hospital members.

5) The Health Care Guidelines formulated by the Federal Trade Commission and the Department of Justice allow joint purchasing agreements for health care supplies if they account for less than 35 percent of the total sales of the purchased product or service in the relevant market. If the market is defined broadly to include all buyers of medical supplies, Premier and Novation are likely below this 35% threshold for most products. However, some specialized care items are primarily purchased by hospitals, and for these items, Premier and Novation may well be approaching the 35% threshold. Do the recent difficulties that some manufacturers have had in gaining entry to the market suggest that the 35% threshold needs to be lowered?

There seems to be some confusion regarding Novation's market share. Novation has approximately a 12.5 percent market share nationwide. To illustrate: UHC and VHA members represent about 30 percent of the nation's hospitals. However, Novation offers only about 75 percent of the items purchased by hospitals. Further, UHC and VHA hospitals only purchase approximately 55 percent of these items through Novation contracts. Thus, Novation represents approximately 12.5 percent of the purchases made by U.S. hospitals (55 percent of 75 percent of 30 percent = 12.5 percent).

In order for Novation to even approach the 35 percent threshold, all hospital members would need to purchase 100 percent of the items at issue through Novation. Because of the voluntary nature of our purchasing program, this simply is not — and never has been — the case. In fact, statistics show that hospitals make approximately 45 to 50 percent of their purchases under non-GPO contracts.

We would also note that joint purchasing arrangements that fall outside the antitrust safety zone do not necessarily raise antitrust concerns. The guidelines specifically provide that antitrust concern is lessened where, as in the Novation process, members are not required to utilize the joint arrangement.

In sum, we do not believe that GPOs present barriers to manufacturer penetration of the hospital market. Indeed, consistent with this belief, it is our understanding that within the past several years, the Antitrust Division of the Department of Justice reviewed this issue and decided to take no action.

6) In 1986, Congress created a safe harbor from the anti-kickback statute to allow the payment of administrative fees to cover the costs associated with the hospital cooperative buying groups. The legislative history indicates that Congress was concerned about the possibility of fees over 3%, but based on the data provided to us, it is clear that many vendors pay administrative fees to GPOs that are more than 3% of sales, and that the share of total revenues raised by these higher fees is significant. What is the rationale for fees over 3%, and should there be a hard cap on administrative fees?

First, please note that the vast majority of Novation's 942 contracts provide for fees of 3 percent or less, and Novation's average fee is approximately 2.1 percent.

Second, neither the statutory GPO exception nor the regulatory GPO safe harbor imposes any artificial ceilings on the type or amount of fees that may be paid to a GPO. (Consistent with the exception and safe harbor, in an advisory opinion issued in 1998, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") confirmed the legality of an 11 percent fee arrangement.) The absence of such a ceiling reflects the (correct) conclusion (by Congress and the OIG) that neither the payment nor the amount of vendor fees triggers the principal policy objective of the anti-kickback law, which is preventing the overutilization of items or services paid for by the government and the concomitant expenditure of government funds.

Third, in contrast to some GPOs, UHC and VHA are cooperatives. It is common for

cooperatives (1) to be funded by fees paid by vendors wishing to do business with coop members and (2) to return substantial portions of their net revenue to coop members (a form of cost reduction for hospitals that has been overlooked by many, including the "pilot" study recently released by the General Accounting Office). Thus, as a general proposition, the larger the fees paid by vendors to GPO cooperatives, the greater the annual dividend to GPO member hospitals, and the greater the annual dividends paid to GPO hospitals, the lower their overall costs.

Under these circumstances, a government-imposed cap on vendor fees —which the OIG long ago concluded is fundamentally a "private matter" (i.e., a matter best left to negotiations among vendors, GPOs and hospital members) — could increase hospital costs. As such, placing a limit on fees — especially in the cooperative context — should not be hastily pursued; at a minimum, it should be carefully considered only in the context of rigorous economic analyses on the most likely impact on the hospital supply chain market and on hospital supply costs.

On a final note, in today's supply chain market, hospitals can choose among GPOs and, therefore, may align themselves with the GPO that best reflects their corporate structure and mission. Forcing all GPOs to operate under a capped fee structure would limit this choice (and reduce market competition).

7) Premier and Novation have only one provider for some of their contract items, which can create a substantial barrier to the market for other suppliers of the same product. What benefit do hospitals gain from these sole-source contracts and is that benefit outweighed by the potential long-term harm to competition?

As an initial matter, we do not believe that GPO sole source contracts create a substantial barrier to market entry. Again, participation in Novation's purchasing program is voluntary. Hospital members are not required to purchase under any Novation contract (as is demonstrated by the fact that approximately 45 to 50 percent of hospital purchases are made under non-GPO contracts).

Further, there are good reasons for entering into sole source contracts. Some vendors, for example, condition their bids on obtaining a sole source contract. Others offer substantially lower prices to hospital members under sole source arrangements.

We should emphasize however, that in general, Novation does not consider sole sourcing to be appropriate unless it is assured — based on the input from its hospital member representatives — that the product at issue is as clinically effective and reliable as the alternatives. When "clinical acceptability" is assured, then (and only then) does price become a focused objective. Even then, hospital member representatives tend to favor sole sourcing only when it results in material price differentials; where the differential is marginal, the contract typically is not sole-sourced.

Prohibiting sole source arrangements within the health care industry would reduce the discounts available to hospitals (especially smaller hospitals, which are unable to obtain the same volume discounts that large hospital systems enjoy) and, as such, increase health care costs. Indeed, such a prohibition would be the equivalent of the government telling manufacturers, "although you would like to give greater discounts to hospitals on medical supplies and equipment, you may not do so." It also would be the equivalent of the government telling hospitals, "although you would like to reduce your costs — and although we (as the largest single payor of hospital bills in the country) also would like you to reduce your costs — you may not do so." This, of course, makes no sense; indeed, now more than ever, the government's goal should be to help hospitals reduce their costs, not increase them.

In sum, sole source contracts allow GPOs to provide more favorable prices for hospital members. As always, however, if a particular hospital member prefers an alternative product to that chosen by Novation (whether pursuant to a sole- or a multi-source contract), that member is free to purchase that product from a non-contracting supplier.

8) Many GPOs generate revenue from administrative fees that far exceed the costs directly associated with the contracting services they provide. The additional revenue has enabled some GPOs to begin new programs or businesses not directly related to volume purchasing. For example, both Premier and Novation have interests in Internet based equipment procurement businesses. If we assume that GPOs will continue to be funded by supplier fees, is it appropriate for GPOs to use these fees on other business ventures, or should GPOs be required to pass on these fees directly to their member hospitals?

Because UHC and VHA are cooperatives, surplus fee revenue belongs — and typically is returned to — member hospitals in the form of cash and equity distributions, which, in turn, serve further to lower hospital costs. The boards of the two cooperatives — which are comprised of hospital representatives — determine the size and form of these distributions. These boards also determine (1) the extent to which excess revenue should be reinvested into the existing (or prospective) operations of the cooperatives and (2) how this revenue should be reinvested. Thus, to the extent that both UHC and VHA perform functions other than group purchasing — including the development of clinical protocols, tools for identifying and learning from medical errors, and the like — they do so at the direction of their hospital members.

With respect to our e-commerce initiative — Marketplace@Novation — the UHC and VHA boards concluded that it was in the best interest of their member hospitals for Novation to develop an e-commerce platform in order to help bring the nation's hospitals into the 21st century and gain the efficiencies that other industries enjoy. Since the two leaders in hospital product e-commerce solutions are the Marketplace@Novation, owned in part by hospital members, and the Global Healthcare Exchange, owned by the world's largest health care suppliers, we continue to believe that this was the right decision. Without Marketplace@Novation, hospital members would be unable to reap the benefits of their own e-commerce platform, but rather would be forced to use one owned and controlled by the suppliers and their shareholders, whose main interest is not reducing hospital costs, but increasing their own profits.

9) GPOs sometimes enter into contracts with vendors that are three, five and even seven years in length. There are some obvious potential benefits to these contracts, including price stability, and they make sense for certain products. However, some categories of medical products often undergo rapid change as technological improvements are made. First, are these type of products locked up in long term contracts, and if so what impact does it have on innovation?

Novation has only one vendor contract with a seven-year term (which was in place prior to the formation of Novation in 1998 and expires in 2004). Other contracts typically have a three-year term with options for renewal (which are exercised based on member hospital guidance).

Furthermore, Novation strives to be sensitive to evolving health care technology in order to remain relevant to those we serve — i.e., the hospitals that created, and control, UHC and VHA. Through our competitive bidding system, Novation ensures that it contracts for the technology that is most useful to UHC and VHA hospitals at the time of the bid award.

Finally, all Novation agreements permit contract termination with 90 days written notice. As such, should technology change during the term of an agreement, Novation can either add other suppliers or terminate the existing agreement (and put out a bid for a new agreement). In a nutshell, Novation's contracting system is designed to easily accommodate technological advances and make new products available to members.

And second, should there be a limit on length of contracts for certain product classes such as physician preference items?

As an initial matter, the definition of "physician preference items" is highly subjective. There will always be a difference of opinion among clinicians regarding the effectiveness of specific medical devices and pharmaceuticals. In any event, we believe the existing 90-day termination clause in our contracts allows for appropriate flexibility in addressing changes in technology. Moreover, hospital members are always free to purchase products from vendors that do not have a Novation contract.

10) It is clear from information provided to us by Premier and Novation, that many of their contracts require hospitals to purchase a high volume of a particular product – sometimes as much as 90% — in order to obtain the discounted price for the item. At other times, significant price discounts are available only if a bundled range of products is purchased. This obviously creates a great incentive on the part of hospitals to meet these purchase requirements in order to receive the discounted price. Given that two GPOs handle purchasing for such a high percentage of the nations hospitals, should we be concerned about such strong incentives for hospitals to purchase products from one or perhaps two suppliers?

We respectfully submit that the answer is, no.

As an initial matter, none of Novation's contracts or programs "require" hospitals to purchase a high volume of any product. The confusion seems to stem from the use of the word "commitment." A hypothetical helps demonstrate the point. Assume bed sheet Manufacturer enters into an agreement with Hospital on December 31, 2001. The agreement provides that Manufacturer's price will be $10 (per unit) for the first 100 bed sheets purchased by Hospital in 2002 and $9 (per unit) thereafter. Under this agreement, has Hospital— simply by virtue of entering into this agreement — "committed" to purchasing (1) bed sheets from any entity, (2) bed sheets from Manufacturer, or (3) a particular volume of bed sheets from Manufacturer?

The answers are "no," "no" and "no." The Hospital — exercising its independent judgment, and considering factors both economic and clinical — may choose (1) to purchase no bed sheets at all, (2) to purchase bed sheets, but not from Manufacturer, or (3) to purchase more or less than 100 bed sheets from Manufacturer under the agreement at issue. But Hospital has not "committed" to doing anything. Indeed, the only entity that has made a "commitment" is Manufacturer, which has "committed" to charging Hospital no more than $10 for the first 100 bed sheets purchased and no more than $9 per unit thereafter. Nor, of course, is there anything "wrong" with this agreement. Indeed, it is the classic, ubiquitous "volume discount" buyer-seller arrangement.

Nor does the analysis change if what Manufacturer offers is a "market share" type discount (or rebate). That is, assume that the Manufacturer-Hospital agreement provides that if Hospital purchases 0-50 percent of its bed sheets from Manufacturer in 2002, the price will be $10 per unit and if the Hospital purchases 51-100 percent of its bed sheets from Manufacturer in 2002, the price will be $9 per unit. As under the volume discount arrangement discussed above, under this arrangement, Hospital has not "committed" to purchasing (1) bed sheets from any entity, (2) bed sheets from Manufacturer, or (3) a particular volume of bed sheets from Manufacturer under the agreement. Nor, again, is there anything "wrong" with this agreement — it is the classic, ubiquitous "market share" discount buyer-seller arrangement.

The bottom line is this: all of Novation's so-called "commitment" or "opportunity" programs constitute variations on the discount and rebate arrangements reflected in these hypothetical agreements. Most importantly, under none of these programs are GPO members required to purchase any amount of any product from any vendor. Indeed, GPO members only do (and should) take advantage of these programs if, exercising their independent judgment, it makes financial and clinical sense to do so.

Three final observations. First, the programs at issue were created at the request of member hospitals. Second, smaller hospitals tend to benefit from the market share components of these programs the most because, due to their size, they are often unable to enjoy the volume discounts offered by vendors to larger organizations. Third, participation in these programs is entirely voluntary — it is not a precondition to joining UHC or VHA or to obtaining the price reductions negotiated by Novation. Nor does such participation preclude a hospital from purchasing products from vendors that are not under contract with Novation.

How should we balance that competitive concern against the potential cost savings?

Since no commitment of any kind is necessary in order to receive a discount, and since hospitals are not required to participate in — and may withdraw at any time from — any of our additional discount programs, we do not believe this a concern.

Moreover, eliminating such programs would be counterproductive and would substantially increase costs, especially for small rural hospitals. Such a prohibition — a price control, in effect — would be the equivalent of the government telling manufacturers, "although you would like to give greater discounts to hospitals on medical supplies and equipment, you may not do so." It also would be the equivalent of the government telling hospitals, "although you would like to reduce your costs — and although we (as the largest single payor of hospital bills in the country) also would like you to reduce your costs — you may not do so." This, of course, makes no sense; indeed, now more than ever, the government's goal should be to help hospital reduce (and not increase) their costs.

Finally, we believe it would be unfair to prohibit GPOs from competing in this manner while allowing large health care companies to continue to do so. Companies such as Johnson and Johnson, Allegiance, Abbott, Tyco and many others — as well as the federal government — engage in the practices described above. Our commitment programs were created, in part, to compete with these corporate programs.

11) The *New York Times* reported recently that GPOs don't necessarily save hospitals money. They rely in part on the GAO study that Senator Kohl and I asked them to conduct. The Times also cited the experience of health care systems that have lowered their costs by negotiating their own contracts for medical devices. At the same time, I have heard from many hospitals in Ohio that they believe they save money by purchasing through GPOs. What accounts for the difference in opinion on cost savings, and how can we ensure that we get an accurate evaluation of any savings?

First, due to the severely limited nature and flawed methodology of the GAO's "pilot" study, we believe that it does not accurately reflect the true value GPOs bring to the health care industry. For example, the study looked at only two products that account for less than one percent of hospital purchases. Further, the study was conducted in only one market. In addition, there are a large number of factors impacting price that were not taken into account (e.g., cooperative distributions and cost avoidance services performed by GPOs). (On the other hand, the GAO study did demonstrate one important fact: participation in GPOs is voluntary and hospitals are free to — and do — purchase products on their own.)

For a more detailed discussion of our observations and concerns relating to the study, see *Novation's Observations Regarding the GAO Report on GPO Price Savings*, a copy of which is included at Appendix No. 1. We have shared our observations and concerns with the GAO and have offered our assistance in helping it to develop a subsequent study.

We would also note that Novation has a team of employees whose sole responsibility is to conduct comparative pricing analyses for hospital members (and prospective members). These comprehensive analyses demonstrate that Novation contract prices are well below those of individual hospitals and our competitors. In fact, in 2001, Novation documented a 5.9 percent price savings in studies conducted for 50 hospitals that covered $136 million in purchases. The methodology and results of these studies are included in Appendix No. 2.

12) Some GPOs have begun contracting for distribution services in addition to medical devices. Distributors are given a contract to provide distribution services and in turn they must pay an administrative fee. Hospitals that purchase items pursuant to GPO contracts must obtain the product through one of the approved distribution companies. Many distributors believe they have been locked out of this market because hospitals are no longer permitted to use their services, even though the hospital may prefer to do so given long standing relationships. What is the benefit to hospitals from having limited distribution outlets?

Standardizing distribution arrangements lowers costs (due to the volume discounts offered through such arrangements) and streamlines processes relating to the delivery, billing and payment for products. Novation offers hospital members eight medical-surgical (non-pharmacy) distribution contracts and 14 distribution agreements for other specific product categories such as pharmacy, food, radiology, lab, etc.

13) Defenders of the GPO contracting system have stated that hospitals are not required to purchase on contract and they are always free to purchase from any vendor they choose. However, some vendors report that hospital staffs often indicate that they are not permitted to buy "off" their GPO contract. How willing are hospitals to actually purchase off contract?

As discussed above, on average, hospitals purchase 45-50 percent of their products using non-GPO contracts.

And what sort of pressure, if any, is exerted by GPOs to keep them from doing so?

None.

Questions from Senator Hatch
"Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovations?"

[Note to panelists: Although the following questions are addressed to specific panelists, I would invite and appreciate responses from any member of the panel.]

Question 1: Mr. McKenna and Mr. Norling, I am very concerned about allegations that the relative market power possessed by Novation and Premier may have enabled or contributed to the types of anticompetitive practices discussed at the hearing. As you may be aware, a recent report by Government Accounting Office, entitled "Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices" ("GAO Report"), concluded that "[p]rice savings had little relationship to the size of the GPO," and further noted that "[t]his lack of consistent price savings is contrary to what would be expected for large GPOs." If increased GPO size does not result in increased savings, could you please identify other anticipated benefits of the consolidations that resulted in Novation and Premier being disproportionately larger than competing GPOs?

We believe that it is dangerous to draw conclusions from this preliminary and, we believe, seriously flawed "pilot" study. We further believe that, as a result of the limited scope and flawed methodology of the GAO's "pilot" study, the study does not accurately reflect the true value group purchasing brings to the health care industry. For example, the study looked at only two products that account for less than one percent of hospital purchases. Further, the study was conducted in only one market. In addition, there are a large number of factors impacting price that were not taken into account (e.g., cooperative distributions and cost avoidance services performed by GPOs). (On the other hand, the GAO study did demonstrate one important fact: participation in GPOs is purely voluntary and hospitals are free to — and, in fact, do — purchase products on their own.)

For a more detailed discussion of our observations and concerns relating to the study, see *Novation's Observations Regarding the GAO Report on GPO Price Savings*, a copy of which is included at Appendix No. 1. We have shared our observations and concerns with the GAO and have offered our assistance in helping it to develop a subsequent study.

Is there available evidence or data demonstrating that these benefits have been achieved?

Novation has a team of employees whose sole responsibility is to conduct comparative pricing analyses for hospital members (and prospective members). These comprehensive analyses demonstrate that Novation contract prices are well below those of individual hospitals and our competitors. In fact, in 2001, Novation documented a 5.9 percent price savings in studies conducted for 50 hospitals that covered $136 million in purchases. The methodology and results of these studies are included in Appendix No. 2.

Further, the simple fact that hospitals use — and have increased their use of — Novation demonstrate that group purchasing is lowering costs and providing significant economic value.

Question 2: Mr. McKenna and Mr. Norling, the creation of the GPO system was based on

the assumption that combining the purchasing power of member hospitals in a single purchasing entity would enable that entity to negotiate lower prices from vendors. The logical extension of this premise would predict an inverse correlation between purchasing power and negotiated prices. However, the GAO Report found no "clear relationship" between price and GPO size. In fact, the GAO Report found that "[h]ospitals of all sizes . . . often paid more for pacemakers, compared to those using smaller GPOs' contracts." Are either of you able to provide additional information elucidating or explaining this counterintuitive finding?

As discussed above, we believe that as a result of its limited scope and flawed methodology, the GAO's "pilot" study does not accurately reflect the true value group purchasing brings to the health care industry. Again, the study looked at only two products that account for less than one percent of hospital purchases and was conducted in only one market. In addition, there are a large number of factors impacting price that were not taken into account by the GAO.

What possible factors might result in smaller GPOs being able to negotiate lower prices than those offered by Novation and Premier?

As discussed above, there are many factors that were not considered in the study. These are covered in *Novation's Observations Regarding the GAO Report on GPO Price Savings*, a copy of which is included in Appendix No. 1.

Question 3: Ms. Barrett, if I understood you correctly, at the hearing you stated that, in assessing new or "breakthrough" products and technologies, GPO evaluators relied on published studies in peer-reviewed journals. In particular, you seemed to imply that a breakthrough technology might not be adopted unless and until published studies demonstrated its advantages, even though numerous smaller, unpublished studies, such as those cited by Mr. Kiani and Dr. Goldstein, were available. Is this a fair interpretation of your comments? If so, to what extent do evaluators rely on published studies rather than unpublished or preliminary findings and studies?

Novation elects not to respond to this question.

Question 4: Mr. Kiani and Dr. Goldstein, as mentioned by Mr. Kiani at the hearing, Utah Medical Products, a small medical device manufacturer based in my home state of Utah, has complained of anticompetitive practices and treatment in the evaluation process similar to those experienced by Masimo, as described by Mr. Kiani. Could each of you comment on whether these and similar complaints describe systematic problems, as opposed to isolated events?

Please note that Utah Medical Products participated in our competitive bidding process in 1999 and ultimately was awarded a sole-source contract. Just a few months later, however, the company concluded that its market share was not growing fast enough and, as a result, terminated its contract with Novation.

Question 4: Mr. Kiani and Dr. Goldstein, in the particular case of Utah Medical Products, the alleged anticompetitive practices focused on one of the two GPOs represented at the

hearing, and – as I understand it – Utah Medical has expressed little or no concern regarding its treatment by any other GPO. To the extent that such treatment of small medical device manufacturers is not limited to a few, isolated instances, are there indications that these practices are either more or less common among the very largest GPOs?

We will take this opportunity to discuss another of the many small supplier success stories. Megadyne, a company from Utah, makes an innovative product — reusable grounding pads — used to protect patients from electrical shock. Although Novation already had disposable grounding pads on contract with 3M and Valley Lab, Megadyne's reusable pads employed a new technology that UHC and VHA members wanted added to their portfolio. This is an example of our fair and open competitive bidding process working for a small, innovative supplier, which won fairly by exhibiting both high quality and economic value.

