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HOSPITAL GROUP PURCHASING: HAS THE MARKET BECOME MORE OPEN TO COMPETITION?

HEARING

BEFORE THE

SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY AND CONSUMER RIGHTS

OF THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

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HOSPITAL GROUP PURCHASING: HAS THE MARKET BECOME MORE OPEN TO COMPETITION?

WEDNESDAY, JULY 16, 2003

UNITED STATES SENATE,
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS, OF THE COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Committee met, pursuant to notice, at 11:09 a.m., in Room SD–226, Dirksen Senate Office Building, Hon. Mike DeWine, Chairman of the Subcommittee, presiding.

Present: Senators DeWine and Kohl.

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

Chairman DEWINE. Good morning. I don't know if it is a good sign or a bad sign when the witnesses are here before the Chairman. Thank you for being prompt.

Welcome to the Antitrust Subcommittee hearing on hospital group purchasing organizations. This hearing is, of course, part of the Subcommittee's ongoing efforts to help inject competition into the market of hospital group purchasing organizations, also known as GPOs, in order to increase the quality of health care that we receive and decrease the prices we pay for it. Senator Kohl and I have focused on this very important issue for a long time.

At our first hearing on GPOs in April of last year, we heard testimony about GPO practices that, quite frankly, disturbed me. For example, there was evidence that some GPO executives, indeed, some GPOs themselves, owned financial interest in their suppliers. This type of cross-ownership raises, at the very least, the appearance of impropriety and was cause for great concern.

Beyond these issues of business ethics, the Subcommittee heard testimony regarding the competitive impact of some GPO businesses and contracting practices. There were questions raised about whether the structure of GPOs and the basic business practices of most GPOs might be impeding the flow of new and innovative medical devices and technologies to the market, and more importantly, preventing these new technologies from getting to the patients and health care workers who need them. These concerns were aimed especially at Premier and Novation, the nation's two leading GPOs.

In the wake of what we heard at that hearing, Senator Kohl and I called for the GPO industry to adopt voluntary codes of conduct

to address the concerns raised by our investigation. To their credit, most of the GPOs, including Premier and Novation, and the industry as a whole, answered our call. After a great deal of work with the Subcommittee, the GPOs adopted codes of conduct reflecting a series of commitments regarding their ethical standards and their business practices.

As promised, we are here today, 15 months later, to examine the progress. Our questions are relatively simple. Are GPO ethical standards stronger today? Are GPO business practices better than they were a year ago? Are new, innovative medical devices more available to hospitals than they were a year ago? Simply put, are the codes of conduct working?

Our answers are a little more complex. The answers themselves are more complex. Based on a year of investigation, interviews with a broad range of industry participants, an interim GAO study, and examination of GPO business documents, I would say the answer is we have made some progress.

We have made a lot of progress with regard to ethical standards. For example, both Premier and Novation now prohibit all their employees from owning shares of their suppliers, which removes even the appearance of impropriety. I think that both Premier and Novation and the industry as a whole should be applauded for these changes.

It is fair to say, however, that the ethical guidelines are, as we might say, the low-hanging fruit. The biggest concerns of the Subcommittee are in regard to GPO business practices, where the progress is a little less clear and a little more difficult to measure. We will hear today some testimony, for example, from medical device manufacturers who believe they still face significant competitive barriers based largely on bundling, sole-source contracting, high commitment levels, and other GPO business practices. On the other hand, I think that many device manufacturers would agree that the marketplace they face today is at least somewhat more open to their efforts.

And, of course, we must not lose sight of the fact that while many of these business practices may have the effect of excluding some competitors from the market, they also may allow GPOs to keep prices down, which is, of course, an important goal sought by GPOs and their member hospitals. In fact, I have heard from a number of hospitals in my home State of Ohio and they are very satisfied with their GPOs.

Now, as I noted earlier, the answers we seek are complex and this hearing will necessarily be only one of a number of steps we take to lock in the positive changes made by GPOs and work with them on potential future changes, as needed. The General Accounting Office has released its interim report on GPO practices, and at the request of the Subcommittee will continue to examine the impact of GPO business practices on prices for medical devices.

The Federal Trade Commission and the Antitrust Division are currently in the midst of a wide-ranging review of antitrust health care policy and are also at the request of the Subcommittee examining the specific question of competition within the GPO industry.

And, of course, the Subcommittee will continue to work with all of the market participants, including the device manufacturers, the

hospitals, and the GPOs themselves, to provide oversight and help increase competition wherever possible. We will spend some time today hearing from our witnesses with regard to any further specific suggestions that they may have.

Before I turn to Senator Kohl, I would like to make a couple of additional points. We have seen some changes in this marketplace. We know that GPO business ethics have improved and we know that some of the smaller manufacturers who were virtually excluded from the process are starting to see some changes. We must recognize, though, that the types of changes implemented in the codes of conduct by the GPOs may take more time to generate significant impact in the market. Many of these changes in business practices have only recently been implemented and will, we hope, have a greater impact in the near future than they have had thus far.

In addition, it is important to recognize that we cannot measure success only by examining how many different medical device manufacturers are awarded a GPO contract. Not every small device manufacturer deserves a contract on every device, and some of the most controversial business practices may save money for hospitals, at least in some circumstances.

In this industry, as in most, one-size-fits-all solutions are not practical nor are they desirable. Instead, we must work to foster a dynamic marketplace in which many device manufacturers have a wide range of options to sell, and GPOs have a wide range of options to buy. Only then will patients be assured that competition is working to give them the best possible medical care at the best possible price.

Let me now turn to the Ranking Member of the Subcommittee, Senator Kohl, who has certainly done a great deal of research and done a great deal of work on this particular issue. Senator Kohl?

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

Senator KOHL. Thank you, Mr. Chairman, and thanks for the bipartisan effort you have made in pursuing this important issue.

It has been more than a year since we first heard troubling allegations that patients and physicians were being denied needed medical devices because of anti-competitive and unethical actions of large hospital buying groups, known as GPOs. After a year of investigation and oversight, we are pleased that our efforts have begun to make the marketplace more open for innovative competitors. We are concerned, however, that not enough is happening and that it is not happening quickly enough.

The primary allegation made against the GPO's business practices was that, in many cases, GPOs prevented hospitals from buying the best and safest products for their patients. For example, the inability of hospitals to purchase safety needles resulted in unnecessary injuries to health care workers, who in some cases developed HIV and hepatitis. Heart surgeons reported incidents where they were not permitted to use the pacemaker that they judged medically necessary because their hospital did not have a GPO contract with that supplier.

The situation was dangerous to patients and compromised public health, so we launched an investigation into the hospital purchasing industry. We discovered that the GPOs' contracting practices, in many cases, froze out competition and entrenched the dominant positions of the large suppliers, often to the detriment of patient care.

We held a hearing last year on our findings. We secured the agreement of Premier and Novation, the nation's two largest GPOs, responsible for over $28 billion of purchasing at two-thirds of our Nation's hospitals, to implement substantial changes in their business practices. To their credit, Premier, Novation, and four other large GPOs promised to change the way they did business. They all agreed to important and voluntary codes of business conduct.

Today, we ask two questions. What progress has been made in the marketplace since Premier and Novation made their agreements nearly a year ago? And what remains to be accomplished?

We identified five major areas in need of reform in the GPO industry. The first was ending conflicts of interest, such as investments by GPOs or their executives in medical suppliers with which they did business.

The second was sole-source contracts, in which one supplier has an exclusive deal for a product with the GPO.

The third area was high commitment levels, in which a hospital must purchase a very high amount, as high as 95 percent, from the GPO-approved vendor in order to get the best prices.

The fourth was bundling practices, giving substantial extra discounts to hospitals that buy a bundle of different products in one contract.

And the fifth was high administrative fees, GPOs collecting payments in excess of 3 percent of the value of the product sold from suppliers. The GPO codes of conduct addressed each of these issues.

The evidence we have received from medical device manufacturers, hospitals, GAO, and the GPOs themselves tells us that while some progress has been made with respect to each of these issues, in many cases, much more needs to be done.

While significant progress was made with respect to conflicts of interest, reform is much less certain in the area of contracting practices. In general, it appears that Premier has made more substantial reforms than Novation, but Premier's reforms are not without their shortcomings.

With respect to sole-sourcing, Premier has promised to ban this practice with respect to physician preference items, but has not done so entirely. Novation did not make the same pledge, and one-third of current contracts for clinical preference items are still sole-sourced.

With respect to commitment levels, Premier has banned GPO-imposed commitment levels, but left the door open to commitment levels initiated by vendors. Novation expressly permits commitment levels above 75 percent with consent of their clinical councils.

With respect to administrative fees, Premier took the laudable step of capping administrative fees at 3 percent in all contracts. Novation has only agreed to a 3 percent fee cap for what it des-

ignates as clinical preference products, and their revenues from high administrative fees continue to rise.

Finally, with respect to bundling, both GPOs still engage in this practice. The GAO report said bundling contracts at one of the two largest GPOs still account for more than 40 percent of its revenue. Novation will not terminate its bundling program until 2004 at the earliest, although it could do so sooner if it wished.

This clearly is only a start on the road to true reform. While we applaud the positive changes that have been implemented, the industry needs to do more and needs to do it now. The past year has taught us that promises to change and actual change, despite the best of intentions, are not the same. We need to be assured that the commitments we have seen so far and the ones that we will ask to be made today become permanent and will last once the spotlight of a Senate hearing room fades away.

Today, we will send a letter to the Secretary of Health and Human Services to seek ways to make these good reforms permanent, including requesting the appointment of an officer to oversee the hospital group purchasing industry. We need to ensure that GPOs fulfill their mission to act on behalf of hospitals to obtain the best products at the best prices for their patients. We also plan to ask the Department of Health and Human Services to strengthen and revise its regulations governing the Medicare safe harbor that permits GPO to accept administrative fees from suppliers. And finally, we will reiterate our request that the FTC reexamine and revise the joint FTC/Justice Department Health Care Guidelines.

Mr. NORLING AND MR. McKenna, as leaders of the two largest GPOs providing supplies for nearly two-thirds of our Nation's hospitals, you particularly bear a special burden. Your companies' decisions on which products to put on contract affects the health and safety of millions of patients and health care workers every day. We depend on your good faith, your judgment, and your integrity to ensure that hospitals have access to the best medical products at the best prices. So it is essential that you continue to follow through on your industry's efforts to reform.

Our investigation so far has determined that your reforms have made a good start in making the market more open, but the job clearly is not finished. We commend you for the reforms that you have made, but we will continue to oversee this industry to see that group purchasing never denies a patient, a physician, or a health care worker a needed medical device.

Thank you, Mr. Chairman.

Chairman DEWINE. Senator Kohl, thank you very much.

We have a vote scheduled around 12 o'clock. That is Senate language for nothing exact. That means that unless you all want to spend the day with us, we probably ought to try to get done before that vote.

So we are going to have—we have your written testimony. We appreciate that. That will be made a part of the record. We would ask you to summarize your testimony. Tell us in three minutes what you think is the most important part of your testimony. We already have your testimony, so we appreciate that. Give us the highlights. Just off the top of your head, give us what you think

is the most important thing that we know. We have seven very qualified, very important witnesses here. Give us three minutes.

We are going to go by the rules. When you see the yellow light, that means you have got a minute left. When you see the red light, you are done and then we are going to go to the next witness. Then we are going to go to questions. Questions will start with Senator Kohl, and then I will have some questions. Unless the Senate changes its mind, we will have until 12 o'clock, so you can see that doesn't give us a whole lot of time for questions.

Mr. Norling, you are first.

Mr. NORLING. Thank you, Chairman DeWine.

Chairman DEWINE. You didn't know which way I was going to go, but that is where we are going.

Mr. NORLING. I had a suspicion.

Chairman DEWINE. Let me give the brief introduction. Richard Norling is Chairman and Chief Executive Officer of Premier. He has served as President and Chief Executive Officer of Fairview Hospital and Health Care. He has testified before this Subcommittee and we welcome him back.

Mark McKenna is President of Novation. He has served in a variety of positions since joining Novation in 1987.

Mr. Said Hilal is the President and Chief Executive Officer of Applied Medical Resources Corporation, the manufacturer of surgical devices, including devices used for minimally invasive surgery.

Mr. Thomas Brown is Executive Vice President of BIOTRONIK, headquartered in Portland, Oregon. I am sure I messed that up, and you can correct me, Mr. Brown, in a minute.

Mr. Gary Heiman is President and Chief Executive Officer of Standard Textile, based on Cincinnati, Ohio. Additionally, he is also on the Board of Trustees for the Jewish Hospital of Cincinnati.

Mr. Lynn Everard is a health care business and supply chain consultant. His publications include a white paper detailing the future of the health care supply chain and the impact of group purchasing organizations on the financial prospects of the health care industry.

Ms. Elizabeth Weatherman has been a member of the health care group of Warburg Pincus since 1988. Ms. Weatherman has testified on this matter in the past and we welcome her back again.

Mr. Norling?

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

Mr. NORLING. Thank you again, Chairman DeWine and Ranking Member Kohl. As I stated at last year's hearing, if there is an opportunity to improve, Premier is going to take that opportunity. Last year, we made commitments, and I am pleased to report to the Subcommittee today that those commitments were kept, and are imbedded.

With the adoption and implementation of the Premier code of conduct, I would like to share with you the highlights of what we have done with respect to our business practices.

First of all, we contract for physician preference items on a multi-source basis, with no GPO commitment levels or bundling with unrelated products. We adopted a contracting approach in the last year that we call strategic sourcing. Fundamentally, this enables suppliers with products focused in very limited product areas to compete effectively with suppliers who offer a much broader product line.

We have also substantially revised and improved our technology assessment and breakthrough process, which offers access even in the face of existing contracts. We have worked with outside firms, such as ECRI, a very well-known national firm that conducts research with respect to medical device products.

I am pleased to see on the panel today Tom Brown of BIOTRONIK. BIOTRONIK is a relatively small producer of pacemakers and defibrillators that Premier recognized as embodying innovative technology. We were pleased to give the company an award this May through our technology breakthrough program.

I am also pleased to see Mr. Hilal from Applied Medical. We have a pending contract proposal for its GelPort product, and last December, we sent the company details about our technology breakthrough process, and encouraged it to submit other products as well. We have yet to receive such, but certainly look forward to it.

We have implemented, as you indicated, our conflict of interest of policy, but let me be specific about other items. We do limit fees to 3 percent. We do not charge up-front fees or marketing fees. We do not accept administrative fees. We do not require vendor participation in other services. We do not private label. We have begun a process of standardizing administrative fees, which Professor Hanson, who we brought in as a third-party ethicist, conveyed as important in limiting the potential of the perception that fees could influence product selection—very, very important. We contract for 3 years or less; the few exceptions being in the interest of our owners. We seek out diversity. We have hired an ethics and compliance officer.

When we introduced our code, both of you gentlemen had some nice things to say about it. You characterized it as industry-leading, and I would agree with you. The code is a very important start and we, indeed, have implemented that code fully.

But I want to commit to you and other members of the Subcommittee in good faith that we are going to be productively involved in continuing to improve the group purchasing industry, as well as health care in America.

In conclusion, I want to emphasize that you can count on our continued cooperation and support. Simultaneously, we believe that the time is right to encourage others to do their part in an ongoing effort to ensure the quality and effectiveness of our Nation's healthcare system, and I believe you made those comments.

The title of this hearing asked the question, "Has the market become more open to competition?" From Premier's perspective, the answer to that is an emphatic yes. Thank you.

Chairman DEWINE. Thank you very much.

[The prepared statement of Mr. Norling appears as a submission for the record.]

Chairman DEWINE. Mr. McKenna?

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

Mr. MCKENNA. Thank you, Chairman DeWine and Ranking Member Kohl. Like my colleague here, a year ago, we were sitting here and weren't sure what to expect. This year, though, we feel very prepared relative to reporting to you the results of what we committed to deliver to the Subcommittee on behalf of our member hospitals that look to us to save dollars on high-quality clinical products and commodity products.

We committed to promote industry best practices. You made it clear to us that you wanted us to ensure that small vendors had an opportunity to participate in group purchasing programs and that member hospitals had ready access to innovative technology. We heard you.

On August 8, we committed to implement seven operating principles. Today, less than a year later, I am pleased to report that we have not only met but in many cases exceeded those principles. We have also systematically trained all of our employees on their responsibilities to follow through and implement these principles as a part of their daily business practice. Let me take a few minutes to highlight a few examples, and I would like to begin with technology.

Novation has dedicated new resources to the identification and evaluation of new and emerging technology. We have also launched a web-based technology forum. We believe it is the only one of its kind in the industry. The forum invites vendors to post information about their new products, whether they are on contract or not on contract, and through our technology pipeline program, Novation is constantly searching the marketplace for emerging medical technology. Once we find a new product, we take the initiative to contact the vendor and work towards a contract position.

The results have been gratifying. In just 7 months, vendors have posted information on the technology forum in 50 product categories, and as a result of that, we have made 20 contract awards to companies with innovative or new technology, and this has been done outside the regular bidding cycle. There currently are an additional 20—excuse me, a dozen more products that are under review, so a total of 32 events in just 8 months since we put the technology forum in place.

Our progress in other areas of the operating principles has also been significant, and let me report out. First, we have revised our Opportunity Spectrum Program around commitment to reemphasize that participation is purely voluntary. We have eliminated all penalties in the event that a member elects to drop from the program, and finally, we have eliminated any requirement that the members purchase a combination of capital equipment and disposables.

Novation has awarded multi-source contracts in six separate clinical preference product categories that were previously offered under a sole-source contract. For example, when I was here last year, we had one safety needle under contract, Senator Kohl, as you pointed out. This year, we have four.

Novation has also enhanced its processes for addressing vendor grievances. Today, we have a formalized process and commit to get back to suppliers within a 90-day period with a result. And, in fact, we have done so with one vendor, resulting in a contract award.

In conclusion, I want to emphasize to you that while I am proud of the progress that we have made in just over 11 months, we at Novation recognize that we have a continuing obligation to live up to the letter and to the spirit of these operating principles. It is an ongoing process that requires resolve, diligence, leadership, and commitment. For its part, Novation will continue to dedicate ourselves to these operating principles and to ensuring that hospital members have unimpeded access to a broad array of high-quality products at the lowest possible prices.

Chairman DEWINE. Thank you very much.

[The prepared statement of Mr. McKenna appears as a submission for the record.]

Chairman DEWINE. Mr. Hilal?

STATEMENT OF SAID HILAL, PRESIDENT AND CHIEF EXECUTIVE OFFICER, APPLIED MEDICAL RESOURCES CORPORATION, RANCHO SANTA MARGARITA, CALIFORNIA

Mr. HILAL. We have only just begun. Chairman DeWine, Senator Kohl, thank you so much. Applied really appreciates this opportunity to be in front of you.

Fourteen years ago, we started out the company with the concept of combining better clinical outcomes with better financial outcomes. Those are not mutually exclusive. They can be done together. We spend 22 percent of our revenue on R&D. We have over 380 pending or issued patents. We have the highest quality.

You would think with a commitment like that and an accomplishment like that that we would have the doors open, that we would be doing well. We are not.

We face markets as closed as a castle, with the GPOs as the most treacherous of outer moats. We are on the other side of the moat. Similar to how castles have concentric lines of defense, the dominant players have used GPOs as the outer moat and then moved on to more of the localized exclusionary contracts, bundling, grants, and so on. It is not one circle. It is not one issue. It is a market that is not open.

In markets unencumbered by GPOs, we have done extremely well. In the clamp market, in the padded clamp market, for example, we went from no market share in 1990 to 70 percent market share today, the market leader. We obsolete our own technology three times in that period. In the progressive European markets, where GPOs are not a factor, we have five times the market share in the trocar market as we do here.

Fourteen months ago, frankly, we were energized and filled with hope, and in May of last year, we went out to the largest 40 customers and we offered them trocars at 60 percent discounts from their GPO prices. Now, that would have taken a $300 million market down to $120 million and the customer would have had the best product. But in the process, I agree, GPOs' income would have gone from $9 million to $3.6 million at the 3 percent. But the issue

is the customer is still waiting. The patient is still waiting. We can help.

Admittedly, we have received some contracts and we are grateful for that, but we are not satisfied. We cannot be limited to the fringe markets where our impact is just the latest and the greatest. We can make a big difference in big markets, in markets where the dominant players day in, day out as the clock is ticking are making hundreds of millions of dollars of additional income. And in this process, we are not helping the patient. We are not helping the process through it.

One hundred days ago, and at about the same time the Subcommittee released the agenda for the hearing, we saw some increased activity. We saw and we hoped the market would be changing. At that time, we asked Novation for an end to the contract with J&J which actually bundles sutures, trocars, and surgical products together. Novation initially turned us down, and as of late, asked us to submit a bid.

In conclusion, Applied is again very grateful for the Subcommittee and for everyone that is following its lead. Fourteen months into the effort, we see no indication that the needed change will take root and grow without your continued intervention. I kindly urge—I respectfully urge you to continue your efforts and that you see that the changes to safe harbor and the prohibitions of sole-source contracts and bundling of unrelated products and vendors and limit to the term of the GPO contracts are done.

This great nation has always been a bastion of free people and free markets and this market is not free and the field is not a level playing field. I urge you to help out. Thank you very much.

[The prepared statement of Mr. Hilal appears as a submission for the record.]

Chairman DEWINE. Mr. Brown?

STATEMENT OF THOMAS V. BROWN, EXECUTIVE VICE PRESIDENT, BIOTRONIK, INC., LAKE OSWEGO, OREGON

Mr. BROWN. Chairman DeWine, Ranking Member Kohl, members of the Subcommittee, I, too, urge this Committee to continue your oversight of this very important issue that affects the innovation, quality, and cost effectiveness of medical care in this country. I would like to thank you for your efforts to date and stress the importance of legislation or comprehensive regulation in order to fix this problem permanently.

I represent a small company. BIOTRONIK has 2.5 percent market share in the United States. But effectively, I am representing hundreds of companies throughout this great United States that have small market share. Over the past 10 years, these companies have found themselves generally locked out of group purchasing organizations due to their size. As a small company, they simply do not generate enough sales to cause GPOs to take notice. We are not considered a player. As a result, these companies have generally found themselves outside the market, looking in, when it comes to GPO contract opportunities. This situation, unfortunately, continues today.

Last year, your Committee initiated hearings and study on this and we sincerely appreciate your efforts, and improvements have

been observed. I am not going to go into those improvements because of the time constraints, but they have been mentioned and I would like to acknowledge those improvements.

These are all positive steps that have resulted from the U.S. Senate Committee on the Judiciary's efforts, but as I noted earlier, there remains much to be done to create equal access for small and large companies alike. The establishment of code of conduct is a good start, but one cannot assume or believe that this action alone will change or radically impact the central problem, which remains fair and equal access to contracts regardless of company size.

The problem continues to be perpetuated by GPOs, and, in fact, one of the reasons this problem exists is that GPOs have a very special privilege. That privilege is the exemption from the Medicare anti-kickback and fraud statute. So long as GPOs are allowed to charge administrative fees and so long as GPOs are allowed to return a large portion or any portion of that fee to the member hospitals, we have a serious conflict of interest that is automatically biased towards large companies with large market share holdings because of the potential fee dollars.

Within our GPO industry, for example, within my industry, a GPO could do a multi-source contract, which is two companies, and they could lock up 80 percent of the market just by a multi-source contract. A dual-source is really what I am referring to. A multi-source contract is the answer. It is the way to allow everybody fair access.

The administrative fee continues to be the core issue impacting small companies' access into GPO systems. GPOs should be required to allow all companies to participate in contracts that incorporate administrative fees. This will eliminate the bias towards large market share holders, eliminate the pressure from large companies on GPOs, and allow small companies to participate on the basis of price, quality, technology, and service. This should improve the competitive process, resulting in cost savings, broader access to life-saving products by physicians, and the creation of a level playing field for all vendors.

Representing all of the small companies in this industry, Senator Kohl, we sincerely appreciate your leadership and interest in this problem. Chairman DeWine, your support has been invaluable and we look forward to your leadership in resolving this issue. Thank you.

Chairman DEWINE. Thank you very much.

[The prepared statement of Mr. Brown appears as a submission for the record.]

Chairman DEWINE. Mr. Heiman?

STATEMENT OF GARY HEIMAN, PRESIDENT AND CHIEF EXECUTIVE OFFICER, STANDARD TEXTILE COMPANY, CINCINNATI, OHIO

Mr. HEIMAN. Chairman DeWine, Ranking Member Kohl, and distinguished members of the Subcommittee, thank you very much for inviting me here today to provide my perspective as a vendor of hospital supplies who has extensive experience with the hospital supply chain. I am the President and CEO of Standard Textile Company in Cincinnati, Ohio, a closely-held, family-owned com-

pany that was founded by my grandfather in 1940. Today in the United States, we employ about 1,200 people, including 350 employees in Ohio and 600 workers in Georgia, amongst eight other locations within this country.

Standard Textile produces reusable products for health care facilities ranging from surgical packs and gowns to incontinence products and bed sheets. We also supply some of the other fabrics that you see around hospitals, such as window treatments, cubicle curtains, and upholstery fabric.

We began working with hospital group purchasing organizations about 20 years ago, competing against much larger companies, for example, Baxter International, Johnson and Johnson, and Kimberly–Clark. Today, we have contracts with virtually all of the GPOs, including AmeriNet, Broadlane, Consorta, Kaiser, MedAssets, Novation, and Premier. About 75 percent of our revenue is generated through GPO contracts.

Using GPOs has helped us to reduce costs and increase the efficiency and efficacy of our marketing, sales, and customer service operations. Our bidding department used to be huge. Today, it has only three people. We have been able to cut our sales force by 15 to 20 percent. And while our prices have dropped significantly under GPO contracts, we also have the benefit and efficiencies of much greater volume. Today, we are still a medium-sized company competing against Goliaths, but we are seven times larger than we were 20 years ago.

I would like to give you just one example of how GPOs helped us as a medium-sized manufacturer, and also helped hospitals to adopt a technically innovative product that greatly enhanced safety and efficacy.

In 1990, Standard Textile developed a patented, proprietary fabric that we use to manufacture surgical packs and gowns and sterile wraps, all Class II medical devices, for operating rooms and other clinical procedures. This fabric has greater barrier resistance to fluids and viral penetration and, as such, enhances safety. it is also more cost effective and environmentally friendly than disposable products because it creates no medical waste on its own.

When we developed these products, VHA, which is one of Novation's owners, already had a contract for disposable products with a much larger publicly traded competitor, Kimberly–Clark. It would have been easy, more convenient, and certainly the path of least resistance for VHA to turn down a small company like ours, but they didn't. Not only did they clinically evaluate our products, they brought in, at their expense, a third party, Deloitte and Touche, to analyze and evaluate our financial model and determine that we could create overall cost savings for hospitals.

Standard Textile doesn't always win the GPO contracts that we bid on. At times, we have been defeated by other companies. As a supplier, we, of course, never like to lose. But the GPO committees that evaluate these contracts are representative of the hospital industry, are qualified, and are fair. We may not always agree or like their conclusions, but we do believe the process is open, fair, and honest.

I can also say that whenever I have encountered a hospital or clinician who wanted to use my product, regardless of whether it was

listed on their GPO contract, I have never had a problem getting it into their hands. They always have the freedom and the choice to buy directly from any supplier or manufacturer.

In addition to being a supplier, I can also speak from a hospital perspective about the benefits of GPOs. I am the Board Chairman of the Jewish Hospital of Cincinnati, a medium-sized tertiary care not-for-profit hospital with about 200 beds, and growing, approximately 15,400 surgeries per year, and about $248 million in annual revenues. In 1998, the hospital was running an annual deficit of approximately $5 million. To help reverse that situation, the hospital made many significant operating changes, including greater utilization of GPOs to assist in managing costs. This year, I am pleased to say that the hospital will report—

Chairman DEWINE. Mr. Heiman—

Mr. HEIMAN. —a net gain from operations of $12 to $13 million.

Chairman DEWINE. We need to move on.

Mr. HEIMAN. I have got three more sentences, if that is okay, Senator.

Chairman DEWINE. We are about there.

Mr. HEIMAN. I have been following with great interest the recent discussions about GPOs. I think it is commendable that this Subcommittee has taken an active interest in the topic and I believe many of the changes in the GPO industry since your first hearing have been positive.

But speaking as both a hospital supplier and a hospital board chairman, I think the existing GPO system brings enormous value to the health care system and I hope it remains that way.

Again, thank you very much for inviting me to share my views at this hearing and I welcome any of your questions.

Chairman DEWINE. Thank you very much.

[The prepared statement of Mr. Heiman appears as a submission for the record.]

Chairman DEWINE. Mr. Everard?

STATEMENT OF LYNN JAMES EVERARD, HEALTHCARE SUPPLY CHAIN STRATEGIST, COCONUT CREEK, FLORIDA

Mr. EVERARD. Mr. Chairman and Senator Kohl, if there was ever any doubt in your minds about the importance of your mission here, let me say that our Nation will not be able to do its job of providing quality care and a safe working environment unless or until the GPO problem is resolved. And Senator Kohl and Senator DeWine, I would like to personally thank you for your commitment and leadership on this issue.

You have already introduced me. I would like to let you know that I am a supply chain strategist and health care business educator, and for 22 years, I have worked in the health care supply chain, studying its strengths, its weaknesses, and its opportunities for improvement.

I am here today because of my deep concern for the safety of patients and caregivers and the financial viability of our Nation's hospitals, all of whom continue to be harmed because competition in the health care supply chain is compromised due to the business practices of some large manufacturers and certain GPOs, fueled by the power granted to GPOs in the safe harbor exemption.

I understand that almost a year ago, you were inclined to continue the safe harbor pending the results of this experiment with self-policing codes of conduct. I understand your desire to take a measured approach, and I think that you were wise in doing so. While I shared your optimism in that approach, a year later, we have seen very little progress and this market desperately needs to be open to competition. Robust competition in the health care supply chain is not only important for small manufacturers, but also for hospitals, as well. I believe that the evidence is insufficient to warrant the continuation of the special treatment in the safe harbor.

Mr. Chairman, you asked me to discuss the progress made in the GPOs developing codes of conduct, and, in fact, GPOs have developed codes of conduct, much to their credit. Unfortunately, those codes of conduct may not have the results that were intended because they are not externally verifiable.

The real question at this point for me is this. Are the GPOs really doing their job of saving money for hospitals? In its testimony before this Committee last year regarding the cost savings by his group, Mr. Norling of Premier stated, "We estimate that we save our member hospitals over $1.5 billion per year." Hospitals need real science proving the savings produced by GPOs, not estimates. Last year's GAO study, the only independent analysis of GPO savings, reported that GPOs don't save money.

What is the real truth? That is not an idle question. By granting the safe harbor, the Congress gave GPOs a great deal of power and a significant ability to create revenue for themselves.

The GPO landscape is extremely complex and complicated. Sometimes it is difficult to know where the GPO ends and the side businesses begin. I believe that Congress must fully understand the flow of money in the health care supply chain and the GPO's role in the flow of that money in order to pronounce that the safe harbor is a benefit to patients and taxpayers. I do not believe that this body can in good conscience implement a code of conduct until all of the questions about GPOs are answered.

GPOs seeking to end years of speculation on the part of their foes should welcome the opportunity to fully disclose their practices and sources and uses of revenue, and skeptics who say, "Trust, but verify," will have what they need, and this entire industry can move beyond the GPO question and focus all of its efforts on providing quality patient care and a safe work environment.

Recently, two major GPOs announced plans to go public with a stock offering. Does it seem right that while other hospitals continue to struggle financially, Broadlane and MedAssets will use the windfall granted to them by the Congress in the form of the safe harbor to enrich themselves by selling stock in their companies? Will this be the legacy of the safe harbor? I hope not, Mr. Chairman.

In conclusion, this hearing has been about GPO behavior, but the implications of that behavior affect our entire health care system. Elsewhere in this Congress on this very day, other members of the House and Senate are grappling with other health care issues. The outcome of your decisions here today will clearly affect the work

that they are doing and the health care system that hundreds of millions of Americans depend on to take care of them. Thank you.

[The prepared statement of Mr. Everard appears as a submission for the record.]

Chairman DEWINE. Ms. Weatherman?

STATEMENT OF ELIZABETH H. WEATHERMAN, MANAGING DIRECTOR, WARBURG PINCUS, LLC, NEW YORK, NEW YORK

Ms. WEATHERMAN. Thank you, Senator DeWine and Senator Kohl. I would like to thank you for inviting me back. I would like to encourage you to refer to my written testimony for the details supporting the views that the National Venture Capital Association and myself, as a 15-year veteran investing in the medical device arena, hold very strongly as our views.

But what I would like to do right now is very quickly emphasize what I think are the true take-homes from my testimony. First and foremost, it is really, really hard to bring innovative new breakthrough technology to market in the U.S. and around the world. There are major technological challenges to developing the technology. There are intellectual property barriers. There are regulatory barriers, the standards to which we must adhere in terms of demonstrating the safety and the efficacy of the devices that are being developed to assure that they are going to work for the American patients and that they are going to be safe. It is a veritable gauntlet, and more new technologies fail to reach market than succeed.

So my second point, that to have an additional roadblock on the part of GPOs, where they can essentially block a new technology based on, I am sure their in some cases good intentions, simply puts up an additional barrier, an additional risk in the mind of venture capitalists who are already taking huge risks, huge amount of capital that they are investing into companies long before they know whether their technology is ever going to generate revenues, much less a profit.

We thank you so much for the spotlight that you have put on the practices that the GPOs have used over the years and we do think that the code of conduct that you have asked them to adopt is significant progress. However, a major flag for us is the effort that Senator Eschutia attempted to make, the State Senator in California, to adopt the code of conduct that the GPOs themselves had adopted for themselves into legislation was fought by many of the GPOs very hard. It makes us wonder, how serious are these guys really about adopting a uniform code of conduct and implementing it and executing it and really being clear and that they are going to continue to be consistent with it and really take it seriously. They may be trying to address the letter of what you have asked them. We question the spirit of some of them.

So in conclusion, we would like to ask you to do any and all things you can to assure that the abuses that they have committed over the years are corrected once and for all and forever. Thank you.

Chairman DEWINE. Thank you very much.

[The prepared statement of Ms. Weatherman appears as a submission for the record.]

Chairman DEWINE. Senator Kohl?

Senator KOHL. Mr. Norling and Mr. McKenna, we spent considerable time and effort working with you last year to draft new codes of conduct. We would like to spend some time today going through each of these most important issues your codes of conduct were supposed to address: Bundling, high administrative fees, sole-sourcing, and high commitment levels. In assessing this progress, one of our main concerns is the conclusion that the GAO reached in its report released to our Subcommittee today that, quote, "Some GPOs' conduct codes include exceptions and qualified language that can limit the potential of the conduct codes to affect change."

One GPO practice which many fear can damage competition is known as bundling. This is the practice of entering into one contract for multiple products, either from one vendor or from multiple vendors. A hospital gets an added discount only if it purchases from the bundle, but typically, it must purchase virtually all of its requirements, often 95 percent, from every product in that bundle. If a hospital does not meet this requirement for just one product, then it loses the additional discount for every product. This makes it very difficult, if not impossible, for the small manufacturers of just one medical product to compete with the bundle offered by the large dominant suppliers.

Mr. McKenna, you pledged to terminate Novation's bundling program, but only after it expires in the first quarter of 2005. We understand that you are now considering revising this program sometime in 2004. Novation's vendor contracts have a provision in which they can be terminated on 90 days' notice by Novation. And so we ask, why not exercise this provision and abrogate the bundling contracts today? Why should those patients who benefit from the products outside the spectrum bundle have to wait another year or two, Mr. McKenna?

Mr. MCKENNA. Senator Kohl, just as a basis, our program is entirely voluntary. There is access pricing for all of our members to utilize any product under contract with no commitment whatsoever.

With that as a basis, as a hospital looks to maximize their value, there are different price points they can purchase at at different levels of commitment. But in no way does the committed program that you reference link one product to another. These contracts are put in place separately and the hospitals on their own determine whether or not they want to purchase at higher levels to gain greater value and benefits. There is no precondition of any of these contracts to contain base pricing. It is their decision alone.

We have eliminated any penalties from a member removing themselves from these programs. That has been completed. We have removed any anti-competitive language that was in the program. We have removed any capital equipment requirements in the program. We have lowered purchasing levels in two particular categories, urology and pulse oximetry products, which we have now also gone to a dual-source on.

And then, lastly, we have accelerated the work to put a next-generation program in place, Senator, and these programs bring significant value to our members. One of our primary obligations is to the hospitals we serve. And so we are very serious about doing

this. We will do it ahead of schedule. But these things do take time to do them properly.

Senator KOHL. Mr. Hilal, would you like to respond?

Mr. HILAL. With all due respect, it sounds like a parallel universe because that is not what we see in the marketplace. We had the case of walking up to an account and showing a group of hospitals how we can save them $400,000 on purchases of about a little under $1 million. The answer came back that should they dare to do that, the cost on the other products would go up by $600,000.

For us, it took a lot of work and a lot of arithmetic and a lot of meetings in order to show the folly of that approach. In our written testimony, you will see an analysis of how the customer is actually not only intimidated by such numbers, but confused by such numbers that actually come from the dominant supplier more often than not.

So with the GPOs leading this whole bundling issue and its impact on penalties and price changes, it becomes very difficult for the customer to make a clear decision on where they can save money and where they can't.

Senator KOHL. Again, Mr. McKenna, why don't you just terminate your bundling program right now?

Mr. MCKENNA. Senator, our commitment program has been built at the request of our members, our hospitals. It brings them high levels of value with them making the sole decision as to whether they access base-level pricing by nothing at all or choose to participate in this program. As previously stated, we have accelerated our efforts to change practices in our committed programs. We have done that. We have communicated that to the supplier community and to our hospitals and we are on schedule to look at this program to make it more user-friendly to all stakeholders in the supply chain way ahead of schedule.

Senator KOHL. Why don't you do it right now?

Mr. MCKENNA. Once again, our primary objective is to make sure that we serve the hospitals that we work at their behest and we—

Senator KOHL. Why don't you offer them the maximum discounts without the bundling?

Mr. MCKENNA. It has been our experience, and we recently just had one, that in some cases, discounts will change, and we want to make sure that as we go through our open competitive bid process, that we give them equal or greater value and it is our commitment to do that.

Senator KOHL. Can you give us a pledge that you will work with even greater intensity to eliminate this practice by the end of 2003?

Mr. MCKENNA. What I can commit to, Senator, is by the end of 2003, we will have initiated a pilot to get this new program out and running within our hospitals with the anticipation that in early 2004, we could then launch it to the broader hospital network.

Senator KOHL. Okay. Mr. Norling, Premier has pledged not to engage in bundling of products across different vendors. However, the GAO's testimony indicates, 5 months later, one of the two large GPOs derived a whopping 40 percent of its purchase volume from medical-surgical products from contracts in which a single vendor bundled products together. Does your code of conduct permit this? This is the very type of bundling practice which Applied Medical

has faced. Mr. Norling, will you agree to revise your code of conduct to ensure that this type of bundling is ended, as well?

Mr. NORLING. Thank you, Senator Kohl, and I would reiterate that we have already agreed not to bundle across multiple vendors. Let us be clear with respect to the single-vendor situation. I think I can illustrate this best, in terms of the challenges involved, with regard to Mr. Hilal's comments.

Later this month, we will be issuing a request for proposals covering the endomechanical product area which includes trocars. We are also going to issue a request for proposals regarding sutures. These are areas that have been bundled traditionally, particularly under the influence of a particular large manufacturer. Applied Medical and all manufacturers in this product area will receive a request for a proposal. We will be breaking these products out into eight separate categories with no bundling.

So specific to the example that has been presented here, and specific to the point I made earlier about what we called strategic sourcing—of trying to get product categories at a level in which small companies can compete effectively with large companies—that is exactly what we are doing.

But large companies have traditionally insisted as a quid pro quo for giving the contract and giving the discounts on this kind of practice. We are seeking to make some changes, the commitments in the existing code. I don't think it needs a modification to the existing code. It needs continued implementation, which we are talking about.

But can we do this alone? No. I think there are some manufacturer behaviors, in this case large manufacturer behaviors, that need to occur. And very frankly, with respect to all of our comments about the larger needs here—I ask where is the manufacturers' code of conduct that applies to these kinds of circumstances as well?

Senator if you would forgive me, just to correct the record, I am told I made the statement that we don't accept administrative fees in my haste to respond to Senator DeWine's time period. I would like to clarify that what I was trying to say was that we don't accept up-front or marketing fees. It may have been Freudian, but we do indeed accept administrative fees.

Senator KOHL. Mr. Hilal, before we move on, do you want to respond to Mr. Norling?

Mr. HILAL. I am delighted. We are looking forward to this openness, to the fact that Premier has chosen to unbundle that package. We believe we can offer value to Premier. We look forward to working with them on that area.

Senator KOHL. Does anybody else want to respond to this whole question of bundling?

Mr. MCKENNA. I would like to offer one additional comment.

Senator KOHL. Yes, Mr. McKenna?

Mr. MCKENNA. We have also looked at—in our definition of a bundle, and time for debate, but it is linking one product to another to get a price discount. What Mr. Norling has described in this product category, we have also put on notice the supplier in question and are working towards unbundling those products so that we can open up this. But as Mr. Norling has stated, this has

not been something that has been easy for the industry. Once again, our primary objective is to do no harm to those that we serve, so with that in mind, we are on a mission, as is our colleague here, to do similar activities.

Mr. HILAL. Senator Kohl, if I may, if I may add just the comment that I truly believe that GPOs that comply with the spirit of what you are aiming at accomplishing also need the support from the dominant suppliers, because in some situations, they have no choice. Facing large organizations that are bundling, I believe that this has to be stopped at the source, also. So I believe there is a sincere attempt here that is moving in the right direction.

Senator KOHL. Before we go back to Senator DeWine, I would like to get your comment, particularly Mr. McKenna, on administrative fees. Premier made an impressive commitment in this area, promising never to accept administrative fees higher than 3 percent from suppliers and standardized fees with respect to each product category.

Mr. McKenna, Novation's pledge on this issue was much more limited and only applied to clinical preference products. Mr. McKenna, I am sure you believe that anything Premier can do, you can do better.

[Laughter.]

Senator KOHL. So will you pledge to us today to follow Premier's lead on administrative fees? Will you do that, Mr. McKenna?

Mr. MCKENNA. Senator Kohl, we believe that—and I think it was made in one of the statements either you or Senator DeWine made, that multiple business models are good. They are good for competition. So our business model may be different than Mr. Norling's. I think our primary objective, however, is to deliver the highest possible quality products at the lowest possible prices.

I also noted in reviewing the panel's testimony that our administrative fee percent, which has been declining over the past few years, was the exact same percent as noted in Mr. Norling's testimony, 2.1 percent.

And if I may, we agreed to lower fees and reduce all fees on clinical preference products to less than 3 percent. For all those categories we have analyzed, we have done that. We agreed to standardize our fees on our private label, and we have done that. And we agreed not to enter into any new contracts for clinical preference products that provide fees above 3 percent, and we have done that.

So with that in mind, we think the system is fair and open. We are committed to fully implementing the principles that we have agreed to with the Subcommittee and we will continue to do so.

Senator KOHL. Senator DeWine?

Chairman DEWINE. Mr. McKenna, Mr. Norling, Mr. Hilal describes a kind of different world than the world you described. You tout your innovative technology programs as giving more access to small innovative companies, such as his. He describes a kind of medieval world where there is this castle and there is this moat, and he didn't describe it as such, but I see in this moat some alligators and crocodiles and he just can't get even close to the castle without getting eaten alive. So it is an entirely different world that I am hearing and Senator Kohl is hearing and the audience is hearing.

How do you explain that to us? Why does the world look so different to Mr. Hilal than it does to you all? You are in the castle. The picture he paints is you are in the castle. You guys are, I guess, the knights in the castle and he is trying to get in. Why is the world so different?

Mr. NORLING. Actually, Senator, if I may, I thought he was portraying us as the moat, frankly.

[Laughter.]

Mr. NORLING. I am not—

Chairman DEWINE. I don't know. I think you have got the drawbridge up, I think.

Mr. NORLING. All right, fair enough.

[Laughter.]

Chairman DEWINE. You have got the drawbridge up. I think he would like the drawbridge down.

Mr. NORLING. I would respectfully submit that the drawbridge is certainly on the way down, if not totally down.

[Laughter.]

Chairman DEWINE. Okay. Well, he wants it all the way down. Now, we have all had enough fun, but why is the world different, in all seriousness? Why are we seeing these different stories here and where are we going?

Mr. NORLING. Senator, let me go to a fundamental point here. It has always been the case that if a hospital wants to purchase a physician preference item off contract, it can, and I can tell you, with the implementation of our code of conduct, there are no consequences from Premier if it does so. So I think that is a significant step associated with the code of conduct.

But beyond that, in 1997—

Chairman DEWINE. If they want to, technically, they can do it.

Mr. NORLING. If the hospitals want to buy, they can. There is nothing that Premier does, as of this point, that restricts them from doing so. I think that is a fundamental point.

Chairman DEWINE. Okay.

Mr. NORLING. I think the other point is—what is Premier doing to encourage access? And I would tell you that it was in 1997 that we put our technology breakthrough clause in place which said, even if there is an existing contract, perhaps a sole-source with one of these big players, someone with innovative technology could access Premier resources, have that technology assessed, and be given the absolute opportunity for a contract.

Now, that is one example, I think, of a very, very aggressive process by Premier to welcome this sort of thing. I am not suggesting we have done absolutely everything they could possibly have done, and I will suggest that we will continue to work hard on this. These not-for-profit hospitals out there are under great pressure. If there is a new technology that either is going to help with cost or quality for patients, it is our obligation to make it accessible, and we are working very hard at doing that.

Chairman DEWINE. But why do you think he is seeing the problem? If you were in his position, why do you see the problem?

Mr. NORLING. Number one, I am speaking for Premier, and so I will let Mr. McKenna make his points, and frankly, there are a lot of others who could very well be here speaking to the moats they—

Chairman DEWINE. You are not helping me understand it. Mr. McKenna?

Mr. MCKENNA. Let me try to be brief but focused on responding. First of all, I think we have got some bridges built and they are down. I am not sure that we have made them visible to all the companies that need to have access. I think that is a tribute, however, and comment to the work that we are doing and the principles that the Subcommittee asked us to implement.

Once again, our program is voluntary. If a clinician wants something and a hospital wants to buy it, they go buy it. It happens every single day.

But more importantly, I think, in particular Mr. Said's company, timing is always an issue. But since we have implemented the principles, we have awarded through our amended agreements process one product contract on one item, and then we have several others in motion. We have started to build a relationship with the company, we have met several times, and I sense it is a speed issue. Our commitment would be to accelerate to a degree possible building this relationship and putting products on contract that our clinicians find advantageous to them and we are committed to do so.

If you look at the access points now as far as building bridges across the moat, there is a technology forum that allows any supplier, whether they are on contract or not, to post their products, and we have trained all of our folks on that that touch contracting.

Mr. NORLING. Senator, can I give you a specific response with regard to Applied Medical—

Chairman DEWINE. Sure.

Mr. NORLING. —because I think Mr. Hilal—

Chairman DEWINE. And then we want to hear from the guy trying to get in the castle.

Mr. NORLING. Absolutely. On December 12 of 2002, we discussed all of Applied Medical's other products other than the one we already had on contract. We told the company about our tech breakthrough program and how to submit reviews for those products. The same day, another Mr. Hilal, their senior vice president, e-mailed a Premier staff member thanking her and indicating an intent to submit Applied's products. We sent the company the whole process of how to do that.

So this isn't an effort—this isn't us holding back. This is us being straightforward and saying, here is how you access Premier, even though we have a contract in place. I have got Federal Express receipts, very frankly, displaying this process. So I am not trying to create a controversy here other than to say, this an example, with one of the members testifying here, where we have gone out of our way to say, here is how you can access this market via our tech breakthrough process.

Mr. HILAL. Senator, if I may answer—

Chairman DEWINE. Yes.

Mr. HILAL. Actually, we had that offer, and later on, Premier individuals advised us specifically to not pursue that route for two reasons. One is because it is very lengthy. We are good at development. We are fast at development. But if delays take two and 3 years at a time, our advantage is gone. Eventually—

Chairman DEWINE. Two or 3 years?

Mr. HILAL. Two or 3 years of getting into an account or getting a technology to take hold. We have to implement—

Chairman DEWINE. What takes two or 3 years?

Mr. HILAL. It takes two to 3 years usually to launch a new product and get the clinical results and get the clinical papers and the efficacy established, and then from that standpoint, the applications to get into these kinds of exceptional clinical. So from that standpoint, Premier advised us, Premier individuals advised us to hold off on that because they felt that the GelPort was already established. It had enough clinical papers behind it and they wanted to get it on a contract immediately, and that happened that way. So we did not have to take the longer route.

Now, interestingly enough, as we got the GelPort in, one thing that we added to it was trocars, additional devices used with the procedure that happened to be on other sole-source contract. Now, we added them gratis. We added them with no additional cost to that device. I submit to you, Senator, that today, Mr. Chairman, that today, we see more hospitals, especially university hospitals, literally throwing away $300 worth of value for fear of violating their contracts and their compliance, and then they turn around to Johnson & Johnson and buy these same equivalent products from them.

And so the market is really not that open except to the niche products. Our issue is not whether or not we can go into niche markets, where our technology is superior, and sometimes the only technology. We would like to participate in the larger markets where we can bring not only innovation, but value and savings. We can make a difference if we are only allowed in.

Right now, if I may push the analogy one more step, we are allowed into the hamlets. We are not allowed into the castle.

Mr. BROWN. Chairman DeWine—

Chairman DEWINE. Mr. Brown?

Mr. BROWN. If I may, sir. Thank you. To answer your question more directly about why is there a moat, the moat is really a direct result of the billions of dollars worth of administrative fees that are at stake within the GPO systems as a whole. Self-regulation is akin to putting the fox in charge of the henhouse. We really need your help in allowing equal and fair access to all companies because of this administrative fee issue. That is the moat. We can't get over it.

Mr. HEIMAN. Senator DeWine?

Chairman DEWINE. Well, how would you do that?

Mr. BROWN. Well, I think there are a number of ways. I will give you an example. There is one GPO by the name of Health Trust that has taken—made the decision to create multi-source contracts, not dual-source. From the eyes of a small vendor, a dual-source contract is no better for the example I used earlier. But if you use a multi-source contract and allow all of the players to play, if you are going to charge a fee, if there is a better way, if the GPOs believe that they can get better pricing without allowing all vendors to play, then let them do that without charging the fee. But if you are going to charge the fee, everyone should have equal access.

Chairman DEWINE. Mr. Heiman?

Mr. HEIMAN. Senator DeWine, I have a somewhat different perspective. When I became President of our company, we were approximately a $70 million company and we were competing against giants like Baxter, Johnson & Johnson, and Kimberly–Clark, and I believe that the smallest of these three was Baxter International, with sales of about $5 billion. I don't think any of these groups have ever been known for their kind and compassionate marketing and sales tactics.

But at the end of the day, this really seems to me to be a story of everyday America. Some people won, some people didn't win, and those that didn't win just aren't happy about it. And what I have always told my people is that if you didn't win, don't come to me and start complaining and griping. Start figuring out how you need to win.

So we started out as a small company. We worked hard. We built better mousetraps and we earned the opportunity. We listened to our customers. We improved and we gained access over time and achieved POs. I think in doing that, we have created a win-win relationship that really is good for everybody in the industry. So that has been my perspective as a small supplier, small manufacturer who has been able to grow in this industry.

Mr. HILAL. Mr. Chairman, if I may just add one comment.

Chairman DEWINE. Sure.

Mr. HILAL. I truly believe that the person that has to win is the patient. Eventually, we are all in this very special business in order to help patients get better medicine, more available medicine, more affordable medicine. It is not enough for one of us to have a good year, to make $1 million, to buy a bigger home. There is an obligation that comes with this industry. We are in it for a special reason. We are caretakers, whether we are making a product or operating on a patient, and my feeling is that we tend to forget that sometimes in a competitive situation. But the fact is, we still have to look for those results that give the best product at the best price.

Chairman DEWINE. Senator Kohl?

Senator KOHL. Ms. Weatherman, you testified before our Subcommittee when we first looked at the GPO issue a year ago. So today, what is your assessment of impact of the GPO's new codes of conduct and the ability of new and innovative medical device manufacturers to gain access to the marketplace?

Ms. WEATHERMAN. I think if you look at venture capital investing over this time period over the last 12 months, it has declined in the medical device arena. In 2001 and 2002, the investment rate per quarter was roughly half-a-billion per quarter, and so far this year, the average has been closer to half of that.

It is a multi-factorial equation as to why the investment has dropped, but my point is, having an additional sort of whimsical barrier that the judgment that key people within GPOs can make in the decision making process to allow a new technology to get on contract, to not get on contract, is another barrier and another factor that increases the risk for VCs to want to invest in technology before it has gotten to market. So it is a factor. How powerful a factor versus other factors, it is hard to measure. But my overall point is, it is a factor that is not conducive, in our experience and

the experience of the companies we have invested in, to furthering innovation.

Senator KOHL. What more, in your opinion, do we need to do to encourage people in your industry to believe that this sector is open to new, innovative competitors?

Ms. WEATHERMAN. It seems to me either the exemption to the antitrust should be rescinded for GPOs or that the code of conduct is actually put into law or a form where we can very clearly see that it is going to be adhered to across the entire universe of GPOs, not sort of depending on the interpretation of different significant players, which I think, as you have heard the testimony, there is a difference in interpretation between the two leaders.

I think an even playing field would be far better. Having the intermediary aspect of deciding what is innovative technology and what is not would be extremely positive, for that not to be the purview of the GPOs or, for that matter, the large manufacturers. Let the customers decide which products they want to purchase and have the full basket available to them.

Senator KOHL. Mr. Everard, do you want to make a comment?

Mr. EVERARD. Sure. I would agree with that completely. I think one of the elements that we are missing is that the GPO product councils do not have—the individuals on those product councils, where there may be 25 individuals, none of those individuals has a fiduciary responsibility to all 1,500 or 2,000 hospitals or whatever it is. And for them to make those decisions, in my mind, seems to, in some ways, usurp the authority of the clinical caregivers in those individual hospitals. So if we could take that out, it would be very helpful.

The other thing that I would like to say at this point is that as we discuss GPOs and the safe harbor, we have really got only two choices. That is, we either eliminate the safe harbor and return this industry to a level playing field where everybody gets the same opportunity to compete for business, one small or medium-size account at a time, where we don't completely change the landscape of competition, or if we want to keep the safe harbor, then we are going to have to implement some very, very significant oversight and there are going to have to be rules for participation and penalties for breaking those rules. That is the only way that we will be able to keep all of this fair and above board, and that is the only way that patients, caregivers, and taxpayers are going to feel comfortable with the system that has been created.

Senator KOHL. Mr. Brown?

Mr. BROWN. Yes, sir. I would like to say—to address this issue of product councils. I think if you look at this on one hand, it looks like a fair way to assess which company should be allowed to participate in the GPO contract. But in actuality, what the product councils generally reflect is the standard market share that is existing today out in the marketplace. And so as a result of that, the little guy is still generally excluded from fair access. So, somehow, that has to be addressed, as well.

I would like to address a comment made by Mr. Norling and that is the new technology assessment program does help small companies, and my company is a good example of that. And while we are very encouraged by this and that we have been selected by Premier

to participate in their program, I would also, on the other side of the ledger, like to say that this only reflects a small percentage of our product line. It only reflects those products that the GPO has considered extremely new and innovative. While I have a complete large sector of products to be able to market to GPOs, I am still locked out from that viewpoint.

Mr. NORLING. Senator, if I may respond to that—the product council process, I think, is an interesting one because you can't bring representatives of 1,500 hospitals together to do that. And if you are asking each hospital to effectively put that sort of process in place, we contract for 300,000 different products. So I think of the mass of attempting to deal with that.

How is this effectively and fairly done is the question that is raised here, and I don't want to get into a debate here, but that is why we have chosen to go outside to, in our case, ECRI to do the technology assessment of products. They offer clear standards in terms of what they do and how they do it.

So our product councils are given clinical results from our databases in terms of where they exist, and where we have good insights. They are given reviews from a number of outside consulting firms, including ECRI. That, in turn, is brought to these councils.

Now, frankly, these folks are a great representation of the 1,500 hospitals and clinicians trying to make a difference for patient care. I am not saying that they perfectly represent every interest, and very frankly, that is why the idea that choice does exist is a very important element. But at some point, you need a resource to effectively screen this incredibly high volume, bring objective data to the process, and then a representative group to make a decision.

Now, if that decision were enforced by Premier arbitrarily on hospitals, on clinicians, I think it would be a good point. But that is indeed not the case, and I think I have submitted that.

You have to have a mechanism to do the best job you can to get fair representation of the patient and the clinicians into the process. I am very open to ideas of what might be better, but I assure you, having individual hospitals putting processes in place to assess 300,000 line items is not the answer.

Senator KOHL. Mr. McKenna, Novation recently informed the Subcommittee that several plainly anti-competitive contract terms had now been removed from all of its contracts. These contract terms forbid Novation hospitals from even evaluating competitive products or forbid a Novation hospital from purchasing any products that competed with products sold in the bundled Opportunity Spectrum Program. While we are glad that Novation has finally seen fit to eliminate these contract terms, we were astounded that such plainly anti-competitive provisions were found in Novation's contracts in the first place.

Mr. McKenna, should the fact that these contract terms were contained in Novation contracts for many years cause us concern that Novation might well revert to these and other similar anti-competitive practices should the spotlight of our oversight ever be lessened?

Mr. MCKENNA. No, Senator Kohl, to the contrary. Broadly, and then specifically, let me address your concern.

We have gone through and taken each of the operating principles. We have put a management-level person responsible for each principle and we have gone through and trained every employee that has anything to do with contracting. So we have made a commitment, which is a long-term commitment, to make systemic changes to our organization culture to, on a daily basis, make this a part of everyone's work.

In regard to the former language that has now been removed, at the time we put those contracts in place, the driver really came from the for-profit side and we were attempting to make sure we stayed level with them relative to value. And so we packaged our stand-alone contracts that were—they were put in place one at a time and then we offered additional value if the customer on their own elected to participate in those contracts.

So just a perspective as to how we got to where we are. But I think a testament to the principles that we have all agreed to, we have now taken the steps to eliminate those issues and have communicated that to both the supplier community and certainly to our membership.

Senator KOHL. Mr. Norling, will you commit to review Premier's contracts for language that could be considered or construed as anti-competitive and report back to this Committee that you have indeed done that review?

Mr. NORLING. I will absolutely commit to that. I am not aware of any language that can be construed as anti-competitive, but we will make a systematic review of our contract terms and conditions.

I will indicate, Senator, that typically that is a negotiating point company-by-company, offering-by-offering. So the terms and conditions, apply to not one contract, but a whole series of them. But I will look at our standard and I will make sure that, with regard to our practices, that guidelines are in place to assure there are no anti-competitive elements to it.

Senator KOHL. Any other comments from the panel? Yes, sir, Mr. Hilal?

Mr. HILAL. Senator, if I may, more important than us recognizing that the drawbridge is down, it is important that hospitals themselves know, because what lingers behind any of these practices is an impression that stays around for years, a misperception of what hospitals can and cannot do, unfortunately fueled by the large or dominant suppliers.

It behooves us when we change these things to strongly urge the GPOs to communicate to their members that things have changed. Unless and until they do that, things do not change in the field. Thank you.

Senator KOHL. Mr. Chairman?

Chairman DEWINE. Mr. Everard, if the GPOs fail to win savings the way you say they do, why don't the hospitals just leave the GPOs?

Mr. EVERARD. That is a very good question.

Chairman DEWINE. They understand the business, don't they?

Mr. EVERARD. That is one of the problems that we have. The arguments of the GPOs is that if they went away, immediately, hospitals would face higher prices. I believe that that argument is—the logic of that argument is really based more upon education

than economics. What I mean by that is that the current pricing structures of GPOs become known the day that they hit the street. They become almost common knowledge. It would be very difficult and a very brazen move on the part of any major manufacturer to raise prices unilaterally, knowing that the prices are already out there, without having a good reason to do it.

In general, hospitals have not devoted much effort to managing their supply chains. They have chosen in many cases to outsource that decision making process to GPOs. As a result, they are now, years later, left defenseless. Within those hospitals, there simply is not a supply chain expert who would be able to properly assess the value of the GPO.

The other part of this is that in most GPO relationships, hospitals receive a substantial rebate check at the end of the year. The rebate is ostensibly money that is left over from GPO operations expenses that is now returned back to the shareholder hospitals. The CEOs of hospitals count on those checks. Some of them are quite large, $1 million. They are wondering what they would do without that $1 million if that relationship and the rebate check went away. So they are almost held hostage by the need to get the rebate.

What many of them don't understand is that a number of hospitals, smaller hospitals, small IDNs, have gotten together and gone out and achieved price savings on their own that take their pricing and make it 13 percent or more below the prices that are being paid by hospitals who are members of the GPO. So there are models out there that have worked. Hospitals are able to move away. But the hospitals generally don't understand that that option is available to them and they are taught to fear going out on their own. Any time a hospital goes out and fails because it didn't do it the right way, the GPOs publicize that to all the other hospitals to make sure that everybody is afraid of making that move.

So one of the issues that we face in this industry is that the hospitals simply don't have the knowledge or understanding of real supply chain, and let me give you an example. Mr. Norling referred to a term called "strategic sourcing." The way that GPOs use strategic sourcing is completely different than the way that it is used in manufacturer outside of health care.

One of the things I find fascinating is the dichotomy between the way that large manufacturers, and small ones, for that matter, in health care go about buying their products from their raw materials suppliers and then the way that they turn around and sell them to hospitals. It is a completely different method and completely different model and I would like to know why that is and I would like to encourage hospitals to adopt that model for themselves.

Chairman DEWINE. I want to thank the panel very much. We have actually, as you can see, survived without a roll call, which they keep telling us is going to occur at any moment. We have survived. I thank you very much for your testimony.

The biggest thing I take away from this hearing is that people in different parts of the industry see a different world. That was brought out very well by the testimony. GPOs feel as though they are very open to new products. Mr. Heiman, as a supplier, certainly

supports that view in very eloquent testimony today. But two other suppliers supported by Mr. Everard and Ms. Weatherman say that the process is too uncertain, it is too burdensome. Simply put, they are locked out. They are outside the castle.