Novation is proud of its relationships with small manufacturers, with whom we have 25 percent of our contracts. We are also proud of our affiliation with the University of Utah Hospitals and Clinics in Salt Lake City, a member of UHC. They employ nearly 4,000 people and annually treat almost 500,000 patients. Last year they spent over $44 million on supply purchases through Novation contracts and saved approximately $2.2 million in the process.

Question 5: Mr. Kiani and Dr. Goldstein, are there any GPOs that you are aware of which have a reputation for being particularly receptive to contracting with small medical device manufacturers? To what would you attribute this willingness to contract with small medical device manufacturers?

Novation elects not to respond to this question.

SUBMISSIONS FOR THE RECORD

Statement

of Gary Cohen, President, BD Medical Systems

Becton Dickinson and Company

Submitted to

United States Senate

Committee on the Judiciary

Subcommittee on Antitrust, Competition,
and Business and Consumer Rights

April 30, 2002

As one of America's oldest and most innovative medical device manufacturers, Becton Dickinson commends Chairman Kohl, Ranking Member DeWine, and the members of this Subcommittee for conducting a balanced and open-minded hearing concerning the role played by hospital group purchasing organizations ("GPOs") in our country's healthcare system. Becton Dickinson stands ready to work with the Subcommittee to help it fully understand the competitive dynamics in our industry.

We are making this submission to set the record straight with respect to the false charges and misrepresentations made to this Subcommittee by one of our competitors. To put our comments in context, we think it would also be useful for the Subcommittee to understand Becton Dickinson's role in the delivery of modern healthcare.

Becton Dickinson has been in the business of inventing, manufacturing and marketing medical devices and diagnostic products for more than 100 years. Our headquarters are in Franklin Lakes, New Jersey and most of our products are manufactured in facilities in Connecticut, New York, Massachusetts, South Carolina, Florida, Nebraska, Utah and California. We design, develop and manufacture a wide array of products for patient care and diagnosis, including those commonly referred to as "sharps," such as syringes and hypodermic needles, blood collection needles and tubes, intravenous catheters, scalpels, lancets, biopsy needles, and anesthesia kits.

The history of Becton Dickinson is one of constant medical breakthroughs and product innovations. Some of the milestones about which we are most proud are these:

- In 1924, we introduced the very first insulin syringe for treating patients with diabetes.

- In 1954, we supplied Jonas Salk with the syringes needed to develop the polio vaccine.
- In the 1960s, we became the first mass provider of sterile, disposable syringes, leading to dramatic reductions in hospital-borne infections.
- In the 1970s, we developed the technology used in cancer, stem cell and AIDS research for identifying and counting human cells.
- In the 1990s, we joined forces with UNICEF to eradicate neonatal tetanus -- a disease that kills 40,000 children every year -- by donating hundreds of millions of syringes.
- Today, we are working with the U.S. Department of Defense to conduct research on the detection and treatment of biological warfare agents.

Becton Dickinson is also the pioneer and industry leader in developing and manufacturing devices designed to protect health providers from accidental needlesticks and the transmission of infectious diseases such as AIDS and Hepatitis. More than a decade before Congress passed (with our enthusiastic support) the Needlestick Safety and Prevention Act of 2000, Becton Dickinson championed the development of "safety" needle products, funded nationwide education programs to train nurses and other caregivers to prevent needlesticks, and donated the seed money needed to spur academic research about healthcare worker safety and create the software needed to track needlestick accidents. We do not know of any company or organization that has committed more money, more human resources, and more technological know-how to preventing needlestick injuries.

This is just some of what we've done:

In 1989, Becton Dickinson introduced the first safety syringe called the Safety-Lok Syringe. In 1991, Becton Dickinson introduced the first needleless syringe for administering I.V. medication called the Interlink system. In 1992, Becton Dickinson introduced the first safety products for blood collection: non-breakable Vacutainer blood collection tubes, the Safety-Lok Needle Holder, and the Safety-Lok Blood Collection Set.

In 1995, Becton Dickinson introduced the first and the most widely used retractable needle product, the Autogard I.V. Catheter. And in 1996 -- still four years before Congress passed legislation requiring the use of safety products -- Becton Dickinson launched its second generation of safety technology with the SafetyGlide hypodermic needle, followed by the Eclipse blood collection needle in 1998.

Having spent more than a half a billion dollars in the development and marketing of safety devices, Becton Dickinson now offers the widest variety of needlestick prevention devices -- over 250 items in all. Last year we sold over one

billion safety products. And we are not done. New safety designs and technologies are in the pipeline and being readied for launch. Perhaps most exciting, Becton Dickinson began clinical trials this year of a technology that administers medicine without puncturing the skin -- in other words, delivering medication quickly, effectively and without any possibility of a needlestick.

We know that the Subcommittee is most interested in learning about the ways in which hospitals and GPOs contract for these products and other medical supplies. Although needle products account for only a small fraction of hospital purchases, we can share these comments for your consideration.

How hospitals organize themselves and make purchases has always been the hospitals' choice. During the course of our company's history, hospitals and other healthcare facilities have chosen a variety of different ways to negotiate and contract for our products. Today, we work with GPOs because many of the hospitals that buy our products ask us to. Many hospitals belong to multiple GPOs, and others do not belong to any GPOs. Therefore, Becton Dickinson not only competes for GPO contracts, it also negotiates one-on-one with those hospitals and healthcare providers that wish to work directly with us.

In the end, however, our experience is that no matter what the form or scope of the contracts our customers desire, we still must compete for sales at the individual hospital and facility level. This competition is particularly intense when it comes to the sale of safety needle products. We are in head-to-head contests with our competitors in hospitals, clinics and labs across the country that are evaluating and implementing safety products in compliance with the Needlestick Safety and Prevention Act. As might be expected, this competitive rivalry, and the collective bargaining power of hospitals through the GPOs, have reduced many of our prices significantly over the past decade. Within our industry, Becton Dickinson has seen the GPOs bring down prices while competition for the sale of needle products has only intensified.

This is why it is so unfortunate that one of our competitors, Retractable Technologies, Inc. ("RTI"), has chosen to exploit this civic forum to try to advance its private agenda -- and to do so by presenting the Subcommittee with falsehoods and distortions about Becton Dickinson and about competition in our industry. As we think the Subcommittee knows, RTI has sued Becton Dickinson and another competitor Tyco. RTI has also sued a start-up safety product company called New Medical Technologies, Inc. It appears to us that RTI is using this inquiry to gain an edge for itself in those litigations rather than to shine light on the truth about our business. We welcome a spirited public discourse, but believe that the statement of Thomas J. Shaw, the President and CEO of RTI, is a disservice to this Subcommittee and the Senate.

Here are the reasons why:

1. RTI suggests that Becton Dickinson showed no interest in licensing RTI's designs because it had no interest in developing "safer devices." That is false. Becton Dickinson pioneered the safety product business before RTI even existed

and launched a host of "safer devices" before RTI sold a single unit. Becton Dickinson chose not to license RTI's design for the same reason it has passed on hundreds of other concepts submitted for our review: RTI's product, in our view, did not meet the clinical needs necessary to provide the best patient care.

2. RTI claims that it has been denied access to the market by supposedly "exclusive" contracts between GPOs and Becton Dickinson. That is false. What RTI fails to disclose to the Subcommittee is that RTI itself has contracts with almost all the national GPOs. Only one year after RTI launched its first product in 1997, it obtained contracts with three GPOs, including Amerinet, which represents more than 10,000 healthcare facilities. By early 1999, RTI had a contract with Premier to supply its products to 30% of the country's hospitals. In May 1999, RTI issued this public announcement: "RTI now has contracts with four of the nation's five largest healthcare group purchasing organizations."

Hospital members of all the GPOs are able to buy RTI's products -- and they do. As a result, RTI reported to the Securities and Exchange Commission in June 2000 that, "The Company anticipates being able to sell all that it is able to produce."

3. RTI portrays itself as a powerless company "blocked" from "America's healthcare facilities" and whose sales people "are ordered to leave" GPO member hospitals. That is false. RTI neglects to inform the Subcommittee that it markets its products to America's hospitals through a partnership with Abbott Laboratories, one of the country's biggest medical supply companies -- and one that is many times the size of Becton Dickinson. Abbott, not RTI, is the primary marketer of RTI products to hospitals. Abbott now sells RTI products to hospital members of every GPO, including Premier and Novation. As a result, RTI recently reported that it is earning record high revenues.

4. RTI claims that there is "collusion" between Becton Dickinson and the GPOs. That is false. Becton Dickinson competes for its contracts with GPOs in the same competitive bidding process along with all its competitors (including RTI) and negotiates its contracts at arm's length.

5. RTI tells the Subcommittee that Becton Dickinson's contract with Premier calls for Becton Dickinson "to give Premier warrants on its stock." That is false. Neither the contract nor any side agreement provide for any such thing. It is irresponsible for RTI to say otherwise because it knows the truth and chose to mislead the Subcommittee.

6. RTI states that Premier hospitals cannot buy RTI products "without facing penalties from Premier or Becton." That is false. No Premier hospital has been denied any benefit, or paid any price or financial penalty, for buying RTI products.

7. RTI accuses Becton Dickinson of paying "kickbacks" to the New Jersey Hospital Association when its members buy Becton Dickinson products. That is

false. We can only presume that RTI is referring to the payment of administrative fees. Becton Dickinson pays administrative fees on purchases by NJHA members just like the administrative fees that RTI or Abbott pays on the sale of RTI's products.

8. RTI claims that Novation "needed permission from Becton" to make a deal with RTI. That is false. We cannot speak to RTI's private discussions with Novation, but we do know this: Becton Dickinson has no control over Novation's contracting decisions. In fact, when Novation negotiated its contract with Becton Dickinson for syringes and needles, it reserved for itself the right to contract with another company for retractable needle products. Novation is free to make any deal it wants with RTI. And under the terms of the contract with Becton Dickinson, Novation hospitals are free to buy whatever and as much as they want from RTI because they are not required to buy anything from Becton Dickinson.

9. RTI accuses Becton of making "tying arrangements" with GPOs that "link the sale of one product to the purchase of another." That is false. We have no GPO contracts which require hospitals to purchase one product in order to obtain our other products. Some GPOs have requested and negotiated price discounts for their members who wish to buy in volume or from multiple product categories, but Becton Dickinson does not withhold any of its products from any hospital or healthcare provider.

We regret having to correct the record, but irresponsible statements like these undermine the mission of the Subcommittee and have no place in a genuine search for the truth. The task of understanding the complex competitive forces and economic trends in our industry, and in the healthcare system generally, is difficult enough. We hope that we have been of assistance to the Subcommittee in that effort and Becton Dickinson remains at your disposal as you continue your investigation.

BIOTRONIK

April 25, 2002

Mr. Seth Bloom
Attorney at Law
U.S. Senate Anti-Trust Committee
308 Hart, Senate Office Building
Washington, D.C. 20510

Dear Mr. Bloom:

At your request, I am forwarding my personal testimony on the subject of Group Purchasing Organizations and their impact on small healthcare corporations. As you know, Biotronik, Inc. is a manufacturer of cardiac pacemakers and implantable ICDs, and we participate in the Cardiac Rhythm Management business sector of the healthcare industry. Over the past ten years, we have observed growing influence by GPOs, and today we are virtually prevented from doing business with the larger GPOs and their members.

My testimony attempts to explain the industry, how our company fits into this industry segment, and the deleterious impact of GPOs on our ability to gain fair market access to GPO hospital members.

I wish you good luck with the Senate Anti-Trust Committee hearing on Group Purchasing Organizations; and if I can be of further assistance to you, please feel free to contact me.

Sincerely,

Thomas V. Brown
Executive Vice President

TVB:kk

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THE QUEST FOR REVENUE AND PROFITS BY GPOs -- HOW IT NEGATIVELY IMPACTS FAIR MARKET ACCESS BY SMALLER MEDICAL COMPANIES

My name is Thomas V. Brown. I am the Executive Vice President for BIOTRONIK, Inc., which is located in Lake Oswego, a suburb of Portland, Oregon. BIOTRONIK, Inc. sells, markets and distributes cardiac pacemakers and implantable cardiac defibrillators. Both products are sold in the Cardiac Rhythm Management market segment, and traditionally have been purchased by individual hospitals throughout the US. I have personally worked within this business sector for twenty-six years, and I have been associated with BIOTRONIK, Inc. for over four years. During my career in the Cardiac Rhythm Management business, I have worked in many capacities. For the past eighteen years, I have served in executive roles with such firms as Cordis Corporation, Telectronics, Inc., St. Jude Medical, Inc., and now BIOTRONIK, Inc.

BIOTRONIK, Inc. is a privately owned US company that became incorporated in the state of Oregon in 1988. During 2001, we achieved approximately $70,000,000 in annual sales. We employ approximately 150 people throughout the US with most residing in the vicinity of Portland, Oregon. Our sister corporation, known as Micro Systems Engineering, is also located in Lake Oswego, Oregon, and is privately held by the same owner as BIOTRONIK, Inc. Micro Systems Engineering was incorporated in Oregon in 1979 and employs approximately 300 people who are principally engaged in the design, development, and manufacturing of cardiac pacemakers and implantable cardiac defibrillators.

The industry known as the Cardiac Rhythm Management business has been in existence since the early 1960s. Cardiac pacemakers and implantable cardiac defibrillators (ICDs) are used to treat cardiac rhythm disturbances, which are very common in the elderly population. Cardiac pacemakers typically treat bradycardia (slow heart beat) disturbances, and ICDs typically treat tachycardia (abnormally fast or erratic heart beat) disturbances. The treatment of both bradycardia and tachycardia rhythm disturbances is typically managed by a cardiologist or an electrophysiologist or EP (a cardiologist who specializes in electrical disturbances of the heart). Essentially, the cardiologist or EP diagnoses the cardiac rhythm disturbance, determines how to treat the disturbance, and then, based on his or her findings, may elect to implant a cardiac pacemaker or ICD into the patient. The patient is commonly admitted to a hospital as a "full-time, admitted patient" and has the necessary surgery for the implantation of the device, or may have the surgery performed as an "out patient" procedure.

Typically, the physician has been the individual who selects the type and brand of device that is best suited for the patient. The hospital buys the product from one of five vendors who sell such devices in the US and makes it available to the physician responsible for implanting the product into the patient.

The bradycardia or tachycardia condition is primarily associated with patients over the age of 60 years and, as such, most of the products are purchased through the United States Medicare System. The individual hospital purchasing the product is reimbursed by Medicare through what is known as the Diagnostic Related Group (DRG) which pays a set amount of money according to "procedure code." A procedure code is provided by

Medicare, and that specific DRG procedure code reimburses the hospital for the total cost associated with buying the implantable device, hospitalizing the patient, costs associated with the surgical suite, and the overall overhead associated with the procedure. The hospital's profit, if any, becomes the positive variance between the reimbursement for the procedure provided through the DRG process and the actual total cost of the procedure, including the cost of the device.

If the procedure is done on an out-patient basis (whereby a patient is discharged from the hospital in less than 24 hours), then a different reimbursement system is used. This is known as the Outpatient Prospective Payment System (OPPS) which is based on Ambulatory Payment Classification groups (APC). This system, in theory, will cover 75% of the estimated device costs and other overhead costs necessary to perform the procedure. Additionally, Medicare supplements the APC payment to provide a total reimbursement to the hospital for patients eligible for "outpatient procedures" under Medicare. Again, any profit gained by the individual hospital for the procedure will be the difference between its total Medicare reimbursement and its actual cost of buying the device and providing the facility support and service.

During 2002, the Cardiac Rhythm Management business in the US is estimated to be represented by 235,000 cardiac pacemaker implants per year [$1.5* billion] and 85,000 implantable cardiac defibrillator implants per year [$2.1* billion]. It is estimated that at least 70% of the implants listed above are covered under the US Medicare reimbursement system due to the advanced age of the device recipients.

The Cardiac Rhythm Management business within the US consists of five companies that have Food and Drug Administration approval to manufacture and market products. Those companies, and their approximate US unit market share per business sector, are listed in alphabetical order as follows:

COMPANY	PACEMAKER UNIT SHARE	ICD UNIT SHARE
BIOTRONIK	4%	1%
ELA MEDICAL	1%	0%
GUIDANT	20%	39%
MEDTRONIC	50%	45%
ST. JUDE MEDICAL	25%	15%

The industry has gone through a substantial change over the past few years. Today, purchasing patterns are controlled or managed by entities known as Group Purchasing Organizations (GPOs). GPOs are either member-owned or independent organizations that attempt to take advantage of buying products and services via the power of a larger group as opposed to the individual buying power of the individual hospital.

The stated objective of the GPO is to reduce costs, improve value, generate revenue (administrative fees), and simplify the contracting process for its members. Within the US, there are approximately seven to ten GPOs that provide services to approximately 80-90% of the hospitals within our country. The principal service provided is that of negotiating and administering the contracts for goods and services that their member hospitals are then expected to adhere to. As stated earlier, the GPOs can be member-owned, such as Premier Purchasing Partners located in Chicago, Illinois. This group represents its owner members, which are either large single hospitals or consortiums of hospitals known as IDNs (Independent Delivery Networks). Members, or potential members, of the Premier GPO have an opportunity to "buy in" and become equity members of the GPO; however, this usually costs millions of dollars as opposed to simply becoming an independent member and paying an annual membership fee. Like all GPOs, Premier Purchasing Partners charge their members an annual membership fee. Additionally, similar to all GPOs, they charge their vendors an "administrative fee," usually a minimum of 3%. This fee is charged across the board on <u>all</u> large national contracts, for <u>all</u> specialties. The GPO *retains a portion* of the revenue generated through this administrative fee, and the *balance is passed* on to its members. The amount passed on to the members is generally based on their percentage equity or membership position. Equity members receive a higher percentage of each dollar generated through the administrative fee process.

Some GPOs are 100% independent, meaning they are not member-owned, but privately owned by "for profit" corporate entities. The independent GPOs, like the member-

owned GPOs, pass a percentage of the administrative fee on to their hospitals or IDN members.

The concept of GPOs on the surface, is valid especially in regard to their attempt to secure better pricing on products purchased by their members through the power of the total organization, as opposed to the power of one single member. In many instances, GPOs provide value-added services to their members and, certainly, in all cases, provide revenue-generating opportunities, which hospitals may elect to deploy in any way they wish.

In other ways, however, the business model on which most GPOs are based upon is flawed and potentially leads to an abuse of the Medicare laws which were, of course, adopted to prevent physicians and hospitals from being improperly influenced by inappropriate and illegal "kickback" schemes. Indeed, the Medicare regulations specifically include Anti-Kickback and Fraud provisions to guard against this risk. Essentially, the statutes have been developed to protect hospitals, IDNs, physicians or other individuals involved in the sale or purchase of goods and services that are purchased through the Medicare system, from being improperly influenced by vendors and manufacturers. Congress has thus sought to reduce the possibility of undue influence that may be directed against all decision makers involved in the very important contract decisions that are reimbursed through Medicare.

Unfortunately, through various lobbying efforts, GPOs were able to procure what are known as "safe harbors" which provide certain exemptions to Medicare's Anti-Kickback

and Fraud regulations. One "safe harbor" permits a GPO to legally charge so-called "administrative fees or transaction fees." Generating administrative fees cause GPOs and their members to become greatly influenced by the revenue generation side of a contract with a vendor, as opposed to the cost savings side of such an agreement. The larger the company, or vendor, the larger its potential revenue-generating capability becomes, and it is easier for the GPO to "sell" such a company to its members. This results in a significant barrier to small companies that either do not have a large market share that can generate "automatic and large revenues", or the ability to pay the "administrative fees" to the GPO.

To further complicate this scenario, it is common for the GPOs to limit their contracts to only one or two vendors. This is done under the guise of cost savings. The GPO will argue that by limiting their contracts to only a single- or a dual-vendor source, they can negotiate better prices and save money by not dealing with multiple vendors. In reality, however, a GPO's limited choice stifles competition and interferes with a physician's medical decision making. This is because a GPO, which limits vendors must provide the vendor who wins a contract with some value in order to charge the administrative fee. The value provided to the vendor is exclusivity within the GPO system. The vendor, or vendors, selected become the only vendor(s) for periods as long as seven years, and all other competition is effectively precluded from selling to the GPO or its member hospitals. The GPOs also promote exclusive utilization of their contracts, and often times threaten the local hospitals with a reduced percentage of the administrative fee returned to the hospitals, or expulsion from the GPO if they fail to adhere to the GPO national contracts. In addition to the "administrative or transaction fee," vendors also

provide rebates based on market penetration and discounts based on sales within hospitals. These rebates and discounts are paid directly to member hospitals, through the GPO, in cash or credit and may further influence the contracting decision made by the GPO.

The following GPOs represent the majority of US hospitals:

- **Premier Purchasing Partners**, Chicago, IL (independent and equity owner membership, privately owned GPO by 200 equity members, 1,800 hospital members).
- **Tenet Health Care/Broadlane**, Dallas, TX (own and/or manage hospitals and GPO, publicly traded corporation, 110 hospital members).
- **Novation, Inc.**, Chicago, IL. (independent membership, privately owned GPO, 2,000* hospital members).
- **HCA/HealthTrust Purchasing**, Nashville, TN (own and/or manage hospitals, publicly traded corporation, 200 hospital members).
- **MedAssets, Inc.**, St. Louis, MO. (independent membership, privately owned GPO, 1,300* hospital members).
- **Amerinet, Inc.**, St. Louis, MO (independent membership, privately owned GPO, 2,000* hospital members).
- **Consorta, Inc.**, Rolling Meadows, IL, (independent membership, privately owned GPO, 3rd largest GPO including 50% of all Catholic hospitals within the US).