You know, this is a big industry. We can't expect complete agreement and uniformity within an industry, but these differences are, I must say, very stark. It suggests to me that this Subcommittee has more work to do. We must continue our oversight, and so I intend to continue this oversight. We will continue to look at this industry. We will continue to have oversight, and we will, I expect, have a hearing in the future again.

I would think it is fair to say that our work in this area is not complete, but we appreciate you all coming in. You have given some very valuable testimony and the hearing is adjourned. Thank you very much.

[Whereupon, at 12:35 p.m., the Subcommittee was adjourned.]

[Questions and answers and submissions for the record follow.]

QUESTIONS AND ANSWERS

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR MIKE DEWINE
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 1. In his testimony, Mr. Brown suggests that an ideal approach to GPO contracting might be for GPOs to offer contracts to all qualified vendors in a product category as long as those vendors are willing to meet a certain GPO price. Is this approach feasible and are there benefits to this approach? For example, wouldn't this approach ease the concerns that some device manufacturers have raised with GPO contracting.

Response. Novation does not believe that the approach suggested by Mr. Brown is feasible. Nor has Novation been able to identify any meaningful benefits that would result from adopting this approach. Moreover, while this approach may be beneficial to certain device manufacturers, it would be at the expense of the community-based, not-for-profit hospitals and academic medical centers that make up the membership of VHA and UHC.

In a word, Mr. Brown's approach is anticompetitive. By offering contracts to every vendor that meets a certain price, Novation would effectively be setting a price floor for the products at issue. Setting a necessarily artificial price floor in this manner would have a number of negative effects and no readily-identifiable benefits.

The most likely effect (and perhaps the most harmful) is that price-based competition through Novation would be essentially eliminated. This would defeat Novation's mission — to secure lower prices for its GPO members by leveraging their collective purchasing power.

Put somewhat differently, although Mr. Brown's approach may "ease concerns" of certain device manufacturers, it would be for the wrong reasons. To the extent a manufacturer could not previously compete on the basis of price, Mr. Brown's approach may help that manufacturer obtain a contract with a GPO. While this will undoubtedly benefit the device manufacturer, it would disadvantage GPO members by reducing their potential cost savings. In the end, Mr. Brown's approach would subsidize vendors at the expense of community-based, not-for-profit hospitals and academic medical centers.

It also is worth noting that the federal government and a number of state governments appear to agree with Novation (and reject Mr. Brown's approach). The General Accounting Office ("GAO"), for example, has encouraged the Department of Veterans Affairs ("VA"), which owns and operates hundreds of hospitals, to take advantage of more opportunities to contract jointly with the Department of Defense ("DOD"). The GAO has explained that such joint contracting efforts serve to lower prices for VA and DOD alike. These benefits, however, only can be obtained by narrowing the universe of vendors under contract. Mr. Brown's approach, on the other hand, would eliminate the potential for any such benefits.

More recently, the Office of Management and Budget ("OMB") negotiated an arrangement on behalf of a number of federal agencies, securing significant discounts on office supplies. It has been reported that the sole-source contract — which is being finalized with Office Depot — will save taxpayers more than $3 million a year. OMB also is in the process of negotiating a similar arrangement with Microsoft, which may yield even greater savings. As noted above, these types of arrangements would be prohibited under Mr. Brown's approach.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR MIKE DEWINE
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 2(a). You have indicated that Novation will not allow vendor fees to act as the determinative factor in contract awards except where the quality and prices of the competing products are "essentially the same." This indicates that Novation may contract with the vendor offering the best financial package if that vendor's products are essentially the same in quality as competing products. Does this create the possibility that companies with products that are inferior, even slightly so, will win contracts because they have a better financial package?

Response. Novation does not award contracts for products that are "inferior," regardless of either (1) the overall financial package offered by the vendor or (2) the administrative fees offered by the vendor. Novation's competitive bidding contract award process is driven by non-financial factors, such as product quality and safety. Moreover, with respect to the financial factors that are considered, product price is far more important, and is given significantly more weight, than vendor fees.

To reinforce this contracting philosophy, the Operating Principles, provide that "on a prospective basis, Novation will implement additional measures to further ensure that vendor fees are not a determinative factor in the award of contracts under [its] competitive bidding process (except in those situations where the quality and pricing of competing products are essentially the same)."

As explained in prior submissions to the Subcommittee, Novation member councils and task forces — which are comprised of VHA and UHC representatives and include clinicians and materials management personnel — utilize a decision criteria award matrix or "DCAM" to assess each bid. The DCAM is designed to identify the "low best bid" through the use of member-determined and weighted (1) non-financial factors unique to each product category, such as product

quality, clinical knowledge of company representatives, customer service and safety, and (2) financial factors, such as price and fees. See Novation Response to Request for Information and Documents by the United States Senate Committee on the Judiciary Subcommittee on Antitrust, Competition Policy, and Consumer Rights, June 30, 2003 ("June 30 Response"), Question 21.

Pursuant to its commitment in the Operating Principles, since August 2002, the DCAM assessment has been conducted twice per bid — once with vendor fees included as an evaluated factor and once with these fees excluded as an evaluated factor.

In the majority of cases, the results of the two DCAMs are the same; that is, the recommendation of whether to award a contract is the same whether or not vendor fees are included in the DCAM analysis. In these cases, it is clear that fees are not the determining factor in the award of the contract.

In other cases, where the results of the two DCAMs are different, the bid is still subject to a methodical, rigorous review by the member council, which arrives at a reasoned decision that is consistent with the admonition in the Operating Principles that vendor fees should not be a determinative factor in the award of contracts except in those situations where the quality and pricing of competing products are essentially the same. See June 30 Response, Question 21.

Again, however, whether the DCAM is done once (reflecting the entire financial package offered by each vendor) or twice (eliminating the vendor fee portion of the financial package), the importance and weight given by the DCAM to non-financial factors ensures that Novation does award a contract to a vendor for a product that is "inferior."

Question 2(b). Is it ever appropriate to award a contract to a vendor with even a very slightly inferior product because the financial package that vendor offers is better than the financial package offered by another vendor?

Response. As explained above, Novation believes that the DCAM assessment ensures that Novation will not contract with any vendor for any product that reasonably could be deemed to be "inferior," regardless of either the overall financial package or the vendor fees offered by the vendor.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR MIKE DEWINE
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 3. If GPOs truly generate demonstrable savings to hospitals, would hospitals themselves pay for the services of GPOs in order to attain the savings, eliminating the need for vendors to fund GPOs?

Response. GPOs do generate demonstrable savings to hospitals. Since its inception, Novation has saved VHA and UHC members more than $1 billion. That Novation delivers savings and other valuable services to its members also is evidenced, of course, by VHA and UHC's continued existence and robust membership. If members did not find true value in VHA and UHC (and Novation on their behalf), members would affect the necessary changes or withdraw from the GPO. In other words, GPOs would become obsolete in the open market it they did not bring value to their members.

This does not mean, however, that member hospitals should be effectively forced to fund GPOs. As explained below, changing the funding model for GPOs would cause a number of deleterious effects, without any corresponding benefit to hospitals or the health care delivery system. As such, there is no reason to obligate hospitals to fund GPOs simply because some hospitals may, if given no other option, choose to do so.

First, shifting the funding model from vendors to hospitals would create a significant financial burden for VHA and UHC members, particularly those community-based, not-for-profit hospitals and academic medical centers that already struggle to meet budget. See, e.g., Statement of Paul Hazen, President and CEO, National Cooperative Business Association before the United States Committee on the Judiciary Subcommittee on Antirust, Competition Policy, and Consumer Rights, April 30, 2003 ("Novation's practice of charging fees to 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.")

Second, changing the funding model would deprive GPO

members of the additional value they currently receive in the form of cooperative distributions. As explained in previous submissions, many GPOs (including VHA and UHC) are cooperatives. Cooperatives return their fee income (generated by vendor administrative fees) to their members in the form of patronage distributions. Thus, requiring hospitals to fund GPOs would eliminate an important source of revenue that serves to reduce hospital costs even further.

In addition to these harmful effects, Novation has been unable to identify any corresponding benefit of forcing an artificial change in the funding of GPOs. For example, Novation seriously doubts whether the elimination of vendor fees would result in a corresponding reduction in product prices, principally because many factors other than administrative fees influence price-setting.

Finally, Congress and the U.S. Department of Health and Human Services have long recognized the benefits of GPOs and have expressly protected vendor funding of GPOs through an exception and safe harbor, respectively, to the federal health care program anti-kickback law. As such, there seems to be no reason, from a health care compliance perspective, to eliminate this funding option.

In sum, requiring hospitals to fund GPOs would cause significant financial hardship to community-based, not-for-profit hospitals and academic medical centers with no corresponding benefit. Thus, there seems to be no rational basis for interfering with the free market by reallocating the burden of funding GPOs to hospitals.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR MIKE DEWINE
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 4. Concerns have been expressed that new vendors may now get contracts under Novation's various methods to identify and contract with companies that offer innovative and breakthrough products, but that there are still unseen barriers in place that prevent the companies that receive contracts under those programs from actually making sales to hospitals on those contracts. Can you provide any information on the amount of sales that have been generated from the Novation contracts that have been awarded to vendors through Novation's various new technology programs?

Response. Novation does not believe that there are any "unseen barriers" preventing any vendors of any products from making any sales to any hospitals through any of their contracts with Novation. Novation handles the administration of all contracts — including those for technologically new products — in the same manner.

In a nutshell, after a contract has been awarded and executed, Novation distributes a launch package — describing the new product and summarizing the terms and conditions of the contract — to each VHA and UHC member. At the same time, Novation lists the product on Marketplace@Novation. Thereafter, whether a particular product is or is not purchased depends solely on the needs, interests and independent clinical and financial judgments and determinations of VHA and UHC members.

As explained during the July 16, 2003 hearing before the Subcommittee, Novation's implementation of the Operating Principles has resulted, as of June 30, 2003, in the award of 19 contracts for new technology. Between August 2002 and July 2003, sales for just five of the products covered by these contracts — silicone feeding tubes, oral re-hydration solutions, AFX pacemakers, vascular sealing devices and insulin dosers — totaled $58,326,646. Novation does not have sales data relating to the remaining products because the contracts at issue either (1) have not yet become effective or (2) have not been effective long enough for member purchasing data to have been reported and captured by Novation's systems.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR MIKE DEWINE
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 5. Private labeling by GPOs has raised some concerns. What value does Novation add to a product when it attaches the NOVAPLUS brand to a product?

Response. As reflected in several prior submissions to the Subcommittee, the key features and significant benefits of the NOVAPLUS program are as follows.

NOVAPLUS, Novation's private label program, was established 18 years ago and since that time has remained true to its founding principles — Prices Lowered Using Standardization. The NOVAPLUS brand offers VHA and UHC members more than 1,500 of the most frequently purchased commodity-oriented items, such as disposable pillows, elastic bandages and ice packs, which are identical to their supplier-branded equivalents. See June 30 Response, Question 18; and Novation Response to Follow-up Questions from Senate, September 11, 2002, Question 8.

Private label programs are not unique to GPOs. To the contrary, private label programs are common in many industries, including food/grocery (e.g., "Safeway Select"), office supply and retail clothing (e.g., department stores). The reason private label programs are so prevalent (and successful) is straightforward: manufacturers are willing to offer steeper discounts where the product sold does not bear their brand name. Brand name products reflect a premium and are priced accordingly. Private label products, on the other hand, need not reflect the price of the brand name premium. Manufacturers are willing to participate in private label programs because the private label does not dilute their brand and the discounted, non-branded products often target and reach a largely separate customer base.

It is not surprising, then, that NOVAPLUS products offer members a variety of benefits, relating to price, quality,

availability and standardization, as described below.

Price. NOVAPLUS products offer average savings of 14 percent over market price on medical-surgical products, according to twenty-six studies conducted in 2002. These studies, which covered 511 medical-surgical line-items, compared these items to products available on NOVAPLUS agreements. Novation then compared the prices the hospitals actually were paying to what they would have paid for equivalent NOVAPLUS products. As noted, Novation found that participating hospitals would have saved an average of 14 percent with NOVAPLUS. Simply put: NOVAPLUS products are less expensive than brand-name products and, as such, save GPO member hospitals money.

Quality and Availability. Quality also is important to the success of the NOVAPLUS program. Novation carefully selects its NOVAPLUS manufacturing partners and evaluates their products and services through a rigorous quality assurance process. In addition, Novation's quality assurance/regulatory affairs team regularly inspects vendor manufacturing plants to ensure that all NOVAPLUS products meet or exceed stringent quality standards. In addition, Novation works closely with manufacturing partners to ensure that NOVAPLUS products are consistently available so that supply shortages will not hinder the ability of GPO members to deliver patient care.

Standardization. NOVAPLUS facilitates member standardization by making available the most frequently used commodity products. By using NOVAPLUS products, health care organizations can realize operational efficiencies by eliminating redundant product codes, reducing purchase orders, and minimizing staff training time.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR MIKE DEWINE
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 6. Novation's Operating Principles indicate that Novation will not award contracts with commitment levels over 75% without review and approval by the relevant clinical council. The information you have submitted to the Subcommittee indicates that five new contracts with commitment levels over 75% have been awarded. Have Novation's clinical councils rejected any contracts where vendors sought contracts with commitment levels over 75%? Also, how can the Subcommittee be assured that review by clinical councils is an effective, meaningful review?

Response. With respect to contracts that offer members the ability to earn additional discounts based on purchasing at a specified level, the Operating Principles provide as follows:

> Any vendor's proposal that offers additional discounts in exchange [for] commitment levels over 75% on clinical preference products will be reviewed and approved by the relevant Novation clinical counsel or task force before going into effect. In making this determination, the relevant council or task force shall endeavor to ensure maximum choice for member hospitals, physicians, clinicians and patients for clinical preference products and to facilitate the introduction of innovative clinical preference products.

Novation has fully complied with this commitment. That is, since adoption of the Operating Principles, Novation has not awarded any contracts for clinical preference products providing for a commitment level over 75% without first obtaining approval by the relevant clinical council or task force.

Further, with respect to the five contracts that have obtained such approval, each contract has an open tier (allowing GPO members to purchase at any level) and, of course, members always have the option not to purchase under the contract at all. See June 30 Response, Question 9.

As for whether Novation's clinical councils reject any contracts where vendors seek commitment levels over 75%, the answer is "yes." As a practical matter, many of the bids that Novation receives have commitment levels over 75%. Pursuant to Novation's stringent bid review process — as enhanced by the Operating Principles — many of these proposals are not accepted.

Finally, the Subcommittee can be assured that council/task force review is effective and meaningful for several reasons. By way of background, Novation's "councils" are permanent advisory groups and Novation's "task forces" are councils formed for a specific initiative, generally for a limited time. Council and task force participants (1) are carefully chosen, (2) include clinicians, procurement specialists and policy experts and (3) represent the full spectrum of providers — large and small, metropolitan and rural, academic and non-academic.

Novation recruits council and task force participants — who serve voluntarily and without compensation — through Novation's members-only web site, newsletters and local, cross-functional member service representatives. Potential participants complete an application and are selected with input from existing council members, as well as VHA and UHC.

In assigning participants to specific councils and task forces, Novation ensures that membership reflects an appropriate ratio of VHA and UHC members. Currently, more than 450 VHA and UHC member representatives provide input through the councils and task forces, including, for example:

- Orthopedic Council
- Pediatrics Council
- Perioperative Council
- Plasma Council
- Respiratory Council
- Supplier Certification Council
- Wound Management Council
- IOL Task Force
- IV Catheters Task Force

- Needles and Syringes Task Force
- Reporting & Analysis Task Force
- Support Services Task Force
- Urine, Sputum & Operating Room Specimen Container Bid Task Force

In terms of process, while council and task force participants have discretion and are encouraged to utilize their particular expertise, they also must work within a formal structure with respect to Novation's bid review and contract award processes.

As explained in prior submissions, councils and task forces utilize a decision criteria award matrix or "DCAM" to assess each bid. The DCAM is designed to identify the "low best bid" through the use of member-determined and weighted (1) non-financial factors unique to each product category, such as product quality, clinical knowledge of company representatives, customer service and safety and (2) financial factors, such as price and fees. See June 30 Response, Question 21.

Historically, only one DCAM assessment was conducted per bid prior to submitting a recommendation to the member council for a final decision. Since adoption of the Operating Principles, however, the DCAM assessment has been conducted twice per bid — once with vendor fees included as an evaluated factor and once with these fees excluded as an evaluated factor.

After the DCAM analysis is complete, Novation's member councils and task forces conduct an additional, rigorous review of each bid. This ensures that no benefits remain unnoticed and that no drawbacks are overlooked.

In sum, Novation's councils and task forces are comprised of diverse, dedicated and impartial VHA and UHC member representatives who are committed to reaching thoroughly reasoned decisions with respect to Novation's contract awards. For these reasons, the Subcommittee should feel confident that councils and task forces review each bid in an effective, meaningful manner.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR MIKE DEWINE
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 7. According to Novation's Operating Principles, one of Novation's criteria for awarding a sole source contract for a clinical preference product is there are not alternative products that offer incremental patient care or safety benefits. Does giving the hospitals additional vendors on contract have some benefit on its own?

Response. As an initial matter, Novation would like to reiterate that the vast majority of its contracts for clinical preference products are dual or multisourced contracts. As set forth in the Operating Principles, Novation only will award a sole-source contract for a clinical preference product if there is no alternative that offers incremental patient care benefits or incremental safety benefits. Since August 8, 2002, Novation has awarded only one sole-source contract for a clinical preference product and that award was previewed by the Subcommittee.

Furthermore, as discussed in several of Novation's previous submissions to the Subcommittee, Novation's group purchasing program is voluntary. That is, VHA and UHC member hospitals may purchase all, some, or none of their products through Novation's contracts. In fact, 40-50 percent of VHA and UHC member purchases are made under non-GPO contracts.

Under these circumstances, there is no need to add vendors to Novation's contract portfolio in order to ensure that GPO members have full and unfettered access to any and all products in the marketplace.

Although adding vendors to Novation's contract portfolio will not increase member choice, it will increase the prices that hospitals pay for health care products. Why? Because GPOs cannot effectively leverage the purchasing power of their members without placing limitations on the number of vendors with which the GPOs contract. This is the essence of group purchasing and the principal reason GPOs are able to secure lower prices for their members.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR MIKE DEWINE
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 8. The structure of Novation's Operating Principles regarding sole source contracts seems to suggest that sole source contracts are the rule, not the exception. Are there any obstacles preventing Novation from following Premier's model and routinely offer multi-source contracts for clinical preference items?

Response. Novation does not believe that sole-source contracts are the rule with respect to clinical preference products. To the contrary, the Operating Principles provide that, on a prospective basis:

- Novation will not award a sole source contract for a clinical preference product that has an alternative that offers incremental patient care or safety benefits;
- Novation will re-bid the relevant product category or make a dual or multisource award (based upon the review and recommendation of the relevant Novation clinical council or task force) in the event a new product enters the market that offers incremental patient care or safety benefits; and
- Novation will require that all recommendations to award a sole-source contract for a clinical preference product receive review and approval by the relevant Novation clinical council or task force before going into effect.

Consistent with the Operating Principles, since August 8, 2002, Novation has awarded only one sole-source contract for a clinical preference product. In that case, involving IV Catheters:

- Novation determined that there were no alternative products that offered incremental patient care or safety benefits;

- the recommendation to award a sole-source contract for the product at issue was reviewed and approved by Novation's Nursing Council and IV Catheter Task Force before the contract was awarded;

- Novation previewed this decision with members of the Subcommittee's staff; and

- the vendor offered significant cost-saving benefits to members (i.e., prices that, in the aggregate, were more than 28 percent lower than the next lowest bid).

Although only one sole-source contract award has been made for a clinical preference product since August 8, 2002, six products that were covered by a sole-source contract prior to August 8, 2002 since have been dual or multisourced.

Under these circumstances, it cannot be said fairly that sole-source contracts for clinical preference products are the rule. To the contrary, sole-source contracts plainly are the exception and multisourced contracts are the rule.

Finally, while Novation is not aware of the specifics of the contracting model used by Premier, Novation believes its current model, painstakingly crafted over the course of many weeks in close coordination with Subcommittee staff, strikes the proper balance between:

- on the one hand, the benefits to VHA and UHC members of having access to multiple vendors of clinical preference products through the Novation contract portfolio (benefits that are somewhat ephemeral because members always are free to purchase any product from any vendor, regardless of whether the product is under contract with Novation), and

- on the other hand, the significant and tangible benefits to members — in terms of greater discounts, rebates and cooperative distributions — that result from Novation maximizing the collective purchasing power of members by limiting the total number of contracts in the Novation portfolio.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR MIKE DEWINE
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 9. In his written testimony, Mr. Everard argues that the GPOs' safe harbor exemption should be tied to more and stronger reporting requirements for the GPOs, along with more outside auditing of GPOs. What do you think about requiring more transparency for GPOs in the way that Mr. Everard suggests? What harm could result from more transparency?

Response. Novation does not believe that the statutory GPO exception or regulatory GPO safe harbor to the federal health care program anti-kickback law should require more or stronger reporting requirements or outside auditing of GPOs. The exception and safe harbor provide for comprehensive reporting by GPOs to their members of both the fees that GPOs may earn under GPO-vendor contracts and the fees that GPOs actually earn under such contracts.

By way of background, in 1986, Congress created the statutory GPO exception and in 1991, the U.S. Department of Health and Human Services ("HHS") created the regulatory GPO safe harbor. The exception and safe harbor protect fees paid by vendors to GPOs, provided certain requirements are met.

These requirements have two provisions that relate to fees. The first ("up-front fee notice") provision requires GPOs to notify their members of any contracts that the GPOs have entered into that provide for vendor fees that are not fixed at three percent or less. Compliance with this requirement ensures that members are aware of the fees that will be generated for the GPO at issue before they make any purchases under such contracts.

The second ("back-end fee notice") requirement provides that the GPO must annually disclose to each of its members the amount of fees that the GPO actually earned during the previous year based on the member's purchases. Compliance with this requirement ensures that members are aware not only of what the GPO had the potential to earn under each vendor

contract, but what the GPO in fact earned under such contracts.

Together, the up-front fee notice and back-end fee notice requirements ensure that all GPO-vendor fee arrangements are transparent to GPO members. Indeed, it is not at all clear that such arrangements could be any more transparent.

Nor does Novation believe that more outside auditing of GPOs is necessary or warranted. GPOs are subject to audit by numerous federal agencies, including the General Accounting Office ("GAO"), the Federal Trade Commission ("FTC") and, by virtue of indirectly participating in federal health care programs, HHS.

In sum, given the stringent, detailed reporting requirements of the GPO exception and safe harbor, combined with the current auditing authority of numerous federal agencies, Novation does not believe that any additional or improved fee disclosure or auditing processes are necessary. Indeed, imposing any additional and, necessarily, duplicative regulatory disclosure or auditing requirements on GPOs can only have one effect: increasing GPO costs and, as a result, decreasing VHA and UHC cooperative distributions — all without any corresponding benefit to our nation's hospitals. This is a lose-lose proposition.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR MIKE DEWINE
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 10. How can this Subcommittee be assured that Novation, and the GPO industry generally, will not simply revert to the practices that originally caused the Subcommittee's concerns? How can the Subcommittee be sure that the reforms that have been implemented will stay in effect without constant oversight by the Subcommittee.

Response. As an initial matter, we should re-emphasize that Novation is owned by VHA and UHC, which in turn, are owned and governed by their community hospital and academic medical center members. Ultimately, then, it will be these community hospitals and academic medical centers that — consistent with their mission and needs — will determine the direction of Novation in our time.

That being said, perhaps the best evidence of Novation's commitment to the Operating Principles is reflected in the substantial progress that Novation has made over the past year — progress that both (1) has been described in considerable detail in our previous submissions and (2) was expressly recognized by the Subcommittee during the July 16, 2003, hearing.

That Novation's commitment will be lasting, in turn, is evidenced by the tremendous investment that Novation has made — in terms of time, effort, money, manpower, training, education and more — in order to develop and implement the wide-ranging and, in many cases, structural/foundational business processes, policies and procedures necessary to implement the Operating Principles.

Although perhaps counter-intuitive at first blush, that Novation's commitment to the Operating Principles will be lasting also is evidenced by the very fact that the Operating Principles are voluntary and were not imposed on Novation by law or regulation. That is, Novation adopted the Operating Principles

precisely because they were consistent with Novation's mission.

Indeed, by their very terms, the Operating Principles are designed and intended (1) to promote "a truly voluntary group purchasing program" that provides VHA and UHC members "with full access to any health care item or service (including new medical technologies) from any vendor regardless of whether that vendor has a contract with Novation" and (2) to "further underscore [Novation's] commitment to improving certain group purchasing policies and procedures."

Simply put, the commitments made by Novation in the Operating Principles — which commitments Novation has lived up to in full — are consistent with Novation's fundamental mission, a mission that has remained unchanged since Novation's creation.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR MIKE DEWINE
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 11. Does Novation require that its vendors enter into agreements with Neoforma, for a fee, as a requirement of contracting with Novation, and if it does, how does that affect the ability of smaller vendors to meet all of the requirements of contracting with Novation?

Response. Vendors that wish to contract with Novation are not required by Novation to enter into any agreements with Neoforma.

In order to ensure that VHA and UHC members have access to a robust and choice-filled e-commerce site, Novation does require contracting vendors to offer their contracted products through Marketplace@Novation, Novation's e-commerce site.

This arrangement is documented in a standard e-commerce agreement between Novation and each vendor. Pursuant to this agreement, vendors agree to provide certain contracted product information to Novation and Novation publishes this information in product catalogue and contract viewing modules on Marketplace@Novation.

There are no fees associated with this arrangement and, as such, it does not financially impact any vendor — small or large. We also should note that (1) any vendor, whether it has a contract with Novation or not, is eligible to participate in Marketplace@Novation and (2) vendors that participate in Marketplace@Novation can (and do) participate in other e-commerce exchanges as well.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR KOHL
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 1. Why have you not followed Premier's lead and standardized administrative fees with respect to each product category, so that all vendors of each product will pay the same administrative fee? Doesn't this eliminate any incentive for the GPO to contract with a vendor that pays a higher fee?

Response. Novation has decided not to adopt a model (such as Premier's) that standardizes fees with respect to each product category because, as explained below, it does not seem necessary or appropriate.

As an initial matter, Novation and Premier's average vendor fees are identical — 2.1 percent. For this reason alone, it is not immediately obvious that any change in Novation's operations to mirror those of Premier would, at least at the macro level, make any material difference. In any event, there are a host of reasons why Novation believes that its current contract bidding and award process and vendor fee policies, as revised to reflect the requirements of the Operating Principles, operate in the best interest of VHA and UHC hospitals and the patients they serve.

First, Novation's bidding process is premised on permitting vendors to submit their best bid, without any preset or artificial floors or ceilings relating to price or fees. Novation does not dictate or restrict the terms or conditions a vendor may include in its contract bid proposal. Novation believes that this model — which is fair, public, and open to all vendors — is essential to identifying the best contracting opportunities for its GPO members.

Second, Novation has taken several steps to ensure that product quality and price — and not vendor fees — are the most important factors in the contract review process. Each proposal is scrutinized by Novation's member councils/task forces, which are comprised of VHA and UHC representatives and include clinicians and materials management personnel. The relevant

council uses a decision criteria award matrix or "DCAM" to assess each bid. The DCAM is designed to identify the "low best bid" through the use of member-determined and weighted (1) non-financial factors unique to each product category, such as product quality, clinical knowledge of company representatives, customer service and safety and (2) financial factors, such as price and fees. See Novation Response to Request for Information and Documents by the United States Senate Committee on the Judiciary Subcommittee on Antitrust, Competition Policy, and Consumer Rights, June 30, 2003 ("June 30 Response"), Question 21. Pursuant to its commitment in the Operating Principles, since August 2002, the DCAM assessment has been conducted twice per bid — once with vendor fees included as an evaluated factor and once with these fees excluded as an evaluated factor.

Third, standardizing vendor fees could have a number of unintended effects. For example, establishing a rigid, pre-set, across-the-board vendor fee may actually create a barrier for small vendors who are unable to afford whatever "standard" administrative fee is ultimately selected. Standardization also would cause some fees to increase (e.g., for product categories where the vendor fees are typically or were historically below the "standardized" fee).

Fourth, federal law does not impose any vendor fee standardization requirement. Neither the statutory GPO exception nor the regulatory GPO safe harbor to the federal health care program anti-kickback law imposes any artificial ceiling on the type or amount of fees that may be paid to a GPO. Indeed, in an advisory opinion issued in 1998, the U.S. Department of Health and Human Services Office of Inspector General affirmed the legality of an 11% fee arrangement.

Finally, we would reemphasize that in contrast to Premier, Novation is the purchasing agent of two cooperatives, VHA and UHC. It is common for cooperatives (1) to be funded by fees paid by vendors wishing to do business with cooperative members and (2) to return substantial portions of their net revenue to cooperative members (a form of cost reduction for hospitals). Thus, as a general proposition, the larger the fees paid by vendors to GPO cooperatives, the greater the annual distributions to GPO member hospitals; and the greater the annual distributions to GPO member hospitals, the lower their

overall costs.

For all of these reasons then, although Premier's vendor fee model may work for Premier and its members, Novation does not believe that adopting this model would be in the best interests of the not-for-profit community hospitals and academic medical centers that make up the membership of the VHA and UHC cooperatives.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR KOHL
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 2. The data Novation has submitted to us specifies that nearly one-third (more than $150 million) of your revenue was derived from sole source contracts in your most recent fiscal year. Further, you have identified 57 clinical preference products on Novation contract, and about 21 of them remain sole sourced today, nearly a year after Novation signed its new code of conduct.

In Novation's new code of conduct, you promised to end sole sourcing of what you call "clinical preference products," but only where an alternative product exists that "offers incremental patient care benefits or incremental safety benefits." And it is left to the sole discretion of Novation councils to decide what products are "clinical preference," and when a product offers "incremental patient care benefits." We're concerned that this provision in Novation's code may be an example of "the exceptions and qualified language" to which the GAO referred in its written testimony.

Will you agree to improve your code of conduct so that Novation less frequently engages in sole sourcing? Will you commit to examine your current sole source contracts for clinical preference items and make every attempt to put additional vendors on contract in advance of contract expiration?

Response. The Operating Principles — which were carefully negotiated, thoughtfully and deliberately drafted, and critically reviewed and revised by both Novation and Subcommittee staff over a period of many weeks — provide that Novation will do several things relating to sole-source contracting on a prospective basis.

As Novation discussed with the Subcommittee staff during the development of the Operating Principles, Novation agreed to take certain actions on a prospective basis because (1) it simply would not be practical, or even feasible, to review, re-negotiate, amend and re-execute hundreds and hundreds of existing

Novation vendor contracts and (2) even if this were practical and feasible, it would be unfair to the hospitals and academic medical centers that were involved in the contracting decision and rely upon (and are operating under) the negotiated terms and conditions of those contracts.

As noted above, however, Novation did agree to take several steps on a prospective basis relating to sole-source contracting.