As a smaller market shareholder specifically within the Cardiac Rhythm Management market, BIOTRONIK, Inc. has observed the following significant problems as a direct result of the current GPO system that we are forced to confront on a daily basis:

1. GPOs are driven by revenue generation through the administrative fee process as opposed to cost savings. As a result, companies with smaller market shares have a much more difficult time securing national contracts with GPOs because, by definition, they do not already have the business or the market share. The GPO's value proposition to their members is clear: "We will contract with the large market shareholders and provide improved pricing and additional revenue through the administrative fee process." GPOs will usually take the "path of least resistance," meaning they contract with the larger companies who currently control market share and are easiest to sell to their members. This makes it almost impossible for a small company to obtain a national contract. Additionally, since BIOTRONIK is frozen out of local hospitals because of the national contract, our company can never resolve the problem of growing our market share. Moreover, physicians who may wish to implant our company's products cannot effectively do so. The situation becomes a "CATCH 22," meaning we want to grow our market share but will never grow our share within a system that is designed to block our sales.

2. Since most GPOs generate the largest amount of their total revenues through the "administrative fee process," as opposed to their membership fee process, marketability of their national contracts and market share ownership of their

vendors becomes paramount. As a result, smaller companies do not play on a level playing field. We are unfairly "locked out" of marketing our products to GPO member hospitals, because we cannot obtain national contracts due to our smaller size; and because it becomes more difficult for the GPO to market our goods and services.

3. Larger vendors utilize GPO relationships and contracts as a way to "lock out" competitors. This fact prevents fair competition and prevents hospitals from obtaining cost saving opportunities that can generally be found because larger companies are less likely to lower pricing, since they already control the market share. The larger companies demand value for whatever pricing reductions they may provide. The GPO creates that value by limiting access of the companies not selected as part of their national contracting program, thus restricting market entrance and fair trade. Clearly, this becomes a situation where the larger, more dominant companies attempt to restrict market access by the smaller companies to keep pricing higher and improve their profit margin.

4. Contracts are set for long periods of time and prevent market entrance by smaller companies. For example, the current Premier contract within the Cardiac Rhythm Management business was negotiated for seven years and has four years remaining. This contract is with Medtronic and Guidant, and effectively prevents BIOTRONIK from doing business within the Premier system for four more years.

5. BIOTRONIK controls much larger market share around the world where GPOs are non-existent and business is done on the traditional merits of the product, price, and service. In Europe, BIOTRONIK is the No. 3 market share leader. In Germany, we control 35% of the bradycardia market and 20% of the tachycardia market. In Brazil, we control 70% of the bradycardia market; in Italy, we control 20%; in France, we control 15%; and in Spain, we control 20%. We do not observe the same barriers to market entry in these countries as in the US due to the GPO influence and their need to create revenues through their contracting process.

SUMMARY and PROPOSED SOLUTION

In summary, as a smaller, yet full-service supplier of cardiac pacemakers and ICDs, BIOTRONIK, Inc. is prevented from fairly competing within the US marketplace. Our unfavorable position is the direct result of the national contracting process that is being perpetuated by GPOs and their control of approximately 80-90% of the hospitals in the US. Due to the drive to generate revenues through the "administrative fee process", GPOs will naturally align themselves with the companies that control the largest market share. This simplifies the selling process of the contract to their members and guarantees the largest revenue return possible through the administrative fee process. Furthermore, the GPO "safe harbor" to Medicare's "Anti-Kickback and Fraud" laws, only enables undue influence. A GPO's equity and general members are incentivized to support contracts that return to the GPO, and its participants, the most profit. The danger of such a system is clear and apparent – hospitals may be inclined to make purchasing decisions based on the cash that may be returned to them by the GPO. As a

result of the safe harbor regulations, this "legalized kickback" allows local hospitals to generate additional revenue and generally increases the cost of healthcare delivery, since these funds could be used to reduce the cost of purchasing products. This creates an uneven playing field and prevents fair competition within our market. It restricts our ability as a full-line, full-service company to grow and compete in a fair and equitable manner.

While BIOTRONIK, Inc. supports the basic concept behind most GPOs, we believe the business model is flawed and becomes a legalized way to circumvent Medicare's Anti-Kickback and Fraud regulations. We believe that fair competition is prevented based on the current system and that decisions are made based on how much money the GPO and its members can make, versus how much money could possibly be saved by allowing smaller companies, who are more willing to compete on cost, service, and general product features, to enter the market. GPOs have become restrictions to market entrance and our ability to grow or even to exist.

BIOTRONIK, Inc. would propose the following:

1. Force GPOs to exist and do business based on what they save their members through cost reductions. This will entail elimination of the safe harbor that allows GPOs to charge administrative fees. As a result, GPOs would make their buying decisions based on price, service, and product features, as opposed to how much revenue is generated through the administrative fee process.

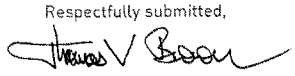
2. Force GPOs to limit their purchases through national contracts that incorporate administrative fees to no more than 50% of their products purchased in any product segment. As a result, at least half of the potential business within the GPO would be "in play" based on price, service, and product features, as opposed to how much money is generated through the administrative fee process.

3. Allow individual hospitals and/or Independent Delivery Networks (IDNs) to charge administrative fees just like GPOs. As a result, local hospitals would be allowed to make their own purchasing decisions based on price, service, and product features, and not be unduly influenced by the GPO because of the cash generated by the GPO's administrative fee that is returned to the hospital. This practice would allow smaller vendors to work with individual hospitals that are members of GPOs to negotiate contracts at the local level without the negative influence of local hospitals losing revenue due to a loss of administrative fees. This change would allow individual hospitals to negotiate their own contracts with smaller vendors, who are not included in GPO contracts, without fear of losing the revenue currently associated with GPO contracts. This would effectively eliminate the one key feature that causes many hospitals to join GPOs; namely, the revenue generating or profit sharing provided by GPOs as a result of the administrative fee process. It would fairly and appropriately level the playing field for all vendors.

4. Force GPOs to allow any company that meets the lowest price offered by their primary vendor to compete as long as they are willing to pay the administrative fee.

As long as the safe harbor statutes remain in place and GPOs are allowed to charge administrative fees, there will generally always be restricted access for small companies. Small companies are discriminated against by GPOs because we cannot generate the revenue through the administrative fee process. GPOs will virtually always choose the "path of least resistance" by contracting with the larger companies, charging the administrative fee, and locking out the smaller vendors; thus providing exclusive access for the "primary" vendor or vendors. Fair and equitable market access is denied smaller companies as a direct result of the process discussed in this testimony.

Respectfully submitted,



Thomas V. Brown
Executive Vice President

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A NONPROFIT AGENCY

April 29, 2002

Senator Herb Kohl
Chairman, Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition, and Business and Consumer Rights
330 Hart Senate Office Building
United States Senate
Washington, DC 20510

Re: Testimony at Subcommittee Hearings on "Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation?"

Dear Senator Kohl:

ECRI just learned that Mr. Joe Kiani, President of Masimo Corporation, will reference ECRI's independent evaluation of Masimo's Signal Extraction Technology (SET) for pulse oximetry during his testimony at the April 30, 2002, Subcommittee hearings on hospital group purchasing organizations (GPOs). ECRI is a nonprofit organization that, for more than 30 years, has independently tested, evaluated, and rated medical devices.

ECRI believes that objective, comparative testing is the best assurance that the nation's patient population has access to the best performing, safest, and most cost-effective medical products.

While ECRI does not permit manufacturers to quote from *Health Devices* in their advertising or promotional materials, the probative value of our findings at Congressional hearings is obvious, and we routinely grant such permission. However, we strongly recommend that our evaluations be read in their entirety, as quotes can be misunderstood when information is reviewed outside its original context. I have mailed a copy of the evaluation, which is published in our journal *Health Devices,* to your Washington office. In addition, a PDF file of the published evaluation is attached to the e-mail version of this letter. ECRI gives permission to the Subcommittee to duplicate and distribute the evaluation for the purpose of the hearings. For your convenience, we have also summarized this evaluation in an abstract attached to the end of this letter.

ECRI has standing to comment on the specific issues of pulse oximeters at the hearings, should we be called upon. In brief, ECRI is a nonprofit health services research agency widely recognized as the world's leading independent organization committed to improving the safety, efficacy, and cost-effectiveness of healthcare technology. For more information about ECRI, please see our Web site at www.ecri.org. Our strict conflict-of-

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interest guidelines are posted at www.ecri.org/documents/447855.htm. We were recently quoted in the *New York Times* on the GPO issues. That article may be found at www.nytimes.com/2002/04/23/business/23SEAL.html (a hard copy is enclosed with the original of this letter).

Should you have any questions about ECRI's published study and findings, please contact Mr. James Keller, Director of ECRI's Health Devices Group, at ECRI at (610) 825-6000, ext. 5279. For information and comments about the broader issues of GPOs for medical technology purchasing, please contact Mr. Tony Montagnolo, ECRI's Chief Operating Officer and Executive Vice President at (610) 825-6000, ext. 5175, or me at ext. 5142. We are available to testify at subsequent hearings on this important healthcare topic.

Sincerely,

[E-mail version not signed]

Jeffrey C. Lerner, PhD
President and Chief Executive Officer
ECRI

United States General Accounting Office

GAO

Testimony

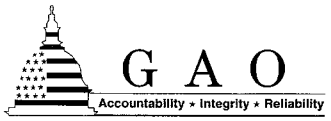
Before the Subcommittee on Antitrust, Competition, and Business and Consumer Rights, Committee on the Judiciary, U.S. Senate

For Release on Delivery
Expected at 2:00 p.m.
Tuesday, April 30, 2002

GROUP PURCHASING ORGANIZATIONS

Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices

Statement for the Record by William J. Scanlon
Director, Health Care Issues



GAO-02-690T

Mr. Chairman and Members of the Subcommittee:

We are pleased to have the opportunity to comment on the role of group purchasing organizations (GPO) in the marketplace for medical devices used in hospitals. Faced with persistent pressures to cut their costs, hospitals over the past two decades have increasingly relied on specialized private firms—GPOs—to keep the cost of supplies in check. Hospitals buy everything from sophisticated medical devices—for example, cardiac defibrillators—to commodities such as saline solution through GPO-negotiated contracts. By pooling the purchases of their member hospitals, these specialized firms are intended to negotiate lower prices from vendors (manufacturers and distributors), which can benefit hospitals and, ultimately, consumers and payers of hospital care (such as insurers and employers). The price advantages of a GPO are expected to be greater for large GPOs, which negotiate on behalf of nearly 2,000 hospitals. To increase its leverage with vendors, a GPO often selects only certain manufacturers and vendors of a product to include in its catalog. According to GPOs, this selection of some vendors and exclusion of others reflects judgments about both product quality and price.

Some manufacturers—especially small manufacturers of medical devices—allege that contracting practices of some large GPOs have blocked their access to hospitals' purchasing decisionmakers. The manufacturers contend that these practices ultimately deny patients access to innovative or superior medical devices. These concerns have spurred calls for reexamining federal antitrust guidelines regarding GPOs. Issued in 1993, these guidelines articulate an antitrust enforcement policy that affords GPOs considerable latitude to merge and grow. The policy has permitted the creation and growth of the largest GPOs, formed in the 1990s.

To assist the Subcommittee as it considers GPOs' effects on medical device purchasing, this statement provides an overview of the GPOs and their operations and summarizes results from our pilot study, which the Subcommittee requested, of a selected metropolitan area's hospital purchasing. This study was exploratory, testing the feasibility of collecting price and purchase data for medical devices, and will be followed by a broader study covering more areas, devices, GPOs, and hospitals. Specifically, this statement details (1) the extent to which, in one market, hospitals buying pacemakers and safety needles saved money by using a GPO contract and (2) the extent to which these hospitals purchased pacemakers and needles from small manufacturers. To learn about GPO operations, we interviewed officials of 11 hospitals, four GPOs, nine medical device manufacturers, two industry associations, and the Department of Justice (DOJ). We established the feasibility of collecting price and purchase data on medical devices by obtaining such data on pacemakers and safety needles[1] for 2000 from 18 hospitals in one greater metropolitan area.[2] We chose to study pacemakers and safety needles because they are two types of medical devices that are commonly purchased by hospitals. Hospitals in our sample purchased 121 models of pacemakers and 196 models of safety needles. We compared GPO-negotiated prices to prices obtained by hospitals purchasing on their own. Because all these hospitals did not purchase each model, price comparisons were only possible for subsets of models. Taken together, comparisons involved contracts of eight GPOs, 23 models of safety needles, and 42 models of pacemakers. In many cases, more than one hospital purchased a particular device; in those cases, the price refers to the median price. We also used the purchase data to determine the extent to which these hospitals purchased these devices from small manufacturers. We did not independently verify the information in appendix I. Our work was conducted from October 2001 through April 2002 in accordance with generally accepted government auditing principles.

[1]The term safety needle includes many different types of devices with features to reduce the risk of needlestick injuries for health care workers.

[2]Price data did not reflect manufacturers' rebates—which hospitals may receive regardless of whether they used a GPO contract or purchased items on their own—or other payments earned by hospitals purchasing with a GPO contract. In our statement, the term "hospitals" refers to single facilities as well as health systems with multiple hospitals. Seven hospitals reported safety needle data for 2001.

In summary, for the hospitals that we studied, a hospital's use of a GPO contract did not guarantee that the hospital saved money: GPOs' prices were not always lower and were often higher than prices paid by hospitals negotiating with vendors directly. Specifically, we examined price savings with respect to three factors:

- Whether hospitals using GPO contracts got better prices than hospitals that did their own contracting varied widely by product model. For some pacemaker models, the hospitals using GPO contracts got considerably better prices—up to 26 percent lower than the hospitals not using a GPO contract. But for other models, hospitals using a GPO contract got prices that were much worse–up to 39 percent higher than hospitals not using a GPO contract. Similar results held for hospitals using large GPOs—those whose members purchase more than $6 billion per year with their contracts—compared to hospitals buying on their own.

- Price savings differed by size of hospital. Large hospitals—those with more than 500 beds—often obtained lower prices on their own than by using a GPO. By contrast, small and medium-sized hospitals were more likely to obtain price savings using a GPO contract. But these hospitals' experiences also ranged widely: Some hospitals' GPO contract prices were much lower—and others much higher—than prices negotiated by hospitals on their own.

- Price savings had little relationship to the size of the GPO. Hospitals using contracts of large GPOs—those whose members purchase over $6 billion per year with their contracts—did not necessarily obtain better prices than hospitals using smaller GPOs' contracts. This lack of consistent price savings is contrary to what would be expected for large GPOs.

In the metropolitan market we studied, hospitals bought pacemakers and safety needles predominantly from large manufacturers. We could not determine the extent to which hospitals' reliance on large manufacturers of these two devices reflected hospitals' independent preferences for large manufacturers' products or the effect of GPOs' contracting practices on hospitals' purchasing decisions, since almost all hospitals in our sample belonged to GPOs.

The data on hospital purchases in our study market raise questions about whether GPOs—and especially large GPOs—achieve price savings

consistently, as expected. In addition, the limited number of purchases from small manufacturers in our study market suggests the need to examine data from additional markets, given small manufacturers' concerns that GPOs' practices inappropriately limit their access to potential purchasers. This additional information on price savings and GPO practices could inform an examination of GPOs' treatment under federal antitrust policy.

Background

Hospitals' budgets for medical devices and other goods are substantial. Many hospitals buy medical devices and other supplies through GPOs, which are generally owned by member hospitals and vary in size and scope of services. GPOs are expected to use volume purchasing as leverage in negotiating prices with vendors. In exchange for administrative services and the ability to sell through a GPO to its member hospitals, vendors pay administrative fees to a GPO based on the hospitals' purchases made using that GPO's contract. These fees, sanctioned under Medicare law, cover the GPO's costs; GPOs often distribute surplus fees to their owners. Federal antitrust guidelines help a GPO determine whether its business practices and market share are likely to be questioned as anticompetitive by enforcement agencies.

Hospitals and Medical Devices

According to an American Hospital Association (AHA) survey, roughly 4,900 nonfederal community hospitals[3] spent an estimated $173 billion on nonlabor supplies, services, and capital in 2000. A significant share of hospitals' nonlabor costs include such goods as pharmaceuticals and medical devices. Hospitals buy these goods through their own purchasing departments, and many hospitals—in addition to contracting on their own with vendors—use GPO-negotiated contracts for at least some of their purchasing. Some hospitals have large or more sophisticated purchasing operations, but even hospitals belonging to large chains or health systems often do at least some purchasing through a GPO. The proportion of hospitals belonging to at least one GPO is substantial: estimates range from 68 percent to 98 percent.[4]

Medical devices that hospitals buy span a wide array of products, such as pacemakers, implantable defibrillators, and infusion pumps. Some device manufacturers are small companies that offer one product or a few closely related products while others are large firms that offer many, often unrelated, products. The Medical Device Manufacturers Association estimates that some devices become obsolete within 2 to 3 years—when the next generation of a particular device becomes available. Manufacturers market medical devices in medical journals and trade shows but place considerable value on having access to clinicians in hospitals as well as to hospital purchasing departments, which make the final buying decisions.

GPOs' Size, Structure, and Benefits

According to the Health Industry Group Purchasing Association, hundreds of GPOs operate today, but only about 30 negotiate sizeable contracts on behalf of their members. The emergence of these large GPOs in part stems from GPO mergers in the mid-1990s. Joint ventures and mergers created the two largest GPOs, Novation and Premier, which have annual purchases by member facilities using their contracts of $17.6 billion and $14 billion, respectively. Other GPOs in our pilot study have less than $6 billion in

[3]Community hospitals include all nonfederal short-term general and special hospitals whose facilities and services are available to the public. Most community hospitals have fewer than 200 beds while roughly 5 percent have over 500 beds.

[4]AHA survey data indicate that 68 percent of hospitals belonged to a GPO in 2000 while, according to the Health Industry Group Purchasing Association, 96 to 98 percent of hospitals belonged to a GPO.

annual purchases by member facilities. (See appendix I for purchasing volumes of GPOs in our pilot study.) In addition to differences in size, GPOs differ in scope. Some negotiate national contracts and offer many services beyond purchasing, such as programs emphasizing the gains in safety and economic value resulting from standardization, or specialized software to help ensure that hospitals are not overcharged. Others serve regional or local hospital markets and provide fewer additional services.

GPOs differ in their corporate structures and their relationships with member hospitals. All large GPOs and many smaller GPOs are for-profit entities, some of which are owned by not-for-profit hospitals.[5] Other GPOs have shareholders independent of the member hospitals, which themselves do not necessarily hold an ownership stake. An example of a for-profit GPO owned by not-for-profit hospitals is Premier. Premier is owned by 203 not-for-profit health care organizations that operate approximately 900 hospitals. Other for-profit GPOs are owned by investors that are not member hospitals; for example, InSource is owned by MedAssets, a private purchasing and contract services company. Broadlane's owners consist of individual investors as well as for-profit and not-for-profit organizations including Tenet Healthcare, a nationwide provider of health care services.[6] Some GPOs are jointly owned. For example, both Novation and Healthcare Purchasing Partners International (HPPI) are owned by the same two networks of hospitals and physicians. Network members purchase using Novation contracts. However, non-network members purchase using HPPI contracts, which are negotiated by Novation. Some GPOs, such as HealthTrust, require that members do not belong to other GPOs. In addition, some GPOs, such as Novation and Amerinet, contract with manufacturers to supply products sold under the GPO's own "private-label" brand name. (See appendix I for a summary of characteristics of GPOs in our pilot.)

According to officials of GPOs and a GPO trade organization, benefits that GPOs provide to member hospitals[7] include, in addition to lower prices,

[5]Hospital-owned GPOs may have nonowning members (affiliates), in addition to member hospitals that are shareholders.

[6]InSource is one of two GPOs owned by MedAssets. Broadlane began as a division of Tenet Healthcare, which is now one of its owners.

[7]In addition to hospitals, many GPOs include as members other health care organizations, such as nursing facilities. We focus on hospitals, which are key buyers in the medical device market.

reduced costs due to hospitals being able to reduce the size of purchasing departments, as well as assistance with product-comparison analysis and standardization of products. Benefits that GPOs say they provide to manufacturers with which they contract include, in addition to access to hospital decisionmakers, cost savings due to reducing manufacturers' contracting, marketing, and sales activities. According to representatives of some manufacturers, many GPOs act as gatekeepers to hospital purchasing decisionmakers and charge the manufacturers administrative fees as the price of access to their member hospitals.

GPO Price Negotiation and Administrative Fees

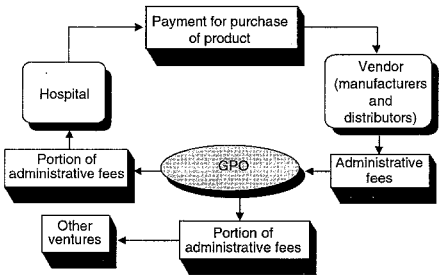
In order to sell to hospitals through GPO contracts, vendors generally submit proposals to a GPO—in response to Requests for Proposals (RFP)—that are then evaluated. Based on these evaluations, the GPO enters into negotiations with select vendors to determine prices and, in some cases, administrative fees that vendors pay to the GPO. Hospitals then buy directly from the manufacturer for a price specified in a GPO contract. Often prices through a GPO-negotiated contract vary based on each hospital's volume of purchases and the extent to which the member hospital delivers on its "commitment" to buy an agreed-upon share of its purchases of a certain product from a particular manufacturer.[8] The more of a product that a hospital purchases, the lower the price per unit it may pay the manufacturer. A hospital's price may also vary depending upon the share of a product it purchases from a manufacturer. For example, a hospital that buys only 25 percent of its cardiac stents from one manufacturer may pay nearly three times more per stent than one that purchases all its stents from that manufacturer. Member hospitals may have an additional financial incentive to use the GPO contract. The extent to which a hospital buys using the GPO's contracts may affect the share of the administrative fees that the GPO returns to the hospital.