First, the Operating Principles provide that, on a prospective basis, Novation will not award a sole-source contract for a clinical preference product that has an alternative that offers incremental patient care benefits or incremental safety benefits. Consistent with the Operating Principles, since August 8, 2002, Novation has awarded only one sole-source contract for a clinical preference product. In that case:

- Novation determined that there were no alternative products that offered incremental patient care benefits or incremental safety benefits;
- Novation determined that the low best bidder's prices would result in substantial member savings;
- Novation's Nursing Council and IV Catheter Task Force reviewed and approved the recommendation to award a sole-source contract before the contract was awarded; and
- Novation previewed this decision with members of the Subcommittee's staff.

In addition, although not required by the Operating Principles, Novation has dual or multisourced six products that were covered by sole-source contracts that had been executed prior to August 8, 2002. See June 30 Response, Question 5.

Second, the Operating Principles provide that, on a prospective basis, Novation will re-bid the relevant product category or make a dual or multisource award (based upon the review and recommendation of the relevant Novation clinical council or task force) in the event a new product enters the market that offers incremental patient care benefits or incremental safety benefits. On ten separate occasions since August 2002, Novation has re-bid a product category, or made a dual or multisource award, for

a clinical preference product because a new product has entered the market that offers incremental patient care or safety benefits. See June 30 Response, Question 6.

Finally, the Operating Principles provide that, on a prospective basis, Novation will require that all recommendations to award a sole-source contract for a clinical preference product receive review and approval by the relevant Novation clinical council or task force before going into effect. Pursuant to this Principle, since August 8, 2002, all recommendations to award a new sole-source contract for a clinical preference product have been reviewed and approved by the relevant Novation clinical council or task force before going into effect. (As noted above, the councils and task forces have approved only one such contract since August 8, 2002.)

In sum, while Novation is always open, where necessary and appropriate, to enhancing its code of conduct in general and the Operating Principles in particular, given (1) the significant commitments Novation already has made relating to sole-source contracting in the Operating Principles, (2) the substantial progress that Novation has made to date in implementing these Principles, (3) the fact that Novation has, in a number of respects, exceeded its commitments relating to sole-source contracting and (4) the short period of time that the Principles have been in effect, Novation believes that it is far too early to begin considering such changes.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR KOHL
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 3(a). Novation's code does not prohibit commitment levels in any respect. It merely provides that any commitment levels above 75% must be approved by the relevant Novation clinical council before going into effect. Since making this pledge last August, the information you have provided us shows that Novation has entered into five contracts for clinical preference products with commitment levels higher than 75%. What assurances do we have that contracts with commitment levels will be the exception, rather than the rule?

Response. Before turning to a discussion of the specific issues raised in this question, Novation would like to clarify certain aspects of its contracts that provide for additional member discounts based on specified purchasing levels (i.e., where members purchase a preset percentage of their needs for a particular product). This information should help place our response in context.

First, and perhaps most importantly, the only reason Novation offers contracts that provide for additional member discounts based on specified purchasing levels is because GPO members insist that we do so. Novation acts as the purchasing agent for GPO member hospitals. Novation does not create buyer dynamics and market conditions — it reflects them. Thus, if Novation did not provide value to VHA and UHC members, they would seek alternatives (e.g., another GPO or direct contracts with vendors) and/or withdraw from Novation. Put somewhat differently, Novation would cease to exist if it did not operate in a competitive manner and respond to the needs of GPO members. In many cases, VHA and UHC members want — in fact demand — the ability to access more significant discounts where they are willing to purchase at specified levels. In fact, these types of contracts often are the only way smaller, not-for-profit hospitals are able to access additional discounts, since they typically do not purchase enough products to qualify for high volume discounts.

Second, offering contracts that include these types of discount provisions to GPO members facilitates their ability to

standardize. Standardization, in turn, helps members realize operational efficiencies by eliminating redundant product codes, reducing purchase orders, minimizing staff training time and decreasing clinical variability.

Third, contracts that provide GPO members with additional discounts based on specified purchasing levels are voluntary — none of the GPO members are required to make a single purchase under any Novation contract.

Notwithstanding their benefits, at the Subcommittee's request, Novation agreed to address contracts that include these types of provisions. Specifically, the Operating Principles provide that:

- "Novation will impose no commitment requirements as a condition to participate in any base vendor group purchasing contracts or as a condition of membership or continued membership in UHC or VHA."

- "Any vendor's proposal that offers additional discounts in exchange [for] commitment levels over 75% on clinical preference products will be reviewed and approved by the relevant Novation clinical counsel or task force before going into effect. In making this determination, the relevant council or task force shall endeavor to ensure maximum choice for member hospitals, physicians, clinicians and patients for clinical preference products and to facilitate the introduction of innovative clinical preference products."

Novation has complied with these commitments. Novation has not awarded a single contract for a clinical preference product with a commitment level over 75% without first obtaining approval by the relevant clinical council or task force.

Further, in each of the five cases where such approval was sought and obtained, the contract at issue has an open tier, meaning that GPO members can purchase at <u>any</u> level they desire (<u>e.g.</u>, 1% or 5%); and, of course, members always have the option not to purchase under the contract at all.

To date, Novation's member councils and task forces have reviewed 408 (out of 468) medical-surgical products for purposes of making clinical preference determinations. Only 30 contracts for these products include discount arrangements

based on purchasing levels in excess of 75%; and 25 of these contracts were entered into prior to implementation of the Operating Principles. These figures, coupled with the processes that Novation has developed in implementing the Operating Principles, should provide the Subcommittee with confidence that such contracts are, indeed, the exception rather than the rule.

Question 3(b). Will Novation agree to revise its code of conduct with us to include more stringent prohibitions on commitment levels in contracts for clinical preference products?

Response. Again, the Operating Principles were carefully negotiated, thoughtfully and deliberately drafted, and critically reviewed and revised by both Novation and the Subcommittee over a period of many weeks. The resulting commitments, naturally, represent a compromise between the Subcommittee's desire to address what it believed to be Novation's potentially anticompetitive practices, and Novation's need to preserve its core mission of providing value — through lower prices, high quality and standardization — to GPO members.

Novation has been implementing the Operating Principles for just over one year, and while substantial changes have clearly been affected, it is too soon to realize their full impact. The General Accounting Office ("GAO") concurs. In its most recent report, the GAO noted that "[i]t is too soon to evaluate the effectiveness of these codes of conduct . . . many conduct codes are recently adopted and sufficient time has not elapsed for GPOs to demonstrate results." Group Purchasing Organizations: Use of Contracting Processes and Strategies to Award Contracts for Medical Surgical Products, GAO-03-998 at 3 (July 16, 2003).

Moreover, because Novation is the purchasing agent of two cooperatives, it is reluctant to further restrict the types of contractual provisions it offers to GPO members without their input, direction and approval. As explained in numerous prior submissions, Novation acts only on behalf of its members — e.g., community-based, not-for-profit rural hospitals and academic medical centers. As discussed above, the only reason Novation offers contracts providing for additional member discounts based on specified purchasing levels is because GPO members insist that we do so.

For all of the reasons set forth above, Novation firmly believes that the agreed-to Operating Principles, and the changes Novation has made in implementing them, adequately address the Subcommittee's concerns while preserving Novation's ability to serve its members.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR KOHL
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 4 (a). Does Novation require that vendors post their products on Novation's web site, "Marketplace At Novation," as a condition of gaining a contract with Novation? If so, why?

Response. Several years ago, a growing number of VHA and UHC member hospitals began to express a strong interest in transitioning their paper-intensive medical supply acquisition, delivery and tracking systems to an electronic platform. In response, Novation established Marketplace@Novation.

In order to ensure that hospitals have access to a robust and choice-filled e-commerce site, Novation decided to require those wishing to do business with Novation to offer their contracted products on Marketplace@Novation. Please note, however, that (1) any vendor, whether it has a contract with Novation or not, is eligible to participate in Marketplace@Novation; (2) vendors can and do participate in other e-commerce exchanges as well; and (3) Novation does not charge a fee to vendors for posting their contracted products on Marketplace@Novation.

Question 4 (b). Do vendors pay a fee to be posted on the "Marketplace At Novation" web site? If so, how much? On what basis is this fee assessed?

Response. As noted above, vendors do not pay a fee to post their contracted products on Marketplace@Novation.

Question 4 (c). Does Novation, or its owners VHA or UHC, have any ownership interest in "Marketplace At Novation" or Neoforma, the entity that runs the web site? If so, explain why this does not present a conflict of interest.

Response. Novation does not have an ownership interest in Neoforma. VHA holds (on behalf of its members) approximately 28% of Neoforma's stock and UHC holds (on behalf of its members) approximately 10% of Neoforma's stock. See Novation

Response to Follow-Up Questions from Senate, September 11, 2002, Question 12.

Novation does not believe that the ownership interests of VHA and UHC in Neoforma create any conflict of interest. See Novation Response to Senator Kohl's Follow-Up Questions to Mark McKenna, May 24, 2002, Question 9(b). In a nutshell, VHA and UHC have simply taken a particular GPO business function — operating an e-commerce platform — that they might have done "in-house" (and, as such, wholly-owned) and outsourced it to an e-commerce company (Neoforma) in which they have a partial ownership interest. It would have been much more costly for Novation to provide this function in-house. Furthermore, Neoforma is a public company so its operations, including those that Novation would otherwise provide, are subject to even greater disclosure requirements than the operations of GPOs. We would also note that Neoforma is not a vendor of health care items and that the member hospitals of VHA and UHC are the true owners of the Neoforma stock.

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RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR KOHL
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 5(a). Many of Novation's most important contracting commitments only apply to what Novation calls "Clinical Preference Products" – in other words, medical devices. Novation is not bound to these commitments when Novation decides an item is not a "clinical preference product." How Novation applies these definitions to specific products is, therefore, crucial.

Premier also made significant commitments to what it refers to as "physician preference products." Premier and Novation define these two very similar terms differently. As a result, the lists of what products fall within these two definitions were significantly different. Please inform us how Novation makes the determination as to whether a product meets the definition of "clinical preference."

Response. As set forth in the Operating Principles, the definition of "clinical preference products" — which was drafted by Subcommittee staff and is broader than that adopted by Premier — is as follows:

> Clinical preference products shall refer to any medical device or any item of medical equipment or supply used to treat a patient for any illness, injury, condition, disease or ailment about which a physician or other clinician (including nurses) could reasonably be expected to express a preference or could be expected to effect patient health or safety or worker health or safety. Relevant member councils or task forces will make the determination as to whether or not a particular product is a clinical preference product.

By way of background, Novation's member "councils" are permanent advisory groups and Novation's member "task forces" are councils formed for a specific initiative, generally for a limited time. Council and task force participants (1) are carefully chosen, (2) include clinicians, procurement specialists

and policy experts, and (3) represent the full spectrum of providers — large and small, metropolitan and rural, academic and non-academic.

Novation recruits council and task force participants — who serve voluntarily and without compensation — through Novation's members-only web site, newsletters and local, cross-functional member service representatives. Prospective participants complete an application and are selected with input from existing council members, as well as VHA and UHC. In assigning participants to specific councils/task forces, Novation ensures that membership reflects an appropriate ratio of VHA and UHC members.

Based on the definition of clinical preference products set forth above, the Chairs and Vice-Chairs of Novation's 23 member councils developed a test — or algorithm — to determine whether a particular product is a "clinical preference product." In a nutshell, this algorithm consists of the following questions:

- First, does a clinical practitioner (e.g., a physician, nurse, or therapist) use the product in the diagnosis or treatment of a patient?
- Second, would a clinical practitioner reasonably express a clinical preference for one brand of product with comparable specifications over another brand of product?
- Third, is this clinical preference based on evidence of incremental benefit to patient care or patient safety?

Since August 8, 2002, Novation's Clinical Solutions Team, which is comprised of trained clinicians, has helped Novation's councils and task forces apply this algorithm to products in all new bids. Novation firmly believes that clinicians who actually use the products in question are best suited to determine whether or not a product is clinically preferenced. See June 30 Response, Question 4.

Question 5(b). ECRI, an Evidence-based Practice Center (EPC) designated by the U.S. Agency for Healthcare Research and Quality, sent the Subcommittee a letter on July 16, 2003 identifying key elements used to determine whether a device or service is of physician or clinician preference. We understand that ECRI is well-

respected in the industry and has in fact worked with Novation. Will you agree to review ECRI's recommendations toward creating better, and more consistent, definitions of clinical preference products so that all medical devices which are essential to the treatment of patients are included?

Response. Novation welcomes the opportunity to review ECRI's recommendations concerning the elements used to determine whether a device or service is of physician or clinical preference. Novation has worked with ECRI in the past in connection with selecting products for contract and appreciates ECRI's expertise and perspective. Novation respectfully requests that the Subcommittee provide Novation with a copy of ECRI's recommendations for review.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR KOHL
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 6. Novation's private label program — the so-called "NOVAPLUS" program — has come under criticism because some fear it may create a conflict of interest. Vendors outside the program have to compete with products bearing Novation's own private label. What is your response to these concerns? Does Novation consider itself to be the vendor or the GPO when it comes to private label products? Doesn't Novation have an interest in seeing that hospitals purchase NOVAPLUS-branded products rather than products made by competitors of the NOVAPLUS-branded products?

Response. Before responding to each of the questions posed above, we note — by way of background — that Novation's private label program, NOVAPLUS, has been an extremely successful undertaking, bringing many benefits to VHA and UHC members. Consistent with its founding principles — Prices Lowered Utilizing Standardization — the NOVAPLUS program offers VHA and UHC members more than 1,500 of the most frequently purchased commodity-oriented items (such as disposable pillows, elastic bandages, ice packs, and the like). Importantly, prices for NOVAPLUS products are unmatched. In 2002, for example, NOVAPLUS provided GPO member hospitals with the greatest savings recorded in the program's 18-year history. VHA and UHC members that chose to purchase NOVAPLUS products in 2002 saved an average of 14 percent over name-brand products.

Quality also is important to the success of the NOVAPLUS program. As described in Novation's earlier submissions, Novation carefully selects its NOVAPLUS manufacturing partners and evaluates their products and services through a rigorous quality assurance process. As such, not only does NOVAPLUS bring GPO members unparalleled savings on commodity products, it also ensures that such products are consistently high in quality.

Finally, we should emphasize that although the benefits of the NOVAPLUS program are important, the program actually is quite small, representing just under five percent of total purchases through Novation each year.

With this background in mind, we address each of your questions below.

Vendors outside the program have to compete with products bearing Novation's own private label. What is your response to these concerns?

Novation does not disagree that vendors outside of the NOVAPLUS program have to compete with NOVAPLUS products. But this is not unique to the NOVAPLUS program specifically or GPOs more generally. Private label arrangements are common in a host of industries, including food/grocery (e.g., "Safeway Select"), office supply and retail clothing (e.g., department stores). In each of these cases, vendors outside of the program have to compete with products bearing the private label brand.

Does Novation consider itself to be the vendor or the GPO when it comes to private label products?

Novation does not consider itself to be a vendor. Novation operates as a GPO when it comes to NOVAPLUS products. The vendors of NOVAPLUS products are the companies that manufacture, package and sell the products to VHA and UHC members, from whom the vendors receive payment directly.

Doesn't Novation have an interest in seeing that hospitals purchase NOVAPLUS-branded products rather than products made by competitors of the NOVAPLUS-branded products?

As explained below, the answer to this question depends on the definition of "interest."

To the extent the question is referring to a financial interest that inures to the benefit of Novation, the answer is "no." The fees that Novation receives based on member purchases of NOVAPLUS products are treated no differently than the fees that Novation receives based on member purchases of non-NOVAPLUS products. In both cases, the fees go directly to

VHA and UHC, which, as cooperatives, distribute their net revenue to their members. Novation is reimbursed by VHA and UHC only for its costs.

To the extent that the question is referring to something other than Novation's financial interest, then the answer, potentially, is "yes." Novation's objective is to make high quality products available to VHA and UHC members at the lowest possible price. The NOVAPLUS program, of course, was developed and is implemented to further this objective. As such, Novation does have an "interest" in VHA and UHC members participating in the NOVAPLUS program, but only if and to the extent that such members conclude, for the reasons discussed above, that it is in their interest to do so.

The bottom line is this: the NOVAPLUS program does not create any conflict of interest between Novation and VHA and UHC members. Novation's interest is to provide member hospitals with access to high quality products at the lowest possible price, by leveraging the collective purchasing power of VHA and UHC. The interest of GPO members — to access quality, low-priced products — obviously dovetails with that of Novation.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR KOHL
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 7. You stated at the hearing that you would terminate Novation's bundling program – the OPPORTUNITY Spectrum program – in your words "ahead of schedule." Please be more precise – when will this program (or any other bundling program) be terminated? Will you commit to do so by January 1, 2004?

Response. The term "bundling" does not appear in the Operating Principles. Since there is no commonly accepted definition of product "bundling," the adoption of principles, practices or procedures relating to "bundling" can be difficult to effectively apply and monitor.

Although Novation did not address "bundling" in the Operating Principles, Novation did make several specific commitments relating to its OPPORTUNITY Program and, more specifically, to one set of contract "portfolios" that are included in this Program, the "Spectrum Portfolios." More specifically, Novation agreed that — on a prospective basis — it would:

- review its OPPORTUNITY Spectrum Portfolio descriptions and contracts to eliminate language that could be construed as anti-competitive;
- eliminate combinations of clinical preference products and non-clinical preference items in OPPORTUNITY Spectrum Portfolios;
- eliminate combinations of capital equipment and consumable products in OPPORTUNITY Spectrum Portfolios;
- increase the percentage of dual and multisource vendor contracts in OPPORTUNITY Spectrum Portfolios; and
- pursue the implementation of lower purchasing commitment levels within the OPPORTUNITY Spectrum Portfolios.

As described in its earlier submissions to the Subcommittee, Novation has lived up to these commitments. See June 30 Response, Question 10.

As the Subcommittee knows, the OPPORTUNITY Program was created by and for the hospital members of VHA and UHC. Novation believes that the Program continues to provide savings and other valuable benefits to those VHA and UHC hospitals that choose to participate in the Program, particularly smaller, community, not-for-profit hospitals that have difficulty achieving savings through high-volume purchasing.

We also should reemphasize that no VHA or UHC member is required to purchase any product from any vendor under any Novation contract. With respect to the OPPORTUNITY Program, this principle manifests itself in two ways. First, no VHA or UHC member is required to participate in the OPPORTUNITY Program. Second, there are no adverse consequences — relating to membership status, penalties or otherwise — if a member chooses to withdraw from the Program.

Because of its voluntary nature, and because participating hospitals have budgeted for — and rely on — the discounts that they earn by participating in the OPPORTUNITY Spectrum Portfolio Program, Novation does not believe it would be appropriate to terminate the Program early.

However, Novation plans to launch its next-generation, non-Spectrum OPPORTUNITY Portfolios during the first quarter of 2004 — one year ahead of schedule. Consistent with the Operating Principles, Novation's new portfolios — which will be open to all members — will not include combinations of clinical preference products and non-clinical preference products or combinations of capital equipment and consumable products. See June 30 Response, Question 10.

Of course, because there is no penalty for non-participation in the OPPORTUNITY Spectrum Program, members will be free to switch to the new program in 2004 or 2005, prior to the termination of the OPPORTUNITY Spectrum Program.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR KOHL
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 8. If you face resistance to ending bundling in your GPO contracts, will you commit to report this resistance to this Subcommittee, to the FTC, and to the Department of Health and Human Services?

Response. As explained in our June 30, 2003 submission to the Subcommittee, only one of our 614 medical-surgical vendor contracts actually packages two product categories in a manner that requires member hospitals that wish to purchase under one product category also to purchase under the second category. See June 30 Response, Question 14.

Novation currently is in discussions with the vendor for this contract — Johnson & Johnson/Ethicon ("J&J") — concerning the decoupling of the two relevant product categories. It is our understanding that the Federal Trade Commission already is aware of our discussions with J&J. However, Novation will be pleased to continue to update the Subcommittee, as well as the Department of Health and Human Services, regarding the status of our negotiations, upon request.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR KOHL
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 9. Novation has stated that it will add additional vendors to existing contracts if the new products provide incremental safety benefits over the contract products. The committee is aware of one particular vendor, Bracco Diagnostics, Inc., whose magnetic resonance (MR) contrast product has been independently proven to provide incremental safety benefits over the contract product, but has been ignored by Novation, even after definitive evidence has been shown to Novation representatives. Isn't this inconsistent with the Code of Conduct you adopted and are steps being taken to address this situation?

Response. Novation has informed Bracco — during several meetings convened at Bracco's request and in written correspondence — that Bracco may submit a bid to Novation during the first quarter of 2004, when the Paramagnetic Contrast Media ("PCM") product category is set to go out to bid. Indeed, Novation has encouraged Bracco to submit a bid.

In anticipation of this product category going out for competitive bid in the first quarter of 2004, Novation has engaged an independent third party to conduct an assessment of the PCM product category. Specifically, Novation has requested an objective comparison of the safety profiles among all manufacturers of all products in this product category, including those manufactured by Bracco (ProHance) and the current Novation vendor, Amersham (Omniscan®), along with a recommendation on whether or not one product offers incremental patient care or safety benefits over another. The results of this study will be presented to Novation's Diagnostic Imaging Council for its consideration at the time of the bid.

Because (1) the relevant product category will go to bid within the next six months, (2) Bracco has been invited and encouraged to participate in that process, and (3) there is an independent study concerning the clinical features and benefits of the products in the PCM category pending, Novation does not believe that it is necessary or would be appropriate to provide a single contrast media vendor (i.e., Bracco) with any procedural, substantive or other advantage in connection with Novation's vendor contracting process.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR KOHL
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 10. Novation has made a commitment to operate a voluntary group purchasing program that allows its members to purchase any healthcare item or service from any vendor. Yet the committee is aware that, in some cases, physicians have expressed an interest to go outside certain Novation contracts, such as one for MR contrast agents, and been threatened with penalties for going off-contract. Can you explain the apparent contradiction between Novation's commitment to physicians' choice and the physicians' assertions in these cases?

Response. As explained in earlier submissions to the Subcommittee, Novation's group purchasing program is completely voluntary. This means that any member can purchase any product at any time from any vendor, whether or not that vendor has a contract with Novation. Where a member does purchase "off-contract" — and all members do — Novation does not impose (or threaten to impose) any fines, fees, assessments or other penalties of any kind. Novation has advised GPO members of this fact, expressly and in writing, on numerous occasions. See June 30 Response, Question 10.

Novation is not aware of any instance where a Novation employee has threatened a physician with penalties for "going off-contract." If, however, the Subcommittee has learned of specific incidents where physicians have been threatened, we urge that this information be shared with Novation. Such threats would violate Novation's policies and procedures and the company would need to undertake an internal investigation and, depending on the results of that investigation, appropriate corrective action.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR KOHL
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 11. We recognize that Novation, and many others in the GPO industry, have expended a great deal of effort in drafting new codes of conduct and examining and revising their business practices. However, these codes of conduct are voluntary agreements in response to the work of this Subcommittee. They do not have the force of law. And someday, of course, Novation will have different management than yourself. How can we be assured that Novation's reforms are truly permanent and lasting? How do we know that these reforms won't be changed, lessened, or withdrawn altogether in a few years when the scrutiny has lessened and we in government have moved on to other priorities?

Response. As an initial matter, we should reemphasize that Novation is owned by VHA and UHC, which in turn, are owned and governed by their community hospital and academic medical center members. Ultimately, then, it will be these community hospitals and academic medical centers that — consistent with their mission and needs — will determine the direction of Novation in our time.

That being said, perhaps the best evidence of Novation's commitment to the Operating Principles is reflected in the substantial progress that Novation has made over the past year — progress that both (1) has been described in considerable detail in our previous submissions and (2) was expressly recognized by the Subcommittee during the July 16, 2003, hearing.

That Novation's commitment will be lasting, in turn, is evidenced by the tremendous investment that Novation has made — in terms of time, effort, money, manpower, training, education and more — in order to develop and implement the wide-ranging and, in many cases, structural/foundational business processes, policies and procedures necessary to implement the Operating Principles.

Although perhaps counter-intuitive at first blush, that Novation's

commitment to the Operating Principles will be lasting also is evidenced by the very fact that the Operating Principles are voluntary and were not imposed on Novation by law or regulation. That is, Novation adopted the Operating Principles precisely because they were consistent with Novation's mission.

Indeed, by their very terms, the Operating Principles are designed and intended (1) to promote "a truly voluntary group purchasing program" that provides VHA and UHC members "with full access to any health care item or service (including new medical technologies) from any vendor regardless of whether that vendor has a contract with Novation" and (2) to "further underscore [Novation's] commitment to improving certain group purchasing policies and procedures."

Simply put, the commitments made by Novation in the Operating Principles — which commitments Novation has lived up to in full — are consistent with Novation's fundamental mission, a mission that has remained unchanged since Novation's creation.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR SAXBY CHAMBLISS
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 1. What do you view as the most important and effective change your organization has made over the last 10 months?

Response. As reflected in our June 30, 2003 submission to the Subcommittee, Novation has made a large number of changes to its policies and practices pursuant to its implementation of the August 2002 Operating Principles. Although we consider all such changes to be important, we would like to highlight those relating to new technology, member flexibility, member choice, and the vendor grievance process.

Before turning to these four areas, however, we would like to emphasize that Novation's successful implementation of the Operating Principles is based, in large part, on various enhancements Novation has made to its business practices in general. For example, implementation of the Operating Principles necessitated the development of numerous new systems and processes (such as a system for reviewing products for clinical preference) and the development of a number of new policies and procedures (such as policies relating to standardizing vendor fees). These structural changes have ensured that Novation's implementation of the Operating Principles is organized and efficient and that the results will be effective and long-lasting.

New Technology

One of the most far-reaching changes that has resulted from Novation's implementation of the Operating Principles relates to new technology. Novation has dedicated substantial resources to the identification and evaluation of new and emerging technology and, as described below, the results have been impressive.

First, Novation launched a web-based "Technology Forum" that permits vendors to submit bids electronically. Notably, vendors

may submit a request for consideration as new technology at any time, including, of course, between Novation's regular bid cycles. In addition, the electronic Technology Forum submission process is quicker than the more traditional paper bid submission process, a feature that is particularly beneficial to vendors of new products, who often are trying to get their products to market as quickly as possible.

Second, Novation has enhanced its outreach — or technology "pipeline monitoring" — program. Pursuant to this proactive program, Novation's Market Research Department monitors the marketplace for emerging medical technology on a continuous basis. Where a promising new product is identified, Novation takes the initiative and contacts the vendor.

Novation also has taken steps to increase member awareness of new technology. For example, the Technology Forum has a special section, called "Now Available," dedicated to showcasing new technology, irrespective of whether the vendor has a contract with Novation. All vendors are invited to submit information to the Technology Forum, which information is posted on the "Now Available" electronic bulletin board.

These efforts have yielded meaningful results. In just 10 months, Novation has awarded 19 contracts to vendors outside of the regular bidding cycle and currently is reviewing a dozen more products. In addition, vendors have posted information on the Technology Forum relating to more than 50 different products. In sum, Novation's efforts related to new technology have collectively served to increase member awareness of and access to new and emerging technology products.

Greater Member Flexibility

Although already voluntary, Novation revised its OPPORTUNITY Spectrum Program to provide even greater member flexibility. Pursuant to the Operating Principles, Novation took a number of steps to re-emphasize that participation in the Program is purely voluntary (e.g., Novation sent a letter to all participating members explaining that both participation in the OPPORTUNITY Spectrum Program and any purchases under the Program are completely at the member's discretion). In addition, although not required by the Operating Principles, Novation eliminated (1) all penalties in the event that a member elects to drop out of the Program and (2) any

requirement that members purchase capital equipment. See Novation Response to Request for Information and Documents by the United States Committee on the Judiciary Subcommittee on Antitrust, Competition Policy, and Consumer Rights, June 30, 2003 ("June 30 Response"), Question 10.

Increased Member Choice; Additional Multi-Source Contracts

Although not required by the Operating Principles, Novation has increased its multi-sourced contracts. For example, Novation has converted six clinical preference product categories from sole-source contracts to dual or multisource contracts. As a result, members now have more choices with respect to product vendors. For example, last year, Novation only had one contract with one vendor for safety needles and syringes. Today, GPO member hospitals may choose among four different vendors.

Enhanced Vendor Grievance Process

Novation also has enhanced its processes for addressing vendor grievances. Where a vendor submits a request for a contract (through the Technology Forum, for example) and this request is denied, Novation has a formal process to address any vendor grievances. In a nutshell, if a vendor believes that Novation incorrectly decided not to award the vendor a supply contract, the vendor may file a grievance in writing to Novation. Novation, upon receipt of the grievance, will (1) respond immediately to acknowledge receipt of the grievance and (2) within 90 days provide a detailed response indicating, among other things, the rationale for Novation's decision.

Novation's grievance procedures have yielded meaningful results. For example, Applied Medical Resources filed a grievance with Novation when it did not receive a contract for embolectomy catheters. Novation's prompt review of the company's grievance gave rise to an additional exchange of information that resulted in Novation awarding a contract to Applied Medical Resources.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR SAXBY CHAMBLISS
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

September 8, 2003

Question 2. Mr. McKenna, how are you going to assure that these changes are long-term and have the intended impact beyond the interest of this subcommittee?

Response. As an initial matter, we should re-emphasize that Novation is owned by VHA and UHC, which in turn, are owned and governed by their community hospital and academic medical center members. Ultimately, then, it will be these community hospitals and academic medical centers that — consistent with their mission and needs — will determine the direction of Novation in our time.

That being said, perhaps the best evidence of Novation's commitment to the Operating Principles is reflected in the substantial progress that Novation has made over the past year — progress that both (1) has been described in considerable detail in our previous submissions and (2) was expressly recognized by the Subcommittee during the July 16, 2003, hearing.

That Novation's commitment will be lasting, in turn, is evidenced by the tremendous investment that Novation has made — in terms of time, effort, money, manpower, training, education and more — in order to develop and implement the wide-ranging and, in many cases, structural/foundational business processes, policies and procedures necessary to implement the Operating Principles.

Although perhaps counter-intuitive at first blush, that Novation's commitment to the Operating Principles will be lasting also is evidenced by the very fact that the Operating Principles <u>are</u> voluntary and were not imposed on Novation by law or regulation. That is, Novation adopted the Operating Principles precisely <u>because</u> they were consistent with Novation's mission.

Indeed, by their very terms, the Operating Principles are

designed and intended (1) to promote "a truly voluntary group purchasing program" that provides VHA and UHC members "with full access to any health care item or service (including new medical technologies) from any vendor regardless of whether that vendor has a contract with Novation" and (2) to "further underscore [Novation's] commitment to improving certain group purchasing policies and procedures."

Simply put, the commitments made by Novation in the Operating Principles — which commitments Novation has lived up to in full — are consistent with Novation's fundamental mission, a mission that has remained unchanged since Novation's creation.

RESPONSE TO FOLLOW-UP QUESTIONS FROM SENATOR SAXBY CHAMBLISS
UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
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September 8, 2003

Question 3. How do you measure success with your hospitals?

Response. Novation measures success with VHA and UHC hospital members in several ways. One of Novation's principal goals, of course, is to obtain lower product prices for VHA and UHC-member hospitals by leveraging their collective purchasing power. Novation conservatively estimates that in 2003 alone, the discounts and rebates negotiated by Novation will save VHA and UHC members over $1 billion.

Aggregating purchasing power, however, is not the only way that Novation saves member hospitals money. Developing and drafting invitations to bid, soliciting responsive bids from prospective vendors, analyzing bids to determine which offers the best combination of clinical value and price, and negotiating contract terms with successful bidders, is a complex process that requires specialized personnel. It also is time consuming and costly. Hospitals avoid these considerable costs by having Novation furnish these various services on their behalf.

Although putting a price tag on cost avoidance can be difficult, there is little question that this provides tremendous value to VHA and UHC members. As one member hospital told the Subcommittee, the member uses the services of Novation "because by avoiding costs we would otherwise be forced to incur, we are able to further our mission to deliver quality health care to our patients." See Letter from Stephen L. Goeser, CEO Shelby County Myrtue Memorial Hospital, to Chairman DeWine, dated July 16, 2003. Similar sentiments were expressed by another VHA hospital board member, who indicated that greater utilization of GPOs to assist in managing costs allowed his hospital to move from an operating deficit of $5 million in 1998 to a net gain of $12 to $13 million in 2003. See Testimony of Mr. Gary Heiman, President and CEO, Standard Textile Co., before the United States Senate Committee on the Judiciary, July 16, 2003.

In addition to value in the form of price reductions and cost avoidance, VHA and UHC are cooperatives. It is common for cooperatives to be funded by fees paid by vendors wishing to do business with cooperative members and to return their net revenue to these members. VHA and UHC are good examples. Each year, VHA and UHC distribute their net revenue — the vast majority of which is generated by administrative fees — to their hospital members. These distributions, which take the form of cash and patronage equity certificates, serve to further reduce the overall supply chain management costs of member hospitals. Between 1997 and 2002, for example, VHA returned more than $400 million in cash to its member hospitals.

Another measure of success relates to membership and purchasing levels. Today, Novation serves the purchasing needs of more than 2,300 VHA and UHC members; and comparing the January-June 2002 and January-June 2003 time periods, member purchases through Novation contracts are up approximately five percent.

To further ensure that Novation is meeting the needs of the members it serves, Novation employs a member-focused strategy to provide each health care organization with multiple opportunities to provide input. Decisions — from the development of award criteria and bid awards to the format of agreement launch packages — are based on member input. Novation works closely with various member councils and task forces to generate input that will enhance the quality of Novation's offerings.

Finally, Novation conducts quarterly member satisfaction surveys and gathers input from VHA and UHC focus groups. This data indicates a continuing upward trend in satisfaction levels among VHA and UHC members, particularly among the clinical groups and materials managers that interface most frequently with Novation.

SUBMISSIONS FOR THE RECORD

Statement for the Record by Robert L. Aromando, Jr.
Vice President of Marketing, Bracco Diagnostics Inc.

Hearing on: "Hospital Group Purchasing: Has the Market Become More Open to Competition?"

United States Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition, and Business and Consumer Rights
The Honorable Mike DeWine, Chairman
The Honorable Herb Kohl, Ranking Member

July 16, 2003

On behalf of Bracco Diagnostics Inc., I want to thank the Committee for inviting me to offer this statement for the record on an issue that matters to so many Americans. Your inquiry into GPO competitive practices is both welcome and timely, and in our view even essential for health care consumers and the health care industry.

Addressing the core issue behind this hearing, we want to commend Chairman DeWine, Ranking Member Kohl and the Committee for highlighting the need to clarify rules of the road for proper Group Purchasing Organization competitive behavior. Every member of the Committee should know that the work they do and the outcomes they impact will be steps toward better and more efficient patient care. Thank you both for taking a leadership role on this matter.

We would like to provide the Committee with some facts and details we have assembled in an attempt to highlight several major flaws we have observed in the behavior of a certain GPO not only prior to its adoption of its own voluntary Code of Conduct but also since this Committee's investigation began well over one year ago. As a result of these flaws, Bracco's inability to compete equally in the marketplace may result in a disincentive for investment in future capacity and production that would otherwise be necessary. Most important, however, is the fact that certain patients that would benefit from Bracco products, and certain physicians who have expressed a desire to switch to Bracco products for legitimate medical reasons, have been denied access to our products because of this GPO's contract restrictions and penalties.

The continued attention and oversight of this Committee is absolutely necessary, in our opinion, if any consequential reform is to be expected. We ask that you take an opportunity to review the information provided and we hope that these details will prove useful as you continue to affect positive change in GPO competitive activity. In our view, this issue has significant implications for the entire industry and for consumers nationwide.

About Bracco Diagnostics Inc.

Bracco Diagnostics Inc. is a global leader in the field of diagnostic imaging. We produce and market a variety of products, including contrast agents for use with X-Ray and MRI procedures, as well as important nuclear medicine products.

Our diagnostic pharmaceuticals help physicians and other health care professionals leverage non-invasive procedures to look inside the body, make diagnoses, and begin treatments. In this regard, we play an active role in improving the way the medical community diagnoses and treats many illnesses and injuries, including cancer, heart disease, and central nervous system conditions.

Bracco Diagnostics Inc. is a member of the Bracco Group. Headquartered in Milan, Italy, the Bracco Group employs over 3,500 people in over 115 countries worldwide – nearly 20 percent of whom are dedicated to research and development efforts. The Bracco Group now accounts for one third of the global X-Ray contrast media market, over 20 million diagnoses are made each year using Bracco contrast agents, and a Bracco imaging product is used in a diagnostic imaging procedure somewhere in the world every two seconds.

The company's flagship North American marketing and research operations – Bracco Diagnostics Inc. and Bracco Research USA – are both located in Princeton, New Jersey, and both were established in 1994.

GPO Impact on Competition

Group Purchasing Organizations (GPOs) have been operating as outsourced organized procurement entities for member hospitals since the 1980s with a clear objective to negotiate on behalf of their subscribers the best possible transaction price for goods and/or services. In the case of the contrast media industry there are four primary providers of products: Bracco, Amersham, Berlex and Mallinkrodt, each with a substantially equal overall market share. In fact, market share for any one supplier barely moves beyond any small, incremental gain because GPO contracts for the most part have long terms (some have 5 year terms and sole source mandates - such as the Novation contract with Amersham for contrast media). In fact, the Amersham contract with Novation has been in place, we believe, since 1988 when Amersham was Winthrop and Novation was Voluntary Hospital Association (VHA). The current Amersham contract with Novation is scheduled to expire in 2006 with no indication it is likely to be awarded to another supplier.

For this reason suppliers are generally discouraged from investing in capacity or innovation when it comes to existing products. In addition, most suppliers are at capacity now with only some room for increased demand. However, if for any reason the Novation contract was awarded to a sole provider other then Amersham it could take that

supplier anywhere from 12-18 months to build adequate inventory to supply such a contract to its full extent.

The inherent risk with this scenario is that it allows the incumbent supplier to simply raise prices almost unimpeded and thus leave Novation hospital members no choice but to pay higher prices.

Assessment of The Problem

Bracco Diagnostics Inc. utilizes a direct sales force of about 95 professionals to market our products to Radiologists, Cardiologists, Radiology Technologists, Radiology Nurses and administrative personnel. Approximately 70-80% of our annual revenue is generated through GPO contracts. We currently maintain contracts with Amerinet, Consorta, HPG, and Tenet and in some cases we are able to do business with Premier subscribers. We have found our relationships with these GPOs to be generally good business arrangements. They require us to constantly compete for small incremental gains in revenue because almost all of these contracts do not have effective compliance enforcement penalties. By comparison, the Novation contract with Amersham – which is highly compliant – contains severe penalties for member hospitals that buy products off-contract. Most GPOs do not mandate compliance with contracts to the extent that Novation does.

As we have indicated, our experience with Novation members and our experience in the market leads us to believe that Novation assesses financial penalties on its members if they choose to use products that are not part of a Novation agreement, even if there are clinical reasons or clinical preference to support the purchase of these products.

Bracco field sales personnel have made numerous attempts (as far back as 1997) to develop a business relationship with Novation member hospitals. In a particular situation, a Bracco representative met with Novation's then-senior radiology product manager and was told that Bracco would be given an opportunity to bid on the Novation contract when it came up for renewal in 2001. Bracco subsequently provided a cost effective proposal and was not selected; rather, the Amersham contract in place was effectively rolled over for another five years.

Recently, in almost every instance, Bracco sales professionals have been discouraged, denied access to the radiology departments, or specifically prohibited from doing business with Novation members. Here are several examples:

- **University of Utah**: The Bracco sales person conducted a 30 day comparative trial demonstrating patient safety, efficiency and contrast optimization to the radiology staff. At the conclusion of the trial all department personnel supported utilization of Bracco's Isovue® 370 prefilled syringe product. When the University of Utah radiology department indicated they wanted to switch to the Bracco products they were informed that any attempt to purchase off contract

would cause the hospital to forfeit up to $80,000 per year in discounts on other products throughout the hospital.

- **Lutheran Medical Center**: The cardiovascular laboratory made an initial "special offer" purchase of Bracco's Isovue 370 product due to its low dose, high iodine concentration feature. The cardiovascular lab manager was specifically told this laboratory was not permitted to purchase any amount of contrast, even under a special offer program. In fact, the local Novation representative and the Amersham representative visited all staff cardiologists and radiologists informing them that they were not allowed to purchase any contrast off contract.
- **University of Colorado**: Staff cardiologists formally requested in writing that they have the ability to purchase Bracco's Isovue 370 due to its unique properties of low dose, high concentration, low viscosity and low osmolality. The cardiologists were specifically denied access to the Bracco product by the director of material management citing the Novation compliance issue.
- **Purchasing Partners (formerly Promina of Georgia)**: This organization manages 12 hospitals in the State of Georgia and has generally permitted the Bracco representative to meet with hospital staff. However, two formal requests were made to the Promina contracts manager by the purchasing department at Piedmont Hospital (the flagship Promina hospital) to allow for a Bracco Isovue prefilled syringe test trial. The contracts manager denied both requests from Piedmont indicating that the current Amersham/Novation contract provided comparable product that was medically acceptable.
- **Faith Regional Medical Center**: The Bracco representative completed a successful trial utilizing Isovue prefilled syringes. The radiology department intended to switch products and requested a contract proposal from Bracco. As the Bracco proposal escalated to administrative levels of the medical center, the radiology lab was denied access to the products claiming that they would lose approximately $30,000 per year in Novation dividends through a bundled Novation compliance program.
- **Allina Hospitals and Clinics**: In a routine meeting with the purchasing department, the Bracco representative was specifically warned about attempting to sell any products to their facilities without getting permission from purchasing. The purchasing manager indicated that a product would have to demonstrate a significant clinical difference before they would consider going outside the Novation contract. The purchasing manager went on to inform the Bracco representative that if it were discovered that Bracco was visiting any of their facilities without permission from purchasing to sell, Bracco would be in "big trouble".
- **Scott and White Hospital**: The lead radiologist made a formal request to switch from the Amersham MR agent to the Bracco MR agent due to its ability to not interfere with colorimetric serum calcium diagnostic tests. The radiologist was formally notified that they were denied permission to go outside the Novation contract due to severe financial penalties if compliance was not 100%.

In every one of these situations, Novation has ventured beyond the simple boundary of encouraging contract compliance to seek out lowest transaction costs. Novation has

actively thwarted open and fair competition on the merits of legitimate product performance, manufacturer service, and clinical preference distinctions. They have done this through multiple level dividend or rebate payments based on broad product bundling packages that severely penalize members who attempt to purchase any product off-contract.

In addition, notwithstanding the commitment it has expressed through adoption of the HIGPA Code of Conduct and its own Operating Principles to allow its members to choose medical products and services they prefer in the exercise of their professional judgment, Novation's actions discourage physicians from selecting products from Bracco or any other competitor of its contract vendor that would offer incremental benefits, including safety-related benefits, to their patients.

Bracco Diagnostics Inc. Efforts to Remedy the Problem

Bracco field personnel and senior management have met several times with Novation in an attempt to have a two-way dialogue regarding key scientific features and benefits of Bracco products and their impact on patient safety and medical outcomes. Specific focus was on Bracco products that would offer Novation members viable alternatives to their existing contracted products from Amersham. The products are ProHance®, Isovue 370 and Isovue prefilled syringes.

As an example of a true and accurate instance where a Bracco product presented a simple solution to an inherent problem with the Novation incumbent product we offer the following illustration:

> The incumbent supplier to Novation is Amersham. They provide all Novation members with an MR agent called Omniscan™ which interferes with colorimetric serum calcium determinations. The Amersham Omniscan package insert now warns the user of this problem. A recently published scientific study confirmed this to be a problem based on the outcome of a 22 month study where 2,096 patients were evaluated (copy of the study is included).

History of Discussions

On **July 15, 2002,** representatives from Bracco met with three members of the Novation staff to present clinical facts related to the serum calcium issue. This information included relevant physiochemical information for all MR contrast agents related to chelate stability and safety. Upon receiving the information, all attendees commented that they appreciated how we presented information that was clinically supported and fairly balanced, especially since Amersham had not bothered to provide Novation with a copy of the serum calcium "Dear Doctor" letter when it was sent out.

- In **October 2002**, Bracco representatives contacted the Director of Diagnostic Imaging for Novation to inquire if there were any further medical information needs

related to the serum calcium issue. It was made clear to Bracco that there did not appear to be any additional clarification needed and Novation was comfortable with the resolution of this issue.

- In **January 2003**, Bracco learned of the Winter-Spring 2003 edition of *The Novation Diagnostic Imaging Bulletin*, which contained an article discussing the serum calcium issue entitled "Contrast Agents Can Interfere with Lab Tests." To our shock and disappointment, this article contained blatantly erroneous and misleading information that is directly contradictory to the clinically supported and fairly balanced information that Bracco presented to Novation on July 15, 2002. Specifically, among other things, this article contends that "[A]ll gadolinium agents sold in the United States for which there are published data affect the colorimetric calcium determination to some degree." This statement is not true. Bracco's gadolinium agent -- ProHance® -- does not affect colorimetric calcium determination, as supported by the lack of a reference to serum calcium in the FDA-approved ProHance package insert. Additionally, calcium measurements by colorimetric method for all MR agents currently on the market were provided to Novation representatives during the meeting in July 2002.

- In **early March, 2003**, Bracco requested a meeting with Novation to discuss the content of the *Diagnostic Imaging Bulletin*, specifically related to our concerns about the inaccuracy of information being provided to Novation members about the serum calcium issue. In that communication we requested that the bulletin be retracted and a revised statement be issued to correct the information that was misleading and potentially damaging to both patients and our product.

- On **March 27, 2003,** representatives from Bracco again met with representatives of Novation, this time in an effort to get Novation to issue a corrected version of the *Diagnostic Imaging Bulletin*. Unfortunately, Novation was not receptive to the idea of re-issuing a *Bulletin* that is clinically accurate in all respects. In fact one Novation representative clearly stated in a derogatory manner during the meeting that the only knowledge she had of ProHance was what she called "ProHurl", apparently an effort to characterize one of the alleged side effects of the product.

What is an MRI procedure and what is the implication of serum calcium?

Magnetic Resonance Imaging (MRI) is a diagnostic imaging tool utilizing a powerful magnetic field to generate high quality images of soft tissue. Intravenous contrast agents such as Omniscan (from Amersham) and ProHance (from Bracco) help to detect tumors, inflammation, infarctions and lesions in the brain, spine and associated tissues, head and neck. There are approximately 22.5 million MRI scans performed in the United States each year. Of those, an estimated 5.7 million are enhanced with a contrast agent such as Omniscan and or ProHance.

Serum Calcium

Calcium is the most abundant mineral in the human body and is vital for many physiologic processes. The management of electrolytes such as calcium is important in many patients. Physicians who manage oncology patients, patients with renal insufficiency, especially those on hemodialysis, patients with cardiac arrhythmia or those in the ICU/CCU, depend on frequent and accurate calcium determinations

Serum Calcium Tests, Impact on Patient Management

Most serum calcium assays are automated and use colorimetric reagents such as o-cresolphthalein (OCP). In fact, 87% of chemistry laboratories use a colorimetric method for determining serum calcium levels. The Amersham product, Omniscan interferes with this test, which can result in a test reading that shows a much lower blood calcium level than actually exists. Consequently a patient with a normal serum calcium level may be inappropriately treated with IV calcium. Conversely, a true hypocalcemic patient may appear normal because of the falsely low level of serum calcium. In fact a recent study conducted at a major medical center reported that of those patients receiving an MRI procedure, almost 50% also received a serum calcium determination test at the same time.

More importantly, the study found that 18 patients received unnecessary and inappropriate calcium treatment based upon false serum calcium test results. The paper goes on to quote; "Although no patient injury was could be traced to the erroneous calcium measurements, even though seven (out of 18) patients received calcium gluconate intravenously, this laboratory "artifact" is a potentially important cause of unnecessary and potentially dangerous medical interventions. There is also substantial institutional cost associated with spurious reports of critical conditions. Such reports consume physician and staff time for emergency assessment and can also lead to additional patient examinations and may delay the diagnosis and management of the patient's condition.

As indicated above Bracco has made several formal presentations to Novation in an attempt to provide clear and accurate scientific information about this subject.

Novation's Operating Principles and the HIGPA Code of Conduct

In response to these proceedings, the Health Industry Group Purchasing Association ("HIGPA"), of which Novation is a member, adopted the HIGPA Code of Conduct Principles (the "Code of Conduct") on July 24, 2002. Novation certified it was in compliance with the Code of Conduct, as reported in a HIGPA press release dated May 19, 2003. In addition, Novation announced in its own press release dated August 8, 2002, that it had adopted Novation Operating Principles (the "Operating Principles"), which evidenced commitments by Novation in addition to those in the Code of Conduct.

A. Clinical Preference Items

The first paragraph of the Operating Principles provides that "Novation is committed to operating a truly voluntary group purchasing program that provides members of UHC and VHA with full access to any health care item or service (including innovative medical technologies) from any vendor regardless of whether that vendor has a contract with Novation." In addition, at Section I, the Operating Principles provide that Novation will "reiterat[e] and reinforc[e] – to UHC and VHA members, vendors and the public at large – Novation's commitment to operating a voluntary group purchasing program that gives members the freedom to purchase any product that they determine offers the best combination of clinical value and price, regardless of whether the product is under contract with Novation." Simply put, Novation is stating a commitment to allow its members to purchase any healthcare item or service from any vendor.

The Code of Conduct espouses a similar commitment at Section I.C.1.a, which requires each GPO to permit its members to (a) communicate directly with vendors who don't have a contract with the GPO, (b) assess products and services from vendors who don't have a contract with the GPO, and (c) purchase "Clinical Preference Items" from vendors who don't have contracts with the GPO. Consistent with this commitment to allow individual members to choose the products and services that they prefer, the HIGPA definition of Clinical Preference Items is:

> "'Clinical Preference Products or Services' shall mean those Clinical Products or Services which require substantial training to learn to use and which have a demonstrable effect on patient care outcomes. Accordingly, they are products or services for which a provider has a particular preference based on factors such as the provider's training and experience, the performance or functionality of such products in a clinical setting and patient clinical outcomes."

See Code of Conduct, Definitions Section A.

While Novation has certified its compliance with the Code of Conduct, its Operating Principles use a far more restrictive definition that effectively negates individual preference:

> "Clinical preference products shall refer to any medical device or item of medical equipment or supply used to treat a patient for any illness, injury, condition, disease or ailment about which a physician or other clinical (including nurses) could reasonably be expected to express a preference or could be expected to effect patient health or safety or worker health or safety. Relevant member councils or task forces will make the determination as to whether a particular product is a clinical preference product."

See Operating Principles, Section II, note 1.

Bracco disagrees with the notion that a "council" or a "task force" may decide for an entire purchasing group whether an individual healthcare provider's expressed preference is "reasonable" or should be honored. This notion effectively negates any commitment to allow members to purchase any healthcare item or service from any vendor. Accordingly, Novation's honoring of its commitments to operate a voluntary group purchasing organization and to give its members the freedom to choose preferred products or services should be considered without reference to such a legalistic definition. Bracco would propose that "clinical preference" should have its plain-meaning, which would logically be the expressed preference of a healthcare provider using his or her professional judgment to make a risk/benefit analysis for each patient.

As detailed herein, there are many instances where Novation members expressed a clinical preference for Bracco's products but were informed by Novation that they were required to use products they did not prefer because of Novation's contractual relationship with another vendor or they would face severe financial consequences. Despite Novation's recent alleged commitments, nothing seems to have changed and its members are being prevented from using products that they would prefer based on their professional judgment.

B. Contract Practices

Section 1.D of the Code of Conduct provides:

> "The goals of the GPO contracting process include promoting quality of patient care and achieving price savings and cost reductions for Members. In order to better achieve those ends, GPOs see to foster competition among vendors. To that end, GPOs have contracting tools that include sole source contracting, commitment level requirements, contract length and multi-product line discount arrangements. GPOs should use these tools alone in combination only in contracting arrangements that achieve the forgoing goals. The goals are most important in relation to Clinical Preference Products or Services. To the extent that multiple contracting tools are use in the contracting process, each GPO shall consider the following factors in each contractual arrangement to achieve the aforementioned goals: market share of the Participating Vendors, the size of the GPO, the number of Vendors available to provide the relevant product or service, ability of the Participating Vendor to meet the needs of the GPO's members, and the occurrence of innovation in the relevant product or service category."

While Novation has adopted the Code of Conduct, its Operating Principles add other requirements on a prospective basis which include:

> [Novation] will not award a sole-source contract for a clinician preference product that has an alternative that offers incremental patient care benefits or incremental safety benefits;
>
> [Novation] will re-bid the relevant product category or make a dual or multisource award (based upon the review and recommendation of the relevant Novation clinical council or task force) in the event a new product enters the market that offers incremental patient care benefits or incremental safety benefits; and
>
> [Novation] will require that all recommendations to award a sole-source contract for a clinical preference product receive review and approval by the relevant Novation clinical council or task force before going into effect.

See Operating Principles, Section II.

In addition to the prospective changes, the Operating Principles also require that "Novation will preserve its existing contracting flexibility by:

- ensuring that all of its vendor contracts permit (and continue to permit) contract termination without cause, upon 90 days' written notice; and
- including a provision in its vendor contracts permitting Novation to add additional vendors or to terminate and re-bid the contract in the event of the introduction of products which offer incremental patient care benefits or incremental safety benefits.

To this point, it must be noted that on April 9, 2002 a Bracco Representative met with the chairman of the Novation Radiology Products Committee at Baylor Medical Center in Garland, Texas. The purpose of the meeting was to discuss the "new technology" exception to the Novation contract and how Bracco's Isovue prefilled syringes could qualify for a re-bid opportunity. The Novation representative indicated that Bracco could have a chance to secure the re-bid opportunity, so he submitted a formal request to Novation for dual award based on Isovue prefilled syringes meeting the criteria of "new technology" in paragraph II of Novation's Code of Conduct. The request was ultimately denied by Novation. In addition, when Baylor Medical Center acquired two free-standing imaging centers (Texas Diagnostic Imaging Centers in Mesquite and Dallas) they were immediately forced to switch from Bracco Isovue prefilled syringes to the Amersham Omnipaque bottle product in the interest of contract compliance.

See Operating Principles, Section IV.

Through the Code of Conduct and its Operating Principles, Novation has stated a commitment to foster competition among vendors and to honor the clinical preferences of its members. It has also stated that it will add additional vendors to those it has

contracted with where the products of additional vendors provide incremental safety benefits. As detailed herein, despite these statements, Bracco (and presumably other vendors) have been prevented from competing for Novation's business and Novation has ignored strong evidence of incremental safety benefits that could be realized by its members and their patients by the use of Bracco's products.

In sum, in these particular instances, Novation's voluntary efforts to address this committee's concerns – including adoption of the Code of Conduct and the Operating Principles – have been ineffective. Despite the alleged commitments, little has changed from Bracco's perspective as a potential supplier.

Recommended Course of Action

In the interest of allowing medical practitioners to make decisions that better serve the patients, this committee should affect change by demanding immediate and swift reform. Such reform must be clear, concise and mandatory in a way that takes into account first and foremost the patients that receive medical treatment. Furthermore, bundling non-related products with financial penalties should be eliminated so that physicians may select clinically appropriate products without fear and intimidation. Finally, multi-year single-source contracts should be modified to allow multiple or second-source contracts in the interest of improved patient outcomes and/or safety benefits.

Conclusion

In summary, the issues outlined and explained in this testimony are important on two key levels. First and foremost, the current system has the effect, in our opinion, of limiting the clinical options available to health care professionals. In this scenario, contracts and purchasing agreements are dictating physicians' treatment choices. Financial pressures are allowed to take precedent over medical opinion and bundling of non-related products is allowed to occur without penalty. And this simply does not serve the best interests of patients.

Secondly, the current scenario runs counter to the notion of open and fair competition where companies are allowed to compete on the merits of product performance, as well as fair pricing. In this situation, the incentive for a company like Bracco to develop and market products that offer clinical and cost advantages is hampered. Again, this ultimately has a negative impact on health care providers and patients.

We urge the committee to take swift and comprehensive action in a manner that will correct this problem and create a situation where physicians and other health care providers are empowered with more choices that enable them to improve patient care.

Again, on behalf of Bracco Diagnostics Inc. I want to thank the committee for inviting me to submit this statement for the record. Your efforts are important and appreciated by

the companies that work hard to develop breakthrough products that enhance patient care and quality of life.

Robert L. Aromando, Jr.
Vice President of Marketing
Bracco Diagnostics Inc.

A ONE YEAR RETROSPECTIVE ANALYSIS OF GROUP PURCHASING ORGANIZATIONS AND THEIR IMPACT ON SMALL-TO-MEDIUM SIZED COMPANIES IN THE UNITED STATES HEALTH CARE DELIVERY SYSTEM

My name is Thomas V. Brown. I am the Executive Vice President for BIOTRONIK, Inc., which is located in Lake Oswego, Oregon. BIOTRONIK, Inc. sells, markets and distributes cardiac pacemakers and implantable cardiac defibrillators. Both products are sold in the Cardiac Rhythm Management market segment in the field of Cardiology. I have worked in many different capacities in this field of medical marketing and sales for over 27 years, and I have been associated with BIOTRONIK for over five years. For the past nineteen years, I have served in executive roles with BIOTRONIK and other companies in this industry.

BIOTRONIK, Inc. is a privately owned US company that became incorporated in the state of Oregon in 1988. During 2002, BIOTRONIK achieved approximately $80,000,000 in annual US sales. BIOTRONIK, Inc. employs approximately 160 people throughout the US and has another 100 people representing the company as independent sales agents. Our sister company, known as Micro Systems Engineering,

Inc., also located in Lake Oswego, employs another 300 employees who are principally engaged in the design, development, and manufacture 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 are used to treat cardiac rhythm disturbances and are "life saving" products. Cardiac pacemaker (pacemaker) or implantable cardiac defibrillator (ICD) therapy is generally managed by a Cardiologist or Electrophysiologist (EP).

Typically, the physician has been the individual who selects the type and brand of device that is best suited for the patient's individual condition. The physician usually instructs the hospital on what brand and model of device he or she desires, and the hospital would then buy the device. As a result, this product is typically known as a "physician preference product".

The medical condition requiring pacemaker or ICD therapy 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 reimbursement codes, which pay a "set" amount of reimbursement to the hospital for the entire procedure. Physicians are reimbursed separately for their professional services.

The US market for pacemakers and ICDs is projected to be $4,884,000,000 during FY 2003. Again, a large percentage of this is paid by the US Medicare Reimbursement System due to the advanced age of the patients.

The US Cardiac Rhythm Management business is composed of five companies who have FDA approval to manufacture and market products. Those companies, and their approximate US market share based on total revenue projected for FY 2003, are listed in alphabetical order as follows:

COMPANY	MARKET SHARE
BIOTRONIK	2.5%
ELA MEDICAL	.5%
GUIDANT	31.0%
MEDTRONIC	50.0%
ST. JUDE MEDICAL	16.0%

Today, purchasing patterns have shifted from individual hospitals generally making buying decisions, to individual hospitals, or small groups of individual hospitals, that are amalgamated together for the benefit of the whole (Independent Delivery Networks - IDNs) joining larger Group Purchasing Organizations (GPOs).

GPOs began as organizations that were primarily interested in taking the collective buying power of the membership and entering into contracts that conceptually save the individual members money in their purchases of medical equipment and supplies. Today, GPOs have become much broader in the scope, service and value they attempt to deliver to their membership. Presently, the contracting element remains a primary piece of their business and continues to be the

"principal" form of revenue generation for GPOs. Via the contracting service, GPOs negotiate and administer contracts at a national level for goods and services that their member hospitals are then expected to adhere to. GPOs typically do not purchase anything; they negotiate and administer contracts and administer the collection and distribution of the administration fees. The concept of GPOs remains valid 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 an individual hospital. GPOs provide value-added services to their members and, certainly, in all cases, provide revenue-generating opportunities which hospitals may not have on their own merit because they do not participate in the same "safe harbors" that the GPOs have been granted in relation to the Medicare Anti-Kickback and Fraud statutes.

As a direct result of the pressures brought to the GPOs by the *New York Times,* and by the investigation of the United States Senate Committee on Antitrust, Competition Policy and Consumer Rights, GPOs have been requested to begin policing themselves and to establish "Codes of Conduct". These so-called "Codes of Conduct" were to be established

to (1) insure conflicts of interest do not exist, (2) insure contracting practices do not reduce or stymie competition or innovation in health care or narrow the ability of the physician to choose the best treatment for their patients, and (3) insure health care cost is being reduced by securing the best prices through volume purchases. In other words, to quote the April 30, 2002 report from the United States Senate Committee on the Judiciary, "The industry should clean up its own house.".

This testimony is to address the question, "Have GPOs in general cleaned up their own house?". As a company attempting to do business within the US market and work within a GPO system that has evolved and now not only influences, but at times actually controls hospital purchasing decisions, I can report the following:

As one would hope, BIOTRONIK has experienced improvements as a result of the efforts of the US Senate Subcommittee investigation. However, there remains "significant" work to be done to insure that all companies, with an emphasis on smaller or newer companies in the

Health Care industry, have equal and fair access to sell within the GPO system.

Areas of Improvement:

1. **Some GPOs, such as PREMIER, have established processes for considering "Breakthrough Technology". While "Breakthrough Technology" is something that does not occur frequently, when it does, companies need a process to formally present this technology to GPOs and have it considered for inclusion in their national contracts. Generally speaking, PREMIER has the most formal process with a fair and impartial approach to reviewing new and innovative technology that qualifies under their "Breakthrough Technology" program. Novation, Consorta, and Broadlane do not appear to have a process; or if they have a process, it is not as formalized or user friendly.**

   BIOTRONIK is pleased to report that PREMIER has reviewed a recent "Breakthrough Technology" submission that has gone before their physician expert panel and was unanimously

endorsed by the physician panel. PREMIER has informed BIOTRONIK that we have been accepted as a vendor under their "Breakthrough Technology" program, and we are in the process of finalizing the contract between the two companies for a product we call "Home Monitoring Technology". This is a very innovative and proprietary technology that allows patients and their implantable devices to automatically be monitored by their physician. It is wireless technology that requires no patient, no hospital, and no physician intervention. The physician receives a report on the patient's device and critical patient parameters that improves the physician's ability to manage the patient's ever-changing needs. However, this contract will allow only a few select pacemakers and ICDs that incorporate "Home Monitoring" technology to be on the PREMIER Cardiac Rhythm Management contract.