[8]Volume and commitment are also important factors in manufacturers' contracts with hospitals that purchase without using a GPO contract.

Although GPOs provide services to hospitals and are often organized by hospitals, many finance their operations primarily through the administrative fees paid by manufacturers and other vendors. These fees are typically calculated as a percentage of each hospital's purchases from a vendor. The Social Security Act, as amended in 1986, allows these fees, which would otherwise be considered 'kickbacks' or other illegal payments to the GPO.[9] Regulations establishing appropriate administrative fees, enforced by the Office of Inspector General in the Department of Health and Human Services, state that the fee structure must be disclosed in an agreement between the GPO and each participating member. The agreement must state that fees are to be 3 percent or less of the purchase price, or if not fixed at 3 percent or less, the amount or maximum amount that each vendor will pay. The GPO must also disclose in writing to each member, at least annually, the amount received from each vendor with respect to purchases made by or on behalf of the member. The fees tend to be higher on purchases by hospitals that buy most or all of an item from one vendor. In addition to covering their operating expenses with these fees, GPOs, with the approval of their boards of directors, often distribute surplus fees to member hospitals but may also use administrative fees to finance new ventures, such as electronic commerce, that are outside their core business. (See fig. 1.)

[9]Any return of a portion of a purchaser's payment for the purpose of obtaining favorable treatment in connection with a contract may be considered a kickback.

Figure 1: Money Flows Related to Hospital Purchases Using a GPO



Source: GAO interviews with GPOs and a GPO trade association.

The complex financial flows among vendors, GPOs, and hospitals have raised concerns that GPOs' interests may diverge from those of hospitals. According to some small manufacturers, GPOs have an incentive not to seek the lowest price because higher prices yield higher administrative fees. These manufacturers further suggest that GPOs, by relying on vendors' fees, become agents of manufacturers and assist them in limiting competition. By contrast, according to some GPOs, they act as an extension of hospitals and GPO members have input into the GPOs' product selections. GPOs acknowledge that a manufacturer dominant in a product line may contract with a GPO, or agree to a favorable contract, to preserve its market share and exclude competitors. However, GPOs assert that this selective contracting is part of a competitive process allowing the GPO to negotiate lower prices. GPOs also emphasize that participation in a GPO is voluntary, so the GPO must reflect what the hospitals want if it is to retain their business.

Antitrust

Recognizing that joint purchasing arrangements among hospitals may enable members to achieve efficiencies that will benefit consumers but may, in some cases, pose risks of harming consumers by reducing competition, DOJ and the Federal Trade Commission (FTC) issued in 1993 a guideline to help GPOs and others gauge whether a particular GPO arrangement is likely to raise antitrust problems.[10] This guideline sets forth an "antitrust safety zone" for GPOs that meet a two-part test, under which the agencies, absent extraordinary circumstances, will not challenge the arrangement as anticompetitive. Essentially, the two-part test is as follows:

1. *Purchases through a GPO must account for less than 35 percent of the total sales of the product or service in question (such as pacemakers) in the relevant market.* This part of the test addresses whether the GPO accounts for such a large share of the purchases of the product or service that it can effectively exercise increased market power as a buyer. If the GPO's buying power drives the price of the product or service below competitive levels, consumers could be harmed if suppliers respond by reducing output, quality, or innovation.

2. *The cost of purchases through a GPO by each member hospital that competes with other members must amount to less than 20 percent of each hospital's total revenues.* This second part of the test looks at whether the GPO purchases constitute such a large share of the revenues of competing member hospitals that they could result in standardizing the hospitals' costs enough to make it easier to fix or coordinate prices.[11]

However, the guideline states that a purchasing arrangement is not necessarily in violation of the antitrust laws simply because it falls outside the safety zone. Likewise, the guideline suggests that even a purchasing arrangement that falls within the safety zone might still raise antitrust concerns under "extraordinary circumstances." Each arrangement has to be examined according to its particular facts. In this regard, the guideline also describes factors that reduce antitrust concerns with purchasing arrangements that fall outside the safety zone.

[10]U.S. Department of Justice and the Federal Trade Commission, *Statements of Antitrust Enforcement Policy in Health Care*, Statement 7 (Washington, D.C.: August 1996).

[11]*Statements of Antitrust Enforcement Policy in Health Care*, Statement 7, p. 23.

Price Savings Not Obtained Consistently with GPO Contract and Savings Varied by Model and Size of Hospital

GPOs did not always obtain better prices for member hospitals. The advantage or disadvantage of GPO prices varied by the model purchased and size of hospital—but lacked a clear relationship to size of GPO. In our pilot study, we compared median GPO and median non-GPO prices for purchases by hospitals and found the following:

- Among hospitals of all sizes, hospitals using GPO-negotiated contracts to buy pacemakers and safety needles often paid more than hospitals negotiating on their own. This finding also held for hospitals using large GPOs, compared to hospitals negotiating on their own.
- Between hospitals of different sizes, small and medium-sized hospitals buying pacemakers were more likely than large hospitals to save money when using GPO-negotiated contracts.[12]

We also compared prices between large GPOs and smaller GPOs: Hospitals of all sizes using a large GPO's contracts almost always saved money on safety needles but often paid more for pacemakers, compared to those using smaller GPOs' contracts. Large GPOs would be expected to achieve price savings consistently. In all these comparisons, the price savings or additional cost that hospitals realized—for example, by using a GPO or by negotiating on their own—often varied widely from model to model.

Use of GPO Contract Often Did Not Yield Price Savings for Hospitals Buying Pacemakers and Safety Needles

Purchasing with GPO contracts did not ensure that hospitals saved money. Among hospitals of all sizes in our study market, those using GPO-negotiated contracts for pacemakers and safety needles often paid more than those negotiating on their own. The median GPO-negotiated price was higher than the median price hospitals paid on their own for all six safety needles models and over three-fifths of the 41 pacemaker models that could be compared.[13] Similarly, the use of a large GPO—one with an annual purchase volume greater than $6 billion—did not guarantee price savings. Hospitals using contracts negotiated by a large GPO paid more

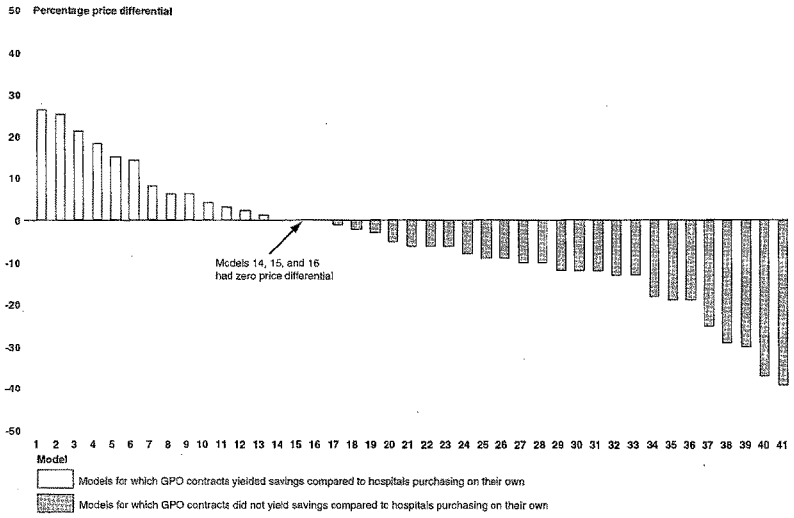
[12]We compared GPO-negotiated prices to non-GPO prices for each size-category of hospital separately. For example, prices were compared for large hospitals using GPO contracts with large hospitals buying on their own.

[13]Price comparisons include instances in which only the purchases of two or three hospitals could be included.

than hospitals purchasing on their own for the six safety needle models and roughly half of the 22 pacemaker models that could be compared.

The price savings or additional costs that hospitals obtained using GPO-negotiated contracts varied by model. For different safety needle models, median GPO-negotiated prices exceeded prices negotiated by a hospital buying on its own by from 1 percent to 5 percent. For different pacemaker models, the variation was much greater: median GPO-negotiated prices ranged from 26 percent less to 39 percent more than the median price paid by hospitals purchasing on their own. (See fig. 2.)

Figure 2: Differences between Median GPO Contract Prices and Median Non-GPO Contract Prices for 41 Pacemaker Models



Note: Each bar refers to a different model of pacemaker. The length of the bar reflects the difference between the price paid by hospitals using GPO contracts and the price paid by hospitals not using GPO contracts to purchase the same model. Median prices were calculated and used in comparisons that included more than one GPO-negotiated price or hospital purchasing on its own.

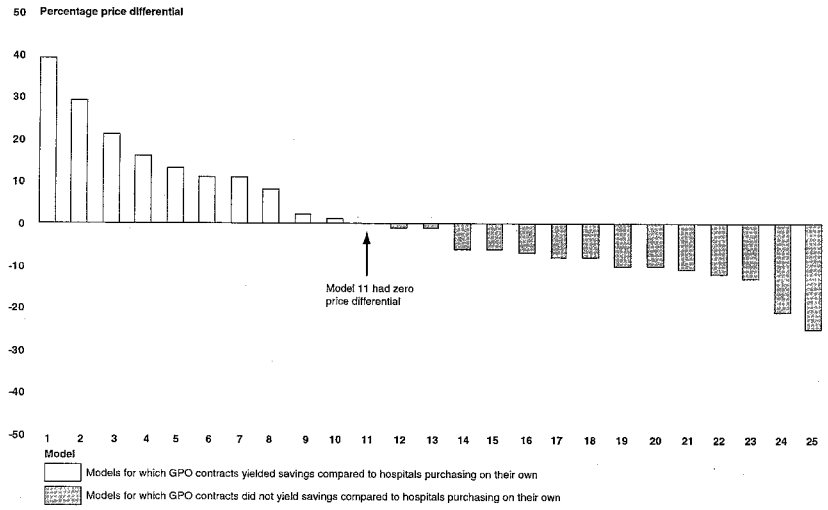
Source: GAO survey of hospitals in a greater metropolitan area.

Small and Medium-Sized Hospitals More Likely Than Large Hospitals to Realize Price Savings on Pacemakers with GPO Contract

We examined how hospitals of different sizes using GPOs fared relative to their peers purchasing pacemakers on their own and found that whether there were savings depended on the size of the hospital.[14] The 4 small hospitals (those with fewer than 200 beds) always did better with a GPO contract. The 11 medium-sized hospitals (those with 200 to 499 beds) did better with a GPO contract for 40 percent of the models (see fig. 3), and the 3 large hospitals rarely did better with a GPO contract—compared with their respective peers purchasing on their own (see fig. 4). Even though small hospitals buying on their own generally paid higher prices than the small hospitals using GPOs, the GPO-negotiated price was not much lower—from 1 to 6 percent—than what they paid on their own.

[14]Comparisons by hospital-size for the purchase of safety needles were not possible. Several small and medium-sized hospitals did not purchase safety needles. Of those that did buy safety needles, the majority used GPO contracts for all their purchases or bought items for which there was no comparable purchase without a GPO contract.

Figure 3: Differences between Median GPO Contract Prices and Median Non-GPO Contract Prices for 25 Pacemaker Models Purchased by Medium-Sized Hospitals

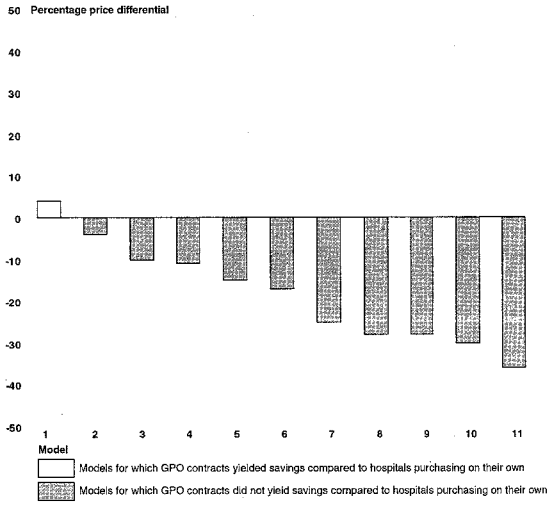


Note: Each bar refers to a different model of pacemaker. The length of the bar reflects the difference between the price paid by medium-sized hospitals using GPO contracts and the price paid by medium-sized hospitals not using GPO contracts to purchase the same model. Medium-sized hospitals are hospitals with from 200 to 499 beds. Median prices were calculated and used in comparisons that included more than one GPO-negotiated price or hospital purchasing on its own.

Source: GAO survey of hospitals in a greater metropolitan area.

As figures 3 and 4 show, the range of price savings or additional costs associated with GPO contracts was considerable. For example, for medium-sized hospitals, the median GPO-negotiated price was 39 percent lower for model 1 and 25 percent higher for model 25 than the median price paid by these hospitals purchasing on their own.

Figure 4: Differences between GPO Contract Prices and Non-GPO Contract Prices for 11 Pacemaker Models Purchased by Large Hospitals



Note: Each bar refers to a different model of pacemaker. The length of the bar reflects the difference in the price paid by large hospitals using GPO contracts and the price paid by large hospitals not using GPO contracts to purchase the same model. Large hospitals are hospitals with 500 or more beds. Median prices were calculated and used in comparisons that included more than one GPO-negotiated price or hospital purchasing on its own.

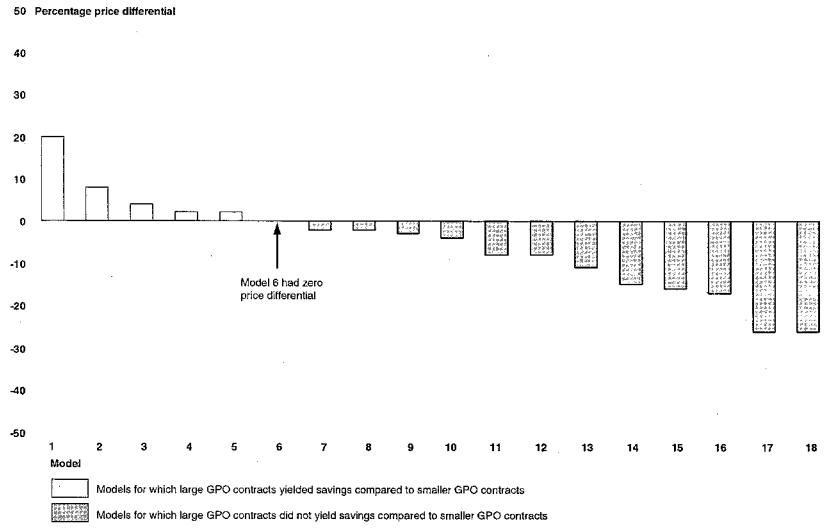
Source: GAO survey of hospitals in a greater metropolitan area.

Compared to Smaller GPOs, Use of Large GPOs Yielded Price Savings for Needles—Less Often for Pacemakers

The size of a GPO was not related consistently to whether a hospital, when using a GPO contract, obtained a better price. Whether use of large GPOs offered price savings varied by type of device: for safety needles, they were more likely to obtain better prices and for pacemakers, they were less likely to do so. Specifically, the median price paid by hospitals using a large

GPO's contract to purchase safety-needles was nearly always lower—for 18 of the 19 types of needles we could compare—than the median price paid by hospitals using a smaller GPO's contract. For pacemakers, a large GPO's contract infrequently yielded better prices than smaller GPOs' contracts—for only 5 of the 18 pacemakers we could compare. In this case, the higher prices associated with most of these pacemaker purchases run counter to the expectation that large GPOs yield substantial price advantages. (See fig. 5.)

Figure 5: Differences in Median Prices between a Large GPO's Contracts and Other GPOs' Contracts for 18 Pacemaker Models



Note: Each bar refers to a different model of pacemaker. The length of the bar reflects the difference in the price paid by hospitals using a large GPO's contract—one whose members purchase over $6 billion per year with its contracts—and the price paid by hospitals using smaller GPOs' contracts to

purchase the same pacemaker model. Median prices were calculated and used in comparisons that included more than one GPO-negotiated price or hospital purchasing on its own.

Source: GAO survey of hospitals in a greater metropolitan area.

Figure 5 shows that, as with the previous comparisons, the range of price savings or additional costs associated with large GPOs was wide. For hospitals using large GPOs' contracts to buy pacemakers, the median price paid ranged from 20 percent less for one model to 26 percent more for another, compared with the median price paid by hospitals using smaller GPOs' contracts.

Hospitals Rarely Purchased Selected Medical Devices from Small Manufacturers

Regardless of whether a GPO contract was used, hospitals bought pacemakers and safety needles predominantly from large manufacturers.[15] In our study, 5 of the 16 manufacturers from which hospitals purchased were small; however, purchases from these 5 represented a small minority of the models bought (1 of 121 pacemaker models and 22 of 196 safety needle models). Almost all purchases from small manufacturers in our pilot were made by hospitals buying on their own; only one hospital purchased from a small manufacturer using a GPO contract.

We could not determine the extent to which hospitals' reliance on large manufacturers of these two devices reflected hospital preference or the effects of GPOs' contracting practices, because almost all hospitals in our sample belonged to GPOs. Representatives from small manufacturers whom we interviewed stated that some incentives in GPO contracts penalize hospitals purchasing off-contract. However, hospital personnel whom we interviewed emphasized different factors as influencing their purchasing decisions, including clinical considerations for pacemakers and cost for safety needles. Seventy-one percent of hospitals purchased a pacemaker and 15 percent a safety needle outside of their GPO contracts.

Concluding Observations

While this is a pilot study based on one market, the data raise questions about one of the intended benefits from having large GPOs. In our study market, GPOs of different sizes realized comparable savings for member hospitals. Buying through a large GPO did not guarantee a hospital the

[15]For our study, we defined small manufacturers of safety needles as those with 500 or fewer employees and small manufacturers of pacemakers as those with a market share of less than 10 percent.

lowest prices. In fact, there were several instances in which individual hospitals using a large GPO's contracts paid prices that were at least 25 percent higher than prices negotiated by hospitals on their own, and smaller GPOs also sometimes offered better prices. Clearly, more evidence on GPOs and their effects is needed, since our data pertain to one urban market, two types of medical devices, eight GPOs, and 18 hospitals. To assist the Subcommittee, we plan to obtain data from a broader array of geographic areas and for other devices, hospitals, and GPOs. Gathering additional information on GPOs' benefits and possible drawbacks could inform an examination of antitrust policy toward GPOs.

Contacts and Acknowledgments

For more information regarding this statement, please contact Janet Heinrich at (202) 512-7114 or Jon Ratner at (202) 512-7107. JoAnne R. Bailey, Hannah F. Fein, Kelly L. Klemstine, and Michael L. Rose made key contributions to this statement.

Appendix I

Characteristics Of Selected GPOs

The information in this appendix illustrates how GPOs in our study market vary in size, ownership structure, and profit status. The appendix contains information obtained both from GPO Web sites during April 2002 and through telephone interviews. We did not independently verify the information in this appendix. (See table 1.)

Table 1: Characteristics of Selected GPOs in Our Pilot Study Market

GPO	Current annual purchasing volume (in billions)	GPO's profit status	Owners of the GPO	Owners' profit status	Members/customers using GPO contracts	Miscellaneous features
Novation	$17.6	For-profit	Novation is owned by VHA, a nationwide network of community-owned health care systems and their physicians, and UHC, an alliance of academic health centers.	VHA: for-profit, UHC: not-for-profit	Members include 2,300 not-for-profit hospitals and other health care sites.	Novation has a private label brand with over 250 product lines and over $1 billion per year in sales.
Premier	14.0	For-profit	Premier is owned by 203 health care organizations that operate approximately 900 hospitals.	Not-for-profit	Members include over 1,800 hospitals and other health care sites.	The average of contract administrative fees paid to Premier is 2 percent.
AmeriNet	5.2	For-profit	AmeriNet is owned by AmeriNet Central, Intermountain Health Care, and Vector.	Intermountain Health Care: Not-for-profit. Profit status for AmeriNet Central and Vector was not readily available.	Members include 14,315 acute care hospitals and other health care sites.	Membership in AmeriNet grew by 3,172 new members in 2000. Many members are health care organizations other than hospitals. Amerinet has a private label brand.
HealthTrust	4.0	For-profit	HealthTrust is owned by HCA, Inc., LifePoint Hospitals, Triad Hospitals, and Health Management Associates.	For-profit	Members include 650 not-for-profit and for-profit acute care hospitals and other health care sites.	There is no membership fee for a member to belong to HealthTrust. HealthTrust does not allow members to belong to more than one GPO.

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GPO	Current annual purchasing volume (in billions)	GPO's profit status	Owners of the GPO	Owners' profit status	Members/customers using GPO contracts	Miscellaneous features
InSource	3.0	For-profit	InSource is owned by MedAssets, a private purchasing and contract services company.	For-profit	Members include over 11,000 acute care hospitals and other health care sites.	MedAssets also owns Health Services Corporation of America, a national GPO.
Consorta	2.5	For-profit	Consorta is owned by 12 Catholic-sponsored, faith-based, not-for-profit health systems: Ancilla Systems, Ascension Health Systems, Catholic Health Initiatives, Hospital Sisters Health Systems, Ministry Health Care, Provena Health, Saint Clare's Health Services, Sisters of St. Francis, St. John Health System, Trinity Health - National Region, Wheaton Franciscan Services, Inc., and Via Christi Health Systems.	Not-for-profit	Members include 320 acute care hospitals and over 800 other health care sites.	Consorta seeks 85 to 90 percent voluntary compliance (buying through its contracts) from its members.
Broadlane	2.3	For-profit	Broadlane is owned by a mix of for-profit and not-for-profit organizations and individual investors. Information about each specific investor was not readily available.	For-profit and Not-for-profit	Customers include 476 acute care hospitals and 1,200 to 1,500 other health care sites.	Broadlane has two types of purchasing programs. Customers that buy through one program buy almost 80 percent of their goods and services through the GPO. The second program is supplemental, with more lenient contracting and buying requirements.

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GPO	Current annual purchasing volume (in billions)	GPO's profit status	Owners of the GPO	Owners' profit status	Members/customers using GPO contracts	Miscellaneous features
HPPI	1.5	For-profit	HPPI is owned by VHA, a nationwide network of community-owned health care systems and their physicians, and UHC, an alliance of academic health centers.	VHA: for-profit, UHC: not-for-profit	Members include 998 acute-care facilities 5,022 other health care sites.	Agreements offered by HPPI are negotiated by Novation. HPPI was created to enable VHA and UHC to market Novation agreements to health care organizations that do not belong to either VHA or UHC.

Note: Current annual purchasing volume was obtained from GPOs or their Web sites during April, 2002. The year that corresponds to a GPO's purchasing volume may differ by GPO; GPO Web sites often referred to this amount as the GPO's "current annual purchasing volume."

Source: GPO Web sites and GAO interviews with GPOs. Additional information was obtained from Modern Healthcare (http://www.modernhealthcare.com/charts/gpo_chart.php3?id=1), accessed September, 2001.

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RE: Testimony for Hearing April 30th at 2:30PM Regarding Group Purchasing Organizations and the Medical Community

Seth Bloom
U.S. Senate Committee on the Judiciary
Sub-committee on Anti-Trust, Competition and Business Consumer Rights
224 Dirksen Senate Office Building
Washington D.C. 20510

Dear Seth,

Attached please find the testimony that I have provided for the hearing this week. I have plane reservations and will be there on Monday afternoon. I will try to get by when I get in, if possible, otherwise I will see you at the hearing. I appreciate your time and patience regarding this issue and look forward to meeting you there. I am not a professional writer and only provided personal testimony once in Jefferson City, Missouri for HB266. I am learning the process slowly. I hope the testimony is not too lengthy. I have to include the part about my son to keep his spirit alive and well inside of me. I promised him the day I left that I would fight this thing until the end. The last thing he said to me was "Mom, I Love You, Life is really great isn't it". I agreed and we hugged. That was the last time I saw him alive, glowing with pride and power. He was behind me all the way and was a fighter himself for many good causes.

Thanks again for your time
Respectfully yours,

Julia Naunheim Hipps RN

April 26, 2002
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U.S. Senate Committee on the Judiciary
Subcommittee on Anti-trust, Competition and Business Consumer Rights
224 Dirksen Senate Office Building
Washington, D.C. 20510
1-202-224-5653
fax: 1-202-228-2294

ATTN: Senator Kohl and all other Committee Members

RE: Group Purchasing Organizations and the Effects on One Human Beings Life:

RN Infected with Hepatitis C from A Needlestick Injury October 29, 1999

Thank you all for taking the time to address this important issue regarding Group Purchasing Organizations and the Health Care Community in the United States. My name is Julia Naunheim Hipps, an RN from St. Louis, Missouri, that was infected in October of 1999 with Hepatitis C, Type 1B, after providing nursing services to a patient in her home. My injury is unique, in that I was doing everything according to Manufacturers guidelines, OSHA guidelines, Nursing Policies and Procedures and training provided by my employer, Barnes Jewish Hospital. The product was designed, intended, marketed and sold to be used as a reusable device, stating that it could be reused hundreds of times from patient to patient. This is in direct violation of OSHA guidelines and continues to pose a danger to both the healthcare providers and the community. The product I am talking about is the reusable blood drawing device that is used to obtain blood specimens from a patient. Manufacturers name will remain anonymous as several other companies market and sell similar products all sold through a Group Purchasing Organization that provides medical supplies to numerous hospitals, BJC included. Novation and Premier are among the top suppliers of this equipment to the healthcare industry and are the primary causes of preventing hospitals from obtaining life saving new equipment and needed medical supplies that are much safer to use in the health care industry.

Over the past 10 years, nurses like Lynda Arnold, infected with HIV, Karen Daley infected with HIV and HCV, Lisa Black infected with HIV and HCV and myself infected with HCV have been very outspoken about our injuries. During this time we have all carried the torch for a period of time and then passed it on to others that have the dedication and energy while recovering from the side effects of treatment to continue the good works that were started in the past. Since that time nurses have come a long way in lobbying for safer devices by influencing the Federal Needlestick Prevention Act in 2000,

signed by President Clinton and the revision to OSHA Guidelines and Bloodborne Pathogens Standard; several states have gone further to present tighter legislation, like Missouri, that protects not only the private sector but the public sector as well. All of these changes have occurred because of the number of nurses who have been willing to participate politically in this cause as a result of their injuries, exposing themselves professionally and personally by revealing their health related problems, including Hepatitis C, HIV and sometimes both as well as other fatal bloodborne pathogens.

While our activism as nurses has been successful in making these legislative changes and working with the political process, the stumbling block in really providing up to date safety devices has been critically discouraged by the on going contracts between Hospitals and Group Purchasing Organizations. Even if the hospitals want to utilize safer devices, they are bound by agreements they entered into years ago, never believing that they would loose all control on purchasing equipment for their patients and healthcare workers. Newer and safer medical treatment and safety devices that have proven to be safer and more cost effective have been locked out by larger corporations that have the market share contractually, providing financial incentives to some and penalizing those who breach these contracts, making it difficult for the healthcare industry to make the necessary changes to save lives of both patients and those who provide care, including nurses, firefighters, policemen, EMT's and other frontline workers.

While these contracts in the past may have provided financial savings to the healthcare industry at a time when the medical community was looking at any and all means of saving costs to remain financially stable, these contracts today are costing the lives of many and putting the financial burden back on the tax payers. Increasing cost for Medicare, Workman's Compensation Fund, Social Security Disability and Lost wages, as well as personal and financial ruin for those who have dedicated their lives to helping others have been sacrificed. The criminal responsibility of holding back innovative and proven treatments by Group Purchasing Organizations is what is in question today. The inability to provide the safety equipment so that healthcare workers can perform their job safely has been seriously violated. The concept of group purchasing is now a detriment to those working in the healthcare industry because it discourages providers from evaluating and purchasing the necessary equipment to save lives and protect caregivers. Those who lose in the end are the patients and the healthcare workers. In this group you can also include yourselves, your family members and friends because it ultimately boils down to the most vulnerable people, the sick, which are denied medical care that could save lives.

I will not get into all the statistical data that I am sure has already been submitted as testimony, the 1000's of people who have become infected for no other reason except by being on the frontline to save others lives. The billions of dollars it is costing taxpayers, the personal trauma it has caused so many and the unnecessary loss of life. 2 healthcare workers die daily as a result of these injuries according to the Service Employees International Union. The loss of dedicated nurses, which is declining at record levels, due to unsafe working conditions in the health care field is another serious issue facing our country today. So many factors that affect so many ordinary citizens should be carefully analyzed so that we can rebuild a foundation of prevention and protection. This

is much more economical and would significantly reduce to rampant spread of HCV and HIV as we know it today. Our country could stand to shut down many things temporarily but frontline workers like Nurses, Policemen, Firemen, EMT's and caregivers would be sorely missed should we all shut down for even 24 hours. Millions of lives would be lost and billions of dollars in the economy would be seriously compromised should ALL firefighters stop doing what they do best: fighting fires and saving lives, ALL nurses stop providing care and saving lives, ALL policemen stop patrolling our streets ad saving lives and ALL EMT's stopped providing life saving procedures on a moments notice and saving lives. We are paying the price while our efforts to protect this country; our families and our friends from harm are being taken advantage of. Big business continues to make its profits at our expense. We only ask for fairness and safety in the work place, you already have our dedication to our chosen professions. That was made very clear on September 11th when all those frontline workers spent endless hours trying to save so many lives. There dedication is unquestionable, as we have all seen.

How Group Purchasing Contracts Have Affected My Life as an RN

I became a nurse activist for safety needles shortly after I became infected with Hepatitis C from a needlestick injury. I had taken my mother to a local hospital for kidney stones, where I saw a product I was not familiar with. It was a blood-drawing device that automatically retracted after use, protecting the caregiver from acquiring a needle stick injury. Its intended use is for single patient use only and provides the best protection available today to prevent the spread of unnecessary infections among healthcare workers. I thought to myself, if only I had this device, I wouldn't be undergoing 48 weeks of chemotherapy to rid my body of this horrible infection. I obtained a device from the nurse and began my research into the product. I contacted my local hospital, working from the bottom all the way to the CEO and discovered that the decisions they made to provide safety devices for nurses was driven by the Group Purchasing Organization that they belonged to. I introduced the safer device, I provided them with contacts, and I provided them with all the necessary data that would indicate the necessity for change to protect others from unnecessary needle stick injuries. It all made very good sense to me, until I discovered, that the safety was not a primary concern, that they would be penalized for even considering this product and severely penalized if they purchased this product. Thus they continue to use the same products they used 2 ½ years ago, making small changes, but skirting the issue of real safety: by holding the healthcare community hostage due to previous agreements with the Group Purchasing Contracts.

I worked with legislators in Missouri to get HB266 passed. I worked with other nurses that had also became infected with HIV and/or HCV lobbying for new prevention strategies of bloodborne pathogens in the workplace to help prevent this from happening to anyone else. I attended conferences with the American Nurses Association (ANA) in Indianapolis where three infected nurses presented a symposium on needlesafety as a result of their injuries. I attended the Frontline Healthcare Workers Safety Conference in Washington D.C. where 6 nurses attended this conference all infected by one or more of

the above-mentioned infections, HIV and/or HCV. I contacted the FDA, OSHA, JCAHO, and other federal agencies. I have been featured in numerous articles about needlesafety, and continue on the mission of getting to the bottom of this problem once and for all. I have presented information to the Missouri Department of Health to assist hospitals in making educated and informative decisions on new products, I have reviewed the Emergency Care Research Institute (ECRI) manual, an independent testing and evaluating group, similar to the Consumer Reports Issues that evaluate many of our products from automobiles to child safety devices and numerous other products. ECRI is one of the only reviewing not-for-profit agencies that evaluate only healthcare products on an annual basis. I have done everything in my power to make my injury count as a part of the process to change and I will continue until The Group Purchasing Organizations open the doors to allow any and all products to be purchased without penalty to the purchasers.

April 30th, 2002 is our day in court to present the testimony of how this has affected numerous small innovative companies, 1000's of healthcare workers and the taxpayers by continuing with this unethical, and immoral business practice. There will be many of the large corporations testifying on their behalf and some testifying about how these business practices have prevented new technology from being implemented in the healthcare system. I offer to you my personal testimony and how this contract trickles down to the people like myself, an ordinary citizen of the United States. I hope that it is clear the effects that this agreement has had on all of us in the medical community and that the changes we request today will be made to make it easier to evaluate and provide the technology that medicine needs today to continue saving lives.

After 9 months into the first 48-week therapy regimen, my 18-year-old son was killed in an automobile accident. He had fallen asleep at the wheel after a long week at school, working and participating in Drug and Alcohol Prevention with Young Teens. He had produced a commercial for PBS about drinking and driving, was a photo-journalist on the yearbook committee, worked 2 jobs to make up for what I could no longer financially provide him as a result of loosing more than 50% of my income for the year. He was the Captain of his Hockey Team at the high school, very involved with the teachers and principals in trying to bring about change in the school regarding drugs and alcohol abuse, counseled other teens about the dangers of doing drugs, was well respected by all of his piers for his ability to make a stand on seriously banning drinking and using drugs at school functions, games and practices and other activities outside of school and was looking forward to voting in his first election. He had just registered for the draft the week before and was so proud to be a "REGISTERED VOTER". He encouraged all of his friends to vote and register, telling them that they had a real voice in our countries future and was actively soliciting young 18 years olds to register to vote. He had always shown an interest in Politics, from a young child, and always stood up for what he believed in. We had a great relationship and talked at length about how to make the world a better place to live. He was well on his way to college at University of Missouri - Columbia for a degree in Journalism and Film Editing. He had already produced several videos and was recognized for his great work when he fell asleep at the wheel. No drugs, no alcohol, no inclement weather conditions, no passengers, no one else

involved, no reason except that he wanted to see his friends after photographing the high school football game and asking his first girl friend out to the high school dance. He only went out one night a week, Fridays, as he was committed all the other days to working, school and counseling other young teens about the dangers of drinking and drug addiction. He started in recovery at the beginning of his Freshman Year in High School and had been sober till his death. As a child, he endured being the child of a single parent, 5 surgeries on his eyes for crossed eyes, braces, adolescence, the murder of his best friends father, (a father figure to him), the trial and conviction of the murderer, who was on a drug binge at the time, and later sentenced to death. He also faced other hurdles and disappointments in his life but always stood up, brushed himself off and continued living his life trying to change things that didn't make sense. He was physically strong, very athletic, energetic and smart. He was sensitive and loving and our relationship and bond was unbreakable. To this day, I can hardly think about starting another day without him being here with me.

His strong belief in the political process and his commitment to change the world remained his primary focus. We used to talk about how change occurred and that you had to take it one step at a time. Often times a long and tedious process, but if it makes the world a better place for our future children then it qualified for a mission accomplished. I promised him that I would take what had happened to me to the highest level of the court system until I got the results that were needed. We discussed the ability of the American people to be heard by writing to our congressmen and politicians who ultimately were the power of the peoples voice, we had in depth conversations about what Martin Luther King's contributions did for the civil rights movement, the accomplishments of each and every one of our Presidents and leaders and what they fought for, what war time brought to our country and what it left behind. He was empowered to feel that change can begin at any place in the cycle. I had told him that I would go to Washington D.C. some day and march up the steps to discuss this issue. The only problem is that we were supposed to have done this together, Should he be alive today, he would have been sitting next to me at this hearing today.

Since his death, I completed the first 48-week course of chemotherapy. The virus returned within 4 weeks off of therapy, I then waited 6 months for FDA approval of the new Pegylated Interferon and started another 48 weeks of therapy. I complete this last course of therapy next week. It has been nearly 2 /12 years since my infection. There are no more roads to follow in therapy. I have been treated with the best available medicine. If the virus returns I have to sit and wait for researchers to catch up with the virus. If I have to have a liver transplant, I would be on a long list of other patients. Even with a transplant, the virus is bloodborne and will return, a transplant is only another temporary measure to stay alive longer. In November of last year I was terminated from my position as a nurse under the FMLA because I couldn't return to work. I had been employed with them for 10 years and was educated in their Nursing Program at Jewish Hospital College of Nursing. Unfortunately I had to look into to other sources to remain somewhat financially stable and I began receiving social security disability payments. I am now insured under Medicare A and B, still receiving workman's compensation benefits and lost everything in my life that ever meant anything to me. I had never relied

on the government financially. I was always employed, paid my way through college the first time and worked my way through the second time.

My son can never be given back to me: His memory will be with me forever. My health can never be given back to me and my career as an RN is over. I am unable to continue providing bedside care as the risk of becoming infected with other bloodborne pathogens is just to great. I still owe $20,000 in student loans that I can't pay and this was all to save 30 cents at the hospital. It seems to me that this cost has been to the detriment of society and myself while the big companies pocketed the change. The mental toll this has played on my life is not even measurable

I can only pray that you will look seriously into this problem and correct it by reviewing the purchasing practices of healthcare organizations and those who provide them with needed supplies. I am only one of 1000 infected workers every year, 10,000 infected in the past 10 years, 1,000,000 needle sticks annually. My injury is estimated to cost in excess of 1 million dollars before I die and that is at today's prices. I wish that I could be present for the hearing but don't know how logistically or financially I can manage it from St. Louis. I will be there if at all possible. This hearing is very important to me. I hope you have time to review this testimony among all of the other business testimonies and realize the impact this has had on so many of us. I appreciate your taking the time to listen to and read this testimony and I hope that we can make the needed changes to the healthcare system to prevent what has happened to me from happening to anyone else.

I encourage the committee to vote to change the policies regarding Group Purchasing Organizations and allow life saving technology back into the hands of those who need it. Allow hospitals to have the control they need to evaluate products that they know will help their patients and healthcare workers, and stop the practice of banning new equipment from being introduced by smaller innovative companies.

Thank you again for your time. I look forward to meeting some of you if I get to Washington D.C.

Sincerely

Julie Naunheim Hipps RN BS

United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510-6275

April 30, 2002

The Honorable Timothy Muris
Chairman, Federal Trade Commission
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

The Honorable Charles James
Assistant Attorney General
Antitrust Division
United States Department of Justice,
9th Street and Pennsylvania Avenue, NW
Washington, DC 20530

Dear Chairman Muris and Assistant Attorney General James:

The Subcommittee on Antitrust, Competition, and Business and Consumer Rights has been investigating the competitive effects of hospital group purchasing and is today conducting a hearing on this issue. Our inquiry has focused on the effect of hospital group purchasing organizations ("GPOs") on smaller and competitive medical equipment manufacturers and pharmaceutical companies seeking to sell their devices, equipment, drugs and supplies to hospitals. Many smaller and start-up medical device and equipment manufacturers have asserted that GPO contracting practices effectively foreclose them from the market. The contracting practices alleged include sole source contracts, long-term contracts with suppliers, requiring high commitment levels from hospitals in order to be eligible for GPO-negotiated discounts, and the bundling of different products so that hospitals much purchase the bulk of their supplies off a list of bundled products in order to qualify for the discount for any one product. Smaller manufacturers allege that the incumbent suppliers, in concert with the GPOs, utilize these contracting practices to eliminate competition and entrench the dominant position of the incumbent suppliers.

In addition to these concerns, it is clear that the GPO market consolidated significantly in recent years. Where once many small and regional groups were responsible for most hospital group buying, today the industry is highly concentrated, with two GPOs – Premier and Novation – responsible for medical devices and equipment contracts for almost 60% of the nation's not-for-profit hospital beds. Some smaller medical device and equipment manufacturers believe that this level of market share has made it essential to obtain contracts with these two GPOs in order to have a viable business plan.

In light of this consolidation and of the allegations of anti-competitive behavior by the

large GPOs, we ask that the Department of Justice and FTC re-examine their Health Care Guidelines as to this issue. Specifically we request that the agencies re-examine Statement 7 of their Antitrust Enforcement Policy in Health Care, which declare an "antitrust safety zone" making protecting joint purchasing arrangements among health care providers from antitrust challenge under the circumstances described therein. We request that the agencies carefully and thoroughly examine these Guidelines to determine if any revisions are now needed in light of current market conditions and the changes in the hospital group purchasing marketplace in the last decade since the Guidelines were adopted. This review should examine whether any modifications are necessary in the "antitrust safety zone" so that these Guidelines better serve the interests of competition and consumers. In this connection, we request that the FTC undertake a study and economic analysis of hospital group purchasing including an inquiry into whether the current functioning of the marketplace under the Guidelines' antitrust safety zone has caused, or has the potential to cause, injury to competition among medical device and equipment manufacturers.

We recognize that group purchasing by hospitals has the potential to create efficiencies and reduce health care costs by permitting small and large hospitals to band together and gain greater bargaining power with suppliers; to the extent that such cost savings exist, we would like to preserve and enhance them. We are concerned, however, about the allegations regarding contracting practices of the large GPOs, and by the consolidation in this industry throughout the last decade. To the degree that such market circumstances have harmed competition in the medical device and equipment marketplace we may run the risk of diminishing the medical innovation so essential to modern health care. We therefore believe that it is now time for the FTC and Justice Department to study this issue and to re-examine its Guidelines to ensure they continue to serve the interests of ensuring a vigorously competitive medical equipment marketplace as well as a cost-effective market for medical supplies overall.

Thank you for your attention to this matter.

Very respectfully yours,

Herb Kohl

HERB KOHL
Chairman, Subcommittee on
Antitrust, Competition, and
Business and Consumer Rights

Mike DeWine

MIKE DeWINE
Ranking Member, Subcommittee on
Antitrust, Competition, and Business
and Consumer Rights

Hospital Group Purchasing:
Lowering Costs at the Expense
of Patient Health and Medical Innovation?

The Innovative, Entrepreneurial Medical Technology Perspective

Testimony of
Larry Holden
President
Medical Device Manufacturers Association

At a Hearing
Of the
Senate Judiciary Committee,
Subcommittee on Antitrust, Competition and Business and Consumer Rights

April 30, 2002

Mr. Chairman and members of the Subcommittee,

Thank you for conducting this hearing into the unintended but nonetheless very real and very serious consequences of the antitrust exemption for hospital group purchasing of medical supplies and equipment.

Over the years, this well-intended exemption has turned into a nightmare of devastating consequences that threaten both the health of our nation's competitive, free enterprise system and, most importantly, the health and well being of our people.

My name is Larry Holden. I write to you on behalf of the small to medium sized medical device manufacturers that comprise the largest portion of the innovative research and development sector of America's medical device industry.

Medical technology enables millions of Americans to live longer, more comfortable and more productive lives. The technological innovations developed by medical device manufacturers, many of them small companies, have produced the wonders of modern medicine and surgery. From *tongue depressors* to *heart pacemakers* to *pulse oximeters* to *intrauterine monitors* to *disposable safety needles*, these individuals and their companies produce the innovations in medical device technology that help people get better faster.

This testimony represents the dreamers ... the inventors ... the engineers, scientists, designers, physicians, techs, and other risk-takers who together offer health professionals, and the patients for whom they care, the safest, most effective, advanced medical technologies known to medicine.

We are able to do this in part because of the free market system that underlies our economy. That system is safeguarded by our antitrust laws. These laws, as the U.S. Supreme Court has stated on numerous occasions, are in place to protect *competition* – not to protect *competitors*.

Unfortunately, an unforeseen and unintended -- but nonetheless crushing – anticompetitive phenomenon now profoundly challenges this technological progress in health care. We respectfully submit that this issue requires your continued oversight and, we believe, a corrective remedy.