2. **BIOTRONIK has seen an increase in GPO activity to reconsider existing long-term contracts and to allow us to formally participate in the contracting process. Specifically, PREMIER has recently issued a new "Request for Proposals" for their**

Cardiac Rhythm Management products. The RFP formally begins their contracting process, and BIOTRONIK has recently submitted their response to the PREMIER RFP. Additionally, we have been informed that Novation is reconsidering their Cardiac Rhythm Management contract and may be sending out a Request for Proposals in the near future. BIOTRONIK has been accepted as a primary vendor with HealthTrust; in fact, HealthTrust opened their contract to all companies within our industry. Med Assets has been excellent about demonstrating interest in working with a smaller vendor, such as BIOTRONIK, and we are currently in negotiations with Med Assets to finalize a contract with them. In general, BIOTRONIK is pleased to see a more willing attitude to consider smaller companies like BIOTRONIK; but this, in itself, does not guarantee a contract. Other factors have tremendous impact on the final decision of the GPO regarding whom they contract with.

3. **Over the past year, BIOTRONIK is pleased to report that GPOs, in general, have moved away from "sole source contracting" and are implementing dual source or multi-source contracts. A great**

example of this is HealthTrust who recently implemented a multi-source contract with all manufacturers within our industry.

4. **Over the past year, BIOTRONIK is pleased to report that GPOs have generally ceased using long-term contracts of five or more years. More recently, we are observing "Request for Proposals" from GPOs in the 24-month to 36-month period which we view as an improvement in the process. A good example is again PREMIER who recently sent out an RFP for a twenty-four month period.**

Unfortunately, there are many areas that still need attention and improvement. The following points will highlight some of the areas of concern that remain for BIOTRONIK and other small companies attempting to compete within the GPO environment.

AREAS OF CONCERN:

1. **Contracting decisions, in general, continue to be "greatly influenced" by the market share of the vendor and the amount of**

money the vendor contract will generate for the GPO. The administration fee averages 3% within the industry; and within the Cardiac Rhythm Management industry, we are talking about a domestic revenue stream estimated to be $4,884,000,000. This means that between most GPOs there is approximately $146,520,000 in "administrative fees" available for distribution. This is a tremendous influence on the decision-making process. Many of the larger vendors pressure the GPOs to limit the contract award to one or two vendors. When you are holding 35% to 50% market share, you may wonder why should one pay the GPO an administrative fee at all, unless you are getting something for it. The something most large vendors are seeking is "exclusivity". Contracts where administrative fees are involved should be open to all vendors. We should not allow the large companies to put pressure on the GPOs to limit access of smaller companies. A case can be made that there is simply too much money involved in this process for GPOs to really be objective about the process. Administrative fees generally prevent a level playing field for small-to-medium sized companies.

2. **GPOs tend to utilize physician advisory panels to help make decisions regarding which company provides the best product or the best combination of products, service, price, etc. At first glance, this appears to be an excellent way to identify which vendors to use; however, the physician panel will always "generally" represent the US market share and usually the contracting decisions nearly always reflect this decision. You can always count on the large market share leaders being accepted because this will represent the consensus of most "expert panels". If the GPO is limiting their contract to two vendors, the small vendor will rarely have a chance, even if their price could save the buyer thousands of dollars per unit. To insure fair access by all vendors, contracts need to be structured in such a way that they do not automatically guarantee the contract award to large market shareholders. Additionally, an almost ideal scenario would be contracts structured in such a way that the GPO allows all vendors to participate if the vendor is willing to meet a certain price (known as capitated pricing).**

3. **GPOs are allowed to return portions of their administrative fees to their hospital members who do the actual purchasing. The Medicare Anti-Kickback and Fraud statutes do not apply to GPOs because of the safe harbors that were put in place to legally allow GPOs to collect "administrative fees" from vendors. The individual hospitals are not allowed to collect administrative fees and the IDNs are not allowed to collect administrative fees since neither are GPOs and since they are either doing the buying of the products (i.e. hospitals) or closer to the buying process (i.e. IDNs). Clearly, they were exempt from the safe harbors because someone recognized the tremendous temptation that would be placed on the hospital if they were allowed to receive money from vendors for the purchases they make. If administrative fees are allowed to continue to be charged by GPOs, the return of a portion of these fees to the hospital needs to be eliminated. This is an example of "having it both ways", and it becomes a tremendous influence on the hospital to buy solely off the contract. It is a financial incentive to participate on the contract that has been negotiated by the GPO. There is virtually no difference between allowing hospitals to charge an administrative fee and allowing**

the GPO to return a portion of the fee. At the end of the day, there is "financial influence" on the buying decision and this is a questionable practice.

4. **The total "projected" GPO industry purchasing volume, based on a survey conducted by Hospital Purchasing News, is estimated to be approximately $54.5 billion dollars. Assuming that most of this is covered by administrative fees on an average of 3%, the net income generated through the administrative fee process is $1,635,000,000. This is a tremendous amount of money and very difficult to be objective about. The administrative fee concept needs to be reevaluated and policies put in place which insure that contracting decisions are not made based on how much revenue is generated by the individual contracts. Decisions should be based on the quality of the product, the service level of the provider and the savings generated by negotiating excellent pricing. Administrative fees should not be allowed to prevent market entry of small companies whether they are new or whether they simply find that they cannot penetrate a system that has the ability to lock out viable competitors. Today, we are seeing**

improvement as mentioned earlier. However, the single largest issue remains that the administrative fee process principally funds GPOs. The "Code of Conduct" does nothing to address this issue or the influence on the contracting decisions the administrative fees have on the system. This must either be corrected to insure all companies have fair access, or GPOs should operate on membership fees, and possibly share in the net savings they bring to their membership for each contract negotiated. In this case, the hospital would pay the GPO for some portion of the net savings realized.

5. **Physician access to new technology, or to specific technology, which they prefer is still limited. Generally speaking, within our industry, most GPOs are operating on a dual source contract basis. While single source situations have improved, dual source situations still effectively prevent small companies from competing. Multi-source contracts must be promoted. An example being what HealthTrust has implemented to allow virtually all companies to participate if they meet a target price range. We applaud HealthTrust's actions in opening their**

contracts to a greater variety of vendors, allowing physicians access to all products and lifting restrictions on their freedom of choice.

Small companies with no access to GPO contracts are effectively prevented from participating. As a direct result, the small company never has the opportunity to build or develop market share within the GPO system and is essentially locked out. This is a major difficulty with GPO contracting as they favor companies with major market share, thus enabling large manufacturers to continue to entrench their market share position. This strategy makes it very simple and easy for the GPO to convince their members, because by contracting with companies who have the largest share, they are creating the "path of least resistance" even though those contracts very often do not provide the best pricing scenarios.

6. **Breakthrough Technology contracting opportunities should exist with all GPOs to allow new and exciting products to enter into the GPO system. Each and every GPO should have a formal process**

for allowing "Breakthrough Technology" to quickly and expediently enter into the system and be evaluated. PREMIER has the most formal, user friendly and fair system on the market. We say this not because we have successfully gone through the process and should be receiving a contract soon, but because the system worked, and we felt PREMIER gave our company a fair and objective review. In comparing it to other GPOs, there is much to be learned by evaluating the PREMIER "Breakthrough Technology" process.

SUMMARY: BIOTRONIK wishes to thank the members of the United States Senate Committee on the Judiciary for their interest, involvement and dedication in attempting to rectify a situation that has made it very difficult, if not impossible, for small-to-medium sized medical companies to have fair and equal access to deliver innovative and competitive products into the US health care system. Your dedication, and the dedication of your staffers, is sincerely appreciated.

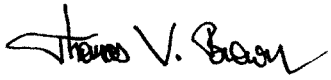
The good news is we are seeing evidence of change. I have focused most of my discussion towards GPO contracting practices and policies. We

have seen improvement; and we believe that generally most GPOs are attempting to improve the contracting environment and allow access to their contracting system -- not all, but most. We have sited some personal examples of improvements that have helped our company to secure contracts or at least be in the queue to receive a contract with specific GPOs.

Some GPOs appear to be managing this change better than others. On the other hand, there is still much to be done to insure that an open market occurs and we see both small and large companies having equal access to the GPO market. Virtually all hospitals in America are members of a GPO, or multiple GPOs. This means that for competition to thrive, for cost to be driven down, for physicians to have access to all technologies that can save lives or improve patient care there is still work to be done. The establishment of specific "Codes of Conduct" by various GPOs is only a start. Talk is cheap; in this case, action clearly speaks louder than words. GPOs must further implement provisions allowing fair access to vendors of any size and demonstrate that they are not being unduly influenced by the revenue generated from the administration fees versus the savings realized for their membership.

As a company, BIOTRONIK believes in the basic concept of GPOs and wants to work with them to assist in achieving their individual objectives. We simply ask for a fair chance to sell to their systems and for a level playing field in which to work. There are still hindrances to this goal, which I discussed in the section of this paper addressing the concerns we are still observing one year after the April 30, 2002 report issued by the United States Senate Committee on the Judiciary "Hospital Group Purchasing: Lowering Cost at the Expense of Patient Health and Medical Innovation? We have every hope that your intervention will continue to provide a positive impact on this situation.

Respectfully submitted,



Thomas V. Brown
Executive Vice President
BIOTRONIK, Inc.

Testimony by

Don Black

President and CEO of the Children's Health Corporation of America

Before the U.S. Senate

Judiciary Committee

Subcommittee on Antitrust, Competition Policy and Consumer Rights

On

The Practices of Group Purchasing Organizations

July 16, 2003

Thank you Chairman DeWine for the opportunity to testify on the practices of group purchasing organizations. In this testimony, I will stress the benefits the GPO system provides and the steps the Children's Health Corporation of America (CHCA) has taken to comply with the requests of this Subcommittee.

CHCA is a business alliance of 41 children's hospitals that provides a range of products and services. It is through this alliance that CHCA reduces costs, increases revenue, and enhances the competitive position of children's hospitals. CHCA represents more than 19,000 physicians and 60,000 employees. It represents $11 billion in hospital revenue and totals $1.1 billion spent on medical, surgical and pharmaceutical products per year. Through its work, CHCA develops competitive business strategies and new business opportunities for children's hospitals.

Because CHCA specializes in pediatrics, it plays a unique role in the GPO market. The medical needs of children are substantially different from those of adults. Therefore, there are significant variations between the devices used to treat the two groups. Because the medical needs of children vary according to their age and size, children's medical devices must be designed and manufactured for specific age groups. For instance, the same surgical instruments cannot be used on a premature infant as on a six year old. CHCA devotes itself to meeting the needs of children of all ages. As a result, CHCA has specialized knowledge, which in turn helps develop pediatric markets and improves the innovation of pediatric products. Without an organization like CHCA, pediatric facilities would be limited in the variety of products available to them.

CHCA's position in the market embodies the benefits of and the power of GPOs. According to a study conducted by Muse & Associates, a Washington, D.C.-based health care research firm, health care providers reported that GPOs saved them between 10 and 15 percent on their purchases, which is between $19 and $33.7 billion, in 2002. While GPOs obviously provide a tremendous savings, there is room for abuse in such a dominant system. It is both the aim of the Subcommittee and CHCA to prevent such abuse.

One manner in which CHCA strives to protect the integrity of the system is by ensuring that member hospitals retain the power of choice. All hospitals voluntarily choose to become part of CHCA; it is a unilateral decision by the hospital whether or not it will participate in a CHCA negotiated contract. Furthermore, member hospitals never relinquish their rights to work with other GPOs or to contract independently. This is one aspect of CHCA's commitment to provide its members, vendors, and the public with a more transparent system of operations and less costly GPO services.

Through our affiliation with Premier, we have endorsed the best ethical principles articulated by Premier, as well as the Health Industry Group Purchasing Association's (HIGPA) Code of Conduct. CHCA affirms Premier's efforts to establish safeguards that move beyond the HIGPA Code of Conduct. In doing so, CHCA requires that contracts for physician preference items are made on a multi-source, unbundled, no commitment level basis. Vendor payments to CHCA are capped at 3 percent. Also, there are no "up

front" administrative or marketing fees. Bundling of products from different vendors is prohibited, as are private label programs. Finally, we attempt to limit contracts to 3 years whenever possible.

The conflict of interest principles drafted by Premier are of great importance to preserving the integrity of this industry. Therefore, CHCA will not allow its employees to receive gifts from a participating vendor or to own equity in any vendor. Furthermore, any equity interests in potential vendors should be publicly disclosed. Because full disclosure is of great important, all shareholders, members, and the public should have access to an annual financial report.

In an effort to demonstrate continuing compliance with the Code of Conduct and this Subcommittee's goals, CHCA engages in and proposes further measures. First, CHCA has appointed a compliance office and has responded to HIGPA's compliance survey, as a means of ensuring compliance. However, this is not a sufficient means of ensuring compliance. The GPO industry should implement all recommendations that emerge from this Subcommittee, but also it should develop its own compliance review process. Furthermore, each GPO should sponsor an independent and public compliance review of its Code of Conduct.

CHCA has demonstrated that it has been at the forefront of this industry's efforts to ensure the transparency of the process and has committed itself to ensuring that all involved parties continue to benefit from the process. To this end, CHCA will continue to make every effort to comply with the requests of this Subcommittee as well as developing its own innovative policies.

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July 10, 2003

The Honorable Mike DeWine, Chairman
The Honorable Herbert Kohl, Ranking Member
U.S. Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights
224 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senators:

We have learned that your Subcommittee has scheduled a hearing on group purchasing ["Hospital Group Purchasing: Has the Market Become More Open to Competition?"], and I would like to comment for the record on the role of GPOs as they relate to new technology. It is very important that our physicians, nurses and other caregivers have access to new technology. It is also important for us to hold down costs and ensure that we're getting the best equipment for the money.

GPOs – in our case, Novation – helps us do this in two ways:

- By combining our purchasing power with other hospitals, they can negotiate more effectively with manufacturers.
- Equally important is their use of clinical councils that include representatives from member hospitals to evaluate new technology products and give us unbiased information.

We also have been pleased with Novation's commitment in the past year to ensure that members have timely access to new and innovative technologies by limiting the initial length of contracts, re-bidding or adding suppliers when new technology becomes available and creating new communications tools to inform us about innovative technology.

However, while technology is important, hospitals choose to standardize. It's ineffective and wasteful to multi-source all contracts. GPOs like Novation are essential to help us buy the most appropriate products at the lowest possible costs. Therefore, we oppose any restrictions on GPOs that would limit their ability to evaluate technology and award appropriate contracts.

We support your Subcommittee's efforts to make sure that health care systems have access to new technology, but we think GPOs are already doing that. We have seen significant improvements in the past year, and we believe the current system works well.

Please let me know if I can be of assistance, and I would respectfully request that this letter become a part of your official record.

Sincerely,

William E. Corley, President

cc: The Honorable Evan Bayh
The Honorable Richard Lugar

GF/dp/L/Senate-Novation 7-10-2003

Testimony of David S. Egilman, MD MPH, Clinical Associate Professor, Brown University*
Senate Anti-Trust Subcommittee Hearing
"Hospital Group Purchasing: Has the Market Become More Open to Competition?"
July 16, 2003

Thank you for the invitation to submit testimony on this important issue. In answer to the question posed by the title of this hearing, I would respond "no." In order for the market to become more open to competition in the future, the GPOs must be eliminated or the industry must be regulated with a mandatory and rigorous code of conduct that can be enforced by an independent agency.

I am a medical doctor and associate clinical professor in the department of Community Health at Brown University. At Brown, I precept medical students and teach courses undergraduate and graduate students. My courses focus on the historical, political, and ethical dimensions of health science and health care. My course, "Science and Power: A Bioethical Inquiry," investigates how economic, social and cultural power shapes public perceptions and experiences around health and medicine. Topics include informed consent, human research subjects, access to health care, and the ethics of medical markets.

In 2002, I was asked by the plaintiff to serve as an expert witness in the case *RTI v. Becton Dickinson*. In fulfilling this role, I have read thousands of published and unpublished documents pertaining to GPOs' contracting practices. Many of these documents are subject to a "gag order." My testimony here is necessarily constrained by this "order," as I am not permitted to present examples and evidence that are part of the legal proceedings. I encourage the Senate to obtain these documents, and the depositions taken in this case, in order to obtain a complete record of the magnitude and severity of the problems posed by GPOS and large medical product manufacturers. This committee will be shocked and disturbed by the evidence produced in this case.

In 2002, the GPO industry responded to litigation and to the Senate Subcommittee on Antitrust, Competition, and Business and Consumer Rights' 2002 inquiry into GPO practices by promulgating a series of codes of conduct. The Health Industry Group Purchasing Association (HIGPA) was the first to adopt a "Code of Conduct Principles."[i] Several GPOs, including Premier and Novation, have expanded on the HIGPA principles and strengthened their own formal codes of conduct. Premier took the additional step of hiring business ethicist Kirk O. Hansen from the Markkula Center for Applied Ethics at Santa Clara University to conduct an independent study of the industry and develop a code of best ethics practices. Premier adopted Hanson's code as their own on October 18, 2002. Unfortunately, all of these codes are a classic example of "too little, too late."

Each of the codes I have is examined omits provisions that are essential to preventing anti-competitive practices in the GPO industry. An adequate code would:

- place strict limits on fees that can be collected by GPOs, including e-commerce fees charged by companies owned wholly or in part by GPOs
- provide a transparent and standardized procedure for the negotiating of contracts
- prohibit GPO or GPO employee ownership of equity in any medical manufacturer[1]

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* Affiliation provided for identification purposes only.

- prohibit bundling
- prohibit private label programs
- prohibit sole source contracts
- prohibit commitment or compliance programs
- prohibit the use of market share as a criterion for vendor selection
- limit contract periods to three years or less
- allow for the breaking of contracts by the GPO in order to provide superior technology to hospitals; and
- provide for an independent evaluation of new technology

I have attached a table, Table 1, which lists the provisions of current GPO codes of conduct, and makes recommendations for additions and/or changes to these codes.

Why Do We Need to Regulate GPOs?

The health-care industry and market for medical products is in many ways unique. Most non-commodity medical products like drugs and high-tech medical devices are supplied by a few companies who have monopoly or oligopoly power in their markets. Historically, most of this market control has been derived from patents and the high cost associated with the development of technically sophisticated medical devices like MRIs or CAT scanners. Since the beginning of this century, hospitals have joined together to form group purchasing organizations to try to offset the market power of the product suppliers. Until the 1980s, most of these GPOs were regional and relatively small. After the federal government passed legislation to allow the GPOs to control a larger percentage of buyers, hospital consortiums formed several large national GPOs.

The "safe harbors" legislation that exempted GPOs from federal anti-kickback statutes was designed to allow hospitals access to economies of scale that they would not have as individual buyers. However, rather than giving hospitals increased buying power, the legislation has created a situation in which powerful middlemen exercise extraordinary control over the purchasing decisions of hospitals. GPOs have become a third force in the medical market, with their own sizable profits (some exceeding one-half billion dollars per year). The managers of these GPOs are highly paid, and have their own institutional goals and objectives separate and apart from the goals of their owners, the hospitals. Because the GPOs are supported by fees paid by suppliers, not by hospitals, the groups have an inherent conflict of interest. GPOs have failed in their goal of saving hospitals money.[ii] Even more importantly, their contracting practices and collusion with suppliers has endangered patients, healthcare workers, and auxiliary hospital staff.

Ideally, healing and health maintenance should be the highest priorities of any hospital. Health maintenance includes the promotion of patient health through providing access to the best-quality

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[i] Currently, Premier's code allow for a GPO to hold equity interest in participating vendors only when the holding of such interest creates "a source of a product where there is no other source, or very limited sources." Premier currently holds an equity interest in several actual and potential vendors, including American BioScience,Global Health Exchange, and Healthcare Waste Systems. See "Disclosure of Corporate Equity Interests," http://www.premierinc.com/all/newsroom/code-of-conduct/corporate-equity-disclosure.pdf.

medical equipment and supplies. Not only patients' but workers' health is also served through the use of high-quality medical supplies. The abuses that have come to characterize the GPO system work against the provision of high-quality medical supplies by prioritizing GPO and manufacturer profit over patient and worker health. It is important to note that the hospitalsthemselves do not select the products that they purchase. The GPOs decide what products will be available through contract to the hospitals. For example, as a March 4, 2002 New York Times story detailed, Premier refused to grant a contract to Masimo, a manufacturer of an innovative pulse oximeter, because the GPO had already negotiated a "sole source" contract with another oximeter company, Nellcor. Hospitals were given deep financial incentives to buy Nellcor's oximeter, even though Premier's own evaluators had determined that the Masimo oximeter was the superior product. The Masimo oximeter was especially effective for use with newborns, giving more accurate blood oxygen level readings that allow practitioners to avoid providing premature infants with too much oxygen and therefore damaging their sight. As Dr. Augusto Sola, former head of neonatology at Cedars-Sinai Medical Center in Los Angeles said, "If the baby was choosing consciously, we know what the baby would choose."[iii] Hospital purchasing decisions have real, tangible effects on patient health. When these decisions are left to actors, such as GPOs, that have no direct hand in patient care but have sizable financial interests in purchasing decisions, the healing function of the hospital will suffer.

GPOs further endanger health care when, by virtue of their sheer buying power, they stifle the development of new or innovative health care devices. Because such a large proportion of the health care market is controlled by GPOs, start-up companies with innovative product ideas do not develop new technologies because GPOs limit their access to the medical market. GPOs should not be permitted to continue to stifle medical advances through exclusive contracting practices. The true magnitude of GPO's impact is found in the innovations that are never made and research that is never done. This impact cannot be measured directly but I have no doubt that the impact must be measured in lost lives, pain and suffering.

Case Study: Accidental Needlesticks and Safety Injection Devices

A consideration of the history of the development of and market for safety injection devices is illustrative of the dangerous pitfalls of the GPO contracting system. Safety injection devices are designed to prevent accidental needlesticks in a health care setting. Accidental needlesticks occur when health care providers or auxiliary medical staff (such as janitors) accidentally prick themselves with used hypodermic needles or other "sharps." Accidental needlesticks are dangerous because needles contaminated with blood or other bodily fluids can transmit diseases such as HIV, hepatitis B, and hepatitis C. There are approximately 8 million healthcare workers employed in the US, and this group experiences an estimated 600,000-800,000 accidental needlesticks annually. The risk of infection from an accidental stick depends on factors including the pathogen involved, the health of the worker, the type of needle stick injury, and the availability and use of post-exposure prophylaxis.

Needlesticks are associated with actions such as the recapping of needles after use, the transfer of body fluids between containers, and the improper disposal of needles. Many of the high-risk activities can be minimized or eliminated through safety engineering of devices such as needles. The passage of the federal Needlestick Safety and Prevention Act in 2000 required healthcare

employers to take a number of steps to reduce the risk of accidental needlestick, including the use of safety-engineered devices.

The OSHA standard and similar state laws have created a market for medical devices engineered to prevent accidental injury. Such devices have been manufactured by Becton Dickinson, Kendall/Sherwood, and Retractable Technologies Incorporated, among others. Safety-engineered needle/syringe combinations and blood collection devices come in a variety of types, but most are designed to avoid the need for high-risk practices such as needle recapping. The main goals of safety engineering are to keep practitioners' hands away from the point of the needle, and to shield the needle after use. The existing models of "safety engineered" injection and blood collection devices have varying degrees of success in protecting health care workers.

Unfortunately, GPO contracts have not favored the most effective safety devices. Instead, special deals with oliogopolist manufacturers have kept the best-rated device out of most hospitals and health care settings. Retractable Technologies, Incorporated (RTI) is a recent entry into the needle/syringe market. RTI manufactures an innovative safety-engineered product that is highly effective at protecting healthcare workers. ECRI, a leading independent health services research agency that regularly publishes results of its tests of safety product quality, has consistently given RTI's products, the VanishPoint syringe and blood collection tube holders, their highest rating ("preferred."). In contrast, the leading manufacturers have garnered ratings including "unacceptable" and "not recommended."[iv] Table 2 (attached) has been adapted from ECRI ratings. Other studies have also favorably evaluated RTI's devices.[v]

While the requirements of healthcare worker safety and the rule of a free market would favor the better product, the GPO system has skewed the laws of supply and demand. Notably, GPO contracts have favored the leading needle manufacturer, Becton Dickinson (BD). Becton Dickinson is a company with a track record of placing profits over quality health care. BD opposed the passage of healthcare safety legislation in the US for many years.[vi] BD has also worked to the detriment of healthcare safety in the third world, where recent research shows the HIV/AIDS epidemic is fueled by unsafe healthcare.[vii] For example, in the early 1990s BD received a free patent for a non-reuseable safety injection device called the Soloshot from PATH (Program for Appropriate Technology in Health). BD priced the needles higher than expected, forcing UNICEF to subsidize the cost to developing nations. BD acquired another patent for a non-re-useable injection device, the Uniject, in 1996, but took more than two years to bring the product to market. In the meantime, BD continued to focus on selling dangerous yet profitable standard disposable needles in the developing world.[viii] When considered in light of their history of unconcern with injection safety, BD's special relationship with leading GPOs inspires grave doubt regarding the GPOs' ability to prioritize patient and healthcare worker safety.

Indeed, Becton Dickinson has not continued to win GPO contracts because it produced the highest quality safety injection devices. Indeed, some of BD's "safety-engineered" products have actually posed an increased risk to users. Not surprisingly, this information has been suppressed and never published in the medical literature. Despite this, the GPOs and BD crafted a deal in which the GPOs garnered high fees for installing the medical supply behemoth as a "sole source" supplier of safety injection devices. For example, in 2000, Becton Dickinson paid Novation $1 million is "special fees" when BD was awarded a three-year contract for syringes and needles. In addition, BD paid a

fee of 3% of total GPO revenues back to the GPO.[ix] Who was the winner in this deal? Novation was left with $1 million plus 3% of sales, and BD got the business of Novation's 2400 members. The losers are healthcare workers who developed hepatitis and AIDs.

The Solution

The GPO system is one in which powerful middlemen and manufacturers are perverting the laws of supply and demand through their ability to craft sweetheart deals that disregard healthcare safety and efficacy. While these GPOs were specifically granted a measure of immunity from normal anti-trust laws and regulations, the GPOs and large medical manufacturers have clearly abused this trust, to the detriment of the health of the American people. For them it is all about the money. As a physician it is my view that it should be all about healthcare. I believe that we should again return to the free market rules that provide incentives to innovators to make the system all about improvements in healthcare.

Adam Smith, who wrote that "monopoly…is a great enemy to good management," believed that the main benefit of the market was that its "invisible hand" would guide participants to maximize wellbeing without any conscious effort on the part of participants to achieve some greater good.[x] A market with a structural defect, one composed of a few large sellers and buyers, in all ways conflicts with the ideal economy described by Adam Smith. It is a marketplace in which the invisible hand is handcuffed unless all participants are motivated to and act ethically. Smith knew that monopoly markets drive prices up, and that sellers would always seek to enhance profits through the creation of monopolies. He wrote that, "People of the same trade seldom meet together, even for merriment and diversion, but the conversation ends in a conspiracy against the public, or in some contrivance to raise prices.[xi] This case confirms Smith's analysis in that the distortions of the market have overcome any ethical constraints that might have corrected its structural defect.

Unfortunately the ethical conduct that might have corrected the structural defect in the medical market has not occurred. As a result the sellers and GPOs have successfully limited the development and sale of innovative new technologies that they do not control. Since some of the products that have been excluded from the market would have reduced work-related disease, these market constraints have caused healthcare workers to contract hepatitis and AIDS.

While many GPOs have adopted codes of conduct, these do not address the most important failures of the industry. If patient health and healthy markets are to be protected, it essential that this committee take steps towards exercising appropriate oversight over the GPO industry. While this committee may consider incremental reforms, I am concerned that these will inevitably be insufficient because these companies have shown an inordinate ability to spend enormous amounts of time and money figuring out ways to manipulate the market. Unfortunately, they have found this to be a more fruitful vehicle to increase profit than actual work on innovation. We have given them an inch, they have taken more than a mile.

	HIGPA	Novation	Premier	Egilman
Fees	Requires: That GPOs and their members sign agreements explicitly authorizing the GPO to act as the contracting agent That each GPO discloses to members that it receives payments from Participating Vendors relating to purchases made by or for that member Requires that GPOs annually disclose to members in writing the *amount* of payments it has received from relating to purchases made by or for that member Requires that GPOs annually disclose to members information on fees received from vendors relating to contracts utilized by the members, but not directly related to purchases made by that member.	Limits administrative fees on clinical preference items to 3%, and prohibit any advance payments or "up-front" fees.	Prohibits administrative fees in excess of 3%, any "up front" administrative fees, any marketing fees, and any fees paid in the form of vendor equity. Fees paid by a vendor should never be the primary rational for making contracting decisions. Fees should be standardized (both for individual bid processes and product and service categories) and disclosed before the bid process to all bidding vendors Requires that detailed contract data, including administrative fee data, be available to members.	Agree with Hanson: Prohibits administrative fees in excess of 3%, any "up front" administrative fees, any marketing fees, and any fees paid in the form of vendor equity. Agree with Hanson: Fees paid by a vendor should never be the primary rational for making contracting decisions. Agree with Hanson: Fees should be standardized (both for individual bid processes and product and service categories) and disclosed before the bid process to all bidding vendors Agree with Hanson: Requires that detailed contract data, including administrative fee data, be available to members.