Medical Technology Innovation Drives Health Care

I am president of the Medical Device Manufacturers Association. MDMA exists solely to provide a collective voice on behalf of the innovative companies whose efforts improve the quality of patient care through the advancement of medical device technology.

innovators and manufacturers of medical devices, diagnostic products and health care information systems.

Together, we represent the future of medical technology in America. I say this not to denigrate or discount the advancements made by our nation's large, established medical device manufacturing firms. These vital enterprises originally created what has become the hallmark of our industry – constant innovation and technological advancement.

And they built the foundation for the medical technology industry on which MDMA members today proudly pursue new research and development.

But I make the distinction, Mr. Chairman, because it has long been true that the vast majority of technological advancements in medical devices and ancillary equipment and diagnostic products are driven by small, innovative, entrepreneurial manufacturer (as is the case in many sectors of the economy).

It has been said reliably that, at any given time, 60 percent of the medical products sold are less than 12 months old. This continuous innovation has traditionally been the hallmark of the entrepreneurial medical device industry.

The large manufacturers that today are so important to the continuity of supply of quality products – Medtronic, Becton-Dickinson, Abbott Laboratories, and Baxter, to name just a few of our industry's great leaders – were themselves once small operations begun in a garage or a converted lab. Their own histories thus urge them to look in the direction of small entrepreneurial companies for innovation.

Today, moreover, these leaders find it economically logical and strategically advantageous to look to us – the next generation – for the innovation that will keep the industry moving in a dynamic and positive way toward the future.

- But we appear before you today, Mr. Chairman, as individuals and organizations profoundly concerned about the future of medical technology in this country.

For years, many of us in the innovative sector have watched with alarm as our new products have cleared the multitude of research and development hurdles, which include, but which are by no means limited to ....

Laboratory testing;
Animal testing;
Initial funding;
Human testing;
Regulatory review;
Patent review; and
Reimbursement assessment

.... only to see our products die because we could not even get a *fair chance to sell them* due to artificially imposed barriers in the marketplace itself.

Because of these barriers to entry in the marketplace, many of MDMA's members are forced into the Hobson's choice of either selling our technologies to larger, more established firms or going out of business altogether.

Moreover, their problems are exacerbated and their ability to fight for survival abridged because many of these artificial barriers, so hostile to the interests of our industry sector and innovation itself, and ultimately the American consumer, were erected by large industry players under the protection of antitrust exemptions created by the Congress for far different and uniformly laudable public policy goals.

If this situation goes on unremedied, however, it would seem to place the imprimatur of the Congress upon the following negative health care consequences, among others, which we firmly believe to be unintended ones flowing from the antitrust exemptions in question:

- Restrictive long-term contracts and lengthy technology-exemption procedures have evolved over the years into the current purchasing system, which has become antithetical to continuous innovation. It now serves only as a barrier to significant market entry by entrepreneurial medical technology companies.

- Improper bundling/tying practices seek to preclude hospitals and care providers from having a choice in selecting the best medical devices for their physicians and patients.

These barriers, of course, in turn prevent health professionals and patients from access to technologies that can save lives, prevent injury, and help control health care costs.

So we were deeply gratified that you, Mr. Chairman, and the other members of this subcommittee – and the full Committee on the Judiciary and members of the staff – have demonstrated your deep and general concern about this issue by calling for this hearing. On behalf of the entire MDMA membership, I thank you.

We are also gratified by the troubling but nevertheless necessary light of truth that has been shed on this previously "hidden" problem by a Pulitzer Prize-winning team of journalists at the world's leading newspaper, *The New York Times*. The *Times*, in an exhaustive three-part series or articles that are the result of more than a year's worth of research -- as well as a parallel article in last Saturday's edition focusing the electronic commerce efforts of one large GPO -- has enunciated this problem more eloquently than I ever could.

But I am going to try.

The Health Care System is Under Anticompetitive Attack

Before going further, I wish to make clear that MDMA does not believe that anyone has maliciously contrived to create the economic and life-threatening nightmare that is today's hospital group purchasing system. This is a creature that "evolved" over the last few years through rational strategic business decisions made in response to the opportunities the antitrust exemptions provided.

We submit that according to the following criteria that Congress itself set forth in the legislative history, it has now become evident that evolution has not proceeded in accord with the will of the Congress:

- To the extent that this subcommittee desires to see a health care marketplace in which our nation's fundamental principles of free enterprise and open, healthy competition are pursued vigorously, it is not happening in the medical technology industry;

- To the extent that this subcommittee desires an environment in which the true costs of health care are the standard against which public policy decisions governing anticompetitive behavior are rendered, it is not happening in the medical technology industry; and

- To the extent that this subcommittee desires an environment in which healthy competition helps minimize adverse health consequences – such as increased health risk to patients and unacceptable safety risks to health care workers -- it is not happening in the medical technology industry.

How Does This Anticompetitive Behavior Show Itself?

In a nutshell, the business practices of the large *Group Purchasing Organizations – GPOs* – that dominate the health care purchasing market stifle innovation and entrepreneurship.

Over the years, it has become incontrovertible that the relaxation of the antitrust and Medicare laws has reduced, rather than enhanced, competition in the health care products industry. A small group of GPOs has emerged to dominate the purchasing side of the industry. As a result, larger device manufacturers, now able to focus their sales attention of just a few purchasers, have offered each of these dominant GPOs sizeable administrative fees to enter into exclusive purchasing agreements.

Such agreements typically require affiliated hospitals to purchase at least 80% (and in some cases, 95-100%) of their medical supplies from large manufacturers for periods of up to seven years—several times the average generational life cycle of a new medical device. As a result, they effectively prevent any hospital affiliated with a GPO from making purchases from other product manufacturers, regardless of quality, safety, or *cost of care delivered.*

There are several manifestations:

- **Due to the nature of *GPO* purchasing contracts, medical technology entrepreneurs have little or no opportunity to market their products to hospitals and cannot effectively compete for their business.**

The two major *GPO*s control purchasing power for two-thirds of the hospital beds in the United States. This was not and could not have been envisioned by the Congress in creating antitrust exemptions that were to enhance the economic and health interests of consumers.

One of these major *GPO*s commits member hospitals to purchase *90 percent* of their supply needs from the one or two manufacturers under contract with it. This could not have been envisioned by the Congress.

Member hospitals are, *for all practical purposes*, prohibited from independently soliciting quotations for products covered under the agreement and are equally forbidden from entering into or renewing independent contracts for covered products. This could not have been envisioned by the Congress.

In essence, GPO contracts prohibit medical technology entrepreneurs from presenting competing proposals to GPO member hospitals, and prevent these hospitals from legitimately comparing the prices or quality of competing products. *This anticompetitive behavior absolutely was not envisioned by the Congress.*

- ***GPO*s engage in "bundling" as a standard marketing tool that guarantees that hospitals pay *higher* prices for certain products.**

Certain *GPO*s bundle a single manufacturer's product lines together under committed-volume *GPO* contracts, requiring hospitals to pay higher prices for products where competition is great (and prices would theoretically be lower) to receive preferred pricing, rebates, and other discounts on products in markets without significant competition (where prices would theoretically be higher).

When medical device manufacturers actually do secure a contract with a major GPO, they are often subjected to a second barrier to entry into the hospital market, namely, bundling arrangements designed by the GPOs to promote the entire product line of a certain large manufacturer or group of large manufacturers.

The majority of these bundling arrangements create significant incentives for hospitals to avoid purchase of individual medical devices not included on the list of preferred products, regardless of their virtues, in order to avail themselves of special discounts spread across a large manufacturer's entire line.

By linking a hospital's savings to its commitment to purchase a certain minimum percentage (for example, 80-90%) of its needed products from those selected as part of a bundle, GPOs employing this contracting method virtually ensure that other product manufacturers can compete for no more than a 10-20% share of the market in the participating hospitals.

Additionally, one *GPO*, Novation, Inc., is known to charge manufacturers an *additional* fee for the right to participate in a Novation bundle above and beyond the 3% administrative fee contemplated by the Congress.

In effect, this additional fee is paid by selected manufacturers in return for ensuring that they will enjoy the benefit of near-exclusive access to hospitals that choose to participate in Novation's bundling program.

This form of bundling by large GPOs protects *GPO*-sponsored manufacturers from targeted competition from small and entrepreneurial manufacturers with innovative technologies.

- **Long-term *GPO* contracts lock out competitors and deny innovative products to patients and health care providers.**

*GPO*s have told us – and they have told you again today -- that their long-term contracts (which range up to 7 years in duration) do not exclude any manufacturer from competing for business from member hospitals. Indeed, as recently as this past month, the *GPO*s have touted the existence of their processes for allowing member hospitals to evaluate and purchase new or advanced technologies from manufacturers that are not under contract.

The pointlessness of this recent effort would be amusing were it not so frustrating to consumer interests, because the issue of contractual lockout has nothing to do with the existence of evaluative processes. Rather, the issue pertains to the lack of integrity of these processes.

As a matter of fact, GPOs devised so-called "breakthrough technology" exceptions only as a fig leaf for the patently exclusionary effects of their contracting practices. The exception ostensibly exists to enable a GPO to deviate from an exclusive or quasi-exclusive purchasing commitment to a vendor when another vendor offers "breakthrough technology."

This name itself, which one GPO actually uses for its "innovation" program, ironically underscores the difficulty of the process and its function as a barrier.

The name is also suggestive of the inappropriately high burden such an innovative company must carry in an industry in which almost all innovation is necessarily incremental improvement carried out by entrepreneurs in response to feedback from practitioners.

The GPOs, of course, have the ultimate decision about whether a technology meets the "breakthrough" criteria and, in practice, frequently make those decisions in concert with the incumbent vendor from whom the GPO stands to lose millions of dollars in fees if a competitor's product were actually to be allowed to be purchased under the breakthrough technology clause.

One *GPO*, for example, requires a member hospital to go through an 18-step process to obtain an exemption from its commitment to purchase a product under contract, and *includes a review of the request by the competing manufacturer that currently holds the contract.*

One small company, Masimo, Inc., of Irvine, California, believes that its experience with the breakthrough process developed by Premier Purchasing Partners is typical if not inevitable: Premier denied Masimo the opportunity to make sales to Premier hospitals for two years while Premier's incumbent, fee-paying vendor Tyco-Nellcor copied Masimo's technology.

In another startling example, innovative safety needles designed and manufactured by Retractable Technologies of Texas were excluded from the GPO-dominated marketplace until an expose by CBS-Television's *60 Minutes* program questioned the practice.

- Ironically, Premier now uses this case as an example of how they make room for breakthrough products from smaller companies to satisfy unmet needs.

  In paid advertisements that ran in selected news journals over the weekend, the GPO trade group actually claimed credit, in a rather strained (some would say shameless) effort to play to American patriotism, for the availability of safe needles in the health care setting!

  But chutzpah will not efface the history of GPO resistance to this technology's entry into the marketplace, which is exhaustively documented in the *60 Minutes* piece.

This sort of activity, especially when coupled with a perfunctory survey paid for by the *GPO*s and released this past month, demonstrates in a way that we never could, that the impact of these alleged innovation-promoting processes is illusory

at best, and a sham at worst. They were to serve as a proxy or substitute for the functioning of a true market in bringing forth innovation.

In reality, however, they serve exactly the opposite end by strangling innovation altogether where it would serve as a competitive threat, or by setting innovative intellectual property up to be either cheaply purchased or stolen outright.

- **The *GPO* business model, which includes exorbitant "administrative fees", "licensing fees", and other charges, is a barrier to market entry and secures the position of incumbent, dominant manufacturers.**

Members of the subcommittee may recall that when Congress originally carved out exemptions for *GPO*s, the Members were concerned about the costs – and the legitimacy – of the administrative fee structure. They were right to have been concerned.

*GPO*s often charge high administrative fees to manufacturers for the right to sell their products through to hospitals – and, as it also turns out – to have their product lines protected from competition by the *GPO*s.

The "administrative fees" typically are based upon:

- vendors' sales figures,
- private-labeling arrangements under which participating manufacturers must pay "licensing fees" to the *GPO* for the ability to market their products under the *GPO*'s name, and
- "product evaluation fees" in which a *GPO* insists that manufacturers pay a fee -- up to $2 million in one case -- for the opportunity to have their product "evaluated" for inclusion on the *GPO* preferred-product list.

All of these exorbitant fees have the effect of creating additional barriers for small manufacturers with limited product lines or capital that might wish to participate in the GPO process.

And these fees absolutely confirm the worst fears of Congress when it contemplated the *GPO* antitrust exemption.

- **The economic incentives for *GPO*s are not aligned with the benefits these institutions are supposed to provide in exchange for their special status under the antitrust laws.**

For-profit *GPO*s make their money based on a percentage of sales made under their contracts, *not* on the basis of a percentage of the savings they generate for

their hospital purchasing members. *GPO*s also make most of this money from the "administrative fees" paid by manufacturers.

- And herein, of course, lies the fundamental problem with the contemporary GPO system: an inherent *conflict-of-interest*. As *The New York Times* explained in the first of its three articles exposing troubling anticompetitive behavior in the GPO scheme (March 4, 2002):

> *"The problem begins with this simple fact: The buying groups are financed not by the hospitals that buy products but by the companies that sell them. In other words, the groups take money from the very companies they are supposed to evaluate objectively. Each year, companies pay Premier and Novation hundreds of millions of dollars in fees that represent a percentage of hospital purchases. The more hospitals spend on medical supplies, the more dollars Premier and Novation get from the suppliers."*

These incentives don't align correctly with the original contemplated purpose of the exemption – which was to encourage the acquisition and use of the *best medical products in the most cost-effective way.*

Instead, these incentives simply encourage *GPO*s to do as much business as possible with as few manufacturers as possible, thereby helping *GPO*s maximize their profits while minimizing their own administrative costs.

Another astonishing example of conflicting incentives in the GPO marketplace – this time by Novation -- was explored by The *Times* just this past Saturday. Reporter Mary Williams Walsh detailed a hauntingly familiar story of corporate executives who have invested shareholders' money in a business that the executives control, which is intended to sell products back to the shareholders. The business has lost hundreds of millions of dollars since its creation five years ago.

This end run past sound conflict-of-interest policy was criticized directly by E. chandler Bramlett, CEO of Infirmary Health System of Alabama, who was quoted in the Times as saying:

> *"This presents a problem to me. If someone has a financial stake in an organization, and they have the ability to determine how much funds will go to this organization, that has the potential to cloud their objectivity."*

Another CEO, Dennis Hall of Baptist Health System, also was quoted in the *Times* as saying:

> *"My board...would be very concerned if they found out I was a stockholder in a company that we were thinking of awarding a contract to."*

- ***GPO*s are unable to demonstrate actual savings, and may actually cost the health care system more money.**

As you may know, and as the columnist *David Broder* pointed out recently in an entire column dedicated to the subject, health care costs are dramatically on the upswing again.

Mr. Chairman and members of the subcommittee, we all have a vital vested interest in controlling health care costs. Rising costs make it difficult for employers to provide coverage for their workers; rising costs exacerbate the already unconscionable problem of the uninsured in America. Rising costs drain productivity and damage our nation's global competitiveness. These phenomena are well known to the public at large.

We have no way of knowing if the recent rise in health care costs is attributable to the GPO's anticompetitive behavior. We do know that the GPOs say they are saving money for their hospital customers. We do know that the GPOs say that they find the best prices for the customers.

Lower Prices Do Not Necessarily Equal Lower Costs

We also know that cost savings in the context of health care is a function of so much more than just price – especially in the health care sector.

- It is for this reason that we respectfully, but firmly, question the fundamental premise implicit in the title of today's hearing, "Lowering Costs at the Expense of Patient Health and Innovation?"

There is no evidence that GPOs are holding down health care costs. They may be holding down prices – but none of us here today can even be sure of that. Historically, in their dealings with our members, GPOs have declined to agree to any transparency in matters pertaining to pricing. This remarkably inappropriate habit, given the GPOs' special status under the antitrust laws, was scrutinized in an alarming new context only three days ago by *The New York Times*.

The article by Mary Williams Walsh that appeared in Saturday's Times to which I have referred earlier, also exposes the sad state of affairs about product pricing in the whole GPO scheme. The article states: "Medical supply companies [were not] interested in signing up with any web site [the Novation-controlled Neoforma e-commerce distribution site] that might post their prices next to competitors' prices, allowing instant comparison by hospitals, said Lawton R. Burns, director of the Center for Health Management and Economics at the Wharton School of the University of Pennsylvania."

But are the manufacturers uninterested in posting their prices out of fear that a competitor might undercut them? Or are they aware, as are we, that in the medical supply world, "price" is only the starting point for discussion.

Health care economists have known for years that the cost-effectiveness equation in health care is not price at all, but rather the factors that collectively are known as the **total cost of care delivered.**

This total cost includes, but is not limited to:

- actual price of the technology, also known as the out-of-pocket cost;
- use costs; that is, the overhead associated with the product – training, monitoring, and administration
- utilization costs; that is, the amount of supporting care or usage of the product that is required to achieve the desired outcome; and
- the costs of complications and unwanted side effects.

Only "price," the first item, is contemplated in GPO contracts, and some of our MDMA members have told us that even price is not a factor in their discussions with GPOs.

Mr. Chairman, sometimes we're not even sure what IS a factor in GPO decisionmaking. The amount of frustration we experience in simply trying to do business with hospitals under GPO contract is all the more troubling because the rules for success are so elusive.

A typical example of the GPO phenomenon -- and, I believe, a *prima facie* case for congressional action to restore sanity to the hospital supply market -- is a small market shareholder in the cardiac rhythm management market, Biotronik, Inc., of Portland, Oregon.

Although tiny by the standards of the industry giants, Biotronik sells its state-of-the-art products around the world. In those areas where GPOs are non-existent and business is done on the traditional merits of product, price, service, and quality, Biotronik is competitive. In Germany, it owns 35% of the bradycardia market and one-fifth of the tachycardia market. In Brazil, Biotronik's share of the bradycardia market is 70%; in Italy, 20%, in France 15%; and in Spain, 20%.

Its market share in the U.S. GPO sphere is less than 5%.

The Search for the Truth

In conclusion, Mr. Chairman and members of the subcommittee, MDMA encourages you and your colleagues in the Congress to recognize that the times, the players, and the marketplace, all have changed dramatically since you decided to facilitate a mechanism for cost savings in the largest single sector of our nation's economy.

Your well-intended effort, soundly rooted in public policy, has been distorted by the strategic behavior of some larger industry players, and some of the larger

GPOs themselves, to the point at which it bears little resemblance to the world you envisioned a dozen years ago.

While we believe GPOs still have merit in the effort to curb health care costs, some mid-course correction of these excesses must be made at the congressional level to preserve the admirable goals Congress sought to achieve in creating the antitrust exemptions that created them.

Today, there is virtually no competition in the health care purchasing sector beyond that which is dictated, controlled, or manipulated by a small group of purchasing agents – the *GPOs* – who instead of acting as facilitators have themselves become the *de facto* arbiters of the practice of medicine.

As The *New York Times* has demonstrated so vividly, health professionals no longer choose the tools they may use to help save a life – the *GPOs* do.

As small innovative manufacturers have told you in their own sworn testimony, hospitals cannot seek out new, safer, more costly products – they take what the *GPOs* offer.

As *60 Minutes* showed, so tragically, health care workers do not control their own destiny in terms of personal health and safety – the *GPOs* do.

As the *GPOs*' need to implement a "breakthrough technology" exemption policy to circumvent exclusive purchasing contracts so astonishingly demonstrates, the *GPO* process is fundamentally anti-competitive.

And, as a demonstrated by a lack of evidence – in fact, in the face of evidence to the contrary – *GPOs* do not save the health care system money, which is the reason for their antitrust exemption in the first place.

We urge to you to evaluate the evidence and the testimony that has been placed in the record here before you today. We ask you to engage your oversight authority over anticompetitive marketplace behavior to further plumb the depths of the hospital purchasing system.

We ask you to use that authority, and to take any legislative steps you deem necessary, to restore competitive principles to this marketplace to ensure the continued health and safety of our people; the continued competitiveness of our medical technology industry; and the resumption of full entrepreneurial innovation and research and development to preserve, protect and defend life.

Thank you.

Statement of Paul Hazen
President and CEO
National Cooperative Business Association
Before the
Subcommittee on Antitrust, Competition, and Consumer Rights
Hearing on

Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation?

April 30, 2002

NCBA is pleased to submit testimony to the Subcommittee on Antitrust, Competition and Consumer Rights on the role of purchasing cooperatives in promoting the survival of small businesses in the U.S., and on the structure of these cooperatives.

NCBA is a national membership association, based in Washington, DC, representing cooperatives of all types and across all sectors of the economy. Our members include farmer co-ops, childcare co-ops, credit unions, housing cooperatives, health care cooperatives, small local food co-ops, mutual insurance companies, rural electric cooperatives, and purchasing cooperatives. VHA falls into this last category. It is a purchasing cooperative owned by non-profit community hospitals. It pools the purchasing power of it members, allowing them to secure lower prices on medical supplies.

NCBA's mission is to develop, advance and protect cooperative enterprise. NCBA also operates cooperative development and civil society programs in 16 developing countries. We are committed to co-ops because we believe they are the key to improving economic opportunity for people throughout the world.

NCBA does not wish to take a position on the underlying issue before the Committee today. But we do want to share with the Committee some fundamentals about purchasing and other cooperatives, how they operate, what constraints they face, how they differ from investor-owned buying groups, and why they are so critical to the survival of small businesses, or non-profit community hospitals, in the case of VHA and its majority-owned subsidiary Novation.

As I'll explain shortly, Novation's practice of charging fees of its vendors is not an unusual or unique practice for purchasing cooperatives. Indeed, this practice is not only commonplace, it is often critical to the survival of the cooperative.

Before providing more detail on how purchasing cooperatives operate, I'd first like to outline some background on the cooperative business model.

Purchasing cooperatives are, like other cooperatives, businesses that are owned and democratically governed by their members. Today, there are approximately 48,000 cooperatives in the U.S. Looking at agriculture alone, in the year 2000, there were

approximately 3,300 farmer co-ops with 3.1 million farmer-members and combined revenues of almost $100 billion. These revenues are an indication of the substantial positive impact cooperatives have had and continue to have on our country.

There are four basic types of cooperatives:

- **marketing cooperatives**, which include most farmer cooperatives, help their members aggregate their products and pool their selling power in order to realize better prices in the marketplace;
- **consumer cooperatives**, which include credit unions, food cooperatives, mutual insurance cooperatives, housing co-ops, rural electric cooperatives and others, sell products or services to their member-owners;
- **worker cooperatives**, which are 100 percent owned and democratically governed by their employees; and
- **purchasing cooperatives**, which help their members pool their buying power to secure lower input costs that help them operate their businesses more cost-effectively and compete against larger competitors. VHA Inc., which is the majority owner of Novation, falls into this last category.

Though they operate in diverse sectors, cooperatives share fundamental features.

First, they are all owned, democratically governed and controlled by the people who buy their goods, or use their services, not by outside investors. In simpler terms—the customers are the owners. That means the co-op members democratically elect the board of directors from within the membership. The board oversees the operation of the co-op, hires and fires the CEO, and governs the organization. It also means that the cooperative is directly accountable to its customer-members, not to outside shareholders. Other types of businesses may make this claim, but only in a cooperative is it literally true.

Second, at the end of the year, the net earnings of a cooperative are returned to the members on a patronage basis. That is, each year, the member receives a "patronage dividend" that is proportional to the amount of business he or she has done with its cooperative. This is true of all cooperatives. It is best illustrated by the largest consumer cooperative in the nation, Recreational Equipment Inc., or REI, an outdoor equipment retail cooperative owned by 1.8 million members.

If REI has net earnings at the end of the year, the majority of those net earning (about 85 percent, according to the co-op) are returned to the members in the form of a patronage refund. At the end of each year, each REI member receives a patronage dividend that is a percentage, usually about 10 percent, of the amount of purchases made by that member during the year. Patronage dividends are a key component of cooperatives. Net earnings go the member-owners, not to third-party investors. VHA follows this same approach, providing dividends to its member and participating-patron hospitals based on the amount of business they conduct through the co-op.

It is also common practice for cooperatives to reinvest a portion of their surplus revenue back into the business. Because the business exists solely to serve its member-owners, members have a vested interest in ensuring the cooperative remains strong, develops new services and continues to grow and compete. Rarely is a co-op able to return all of its net earnings to its members and remain successful.

As many members of this committee are aware, cooperatives have played a key role in the development of the nation's rural economy, allowing farmers throughout the country to combine their marketing power to secure better prices for the commodities their member-owners produce. It became clear early in the 20th century, that without the power of a cooperative, farmers were powerless to negotiate reasonable prices from food processors and manufacturers. Cooperatives like Associated Milk Producers Inc. in the Midwest, and Cabot Creamery Cooperative in the Northeast were formed specifically to ensure the economic survival and well being of their farmer-owners.

Similarly, non-agricultural purchasing cooperatives have formed over the last several decades to help their members—usually independent business owners—secure better prices from suppliers and reduce costs in an increasingly competitive and consolidated marketplace. These co-ops represent one of the only means of survival for small businesses. Simply put, purchasing cooperatives pool the purchasing power of many small businesses to create the buying power of a large market player. By allowing small players to survive, these co-ops protect local economies where small businesses operate and ensure the type of innovation that smaller firms bring to our national economy.

Although it is not generally known, purchasing cooperatives are prevalent in our economy. The largest floor covering retailer in the world, Carpet One, is a purchasing cooperative made up of individual owners of floor covering stores in hundreds of communities throughout the U.S. ACE Hardware and TruServ are purchasing cooperatives of independent hardware store owners. The hardware purchasing co-ops help the independent store-owner members compete with giants like Loews and Home Depot by amassing the purchasing power of a chain while retaining the independence of their members.

Owners of fast food franchises, like Dunkin' Donuts, Kentucky Fried Chicken, Taco Bell, Pizza Hut and Subway have formed purchasing co-ops among themselves so that they are not held hostage to the franchisor's prices for the inputs the franchisee is required to buy. Those are some well-known brands, but hundreds of other lesser-known purchasing cooperatives provide similar services for their members.

Independent Pharmacy Cooperative, based in Sun Prairie, Wisconsin, is owned by independent drug store owners around the nation. It helps them purchase pharmaceuticals and over-the-counter products at lower prices, allowing independents to compete with mass merchandiser Wal-Mart, which poses a serious threat to the survival of Main Street drug stores.

Just last year, a purchasing cooperative of independent specialty bicycle retailers formed to help these business compete against mass retailers and gain greater buying power and better prices from bicycle equipment distributors. The co-op helps members, like Wisconsin retailers Wheel and Sprocket and Williamson Bicycle Works, compete in an industry known for its tight margins.

A cooperative of drywall distributors, known as AMAROK, began with seven small distributors trying to compete with investor-owned hardware and building supply chains, and now has hundreds of members around the nation. Together those members now move more drywall than Loews and Home Depot combined. There are hundreds of other examples.

Each of these purchasing cooperatives exists to protect and promote the businesses of its member-owners. Similarly, VHA was formed in 1977 to help non-profit hospitals amass purchasing power and protect themselves from takeovers by health care giants. Small non-profit hospitals didn't create the "bigness" situation, but they had to respond to it if they were going to survive. They did that in the only way they could – by forming a purchasing cooperative that gave them the critical mass they needed to compete.

It's important to note that there are few business entities that embody the spirit of democracy of a cooperative. Most co-ops are governed on a one-member, one-vote basis, and every member has an opportunity to run for the governing board. Members unhappy with the operation of the cooperative have an opportunity to do something about it.

Just last September, *INC Magazine*, the leading publication for entrepreneurs, featured purchasing co-ops as a key tool for the survival of independent businesses. I've attached the article, with permission from the publisher, for inclusion in the record. The writer, Susan Greco, contrasted the new trend toward purchasing cooperatives against what has historically happened to small businesses–acquisition by larger market players. She described the phenomenon like this: "The old strategic alliance is Goliath + David. The new one is David + David + David + David."

This metaphor aptly describes the purchasing cooperative phenomena and the effort of non-profit hospitals to protect themselves and their non-profit status from the trend towards buyouts by large, for-profit health care providers.

I want to take a moment to talk a little about the way purchasing cooperatives operate and finance their businesses. The way VHA operates, through its purchasing agent Novation, in terms of charging vendor fees and negotiating preferred supplier arrangements, is neither unique nor unusual. Both are common and necessary practices for many purchasing cooperatives.

Though some purchasing cooperatives actually take title and possession of the products their members buy, and distribute those products themselves, increasingly, new purchasing co-ops instead negotiate preferred-vendor arrangements with suppliers to secure lower prices for their members. Members then purchase directly from the supplier. By

negating the need for distribution facilities, this model allows the cooperative to operate at lower cost for its members. Still, all cooperatives need an infrastructure to provide services to their members. That costs money. They need purchasing specialists, marketing specialists, educators, accountants, lawyers, communications specialists and they must cover their basic operating costs.

Cooperatives face a substantial barrier that investor-owned businesses do not encounter. Because they are owned and controlled by their members, they are significantly limited in the amount of outside investment they can accept to start and run their businesses. Bringing in outside investment dilutes cooperative ownership and member-control, defeating the purpose of forming a purchasing co-op. That means the members must capitalize the business themselves. For independent business owners and non-profits, that can be a substantial barrier. They simply don't have enough equity capital to start and operate the business.

Depending on the structure of a purchasing co-op, membership dues alone are not enough to run the business. And if many purchasing co-ops attempted to operate on membership dues alone, the cost of membership would be prohibitive for most independents and non-profits. By creating high barriers to membership through costly dues structures, the co-op would be prevented from amassing the buying power it needs to negotiate lower prices for its members.

That is why many purchasing cooperatives, including VHA, charge fees of their preferred vendors. Though the structure of those fees varies from co-op to co-op, without them many purchasing cooperatives could not run their business or serve their members. The fees, which are sometimes called rebates, help cover the operating costs of the cooperative and any excess revenues generated by the fees that are not needed for reinvestment in the business are distributed to the member-owners as patronage dividend in proportion to their purchases. Members benefit from both lower prices and increased income.

It is also not unusual for purchasing cooperatives to negotiate sole or limited supplier contracts with vendors of products their members buy. Such contracts can provide cooperatives with leverage to negotiate the best prices for their members, and provide suppliers with the incentive to agree to those prices. However, there are few cases in which members of purchasing cooperatives are required to buy *only* from the vendors with whom the co-op has a preferred-supplier arrangement. Generally, as in the case of VHA, members can buy from any supplier they want.

In addition, in most cases, the members, as owners, are directly involved in recommending and selecting the suppliers with whom they wish to negotiate preferred-vendor arrangements. That's all part of the democratic governance—member ownership and control—of cooperatives.

In many market niches, for-profit, investor-owned corporations have attempted to "roll-up" independent businesses, allowing the corporation to develop the scale of a national

chain. In most cases, the corporation's new ownership of what were once independent business results in a reduction of service, innovation and profit. By contrast, a purchasing cooperative is driven and controlled by the independents, and the co-op allows those independent businesses to grow, thrive, and innovate.

Cooperatives have served this country well. They enable their members to work together on joint endeavors while still maintaining their independence. They step in where the marketplace has failed. They provide their members with ownership and control over the cooperative business which operates solely to serve them. And, in the case of VHA, they give nonprofit hospitals a way to solve economic problems, and continue to provide quality health care to the communities in which they operate.

NCBA understands the concerns of small businesses that manufacture medical devices. We recognize some of the market barriers they face as small players seeking market access in a highly competitive and increasingly concentrated industry. But cooperatives represent a solution for them in the marketplace as well.

Small manufacturers of medical devices may want to consider following the example of the nation's farmers who formed cooperatives to increase their bargaining power with large buyers. Medical device manufacturers, too, can come together to form, not a purchasing cooperative, but a marketing cooperative that pools their selling power and gives them greater leverage in the competitive health care industry, while allowing them to retain ownership and control of their businesses. A marketing cooperative could enhance the bargaining power of medical device manufacturers with large buying institutions.

"David + David + David + David" *is* a market-based solution tailor made for the entrepreneur seeking business success while maintaining independence.

Thank you for the opportunity to submit testimony for the record.

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May 9, 2002

The Honorable Herbert H. Kohl
Chairman, Subcommittee on Antitrust
Competition, and Business and Consumer Rights
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

On behalf of Nellcor, thank you for the opportunity to respond to the testimony the Senate Antitrust Subcommittee heard on April 30.

We appreciate the Subcommittee's interest in examining the operations of Group Purchasing Organizations (GPOs). At a time when all Americans are concerned about the rising costs of healthcare and the need to provide our citizens with the most advanced technologies available, our healthcare delivery systems should be as good as we can make them. However, we would like to set the record straight in light of some misleading testimony that the Subcommittee heard.

In brief:

1. Nellcor's GPO contracts have been properly awarded on the basis of our superior product quality, superior customer support, and most favorable pricing to the customer. Nellcor has always competed vigorously in the market place as an innovator of the highest level of oximetry technology.

2. The allegations made about us in unsworn testimony by Mr. Joe E. Kiani, the Chief Executive Officer of the Masimo Corporation, are groundless and are contradicted by the facts.

3. It is important that you also understand that Masimo Corporation and its CEO, Mr. Joe E. Kiani, have engaged in a strategy to impugn Nellcor's reputation in the medical community, the courts, and the news media. We believe they have similarly misused their opportunity to testify before the Subcommittee.

In this letter, and the attached exhibits, we address each of these points and we summarize the facts and the record:

Masimo's claim that it has technology superior to Nellcor's is unfounded.

Nellcor is proud of its pioneering role in developing pulse oximetry and in its continuing advances in pulse oximetry. Nellcor is one of this country's success stories; a start-up where the founders and investors took high risks in the early 1980's to bring a technology

it believed in to the marketplace. **[Exhibit 1 Nellcor Pulse Oximetry Technology Timeline]**[1] Our products are widely considered in the medical community as equal to or technologically superior to alternative products, and we successfully compete against those products in all medical domestic and foreign markets.

We are unaware of any peer-reviewed[2] publications that both compare the performance of our most recent (post 1999) generations of Nellcor technology (O4, O5) with Masimo SET technology and confirm their claim of superiority. There are two comparative studies of Nellcor O4 and Masimo SET (and none for O5) that we are aware of and that were published in peer- reviewed journals [***see items 7 and 9 in*** **Exhibit 2, Nellcor Technology White Paper**]. Neither study supports Masimo's claims of product or technology superiority.

What Masimo has consistently done is provide "apples-to-oranges" comparisons of our products. They match Nellcor products from the 1980's and early 1990's against newer Masimo technology to produce results that appear favorable to Masimo but are meaningless analogies. This tactic was evident during the GPO bidding process and continues to this day.

Also, several key studies and abstracts cited by Masimo were based on conditions that do not exist in the real world. Therefore, Masimo's claim that those tests prove their products' superiority is meaningless. The tests, especially those of Dr. Steven Barker, used artificial rhythmic conditions that are similar in nature to a heart rate signal, but unlike the patient conditions that exist in a clinical environment. These test conditions bias the study results in favor of the unique underlying design assumptions of Masimo SET technology and against other manufacturers' approaches that are designed to continuously track signals found in actual clinical environments. The scientific evidence (***described more completely in reference 19 of*** **Exhibit 2**) makes clear that the conditions tested by Dr. Barker do not represent the real-world environment.

Masimo's claim that its oximetry is superior to Nellcor's in preventing Retinopathy of Prematurity (ROP) is unfounded.

Dr. Goldstein and Masimo imply that the reduction in ROP observed at Cedar Sinai Medical Center was the result of Masimo oximetry technology. This conclusion is misleading and cannot be supported by the facts given the large number of simultaneous changes in patient treatment instituted in the NICU at that time and the lack of controlled comparisons of Nellcor and Masimo technologies. [***see detailed discussion in*** **Exhibit 3, Pulse Oximetry and Retinopathy of Prematurity**]

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[1] Attached exhibits have been prepared by Nellcor clinical and technical staff and consultants.
[2] We use the definition of "peer-reviewed" commonly accepted by the scientific community, which is a manuscript critically reviewed by independent qualified scientists not connected with the work under consideration and accepted for publication by the editorial review board of a relevant journal, containing sufficient information that peers can evaluate the validity of the experiment

Masimo's claim that its oximetry saves babies with life-threatening illnesses, and that Nellcor's cannot, is unfounded.

Dr. Goldstein recounted in his testimony a single seven year old event involving an infant with left heart hypoplasia to imply that Nellcor oximetry is unsafe for neonates. His assertion that "if not for the presence of the Masimo [prototype] pulse oximeter, life-sustaining efforts would have been discontinued," belies the facts of the case. **[*see* Exhibit 4, Analysis of Dr. Goldstein's Senate Testimony of Infant Case History].** Pulse oximetry is an invaluable *aid* to clinicians in these circumstances, but it is not the *solution.* It is well documented in the scientific literature that the treatment of clinical conditions such as left heart hypoplasia is highly complex and pulse oximetry is only one of the tools available in the very large armementarium employed by neonatologists to battle these debilitating and life-threatening illnesses.

Masimo's claim that Nellcor oximetry jeopardizes infants at risk for sudden infant death syndrome is unfounded.

Dr. Goldstein also testified that use of Nellcor oximetry jeopardizes infants at risk for sudden infant death syndrome. In truth, he conducted a study of an alarm management feature (known as "SatSeconds") available in the N-395 pulse oximeter that is not suitable nor intended for use in the population of neonates he elected to study (i.e., neonates with known episodes of periodic breathing and apnea that are *clinically meaningful*). SatSeconds is an optional feature that a clinician must knowingly enable and choose to utilize on select patients whose alarm events are known to be "nuisance alarms" attributable to *clinically insignificant* events. This is explicitly stated in the Directions for Use provided to clinicians. It appears the purpose of Dr. Goldstein's study was not to "test the relevance" of this technology but, rather, to attempt to discredit the technology by improper application in the clinical environment.

Mr. Kiani's assertion that Nellcor has made "kickbacks" to the GPOs with whom we do business is unfounded.

We abide by the laws and regulations that govern our business, including those that pertain to GPOs. Our corporate policy prohibits the payment of kickbacks, signing bonuses, up-front payments, prepaid advances on administrative fees or prebates in connection with GPO contracts. We rigorously adhere to this policy. Mr. Kiani produced no evidence that Nellcor has made such payments. Mr. Kiani has conveniently blurred the distinction between GPO fees of an administrative nature and rebate incentives and other discounts paid or passed through to hospital participants, which reduce their costs.

Nellcor currently has sole, dual and multiple source oximetry contracts with the major GPOs. Sole source contracts offer vendors high volume guarantees in exchange for price concessions, not in exchange for larger fees to GPOs. Where Nellcor has been awarded a sole source contract, it has done so in exchange for major price concessions for GPO member hospitals. On dual and multisource accounts, Nellcor's products have proven to be consistently the favorite among GPO members. As one example, AmeriNet, which

has one of the largest memberships of any GPO in the United States, currently has both Nellcor and Masimo on contract. Masimo has been on contract with AmeriNet since March 2000. While on a multisource basis at AmeriNet for over two years, Nellcor's sales within AmeriNet continue to increase due to end user preference for Nellcor's advanced technology, standardization, and competitive pricing.

Mr. Kiani stated in his prepared testimony that Nellcor pays Novation $16-to-$30 million in administrative fees for sensors alone. He further stated in his oral remarks, which were transcribed and published on the Kaiser Network website, that in addition to those fees, Nellcor paid a "kicker" of $6,000,000 more per year to Novation. Mr. Kiani then concludes that Nellcor is paying "kickbacks" to Novation for an exclusion.

The truth is, we participate in Novation's NovaPlus private label program, as do many other companies, large and small. Our NovaPlus oximetry sales are less than one-fifth of our total oximetry sales to Novation participants. Our aggregate total annual oximetry fees to Novation in our FY01, (or annualized for the current fiscal year), are approximately one tenth of the large amount claimed by Mr. Kiani. The aggregate fees we pay to Novation and other GPOs are well within the industry mainstream for contracts of this size.

Mr. Kiani's testimony suggesting there is something wrong with providing OEM partners with engineering funds for technical assistance distorts the truth.

Nellcor recognizes that with the development and release of new levels of technology, an advanced OEM pulse oximetry module may become available in a time frame in which a critical medical device manufacturer may not have all the necessary R&D resources to make the change from a previous generation. It is in Nellcor's, our OEM customers' and our mutual end-user customers' best interests to offer the latest available Nellcor technology. To facilitate a favorable timeline and to be a good business partner, Nellcor offers its OEM customers engineering support, clinical testing capabilities and, when the situation warrants, non-recurring engineering expense dollars to enable the OEM customer to engage contract or other employees for software or hardware integration tasks.

Mr. Kiani's testimony that Masimo's pricing is 30% better than Nellcor's pricing is exaggerated.

The alleged examples of significant price differential are generally the result of Masimo's tactics of comparing differing grades of product against our premium products, of claiming no comparable products when the obvious product comparison would show Masimo as more expensive, and making "price adjustments" in their analysis based on their projections, which we dispute, of product longevity. The Novation Pricing Analysis submitted to the Subcommittee contains such tactics. Our customers know the value of what they are purchasing.

Nellcor currently offers four different oximeter models (NPB-290, NPB-295, N-395, and N-595) at differing price points and with differing feature sets which best meet the needs for a wide range of customers. GPO organizations have memberships, which include large teaching hospitals, medical centers, small rural hospitals, nursing homes, and clinics. These customers have diverse oximetry needs and financial resources driving GPOs to find vendors that have a breadth of products. They turn to Nellcor because we offer, under one roof:

- The broadest range of pulse oximetry monitoring products in the industry
- Stand-alone monitors
- Hand-held monitors
- Combined pulse oximetry and end tidal CO2 monitors
- OEM oximeter circuit board supplier to over 85 manufacturers of multiparameter patient monitors which include pulse oximetry and technology licensor to four other multiparameter manufacturers
- OxiFirst fetal oxygen saturation monitoring system for use on babies during labor and delivery
- Oxinet Central Station monitoring system
- InTouch Remote Alarm Notification System
- Broadest choice of reusable and disposable sensors: 17 disposable and 9 reusable sensor choices
- OxiMax Pulse Oximetry System, Nellcor's 5th Generation family of intelligent, interactive OxiMax sensors and MP 506 OEM board which fundamentally improves core pulse oximetry technology via a platform that delivers innovation today and in the future
- OxiSmart XL, Nellcor's 4th Generation signal processing algorithm for read-through-motion performance
- SatSeconds Alarm Management that allows the caregiver to safely manage clinically insignificant nuisance alarm events
- Sensors manufactured by Nellcor that are compatible with the largest number of existing monitors in the market
- Sensor recycling program that allows hospitals to reduce costs and medical waste
- Sensor Utilization Analysis program to maximize hospital efficiency and costs
- In-Service/Staff Development program provided by highly experienced, credentialed clinical consultants to support customer training and education needs.
- Continuing Education (CE) credit program for nurses and respiratory care practitioners
- Track record of outstanding service and support to our customers (five Zenith Awards in the past six years).[3]

[3] Zenith Award is the "peoples choice" award of the respiratory care profession because its recipients are chosen by the respiratory care professional for companies that have done the most outstanding job according to these criteria: quality of equipment and/ or supplies, accessibility and helpfulness of sales personnel, responsiveness, service record, truth in advertising and support of the respiratory care profession. They are awarded every year at the AARC meeting.