	HIGPA	Novation	Premier	Egilman
Gifts, Travel Expenses, and Entertainment	Employees who may influence contracting decisions prohibited from accepting any but nominal "gifts, entertainment, favors, honoraria" from any "participating vendors." A non-employee officer, director, or advisory board member must disclose the acceptance of any gifts, etc. to a governing body, and must recuse him or herself from any decision-making regarding the gift-giving vendor.	Prohibits all Novation employees from accepting gifts, entertainment, favors and the like (other than those of nominal value) from vendors.	Prohibits *all* employees and their family members, from accepting gifts or other payments of other than nominal value from any vendors. Likewise, no non-employee who is the position to influence contract decision-making should accept gifts other than those of nominal value from a participating vendor. If non-employee contract decision-makers have received gifts, they are to recuse themselves from the contracting process.	Agree with Hanson: Prohibits *all* employees and their family members, from accepting gifts or other payments of other than nominal value from any vendors. Likewise, no non-employee who is the position to influence contract decision-making should accept gifts other than those of nominal value from a participating vendor. If non-employee contract decision-makers have received gifts, they are to recuse themselves from the contracting process.
Insider Trading			Should be explicitly prohibited	Agree with Hanson: Should be explicitly prohibited

	HIGPA	Novation	Premier	Egilman
Investments and Ownership	Prohibits individual employees who may influence contracting decisions from holding an "Individual Equity Interest" in participating vendor. A non-employee officer, director, or advisory board member must disclose any such interest and recuse him or herself from any decision-making regarding the vendor. GPOs as organizations will not maintain a "Corporate Equity Interest" in a vendor of goods or services, unless that interest is demonstrated to provide a source of an otherwise unavailable or scarce product. Such interest must be disclosed to members in writing either when the GPO acquires an interest in a vendor with an existing contract, or signs a contract with a vendor in which it holds an interest. The interest must also be disclosed to members on an annual basis. The code requires that such an interest also be disclosed to the public, but does not specify how or when. Further, a GPO that holds a Corporate Equity Interest in a participating vendor will impose no obligation commitment or other requirements or restrictions that in any way obligates any member to purchase goods or services from such participating vendor."	Prohibits the ownership of individual equity interst by all directors, employees and their spouses and minor children in companies in which Novation, UHC or VHA own securites, warrants, option, or debt instruments, or rights to acquire the foregoing. Novation employees who may influence contracting decisions in a particular product category (and their spouses and minor children) may not hold equity interest in a vendor or potential vendor within that product category. Senior management (and their spouses and minor children) may not hold equity interest in a vendor or potential vendor of clinician preference products. Novation may not own any equity interests in any vendor that sells (or can reasonably be expected to sell in the next two years) items or services to hospitals (regardless of whether the vendor has a contract with Novation) Participatin vendors many not own equity interests in Novation.	GPO itself should avoid any conflicts of interest "arising from ownership of equity in vendors where these relationships do not directly serve the members and their interests." Prohibits all management level employees from holding an "Individual Equity Interest" in participating vendor. Disclosure by and recusal of non-employees who own equity interest in a participating vendor and are in a position to influence contracting decisions. No non-employee advisor shall hold extensive equity interests in a participating vendor if s/he advises in the area in which s/he hold equity interest. No participating vendors own equity in a GPO. No GPO (or non-GPO subsidiary of shared parent company) shall hold an equity interest in participating vendors, unless the holding of such interest creates "a source of a product where there is no other source, or very limited sources." Disclosure of GPO holding of equity interest in participating vendors to members and the public.	GPO itself should avoid any conflicts of interest arising from ownership of equity in any actual or potential vendor. GPOs should not enter into joint ventures with suppliers. <u>Agree with Hanson:</u> Prohibits all management level employees from holding an "Individual Equity Interest" in participating vendor. <u>Agree with Hanson:</u> No GPO employees own equity in a participating vendor No participating vendors own equity in a GPO <u>Agree with Hanson:</u> Disclosure by and recusal of non-employees who own equity interest in a participating vendor and are in a position to influence contracting decisions. No non-employee advisor shall hold any equity interests in a participating vendor if s/he advises in the area in which s/he holds equity interest. No GPO (or non-GPO subsidiary of shared parent company) shall hold an equity interest in a participating vendor.

	HIGPA	Novation	Premier	Egilman
Private Label		Novaplus will not include any clinical preference products	Prohibited	Agree with Hanson: Prohibited
Product Quality and Innovation		Novation will communicate more widely with "all relevant audiences" about new technologies. Novation will also assure more involvement of member hospitals and outside experts ("where appropriate") in Novation's review of innovative technology. Novation will re-open the bid process or add vendors to existing agreements when a new technology is found to offer "incremental patient care or incremental safety benefits," by Novation member councils	Premier will contract for high-quality, reasonably priced healthcare products and services that improve both the process and outcome of care while ensuring the safety of member employees and patients Premier will promote innovation in healthcare technology. Premier will ensure that its members have access to the most technologically advanced products.	I agree that Premier and Novation should abide by their existing principles.
Role Conflicts				All advisors and personnel should recuse themselves from any decision-making involving a company or individual with whom they have a relationship (ie, family member, spouse, former employer, former employee, co-board member, etc.) not directly related to their GPO responsibilities.

	HIGPA	Novation	Premier	Egilman
Evaluation Procedures		Ensure that the evaluation process is "open and fair, protects the confidentiality of innovative technology, and is not unduly burdensome, time-consuming, or cost-prohibitive. Will consider innovative technology outside of the applicable contracting cycle. More involvement of member hospitals and outside experts ("where appropriate") in Novation's review of innovative technology Adheres to policies and procedures that offer a defined and objective process to address vendor grievances relating to the evaluation of innovative technology. Increase awareness of innovative technology through the creation of a website forum.	GPOs should strive to institute an evaluation process for new technology that is "as objective as possible" The assessment of technology, including breakthrough technology must be "fair, timely, confidential and unbiased, with an opportunity for review of decisions." To determine whether a product should be considered a breakthrough product, Premier subjects it to a review process. This four-stage process involves a submission screen, breakthrough review, committee process, and finally, contract action.	Hospital members should be able to determine on their own whether they consider a technology to be a "breakthrough technology."
Communication		Novation will communicate more widely with "all relevant audiences" about new technologies	All GPO members should have the opportunity to have input into the assessment process. All vendors should be able to review the results of the assessment of their own products.	<u>Agree with Hanson:</u> All vendors should be able to review the results of the assessment of their own products.

Table 2. ECRI's Evaluations of Safety Products

	Injection				Blood Collection needles and Tube Holders					
Date	RTI	BD		Tyco Kendall	RTI	Tyco Kendall	BD			
	VanishPoint	Safety Glide	Safety Lok	Monoject Safety	Vanish Point	Pro-Guard II	Safety-Gard	Eclipse with disposable holder	Eclipse with reusable holder	SafetyLok
10/99[xii]	Preferred	Not Rec.	Unaccept.	Unaccept.	Preferred	N/A	Accept.	Accept.	Not Rec.	Unaccept.
2000[xiii]	Preferred	Accept.	Unaccept.	Unaccept.	Preferred	N/A	Accept.	Accept.	Accept.	Unaccept.
2001[xiv]	Preferred	Preferred	Unaccept.	Not Rec.	Preferred	Not Rec.	N/A	Accept.	Accept.	N/A

[i] Robert Betz (HIGPA) July 29, 2002, Letter to Sen. Herbert Kohl.

[ii] United States General Accounting Office, Testimony before the Subcommittee on Antitrust, Competition, and Business and Consumer rights, Committee on the Judiciary, U.S. Senate. Group Purchasing Organizations: Pilot Study Suggest 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.

[iii] Walt Bogdanich, Barry Meier, Mary Williams, "Questions Raised of Conflicts At Two Hospital Buying Groups," New York Times, March 4, 2001, page A1.

[iv][v] "Update Evaluation," October 1999. *Health Devices* 28 (10):381-408.; *Health Devices Special Report: Needlestick-Prevention Device Selection Guide.* Plymouth Meeting, PA: ECRI, 2000, 58.; *Sharps Safety and Needlestick Prevention: An ECRI Resource for Evaluating and Selecting Protective Devices* . Plymouth Meeting, PA: ECRI, 2001

[v] Kathryn D. Duesman, Jean Ross. Survey of Accidental Needlesticks in 26 facilities using Vanishpoint automated retraction syringe. *Journal of Healthcare Safety, Compliance and Infection Control* March 1998: 111-114. New York State Department of Health, "Pilot Study of Non-Reusable Syringes." Report to the New York State Legislature, June 30, 1998; Carolyn Squillace, "A Team Approach to Needlestick Injuries," October 1999, *Journal of Healthcare Safety, Compliance and Infection Control* 3 (8): 354-356.

[vi] Gary Cohen, Vice President, Marketing and Development, Becton Dickinson and Co., "Why Sharps Safety Regulations Won't Work," *Medical Device and Diagnostic Industry*, November 1993: 30.

[vii] Gisselquist, et. al., "HIV Infections in sub-Saharan African not explained by sexual or vertical transmission" *International Journal of STD & AIDS* 2002; 13: 658.

[viii] "Lost Chance to Avert Crisis," *San Franciso Chronicle*, Wednesday, October 28, 1998.

[ix] Meier, Barry with Mary Williams Walsh, "Questioning $1 Million Fee in a Needle Deal. *New York Times*, July 19, 2002.

[x] Adam Smith, *The Wealth of Nations*, Book I Chapter XI Part I.

[xi] Adam Smith, *The Wealth of Nations*, Book I Chapter X.

[xii] "Update Evaluation," October 1999. *Health Devices* 28 (10):381-408.

[xiii] *Health Devices Special Report: Needlestick-Prevention Device Selection Guide.* Plymouth Meeting, PA: ECRI, 2000, 58.

[xiv] *Sharps Safety and Needlestick Prevention: An ECRI Resource for Evaluating and Selecting Protective Devices* . Plymouth Meeting, PA: ECRI, 2001.

Hospital Group Purchasing: Has the Market Become More Open to Competition?

Testimony of Lynn James Everard

United States Senate Committee on the Judiciary

Subcommittee on Antitrust, Competition and Business and Consumer Rights

July 16, 2003

Good afternoon Chairman DeWine, Senator Kohl, and distinguished members of the Subcommittee. My name is Lynn James Everard and I am an author, speaker, health care business educator, and supply chain strategist. For almost twenty-two years I have worked in the health care supply chain, studying its strengths, weaknesses, and prospects for improvement. I have held various supply chain management positions in the hospital, long-term care, homecare, and medical product distribution environments. I have worked with group purchasing organizations (GPOs), including sitting on a GPO pharmacy contract review committee. I am a Certified Purchasing Manager and a Certified Business Manager. During my years studying the health care supply chain, I have authored more than 75 published articles and four white papers including, "The Impact of Group Purchasing on the Financial Prospects of Health Systems: Changing Value Perceptions and Unintended Consequences", which some of you may have seen.

I am here today because of my deep concern for the safety of patients and caregivers and the financial viability of our nation's hospitals. The business practices of some large manufacturers and certain GPOs, fueled by the power granted to GPOs in the Safe Harbor exemption, have compromised competition in the health care supply chain. I am also here to ask you to carefully review the information being presented and reconsider the appropriateness of a Safe Harbor for health care group purchasing organizations. It is important that you know that I am completely independent from any player in the health care supply chain. However, I do freely admit that I represent an important special interest group: patients, caregivers, and their families who every day must deal with the consequences of unsafe or ineffective products. The financial power wielded by health care GPOs exacerbates this situation. Unchecked business practices of GPOs, in concert with some manufacturers and distributors, affect patients, caregivers, and their families, and threaten the ongoing financial viability of large numbers of hospitals.

Voluntary Codes of Conducts Have Not Spurred Enough Reform

I believe that robust competition in the health care supply chain will ultimately provide a significant dose of the financial healing that most hospitals will need to survive. As a health care supply chain strategist I struggle to understand the value of the Safe Harbor as currently drafted. I do not believe that the continuance of the Safe Harbor is good for either our hospitals or our health care system. I fear that voluntary GPO Codes of

Conduct ("Codes") that fail to address many of the contracting and business practices will provide the public with a false sense of security and fail to fix the problems that were highlighted at last April's hearing. Last year Senator Kohl concluded the hearing by stating, "So this, I hope, is not a hearing, which so often on Capitol Hill, hearings that are hearings and then vanish into history." I share that sentiment and hope that the necessary reforms and oversight do not simply vanish into history as well. The only way that any Code of Conduct can be made acceptable is if it is a prerequisite for any GPO seeking the Safe Harbor exemption from anti-kickback laws and if it is given only upon a full review of the GPO's business practices and sources and uses of funds. To ensure that a GPO enjoying the Safe Harbor meets the obligations of its mission and the special exemption it is given, it must submit to regular, ongoing, and determined oversight. Accordingly, each GPO must provide full disclosure of its business and contracting practices, its organizational makeup, and its financial transactions.

The proposed Codes are incomplete and cannot possibly be made complete until the business practices of GPOs are fully investigated and the assumed bad behavior that the Codes seek to address are fully identified and evaluated. I believe that in order to qualify to retain the Safe Harbor exemption, each GPO should willingly submit to a thorough audit by the government agency that ultimately is delegated the task of providing oversight. For many years GPOs have been subjected to suspicion by many in the industry. A mandatory, verifiable and comprehensive Code of Conduct in exchange for the benefits of the Safe Harbor would be a small price to pay and would allow those GPOs desiring to clear their names and remove the suspicion from their practices to do so.

Is the Congressional Safe Harbor Being Used As Intended?

It is essential that each GPO be required to produce verifiable evidence of the value it produces for its members. In his testimony before this Subcommittee last year regarding the cost savings by his group Mr. Norling of Premier stated, "We estimate that we save our member hospitals over $1.5 billion per year..." With all due respect, we need real science, not estimates, of the savings produced by GPOs. Without this knowledge how can we know if the Safe Harbor, let alone a Code of Conduct, is worthy of this Subcommittee's time and effort?

By granting the Safe Harbor the Congress granted GPOs a great deal of power and a significant ability to create revenue for themselves. By ensuring the financial viability of GPOs, the Congress in effect created a quasi government agency. With that comes a responsibility to provide oversight and direction. In 1986 when the Safe Harbor was created the health care supply industry was very different from what it is today. Unfortunately, the lack of oversight over the activities of GPOs has led us to where we are now. There is a growing body of information and experience that suggests that, at best, GPOs are not focused on their original missions of saving hospitals money. At worst they are adding significant cost to the health care supply chain while stifling innovation and creating a roadblock between caregivers and the products they need to provide safe patient care.

At the time the Safe Harbor was granted GPOs tended to be small regional contracting-focused organizations. Today the largest GPOs have become complicated, intertwined strings of related businesses that defy the ability to determine where the GPO ends and the rest of the conglomerate begins. The health care supply chain has become incredibly complex, due at least in part the presence and practices of GPOs. Before GPOs, a hospital and a supplier could actually enter into mutually beneficial business agreements that did not preclude the ability of any other hospital or supplier to thrive in its own marketplace.

Congress must fully understand the flow of money in the health care supply chain and the GPO's role in that flow in order to pronounce that the Safe Harbor is of benefit to patients and taxpayers. Last year, the GAO conducted a study, which showed that GPOs were not actually saving hospitals money in many cases. It was my understanding that a follow up study was going to focus on the "money trail", but my latest conversations with GAO suggest that study has been delayed. I do not believe that the Subcommittee should endorse Codes of Conduct without studying the "money trail". GPOs seeking to end years of speculation on the part of the public should welcome the opportunity to disclose fully their practices and sources and uses of revenue. Then, this entire industry can refocus its efforts on providing quality patient care in a safe work environment. Congress must also scrutinize the role of manufacturers in making excessive payments to GPOs. Do these payments make the GPO an accomplice in establishing product-pricing floors that give manufacturers permission not to compete for business and maintain the market power of the GPOs?

Our nation's hospitals are the backbone of our health care delivery system. I do not have to tell you that Medicare and Medicaid patients depend heavily on hospitals for care. In late 2002, the American Hospital Association reported that the average operating margin of U. S. hospitals was just 2.8 percent. Increasing demand for services, combined with diminishing reimbursement, a growing staffing shortage, increases in malpractice insurance costs and settlements, and cost of implementing HIPAA and other regulations are eroding that margin and placing many of the nation's hospitals in financial danger. Without a way to increase their operating margins or a major increase in government funding, hospitals will not be able to take on a flood of additional patients. For a hospital with an operating budget of $100 million dollars that is spending $33 million dollars in its supply chain, a supply chain savings of just 4% would increase that 2.8 percent operating margin to 4.1 percent. A twenty percent supply chain savings would move the 2.8 percent margin to 9.4 percent. Why is this significant? Hospitals that have left their GPOs are reporting savings of *thirteen percent* or more. For many hospitals the supply chain opportunity represents the largest single area of cost savings opportunity.

As a procurement professional, I am concerned that the Safe Harbor provides a special privilege to GPOs in allowing them to conduct business in a way that I or any other procurement professional in any industry would avoid for fear of losing our integrity, our jobs, and our careers. Procurement professionals shun kickbacks or other illegal financial incentives because they presents a serious conflict of interest and violate the agency relationship they have with their employers or clients. These clients depend upon

procurement professionals' unbiased and independent judgment in creating critical financial relationships, often worth billions of dollars.

Let me be clear. My intent here today is not to impugn the judgment of Congress for decisions made in the past. Given the circumstances and the challenges facing hospitals at that time, the decision to grant the Safe Harbor may well be beyond reproach. In the seventeen years that have passed since the Safe Harbor was granted, the health care industry and the health care supply chain have seen significant changes. For example, when the Safe Harbor was granted, hospital buying was largely a regional undertaking managed by a large number of small buying groups. Congress simply could not have foreseen the flurry of merger activity that would create the large groups that dominate the hospital buying landscape today.

Ongoing Concerns with GPO Contracting Practices

The practice of sole sourcing, when conducted in an open and transparent bid process and on a small scale, is typically the most effective tool in gaining lower product prices is the lifeblood of procurement for smaller hospitals or smaller regional groups. The problem comes when a large GPO uses sole sourcing. The difference in scope and scale is the difference between sound purchasing practice and wholesale marketplace foreclosure for a small manufacturer. This has the potential to reduce competition and increase pricing in the market. It is not the aggregation of volume that drives down prices once price equilibrium has been reached. Rather, competition produces price reductions.

Likewise the practice of bundling can result in market foreclosure. The wise and competent buyer knows that, in the long term, his best interests are always best served by making certain that there are enough viable competitors to make sure that real competition exists. Procurement professionals spend time cultivating familiarity with the products and services of companies that do not currently enjoy their business to ensure that competition exists at all times. This process is called supplier development. Procurement professionals know that their success largely depends upon their ability to cultivate competition. To learn more about this I urge the Members of the Subcommittee to study the procurement practices of government subcontractors and see how they work with small companies to make sure they are there to drive competition.

Competition is the lifeblood of a free, open, and capitalist society. In fact, competition in the health care supply chain may be the best financial hope this nation has in being able to afford to provide health care services to an estimated 42 million uninsured Americans.

GPOs and their large manufacturer counterparts claim to promote competition in the health care supply chain. In last year's hearing, Senator Kohl expressed concern about one GPO requiring its suppliers to participate in its E-Commerce company. For all intents and purposes there are only two remaining E-Commerce companies: Neoforma with Novation as its majority owner and primary source of its revenue; and GHX, also known as the Global Healthcare Exchange. Now GHX is owned mainly by several large manufacturers but it is also partly owned by Premier. Neoforma and GHX have a two

year old collaboration agreement so there is even less competition now. In industries outside of health care where the E-Commerce companies are not owned by suppliers but instead are independently owned, they are producing actual line-item product cost savings along with some modicum of efficiency for users. That is what was supposed to happen in health care. In fact, one of the first health care E-Commerce companies, Medibuy, was designed to be an open marketplace that would allow hospitals to access the entire universe of products and save time in the procurement process, while creating competition on-line and achieving a reduction in product costs. GHX proclaims on its web site that it is open and neutral but what incentive would the largest manufacturers in the industry have to create more competition for themselves? Likewise, why would Neoforma, or Novation, want to create an environment in which its members could locate other products from non-contracted suppliers? The E-Commerce monopoly that exists today in this industry has all but destroyed the competitive benefits of E-Commerce while providing little in the way of efficiency benefits.

How important is the E-Commerce monopoly to those who control it? Over the past year one start-up company has been blocked twice from market entry. The first time, a bank tied to an investment house that has seventy percent of its holdings in health care suppliers refused to provide the company with simple escrow services through a blatant misapplication of the USA Patriot Act. Most recently an international conglomerate that is a founder of GHX was willing to take a $15 million dollar loss on a real estate deal just to keep this company out of the market. There may be other companies who have tried to enter this market but who have also been blocked from doing so. When any industry's largest competitors are allowed to go into business together, even if it is allegedly to promote competition or efficiency, something is very wrong and someone needs to ask a lot of questions.

Certainly, when competition is threatened it makes perfect sense for the federal government to step in and act to restore competition. The Federal Trade Commission exists for that very purpose. I know that both Senators DeWine and Kohl wrote to the FTC last April concerning this issue and I would stress the importance of the FTC's continued involvement if competition and innovation are to be permanently restored in the healthcare marketplace.

While this Subcommittee has given GPOs the opportunity to implement self-imposed, voluntary Codes, I firmly believe that the current Codes fail to remedy the problem. Further action is required. I believe that in today's environment the Safe Harbor represents an unnecessary and unwelcome intrusion into a once open and competitive health care supply chain arena. The Safe Harbor combined with a lack of oversight have created an environment in which the actions of certain GPOs have served to reduce competition and perhaps even raise prices. Its repeal must be considered for the following reasons:

1. Any fees paid to a GPO by suppliers are ultimately paid by hospitals because suppliers must add additional markup to their prices to cover those costs.

2. The Safe Harbor treats hospitals as incapable of managing their own business affairs. If the government cannot trust hospitals to run their businesses, why should it trust them to deliver quality patient care? Both GPOs and hospitals must become more accountable for their business practices.
3. Some GPOs have become much larger and more powerful than the Safe Harbor could have contemplated. That power used on a wide scale has created an environment in which large suppliers dominate the marketplace and smaller less powerful suppliers are unable to compete. This has reduced competition and ensured the long-term dominance of large suppliers.
4. GPOs have failed to demonstrate their bottom-line value to hospitals. Studies contain no science and are self-serving and inconclusive at best and are misleading and error prone at worst. For example, GPOs claim that without them a hospital would have to add as much as $300,000 in annual cost to make up for their absence. But, if one assumes that the GPO is only generating three percent in total fees from the suppliers and the hospital could itself be paid the admin fees, then a hospital that spends $50 million dollars per year through its GPO would actually come out ahead by $1.2 million dollars per year by spending the $300,000 per year, EVEN if it did not reduce the price of a single line item. Why should the government provide a special privilege for a class of entities who have not been able to demonstrate their value?
5. Some GPOs place too much emphasis on the creation of fee revenue. While some hospitals may come out ahead on fee revenue, others will end up paying for it because the cost of the revenue has to be paid for by someone. Fee revenue is nothing more than an additional product discount. If suppliers can pay enough in fees to produce fee revenue for hospitals then isn't that really an indication that their prices are inflated and that they can afford to sell their products to hospitals for less?
6. Self-contracting hospitals have shown that additional cost savings can be obtained without using GPOs. This may be an indication that the GPO is not the right vehicle to generate additional savings.
7. Senator Kohl, in your remarks during last year's hearing you expressed an interest in and a commitment to eliminating what you termed conflicts of interest. It is my belief that the Safe Harbor creates a conflict of interest for the GPO by allowing it to accept money from the suppliers among whom it is supposed to be creating increased competition. A kickback is a kickback regardless of who sanctions it.
8. The Safe Harbor provides a powerful incentive for GPOs to act as brokers in transactions representing both sides rather than as agents of their members. In court, an attorney cannot effectively represent both the defense and the prosecution.
9. Most GPO contracting-related press releases talk about renewals or extensions. Renewals and extensions do not stimulate competition but they do discourage new entrants into the marketplace.

10. The Safe Harbor allows GPOs to conduct business as they see fi,t and they are free to do whatever they want with no one to answer to but themselves. The Safe Harbor came with no provision for oversight and no rules of engagement against which compliance could be measured. GPOs claim that they are governed by their members, but an occasional meeting at a golf resort is not governance. Most hospital CEOs are either too busy with other issues in their hospitals or are not versed in supply chain management enough to provide any real significant oversight even if they were interested in doing so.

11. GPOs claim to take direction from their product councils. It is simply naïve to believe that total consensus on product can be created for as many as two thousand hospitals.

12. By submitting themselves to the decisions of GPO product councils with whom they have no fiduciary relationship, physicians may unknowingly outsource part of their medical decision making authority and responsibility to the GPO. If this is even legal it certainly cannot be comforting to patients and caregivers.

13. The Safe Harbor creates a flow of money from suppliers to GPOs and gives them significant financial leverage over their members. While GPOs argue that membership is voluntary, hospital CEOs know that the more compliant they are to the contracts, even if the contracts are not in the hospital's best interest, the larger their rebate checks will be. It is the rebate checks and not supply chain expertise that draw hospitals to GPOs. Without the Safe Harbor the rebate checks would be smaller and hospitals would be forced to use sound judgment rather than rebate addiction to make their GPO membership decisions. When a hospital chooses to use a contracted but unsafe product instead of an available safe product it chooses money over patient and caregiver safety. In doing so, hospitals violate the trust of their clinicians and patients and perhaps fail to fulfill their own fiduciary responsibility.

14. Supply chain management has revolutionized competition for many companies in many different industries outside of the hospital market. Buyers are experts in their fields and use scientific methods and market intelligence to create sound procurement strategies. Hospitals, in their own way, are factories. The medical product raw materials purchased by hospitals are combined with clinical expertise to produce patient outcomes. Yet hospitals seem to buy pacemakers the same way they buy paper clips. Could it be that an over-reliance on GPOs has made hospitals lazy in how they manage their supply chains? While the hospitals have become weaker the GPOs have become stronger. The Safe Harbor perpetuates supply chain weakness in hospitals by effectively endorsing the use of GPOs.

15. Hospitals are in competition every day for patients, physicians, staff, payer relationships and community resources. Not every hospital in every market will survive. There are few potential strategic advantages for a hospital but one of them certainly should be the supply chain yet most hospitals are far too willing to trade the possibility of gaining a competitive advantage in their supply chain for the assurance that they won't do any worse than the competition. For a larger hospital, using a GPO may be an anti-competitive move against itself. It is ironic

> that in most well run businesses the management out sources the areas where it lacks expertise but retains strategic decision making for itself. Inexplicably, hospitals maintain tight control over inefficient internal supply chain processes but choose to outsource their strategic contracting decisions.

The GPO issue would not have made it to this Subcommittee without scores of complaints about alleged bad behavior of certain GPOs. Surely, those GPOs who operate under the Safe Harbor owe a duty of care to the Congress for granting the Safe Harbor. It is my sincere hope that you will move to eliminate the Safe Harbor and require GPOs to be paid for their services by hospitals the way every other supplier is paid. But if you choose to leave the Safe Harbor in place, from this point forward any bad behavior that is given license by the Safe Harbor must become, at least in part, the responsibility of this Subcommittee and the personal responsibility of each Member. Bad behavior at Enron cost people their money. Bad behavior at GPOs and suppliers could be costing people their health and their very lives. If you leave the Safe Harbor in place I urge you in the strongest possible terms to fully investigate the alleged bad behavior of certain GPOs. And I plead with you to use people who know what to look for.

I believe that there are answers to the dilemma we now face but that they will require careful examination of GPO practices and the actual value they produce for hospitals. Then, with detailed planning and meticulous execution, we can create a new approach that places hospitals as the priority and creates a supply chain procurement model that supports high-quality, safe patient care and effective management of cost issues. As a health care supply chain expert I have given this area a great deal of thought and I am prepared to work with this body, the Department of Justice, and the Federal Trade Commission to create an effective solution.

Recently, two major GPOs announced plans to go public with a stock offering. Does it seem right that while their hospital members continue to struggle financially, Broadlane and MedAssets will use the windfall granted to them by the Congress in the form of the Safe Harbor to enrich themselves by selling stock in their companies? Will this be the legacy of the Safe Harbor? Will this body demand a full accounting of GPO business practices and full disclosure of the supply chain money trail that alone will lead to a meaningful and useful Code of Conduct? Or is the goal to place a band-aid on a scratched arm while the patient continues to hemorrhage from a severed aorta?

I have never believed that the answers to all of the country's problems reside in Washington, D.C. I also do not believe that most of our problems lie here either. Rather, the answers to many of our greatest challenges lie in individuals and corporations. The answers to the ills of the health care supply chain lie in the ability and willingness of manufacturers, GPOs, distributors, and hospitals to do what is right, fair, and just so as to do the most good for patients, caregivers, and their families at the lowest reasonable total cost. The role of the government is to provide a watchful eye and ensure that the playing field is level so that the market of patients, caregivers, and hospitals, and not the government, determines the winners and losers. By eliminating the Safe Harbor, the playing field can be leveled. Thank you for inviting me to testify today.

United States General Accounting Office

GAO

Testimony

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

For Release on Delivery
Expected at 2:30 p.m.
Wednesday, July 16, 2003

GROUP PURCHASING ORGANIZATIONS

Use of Contracting Processes and Strategies to Award Contracts for Medical-Surgical Products

Statement for the Record by Marjorie Kanof
Director, Health Care—Clinical and Military Health Care Issues

GAO-03-998T

DRAFT

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-surgical products. Faced with persistent pressures to cut rising costs, hospitals over the past two decades have increasingly relied on purchasing intermediaries—GPOs—to keep the cost of their medical-surgical products in check. Hospitals buy everything from commodities—for example, cotton balls and bandages—to high-technology medical devices, such as pacemakers and stents,[1] through GPO-negotiated contracts. By pooling the purchases of their member hospitals, GPOs may negotiate lower prices from vendors (manufacturers, distributors, and other suppliers), which can benefit hospitals and, ultimately, consumers and payers of hospital care (such as insurers and employers).

Some manufacturers—especially small manufacturers of medical devices—have contended that GPOs employ a slow process for selecting products to place on contract and set high administrative fees that have made it difficult for some firms to obtain a GPO contract. They have also expressed concerns about certain contracting strategies that GPOs use as leverage to obtain better prices. They contend that these strategies have the potential to limit competition when practiced by GPOs with a large share of the market.

At the request of the subcommittee, we examined certain GPO business practices that critics contend have the potential to create an uneven playing field for manufacturers. This statement focuses on seven large GPOs serving hospitals nationwide regarding their (1) processes to select manufacturers' medical-surgical products for their hospital members and the level of administrative fees they receive from manufacturers, (2) use of contracting strategies to obtain favorable prices from manufacturers, and (3) recent initiatives taken to respond to concerns about GPO business practices. In a subsequent report for this subcommittee, we will expand our earlier work and examine the extent to

[1]A stent is a device used to provide support for tubular structures like blood vessels. It can be made of rigid wire mesh or may be a metal wire or tube.

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which hospitals benefit from participation in GPOs.[2] In April 2002, we reported that for two products in one local market, a hospital's use of a GPO contract did not guarantee that the hospital paid a lower price.

We focused our current work on purchases made by acute care hospitals for medical-surgical products, including commodities, such as cotton balls and bandages, and medical devices, such as pacemakers and stents.[3] We did not investigate GPOs' business practices with regard to other products that hospitals purchase, such as pharmaceutical products, capital equipment, and food supplies. Our findings are based on structured interviews with representatives of seven major national GPOs. We also interviewed representatives of 13 medical-surgical product manufacturers of various sizes and representatives of trade associations from the following industries: group purchasing, medical-surgical product manufacturing, supply distribution, and venture capital. We also consulted with experts, including representatives from two hospitals, three venture capital firms, two industry consultants, and one technology assessment company. In addition, we reviewed literature on group purchasing and antitrust law. We did not independently verify the information we obtained. The information GPOs provided was self-reported. We conducted our work from May 2002 through July 2003 in accordance with generally accepted government auditing standards.

Results in Brief

The GPOs we studied were able to alter the duration of their process for selecting products to place on contract, particularly when they considered these products to be innovative. GPOs' product selection processes generally took 6 months, and ranged from as short as 1 month to as long as 18 months. One GPO specifically reported expediting or modifying its formal selection process when it considered a product to be innovative and wanted to award a contract quickly. The seven GPOs also reported receiving from manufacturers administrative fees at levels that were generally consistent

[2]U.S. General Accounting Office, *Group Purchasing Organizations: Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices*, GAO-02-690T (Washington, D.C.: Apr. 30, 2002).

with the 3-percent-of-purchase-price threshold in federal guidance. However, for certain products, they reported higher fees—in one case, nearly 18 percent.

The seven GPOs we studied, including two with the largest market shares, used sole-source contracting (giving one of several manufacturers of comparable products an exclusive right to sell a particular product through a GPO), product bundling (combining the sale of products and linking price discounts to purchases of a specified group of products), and other contracting strategies to varying degrees to obtain favorable prices. For example, while all seven GPOs reported using sole-source contracts, some GPOs, including one of the two largest, used them extensively, whereas others used them on a more limited basis. Most GPOs used some form of bundling, and the two largest GPOs used either contracts or programs that bundle multiple products for a notable portion of their business.