By contrast, until recently Masimo offered only one oximeter model. This helps explain that the decision to purchase the Nellcor product was based on the total attributes of the Nellcor product line. Masimo:

- does not offer true hand held oximeters
- does not offer any central monitoring systems
- does not offer any remote alarm or telemetry products
- does not offer any products which incorporate oximetry and end tidal CO2
- does not offer a one piece disposable finger sensor, only a two-piece disposable sensor
- does not offer a variety of special application sensors like nasal, pediatric finger clip and forehead. Masimo only started offering an ear sensor within the past few months.

In short, Nellcor offers a complete range of products and services including motion-tolerant oximetry, the broadest line of sensors and superior clinical service and support. Nellcor has been as responsive to customers and the marketplace as technically possible, and has a proven track record of technical innovation. We provide outstanding service and value and have earned our excellent reputation in the medical device industry. Nellcor continues to be the oximeter of choice by the majority of both clinical and financial buyers.

Masimo and Mr. Kiani have misused the Subcommittee's inquiry

In conducting its inquiry, the Subcommittee is seeking to examine the important as well as complicated and technical subject of GPOs and attendant issues. It is critically important that the facts and testimony it gets be truthful and objective. The Subcommittee should understand that Masimo and Mr. Kiani are engaged in litigation with Nellcor over claims of patent infringement and have embarked on a campaign in the medical community, the media, and the courts to discredit Nellcor. We question whether the testimony they presented accords with the requirements of objectivity and accuracy that the Subcommittee is entitled to demand.

We appreciate your willingness to allow us to present our view to the Subcommittee and trust that this information will assist you.

Respectfully submitted,

Doris Engibous
President, Nellcor
Tyco Healthcare

cc: Senator Mike DeWine

FROM :PEVCO SYSTEMS FAX NO. :410-931-4660 Apr. 25 2002 04:30PM P2

PEVCO SYSTEMS INTERNATIONAL, INC.

April 25, 2002

U.S. Senate Committee on the Judiciary
Subcommittee on AntiTrust, Competition, and Business and Consumer Rights
224 Dirksen Senate Office Building
Washington, D.C. 20510

ATTN: Mr. Herbert Kohl
Chairman

RE: "Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation?"

Dear Chairman Kohl and Honorable Committee Members:

In anticipation of the upcoming hearing on the healthcare group purchasing organizations (GPO's), we feel compelled, as a specialty manufacturer of healthcare transport systems, to express our concern regarding unfair financial barriers, imposed by GPO's which we believe inhibit competitive processes.

Pevco Systems is a family owned, Maryland based manufacturer and installer of computerized pneumatic tube systems used to convey laboratory specimens and pharmaceuticals throughout hospitals and medical centers. Pevco was founded in 1978 by Fred Valerino, Sr. who has over 50 years of industry experience. Our annual sales average is $13,000,000. Pevco employs 45 people in Maryland with 15 other employees in field offices across the country.

Our products and services are recognized for their quality. Pevco was the proud recipient of the 1995 Blue Chip Enterprise Award which is co-sponsored by the U.S. Chamber of Commerce. I have attached literature describing this prestigious award.

The computerized pneumatic tube system industry for healthcare is highly specialized. All systems are client specific; designed and engineered to integrate into new and existing facilities. System costs usually range between $50,000 and $1,000,000 depending upon system size and complexity.

Today, Pevco is just one of two companies currently servicing this market. Our competitor, TransLogic Corporation of Denver, Colorado was purchased in 2000

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DESIGN . MANUFACTURE . INSTALLATION AND SERVICE OF PNEUMATIC TUBE SYSTEMS

by the Switzerland based multi-national corporation, SwissLog. In September of 2001, SwissLog/TransLogic purchased Quantum Industries of Santa Rosa, California, the only other U.S. based computerized pneumatic tube system manufacturer. With this acquisition, SwissLog/TransLogic now controls 80-85 percent of this $75,000,000 niche market.

Pevco has been solicited by most of the GPO's to participate in their preferred vendor programs. Pevco has declined most of these offers based upon the excessive administrative fees charged by the GPO's. In all such cases, Pevco's products met and exceeded performance criteria set forth by the GPO. However, Pevco did not have the financial resources to participate in all of the GPO programs.

Pevco chose to concentrate it's efforts on the Novation and Premier programs, which control about two thirds of the hospital purchasing market.

We analyzed the Novation vendor solicitation very carefully. We wrote to Novation expressing our interest in the program but asked for a more competitive fee structure for a company of our size. Novation decided to enter into a three year sole source contract with TransLogic.

In 1998, Pevco and TransLogic each entered into a three year agreement with Premier. With their market share 70 percent and growing, TransLogic was able to generate substantial administrative fees for Premier. Premier advised Pevco in July 2001, that they would not renew Pevco's vendor participation agreement that was to expire on November 1, 2001. We were shocked and surprised with Premier's decision. Pevco requested and was granted a meeting to discuss Pevco's termination by Premier in August, 2001.

At the meeting, Pevco was told that the decision to not renew Pevco was strictly a financial decision. Premier "made more money with TransLogic," and entered into a sole source agreement with SwissLog/TransLogic for twice the standard administrative fee. We argued that our technology was superior. Premier countered by saying, "We are not looking for technological superiority, just volume."

The practice of sole source group purchasing eliminates and stifles innovation of systems and product line. Pevco Systems has developed several products that provide improved system performance, reduced costs and improved patient care yet we still experience resistance to purchasing them due to our competitor's sole

source agreements with the GPO's.

Financial barriers such as these cause harm to companies such as Pevco. We cannot compete with the bulk volume and proprietary administrative fees offered by large national and multi-national corporations. I am attaching a page from our competitor's newsletter detailing the number of sole source agreements they enjoy with GPO's. Is this legal and ethical?

We need your help. Please regulate or abolish healthcare GPO's so we can compete in a fair and impartial market where the product, the service, the company, and the price are the determining factors for product selection.

Sincerely,

Frederick M. Valerino, Jr.
President

Statement

Of Thomas J. Shaw, President & CEO

Retractable Technologies, Inc.

Before the

United States Senate

Committee on the Judiciary

Subcommittee on Antitrust, Competition, and Business and Consumer Rights

April 30, 2002

On behalf of my colleagues at Retractable Technologies, Inc. and other small medical device makers, I would like to commend Chairman Kohl for his leadership and the Members of this Subcommittee for their time and interest in examining the role of hospital group purchasing organizations (GPOs) in the American healthcare system. As an inventor, entrepreneur, and CEO of Retractable, a small Texas company that manufactures and markets safety needle devices, I thank you for the opportunity to describe the harmful impact these purchasing cartels are having on patient care, healthcare worker safety, and innovation. More specifically, I would like to explain how the GPOs, operating in collusion with the nation's largest needle manufacturers, have used anti-competitive, unfair, and we believe, illegal trade practices to block us from introducing safe needle technology into America's healthcare facilities.

I would also like to congratulate *The New York Times* for its courage and perseverance in exposing these abuses and helping to put this critical healthcare issue on the national agenda. The reporters and editors working on this story surely deserve a Pulitzer Prize. As *The Times* documented in shocking detail, patients and healthcare workers get inferior drugs, needles, and pacemakers, while GPO executives get stock and options in giant medical supply companies. Put another way, the rich get richer and the sick get sicker.

Today, the two largest GPOs, Novation and Premier, control the purchasing of more than $34 billion of supplies at more than two-thirds of America's hospitals. Even though these GPOs are conduits for billions in federal dollars, they apparently are not subject to any regulatory scrutiny or oversight. They are not required to disclose anything to anybody. No one outside of this secretive, closed system seems to know where all this money is going. That is not right.

And it is certainly not what Congress envisioned in the 1980's and early 1990's when it attempted to respond to the entreaties of small hospitals that were seeking ways to enhance their bargaining power with the dominant medical device manufacturers. In an effort to encourage small hospitals in a single town or county to band together to obtain lower prices for medical supplies, Congress and the Department of Justice decided to grant these small group purchasing organizations an exemption from the Medicare anti-kickback provisions (concerning limitations on "administrative fees") and to create "safe harbors" for collective purchasing under the Health Care Antitrust Guidelines. Unfortunately, Congress did not foresee that these GPOs would soon divorce their financial interests from those of the hospitals and acquire enormous financial power for themselves. During the past decade, the GPOs inserted themselves between the manufacturers of the products on the one hand, and the hospitals and physicians who needed those products on the other. In doing so, they developed a business model whereby they would become the "marketing arm" of dominant manufacturers willing to pay millions in "administrative fees."

Since 1994, when these safe harbor rules were instituted, there has been no congressional oversight over them. That state of affairs remains the case up to this very day. But today marks a new beginning with the first congressional oversight hearing focused on the GPO phenomenon. I sincerely hope Congress will take whatever steps are necessary to break their stranglehold and restore free market competition to the healthcare industry.

Although the GPOs would like you to believe that they save hospitals money, the opposite is in fact the case. As history has shown time and again, competition, not cartels, drives down prices. If Congress would like to understand why healthcare costs continue to surge at

double-digit annual rates, I would urge it to begin by examining the fatally flawed economics of the GPO system. Worse still, the GPOs' monopolistic stranglehold on the healthcare supply chain is a hazard to the health and safety of patients and workers. In my opinion, this scandal will emerge as the "Enron of the healthcare industry." Enron is only about money. This is about life and death.

Before going into detail on our experience with GPOs, I thought it would be useful to give you some background on our company and our automated retraction VanishPoint® syringes and blood collection devices. They virtually eliminate the risk of accidental needlestick injuries through the use of a spring-loaded mechanism that causes the contaminated needle to retract automatically from the patient after an injection is given. Back in the late 1980's, I saw a TV news segment about a doctor who had contracted HIV/AIDS from a needlestick injury. As a structural engineer, I wondered if better needle technology could be developed to prevent such injuries. I learned that American healthcare workers suffer more than 800,000 such injuries each year. Many workers who get stuck with contaminated needles contract potentially deadly bloodborne diseases such as hepatitis C and AIDS. Overseas, reuse of contaminated needles is responsible for millions of AIDS deaths. After producing some designs for an automated retraction syringe, I received grants from the National Institutes of Health and continued to develop them. I then approached Becton Dickinson and Sherwood Medical [now part of Tyco International], which together control almost 100% of the U.S. syringe market, to discuss possible licensing agreements.

Neither Becton Dickinson nor Sherwood showed any interest whatsoever. Company officials contended that hospitals would never pay the additional up-front cost per unit for

devices that would protect workers. They also indicated that they did not want to invest in the new equipment needed to manufacture these devices, since they already had a dependable cash flow from sales of conventional needles. I should point out here that when the cost of testing injured workers is considered, the real cost of safer devices like ours is substantially less than that of standard syringes. In fact, our product is really needlestick injury protection, not simply needles.

So it became clear that if this technology were ever going to become available to healthcare workers, I would have to manufacture it myself. In 1994, Retractable Technologies was incorporated. Our mission: to rid the U.S. and the world of the scourge of needlestick injuries and reuse of syringes. With the help of friends and associates, I raised $42 million from several hundred individual investors to build a state-of-the-art manufacturing facility and headquarters in Little Elm. Our products were tested and evaluated in Parkland and Presbyterian Hospitals in Dallas, where they received an overwhelmingly enthusiastic response from healthcare workers. In 1996, Douglas Hawthorne, CEO of Presbyterian, assured me that he would see to it that our line of syringes would be adopted by his facility. That same year, we received FDA approval for our syringes and two years later got approval for our blood collection tube holder. Our safety syringe and blood collection tube holder have received the top evaluation from ECRI, the leading independent, objective, nonprofit health safety rating agency.

In December 1996, we got a rude awakening to the power of the new alliance between the GPOs and the dominant manufacturers. Becton Dickinson signed a seven and a half year, multi-billion dollar exclusive contract with Premier to supply Premier's member hospitals with needle devices. This was the beginning of a Kafkaesque nightmare that we continue to live to

this very day. According to published reports at the time, part of the deal called for Becton Dickinson to give Premier warrants on its stock. A month later, Mr. Hawthorne informed me that there was now no way Presbyterian could buy VanishPoint® devices. When our sales people try to show our products to clinicians and purchasing agents at hospitals that are members of GPOs, they are ordered to leave, sometimes even under threat of arrest. Doctors and nurses who request our lifesaving products are often threatened with dismissal if they persist. On a visit to Mt. Sinai Hospital in New York, a Premier member, a hospital official advised us that if we wanted a contract with Premier, we should offer to sell part of the company to Premier. We were stunned.

In a 1998 meeting with officials of Novation, the largest purchasing organization, it was clear that the real aim of the GPOs was to generate profits for themselves, not to reduce healthcare costs. A Novation representative proposed to us that they put a private label on our blood collection tube holder and raise the per unit price -- for its own member hospitals, mind you -- from our bid price of 27 cents to one dollar and split the difference with us. As I understood it, this was a common practice, but they needed permission from Becton Dickinson to go forward with us. Needless to say, that never happened. So much for saving hospitals money!

These exclusive contracts that Premier and Novation have signed with Becton Dickinson and Sherwood, like the many other big contracts they've signed with other giant suppliers, call for tying and bundling of products. These tying arrangements, which are illegal, link the sale of one product to the purchase of another. Becton Dickinson uses the market power they have in the syringe business to leverage and increase sales in other product markets.

Likewise, Premier has displayed great ingenuity and imagination in devising new roadblocks to throw in our path, roadblocks that have served to enrich Premier executives at the expense of healthcare workers. As Premier's own correspondence shows, Premier in 1997 suggested that we have our devices evaluated at a Premier-Becton Dickinson testing facility. Incredibly, we discovered that we'd have to pay the so-called "Premier Innovation Institute" a $1 million evaluation fee before they could be considered. That's like the federal government requiring Ford to pay GM to evaluate its 2002 models before the government could consider signing a purchase contract with Ford. I think it's fair to say that members of your committee would get a few visits from well-heeled Ford lobbyists if that ever happened.

In 1998, a few media organizations began to take an interest in the issue, and several of your fellow senators, including John McCain and Paul Sarbanes, wrote to Joel Klein, then chief of the Justice Department's antitrust division, requesting an inquiry into GPO practices. In September 1998, we prepared a long list of potential witnesses and met with Justice Department officials. To our knowledge, none of those potential witnesses was ever contacted. We were later informed that the "investigation" was turned over to a junior economist, who shelved the inquiry. At about that time, we filed a civil antitrust suit against Becton Dickinson, Sherwood, and VHA (Novation) and later Premier. A trial date of January 2003 has been set in federal district court in Texarkana, Texas, and we fully expect that justice will prevail.

As time went on, it became abundantly clear that the strategy of Premier and Novation was to stall for time to enable Becton Dickinson to produce a competitive product that did not kill or injure healthcare workers. In May 1999, Premier "awarded" us an 18 month so-called "evaluation contract" for our syringes. During this period, they were to be evaluated in six

Premier facilities around the country. No Premier facility could buy them without facing penalties from Premier or Becton Dickinson or both. The fact is, syringes are not like cancer drugs. It should not take longer than a month for a hospital to determine whether or not a device like ours -- which was already FDA-approved and recognized as the preferred product -- is suitable. At the end of this evaluation period, the Johns Hopkins researcher on the project informed us that our devices passed with flying colors. But despite repeated requests, Premier officials refused to publish, disseminate, or provide us with the evaluation data. It was deja vu all over again in November 2000, when Premier "awarded" us an evaluation contract for our blood collection tube holders -- despite the fact that a year earlier ECRI had given our blood collection device the highest possible evaluation.

All this was occurring, as you may be aware, while the needle safety movement was gaining momentum throughout the country. We are proud of our contribution to that effort. Working closely with the Service Employees International Union (SEIU), we helped draft the California safe needle law that became the model for similar legislation in many other states. In November 2000, President Clinton signed the federal Needlestick Safety and Prevention Act, which went into effect a year ago. Among other provisions, that legislation calls for healthcare facilities to involve frontline healthcare workers in the evaluation of safety products. Nonetheless, Novation, Premier, and their manufacturer partners have continued to block our efforts to offer our products to their member hospitals.

As last year's *60 Minutes* segment on needle safety revealed, small companies like ours can't even demonstrate their products at what are supposed to be "educational seminars" for healthcare workers. When Mike Wallace and his crew arrived at one such seminar at the New

Jersey Hospital Association in October 2000, NJHA officials explained that Becton Dickinson was their "preferred vendor." He also discovered that the association was really a business operating in the guise of a nonprofit organization. It negotiates contracts for its member hospitals with Novation, and receives kickbacks from Becton Dickinson for every needle sold under their contracts.

I should emphasize that the obstacles we face in selling our products in GPO hospitals are in marked contrast to the strides we are making in gaining access to public facilities. Our public sector customers include the United States Armed Forces, Veterans Administration hospitals, the New York City Health and Hospital Corporation, the New York City Fire Department, the health departments of Mississippi, Tennessee, and Florida, Parkland Hospital in Dallas, and many county health departments in California.

Let me point out that we have no quarrel with the model of group purchasing that was based on buying in volume to achieve discounts. But that legitimate model has been subverted by the Novations and Premiers of the world. The Novation and Premier model, as *The New York Times* documented so well, is nothing more than a "pay to play" scheme, "payola," as one source put it. It is a case of the tail wagging the dog. Big suppliers pay administrative fees, prebates, rebates -- most reasonable people would call them bribes and kickbacks -- to give them access to America's hospitals and deny access to others. Senator Leahy got it right when he told *The New York Times* that hospitals, not suppliers, should pay for buying groups.

This is not a mere corporate shooting match over revenues and market share. It is not a fight over supermarket shelf space or browsers and servers. It is, in our view, a criminal antitrust

case with life and death consequences. As such, it is virtually impossible to put a price tag on the harm that these egregious practices have inflicted on patients and healthcare workers. You cannot put a dollar figure on the suffering endured by needlestick victims like Karen Daley, a Boston nurse who suffers from hepatitis C and AIDS, or Julie Hipps, a St. Louis nurse who contracted hepatitis C, because they were denied access to the best available technology. And you cannot quantify in dollar terms the pain and suffering endured by a Florida heart disease patient because his cardiologist was not permitted to implant the best available pacemaker. Or the New York stomach cancer patient who must go through an operation that is unnecessarily long and complicated because his surgeon was not allowed to use a state-of-the-art minimally invasive surgical device.

It is also impossible to measure the impact of the GPOs in discouraging other inventors of potentially lifesaving medical devices from developing and marketing their designs. I can tell you that if I knew in the early 1990's that I would have to do battle with not just one but four Goliaths, I would not have believed it. I assure you that I am not alone. Because of the GPOs, we also run the risk of losing thousands of American jobs in an important sector of our economy to potential overseas competitors. This situation needs to be rectified immediately to rekindle innovation in healthcare. Since most breakthrough innovations originate with small businesses, this is a very serious matter for the entire economy.

I did not become an entrepreneurial manufacturer of medical devices either by training or inclination. I did so only because of my abiding concern that we needed to protect our patients and healthcare workers with the safest and best designed medical equipment. I am certainly not alone in this mission. I am a true believer in our free enterprise system, and I knew when I

embarked on this enterprise that success was not guaranteed. But I never expected that the door to the hospital, the door to the patients and healthcare workers I wanted to serve, would be closed to me -- all because the doorkeeper was being paid by my largest rivals for the right to exclusive, long-term contracts that could never be justified on the basis of cost or patient well-being.

That is not the free enterprise system at work. That is not a model by which innovation and safety will be maximized through the entry of new players seeking to compete in a free marketplace. That is, instead, a prescription for the destruction of the healthcare economy of our nation. Worse still, if we as manufacturers, policymakers, antitrust enforcers, hospitals, and physicians fail to reopen the door to competition and innovation, we will have failed in discharging our "duty of care" to the American public.

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NURSING HOMES
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ADDITIONAL SERVICES
Saint Vincent Catholic Medical Centers Behavioral Health Services
Saint Vincent Catholic Medical Centers Home Health Care
Saint Vincent Catholic Medical Centers Community-Based Outpatient Services
Pax Christi Hospice

March 13, 2002

Editor
New York Times

Re: Questions Raised of Conflicts at 2 Hospital Buying Groups
(front page, March 4):

As a New York area hospital, I want to highlight the positive relationship we have with Premier. We have been a Premier owner for over seven years and have first-hand experience with the benefits of group purchasing. Premier contracting makes it possible for us to obtain the highest quality products and save an estimated 7-10% annually.

The flexibility within Premier's contracts also allows us to choose those products that physician's 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' preferences, with no "penalty" from Premier. We currently use Masimo's technology in our hospitals, although your article would not lead readers to the conclusion that institutions such as Saint Vincent Catholic Medical Centers have this flexibility.

Our relationship with Premier helps to provide the highest quality healthcare to our patients in a cost-effective way. I am concerned that your coverage did not portray this side of Premier.

David J. Campbell
President and Chief Executive Officer
Saint Vincent Catholic Medical Centers of New York

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April 19, 2002

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

Dear Senator Kohl:

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

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

Sincerely,

Augusto Sola, M.D.
Professor of Pediatrics and Obstetrics and Gynecology
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Dear Senator Kohl:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Summary of results:
Since 1999 the outcomes not only improved but the results in this NICU are amazing:
a) No baby over 750 gm developed severe RoP (stages III-IV). (Down from 12% to 0%)
b) Decrease in the rates of severe RoP in the tiniest (at highest risk babies, birth weight 500-750 gm) from about 30% to 10%.
c) No preterm infant required laser surgery for RoP. (Down from about 5%)
d) No blind babies.

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

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

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

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

Sincerely,

Augusto Sola, M.D.

Augusto Sola, M.D.
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