In response to congressional concerns raised in 2002 about GPOs' potentially anticompetitive business practices, the group purchasing industry's trade association established a code of conduct that directs member GPOs to, among other things, address their contracting processes. The conduct code also includes reporting and education responsibilities for the trade association. The seven GPOs we studied drafted or revised their own codes of conduct, but the conduct codes are not uniform in how they address GPO business practices. Moreover, some GPOs' conduct codes include exceptions and qualified language that could limit the potential of the conduct codes to effect change. It is too soon to evaluate the effectiveness of these codes of conduct in addressing concerns about potentially anticompetitive practices, as many conduct codes are recently adopted and sufficient time has not elapsed for GPOs to demonstrate results.

Background

In seeking to provide their hospital customers with medical-surgical products at favorable prices, GPOs engage with manufacturers in certain contracting processes and

[3]We did not include government hospitals, such as those of the Department of Veterans Affairs, in our study.

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sometimes use certain strategies to obtain price discounts. Many manufacturers bid for GPO contracts because hospital purchases with these contracts may increase manufacturers' market share. GPOs are subject to federal antitrust laws. A statement developed by enforcement agencies helps GPOs determine whether their business practices are likely to be challenged under the antitrust laws.

Manufacturers Contract with GPOs to Sell Their Medical-Surgical Products

Many manufacturers use GPO contracts to sell their medical-surgical products. These products include two types—commodities and medical devices. Commodities such as cotton balls and bandages are examples of items for which physicians and other clinicians generally do not have strong preferences. Manufacturers commonly use GPO contracts to sell hospitals these non-preference products because hospitals purchase these items in large quantities. In contrast, medical devices can be "clinical preference" items—that is, those for which physicians and other practitioners are likely to express a preference. High-technology medical devices such as pacemakers and stents are examples of clinical preference items. Some manufacturers prefer to sell these items directly to hospitals.

A Few GPOs Dominate the Market for Medical-Surgical Products Sold through Contracts

The GPO industry that purchases products for hospitals is large and moderately concentrated. Experts have not determined a precise number of GPOs currently in business, but some estimate that there are hundreds of GPOs. While some GPOs operate regionally, this study focused on seven national GPOs with purchasing volumes over $1 billion that account for more than 85 percent of all hospital purchases nationwide made through GPO contracts. In 2002, the combined purchasing volume of these GPOs totaled about $43 billion, excluding distribution dollars. (See table 1.)

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Table 1: Seven GPOs' Purchasing Volumes for Total Customer Purchases Made Through Contracts, 2002

GPO	Purchasing volume (dollars in millions)
GPO 1	$14,330
GPO 2	14,413
GPO 3	4,400
GPO 4	3,233
GPO 5	2,837
GPO 6	2,564
GPO 7	1,466
Total	$43,243

Source: GPO-reported data.

Note: These purchasing volumes exclude distribution dollars.

Among the GPOs in our study, the two largest GPOs account for about 66 percent of total GPO purchasing volume for all medical products (including, among other things, medical-surgical products, pharmaceuticals, capital equipment, and food). These two GPOs also account for 70 percent of the seven GPOs' total medical-surgical product volume. One of the two largest GPOs has as members 1,569 of the nation's approximately 6,900 hospitals; the other has 1,469 hospital members.[4] One of the two largest GPOs permits its members to belong to other national GPOs, whereas the other largest GPO does not.

GPOs Business Practices Encompass Contracting Processes and Strategies

A GPO's contracting process for manufacturers' medical-surgical products generally includes several phases—namely, product identification and selection, requests for proposals or invitations to bid, review of submitted proposals and applications, assessment of product quality, contract negotiation, and contract award. The contract negotiation phase may include the negotiation of a contract administrative fee. This fee

[4]The approximately 6,900 hospitals include government hospitals such as those of the Department of Veterans Affairs and county hospitals.

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is designed to cover a GPO's operating expenses and serves as its main source of revenue.[5] Contract administrative fees are calculated as a percentage of each customer's purchases of the particular product included in a GPO contract.

In negotiating contracts, GPOs use certain contracting strategies as incentives for manufacturers to provide deeper discounts and for hospital members to concentrate purchasing volume to obtain better prices. These strategies are not limited to use by GPOs, as some manufacturers also use them in negotiating contracts with GPOs to increase market share. Key contracting strategies include the following:

- *Sole-source contracts* give one of several manufacturers of comparable products an exclusive right to sell a particular product through a GPO.

- *Commitment* refers to a specified percentage of purchasing volume that, when met by the GPO's customer (such as a hospital), will result in a deeper price discount. Commitment levels can be set either by the GPO or the manufacturer. For example, a manufacturer might offer greater discounts to GPO customers that purchase at least 80 percent of a certain group of products from that manufacturer. Commitment requirements can also be tiered, resulting in the opportunity for the customer to commit to different percentages of purchasing volume: the higher the percentage, the lower the price.

- *Bundling* links price discounts to purchases of a specified group of products. GPOs award several types of bundling arrangements. One type bundles combinations of products from one manufacturer. A manufacturer may find this arrangement advantageous because it allows increased sales of products in the bundle that may not fare well as stand-alone products. Another type bundles products from two or more manufacturers. Also, contracts can be bundled for complementary products, such as protective hats and shoe coverings used in hospital operating rooms, while

[5]In addition to using these fees to cover their operating expenses, GPOs often distribute surplus fees to member hospitals. They may also use administrative fees to finance new ventures, such as electronic commerce, that are outside their core business.

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others bundle unrelated products such as patient gowns and intravenous solutions. Hospitals that purchase bundles of unrelated products receive a price discount on all products included in the bundle.

- *Contracts of long duration*—those in effect for 5 years or more—can direct business to manufacturers for an extended period.

When used by GPOs with a large market share, these contracting strategies have the potential to reduce competition. For example, if a large GPO negotiates a sole-source contract with a manufacturer, the contract could cause an efficient, competing manufacturer to lose business and exit from the market and could discourage other manufacturers from entering the market.

Federal Safe Harbor and Antitrust Safety Zone Exist for GPOs

Certain aspects of GPOs' operations are specifically addressed by federal statute, regulation, and policy. While "anti-kickback" provisions of the Social Security Act prohibit payments in return for orders or purchases of items for which payment may be made under a federal health care program, the act also contains an exception for amounts paid by vendors of goods or services to a GPO.[6] Therefore, GPOs are allowed to collect contract administrative fees from manufacturers and other vendors that could otherwise be considered unlawful. In addition, regulations issued by the Department of Health and Human Services establishing "safe harbors" for purposes of the "anti-kickback" provisions provide that GPOs are to have written agreements with their customers either stating that fees are to be 3 percent or less of the purchase price, or specifying the amount or maximum amount that each vendor will pay.[7] The Office of Inspector General in the Department of Health and Human Services is responsible for enforcing these regulations. The GPOs must also disclose in writing to each customer, at

[6] See 42 U.S.C. § 1320a-7b(b) (2000).
[7] See 42 C.F.R. § 1001.952(j) (2002).

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least annually, the amount received from each vendor with respect to purchases made by or on behalf of the customer.

Recognizing that GPO arrangements may promote competition among manufacturers and yield lower prices in some cases and may reduce competition in other cases, the U.S. Department of Justice and the Federal Trade Commission issued a statement in 1993 for joint purchasing arrangements. This statement sets forth an "antitrust safety zone"[8] for GPOs that meet a two-part test, under which the agencies will not generally challenge GPO business practices under the antitrust laws. Essentially, the two-part test in the context of medical-surgical products is as follows: (1) purchases through the GPO account for less than 35 percent of the total sales of the product in the relevant market,[9] and (2) the cost of the products purchased through the GPO accounts for less than 20 percent of the total revenues from all products sold by each GPO member.

GPOs Reported Modifying Contracting Processes When Desirable and Receiving Administrative Fees That Were Generally Consistent with Federal Guidance

In recent years, some manufacturers of medical-surgical products have contended that GPOs employ a slow product selection process and set high administrative fees that have made it difficult for some firms to obtain GPO contracts. These firms tend to be small manufacturers that may have fewer financial resources available to successfully complete GPOs' contracting processes than large manufacturers. The GPOs we studied reported generally having contracting processes that can be modified for certain types of products. They also reported receiving from manufacturers administrative fees at levels that were generally consistent with federal guidance.

[8] *Statements of Antitrust Enforcement Policy in Health Care*, Statement 7, p. 23.
[9] Although the GPOs in this study each has less than 35 percent of total GPO purchasing volume for all medical products, it is possible, for example, that a GPO could have greater than 35 percent of the total sales of one or more particular products.

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GPOs Reported Expediting Reviews and Using a Public Solicitation Process for Certain Products

In discussing GPOs' selection of products and negotiation of fees, several manufacturers we contacted pointed to the paperwork and duration of these processes as burdensome. Not all manufacturers shared the same perspective. One small manufacturer commented that the process could sometimes be relatively easy but that the selection process can be more difficult if the manufacturer is selling only one product.

The GPOs we studied were able to alter the duration of their process for selecting products to place on contract, particularly when they considered these products to be innovative. Based on their reported information, GPOs' product selection processes generally took 6 months, and ranged from as short as 1 month to as long as 18 months. One GPO specifically reported expediting or modifying its formal selection process when it considered a product to be innovative and wanted to award a contract quickly. Most GPOs did not have a distinctly separate process for selecting innovative technology but reported that these products were generally selected in a shorter amount of time compared with other products.

Figure 1 shows, across the seven GPOs, the average minimum, most frequent, and maximum times taken for product selection.

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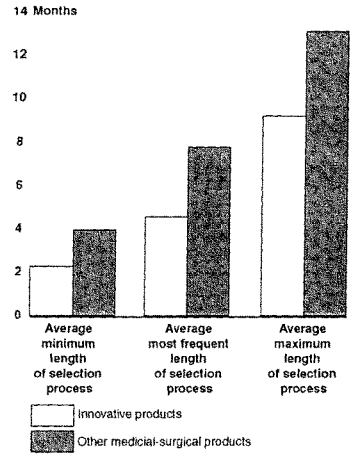
Figure 1: Duration of the GPO Product Selection Process



Source: Interviews with representatives of seven GPOs.

Note: Averages weighted by GPO-reported dollar purchasing volume, excluding distribution dollars.

The GPOs in our study reported consulting various sources before making a decision, including the GPO's customers requesting the product; published studies about the product; internal and external technology assessments; and different manufacturers of the product, both with and without a GPO contract. In all cases, the GPOs cited customer requests for products as the most important factor in identifying which products to place on contract.

In selecting a manufacturer, six of the seven GPOs, including the two largest, solicit proposals publicly—either through requests for proposals or requests for bids through their Web sites. The extent to which these processes are open to all manufacturers varies by GPO and by product. For example, one of the GPOs solicits proposals publicly for clinical preference products, but not for commodities.

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GPO-reported information on new contracts awarded in 2002 suggest that GPOs' solicitations were not limited to manufacturers already on contract. Nearly one-third of all the newly negotiated contracts awarded by the seven GPOs in 2002 were awarded to manufacturers with which the GPO had not previously contracted. The percentage of such contracts ranged from 16 percent to 55 percent for the GPOs in our study. For the two largest GPOs, this share was 29 percent and 55 percent. We could not determine, from the information provided, whether these first-time contract awardees were, for example, small manufacturers or companies new to the industry or whether the products purchased through these contracts were clinical preference items or commodities.

GPO-Reported Information Indicates that Contract Administrative Fees Received Were Generally Consistent with Federal Guidance

Manufacturers have expressed concerns that contract administrative fees, which are typically calculated as a percentage of each customer's purchase of products under contract, can be too high for some manufacturers. These fees, combined with lower prices negotiated by the GPO, may decrease revenue for manufacturers and may make it more difficult to obtain a GPO contract for newer and smaller manufacturers with fewer financial resources than for larger, more established companies.

Five out of seven GPOs reported that the maximum contract administrative fee received from manufacturers in 2002 did not exceed the 3-percent-of-purchase-price threshold contained in federal guidance. The most frequent administrative fee level that 4 out of 7 GPOs received from manufacturers in 2002 was 2 percent; the lowest fee level received by each GPO was 1 percent or less. Except for one of the two largest GPOs, the GPOs reported that they have not negotiated any new or renewed contracts in 2003 that include administrative fees from medical-surgical product manufacturers that exceed 3 percent.

Fee levels for private label products —products sold under a GPO's brand name—were an exception: The typical contract administrative fee paid by private label manufacturers

was 5 percent. For one of the two GPOs in our study with private label products, the maximum administrative fee was nearly 18 percent. In addition to an administrative fee, the other GPO charged a separate "licensing" fee for private-label products.[10]

Seven National GPOs Varied in the Extent to Which They Used Certain Contracting Strategies

GPOs use certain contracting strategies—which include sole-source contracts, product bundling, and extended contract duration—to obtain discounts from manufacturers in exchange for providing the manufacturer with increased sales from an established customer base. Manufacturers and other industry observers have expressed concerns that use of these strategies by the two largest GPOs can reduce competition. For example, when GPOs with substantial market shares award long-term sole-source contracts to large, well-established manufacturers, some newer, single-product manufacturers—left to compete with other manufacturers for a significantly reduced share of the market—may lose business and be forced to exit the market altogether.

The seven GPOs we studied, including two with the largest market shares, used these contracting strategies to varying degrees. For example, while all study GPOs reported using sole-source contracts, some GPOs, including one of the two largest GPOs, used it extensively, whereas others used it on a more limited basis. GPOs also varied in their approach to requiring commitment levels from their customers. With respect to bundling, most GPOs used some form of bundling, and the two largest GPOs used either contracts or programs that bundled multiple products for a notable portion of their business. With respect to contract duration, the two largest GPOs typically negotiated longer contract terms than the other five GPOs.

[10]Some manufacturers pay this GPO licensing fees in exchange for using the GPO's brand name.

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For Some of the GPOs, Sole-Source Contracts Accounted for a Substantial Portion of the Purchasing Volume

The use of sole-source contracting by the study GPOs varied widely with respect to the relative amount of sole source contracting they did and the types of products included in the contracts. For five of the GPOs, sole-source contracts accounted for between 2 percent and 46 percent of their medical-surgical product dollar purchasing volume.[11] For the rest—the two largest GPOs—the shares of dollar purchasing volume accounted for by sole-source contracts were 19 percent and 42 percent. Such levels of sole-sourcing are worth noting, given the sizeable market shares of these two GPOs.

GPOs also varied in their use of sole-source contracts for commodity products as compared to medical devices for which providers may desire a choice of products. For one of the two largest GPOs, clinical preference products accounted for the bulk—82 percent—of its sole-source dollar purchasing volume.[12] Two GPOs reported cases in which manufacturers refused to contract with the GPO unless they were awarded a sole-source contract. In contrast, commodities accounted for the bulk—between 62 percent and 91 percent—of the dollar purchasing volume that the smaller of the seven GPOs purchased through sole-source contracts. GPO-reported data indicate that the proportion of contracts that were sole source, as a share of all contracts for medical-surgical products for the past 3 years, remained relatively consistent for GPOs.

GPOs Considered Customer Commitment to Be Important, but Commitment Requirements Varied

The seven GPOs in our study reported that hospital customers' commitment to purchase a certain percentage of their products through GPO contracts was an important factor in obtaining favorable prices with manufacturers, and all reported establishing commitment

[11]One GPO did not provide us information on purchasing volume for medical-surgical products through sole-source contracts.
[12]The second GPO did not provide us information on sole-source purchases represented by the two product types.

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level requirements to some degree. Most of the smaller of the seven GPOs reported that customer adherence to commitment levels and contracts were the most important factor in obtaining favorable pricing with manufacturers. In principle, for GPOs with a small customer base, the assurance of customer commitment to purchasing helps enable them to achieve the higher volumes needed to leverage favorable prices from manufacturers. The two largest GPOs reported that volume was the most important factor for obtaining favorable prices and that customer compliance with commitment level and contracts was next in importance. For the two largest GPOs, a sizable customer base may provide the volume levels needed to obtain favorable prices.

GPOs varied in their approach to requiring purchasing commitment levels. One GPO requires customers to commit to an overall average dollar purchasing level of 80 percent for those products available through the GPO, although the percentage could vary for individual products. The GPO reported terminating the membership of at least one customer that did not meet this target. Other GPOs reported establishing customer commitment levels in certain contracts in order to obtain a certain price level, but customers were not required to buy under the contract or buy at the commitment level in order to retain GPO membership. Some GPOs' contracts include multiple, or tiered commitment levels so that customers can choose from a range of commitment levels and obtain price discounts accordingly.

Most GPOs Use Some Form of Bundling, and the Two Largest GPOs Use It for a Notable Portion of Their Business

All but one of the GPOs in our study reported using some form of bundling, including the bundling of complementary products, bundling several unrelated products from one manufacturer, and bundling several products for which there are commitment-level requirements. One bundling arrangement that GPOs reported using gave customers a discount when they purchased a bundle of complementary products, such as protective hats and shoe coverings. Four GPOs reported bundling complementary products. These

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bundles were included in a small percentage of the GPOs' contracts; each of the four GPOs reported having no more than three contracts that bundle complementary products. One GPO reported awarding only one bundled contract for two complementary products—the only bundling arrangement the GPO had in effect at the time it reported to us.

A second type of bundling reported by three GPOs, including the two largest, gave customers a discount if they purchased a group of unrelated products from one manufacturer. We define this type of bundling as a corporate agreement. One of the two largest GPOs reported that corporate agreements for medical-surgical products accounted for about 40 percent of its dollar purchasing volume for medical-surgical products under contracts in effect on January 1, 2003.

Four GPOs, including one of the two largest, used a third type of arrangement that typically bundled products from different manufacturers and required customers that chose this arrangement to purchase a certain minimum percentage from the product categories specified in the bundle in order to obtain the discount. We defined this type of bundling as a structured commitment program. A structured commitment program available through one GPO bundled brand name and GPO private label items for 12 product categories and had a 95 percent commitment-level requirement. In 2002, one of the two largest GPOs reported receiving about 20 percent of its medical-surgical dollar purchasing volume from its structured commitment programs.

The use of bundling arrangements may be declining. For example, data reported by one GPO showed a decline in the percent of its contracts that were corporate agreements from 2001 to 2003.[13] This trend was consistent with comments made by one manufacturer and two medical-surgical product distributors. The manufacturer told us that GPOs are less interested in bundling different manufacturers together. Two distributors' representatives told us that since the summer of 2002, GPOs have fewer bundling arrangements and that some bundles were "pulled apart."

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The Two Largest GPOs Typically Award Contracts with Longer Terms than the Other Five

Our analysis of data reported by the study GPOs showed that, in 2002, the two largest GPOs typically awarded 5-year contracts, whereas the other five GPOs typically awarded 3-year contracts.[14] Those contract terms remained fairly consistent between 2001 and 2003, although two of the five GPOs reported that their most frequent contract term declined by about 1 year. Some GPOs reported implementing policies that may lead to a future reduction in contract terms. One of the two largest GPOs began in the first quarter of 2003 to exclude from new contracts the option for two 1-year contract extensions, so that when a contract expires, this GPO will solicit proposals for a new contract.

GPOs Have Taken Initiatives to Address Concerns about Business Practices, but It Is Too Early to Evaluate Their Efforts

In response to congressional concerns raised in 2002 about GPOs' potentially anticompetitive business practices, the group purchasing industry's trade association established a code of conduct that directs member GPOs to, among other things, address their contracting processes. The conduct code also includes reporting and education responsibilities for the trade association. The seven GPOs we studied drafted or revised their own codes of conduct, but the conduct codes are not uniform in how they address GPO business practices. Moreover, some GPOs' conduct codes include exceptions and qualified language that can limit the potential of the conduct codes to effect change. It is too soon to evaluate the effectiveness of these codes of conduct in addressing concerns about potentially anticompetitive practices, as many conduct codes are recently adopted and sufficient time has not elapsed for GPOs to demonstrate results.

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[13]This period reflects contracts in effect on three dates—January 1, 2001, January 1, 2002, and January 1, 2003.

[14]For some of these contracts, potential renewal periods constitute a portion of the contract duration.

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Trade Association Code of Conduct Laid Groundwork for Industry Self-Regulation

On July 24, 2002, the Health Industry Group Purchasing Association (HIGPA) adopted a code of conduct providing principles for GPO business practices. HIGPA represents 28 U.S.-based GPOs—including five of the seven major GPOs that we studied. HIGPA members also include health care systems and alliances, manufacturers, and other vendors. The HIGPA code of conduct provides principles for GPO business practices and also intends to address actual, potential, or perceived conflicts of interest. As a condition of membership, the HIGPA code requires, among other things, that GPOs

- allow hospital and other provider members to purchase clinical preference items directly from all vendors, regardless of whether the vendors have a GPO contract;
- implement an open contract solicitation process;
- participate in processes to evaluate and make available innovative products;
- address conflicts of interest, such as disallowing staff in positions of influence over contracting to hold equity interest in, or accept gifts or entertainment from, "participating vendors";[15] and
- establish accountability measures, such as appointing an oversight officer and certifying annually that the GPO is in compliance with the HIGPA code.

The HIGPA code also includes several provisions regarding the trade association's education and reporting responsibilities, including

- assessing and updating the conduct code to be consistent with newly identified best business practices;
- implementing industry wide educational programs on clinical innovations, contracting strategies, patient safety, public policy, legal requirements, and best practices;

[15] Participating vendors are those that have a contract or submit a bid or offer to contract with a GPO.

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- making available a Web-based directory that posts manufacturers' and other vendors' product information; and
- publishing an annual report listing GPOs that have certified their compliance for the year with the HIGPA conduct code.

As of May 19, 2003, HIGPA's 28 U.S.-based GPO members certified that they are in compliance with the HIGPA code of conduct.

Variations Exist in GPOs' Efforts to Address Business Practices

Although the HIGPA code of conduct laid the groundwork for many GPOs to change their business practices, its guidelines do not comprehensively address certain business practices. Specifically, the HIGPA code of conduct requires GPOs to address business practices associated with contracting, conflicts of interest, and accountability, and it grants GPOs discretion in using contracting strategies. It recommends that GPOs consider factors such as vendor market share, GPO size, and product innovation when using multiple contracting strategies. However, the HIGPA code of conduct does not directly address levels of contract administrative fees or the offering of private label products.

Since August 2002, the seven GPOs we studied, even those that were not HIGPA members, drafted and adopted their own codes of conduct or revised their existing conduct codes. One GPO stated that its revised code, while consistent with the HIGPA code, was more specific than HIGPA's principles, particularly in the GPO's rules on stock ownership, travel, and entertainment. Another GPO reported expanding on HIGPA's code by including provisions to cap administrative fees and prohibit bundling. Similarly, GPOs who were not HIGPA members said they had revised their existing codes of conduct and that their conduct codes were in some respects stronger than HIGPA's.

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Nevertheless, GPOs' individual codes of conduct varied in the extent to which they addressed GPOs' business practices, such as contracting processes and strategies. Figure 2 provides an overview of the seven GPOs' conduct codes with respect to their business practices. The table indicates whether a business practice was identified in a code of conduct, but not how the practice was to be addressed.

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Figure 2: Business Practices Identified in GPOs' Codes of Conduct

Business practice	HIGPA members					Non-HIGPA members	
	GPO A	GPO B	GPO C	GPO D	GPO E	GPO F	GPO G
Product selection contracting processes	●			●	●	●	
Innovative product selection	●	●	●	●	●	●	
Contract administrative fees	●	●		●	●	●	
Sole-source contracting	●	●		●	●	●	
Bundling	●	●	●	●	●	●	
Commitment level requirements	●	●		●	●	●	
Contract durations	●	●		●	●	●	
Private labeling	●	●		●		●	
Conflicts of interest-equity	●	●	●	●	●	●	●
Conflicts of interest-other	●	●	●	●	●	●	●
Internal accountability	●	●	●	●	●	●	●
External accountability		●		●			

Identified in HIGPA code of conduct

● Identified in both HIGPA and individual GPO code of conduct

● Identified in individual GPO code of conduct

Not identified in code of conduct

Source: Codes of conduct provided by HIGPA and the seven GPOs in our study.

Note: A code of conduct was determined to identify a business practice if it was mentioned in the conduct code's text.

As figure 2 shows, the conduct codes of all the study GPOs explicitly mentioned conflict of interest issues such as those dealing with equity holdings and other conflicts such as receipt of gifts and entertainment and the need for internal accountability. In addition, the conduct codes of most GPOs, including the two largest, included provisions dealing

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with the contracting strategies, such as sole-source contracting and bundling. For GPOs that are HIGPA members, the lack of additional provisions in their individual conduct codes for certain business practices such as contracting processes may not be significant, as provisions covering these areas are included in the HIGPA code. However, for one of our study GPOs that is not a HIGPA member, the conduct code lacked any provisions pertaining to contracting processes, product selection, administrative fees, sole-source contracting, commitment level requirements, contract duration, and private labeling.

The provisions in the seven GPOs' conduct codes were not uniform in how they addressed business practices. For example:

- Four GPOs, including one of the two largest, had unqualified provisions for capping administrative fees at the 3-percent threshold contained in federal guidance. The other largest GPO had a provision for capping administrative fees at 3 percent only for clinical preference items and only for contracts awarded after the establishment of the GPO's conduct code.

- Four conduct codes had provisions limiting the use of sole-source contracts for clinical preference items specifically. Another conduct code limited the use of sole-sourcing to contracts meeting certain criteria, such as approval for use by a 75-percent majority of the GPO's contracting committee. The language of one of the two remaining GPO's conduct codes was vague with respect to sole-sourcing, stating that the GPO will provide customers with choices for each product or service, without explicitly mentioning the use of sole-source contracts.

- In their conduct codes, two GPOs had provisions prohibiting the practice of bundling of unrelated products, two GPOs prohibited and two limited bundling for clinical preference items, and three GPOs prohibited the practice of bundling products from different manufacturers. One GPO's conduct code stated that the GPO would not

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obligate its customers to purchase bundles of unrelated products, allowing the possibility for bundles to be available to customers on a voluntary basis.

Exceptions and qualified language in the provisions have the potential to weaken the codes of conduct. Table 2 shows examples of exceptions and qualified language that can limit the potential of the individual GPOs' conduct codes to effect change.

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Table 2: Examples of Exceptions and Qualifications in Code of Conduct Provisions for the GPOs in Our Study

Business practice	Specific provision including exceptions and qualifiers (in italics)	Potential implications
Contracting processes	Will use request for proposal process *for clinical preference products but not for most commodities.*	Contract bids for most commodities will not go through solicitation process.
Contract administrative fees	Will reduce contract administrative fees that are greater than 3 percent to 3 percent *for clinical preference products on a prospective basis.*	For clinical preference products, contract administrative fees negotiated prior to adoption of conduct code are not subject to provision; in future contracts, administrative fee for all other items may continue to exceed 3 percent.
Sole-source contracting	No sole-source contracts for clinical preference products *unless there is no other means by which the GPO can obtain access to the product for customers.*	Manufacturers have incentives to link price discounts in return for exclusive contract awards.
Bundling	No bundling of clinical preference products *on a prospective basis,* and no bundling of products *across different vendors.*	For clinical preference products, bundled contracts awarded prior to adoption of conduct code are not subject to provision; contracts for bundles of unrelated, non-clinical preference products with one manufacturer are not subject to the provision.
Commitment level requirements	No commitment level requirements *for clinical preference products, on a prospective basis.*	For clinical preference products, commitment levels negotiated prior to adoption of conduct code are not subject to provision; all other products could have commitment requirements.
	Commitment level requirements *not to exceed 80 percent of purchasing volume for clinical preference products, unless relevant committee approves otherwise.*	Commitment-level requirements for clinical preference products have potential to remain as high as 80 percent of purchasing volume and, under certain circumstances, may be higher.
Conflicts of interest-equity	No equity interests may be held *by GPO management and other staff with influence over contracting in any participating vendors.*	Other GPO staff may hold equity interest in participating vendors, that is, those on contract or bidding for a contract. GPO staff with influence over contracting may hold equity interest in nonparticipating vendors.

Source: Individual GPOs' codes of conduct.

DRAFT

Too Soon to Evaluate Impact
of GPOs' Codes of Conduct

Given the individual GPOs' relatively recent adoption of codes of conduct—since August 2002—sufficient time has not yet elapsed for GPOs to develop a history of compliance with certain conduct code provisions. Two of the manufacturers and two distributors we interviewed reported noticing improvements, stating that some GPOs are no longer using certain contracting strategies. This observation is consistent with the study GPOs' reports of a decline in the use of bundling. One manufacturer that had had difficulty in obtaining a contract with a large national GPO prior to 2002 said it has since been awarded a contract for a clinical preference item. The manufacturer also noted that, since September 2002, it has been awarded several new contracts. However, two other manufacturers told us they are skeptical that improvements have been made with regard to business practices. Notwithstanding such anecdotal evidence, because of the recency of GPOs' actions taken, the ability to assess the impact of the conduct codes systematically remains limited. One year is not sufficient time for the codes of conduct to produce measurable trends that could demonstrate an impact on the industry.

Contact and Acknowledgments

For more information regarding this statement, please contact Marjorie Kanof at (202) 512-7101. Hannah Fein, Mary Giffin, Kelly Klemstine, Emily Rowe, and Merrile Sing made key contributions to this statement.

(290198)

UNION HOSPITAL
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July 23, 2003

The Honorable Mike DeWine, Chairman
U. S. Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator DeWine:

I read that your subcommittee held another hearing on July 16 on the group purchasing industry. I believe your committee should work to ensure that suppliers and group purchasing organizations are providing necessary services to hospitals in an appropriate manner. However, I am concerned that active government interference in the GPO industry could cause supply prices to increase and complicate our efforts to streamline operations.

Our organization is a member of VHA, and we buy the majority of the supplies that we don't access locally through Novation. In fact, we have engaged in an effort to standardize our supply purchases by taking advantage of the contracts Novation offers. We know Novation saves us money on supply purchases, certainly more than we could negotiate on our own across the entire portfolio.

By standardizing the products we use, we create uniformity in the process of care, which raises quality, improves safety and makes training easier. I know Novation and other GPOs have implements several new business practices over the last year to address the concerns your subcommittee has raised about issues such as sole sourcing, private labeling and bundling. It seems one of the key flash points for the committee was the issue of sole sourcing. From my perspective, and through our use of many sole source agreements offered by Novation, I know that sometimes, sole source contracts offer the best opportunity for my organization to maximize price savings.

As a small, rural medical facility, Union Hospital must squeeze the most value out of every dollar we spend, and that means taking advantage of every lever at our disposal, especially group purchasing. If GPOs are forced to contract with numerous suppliers - disregarding quality and value – they not only lose bargaining power, but hospitals, physicians and patients lose the benefits of standardization because we will be dealing with so many suppliers.

GPOs help us create efficiencies, lower costs and improve quality. I would appreciate it if you would include my comments in your official record for the hearing and factor my comments into your ongoing efforts to monitor GPO activities.

Sincerely,

William W. Harding

William W. Harding
President and Chief Executive Officer

cc: The Honorable Herbert Kohl, Ranking Member
The Honorable George Voinovich

News Release

JUDICIARY COMMITTEE

United States Senate • Senator Orrin Hatch, Chairman

July 16, 2003 Contact: Margarita Tapia, 202/224-5225

Statement of Chairman Orrin G. Hatch
Before the United States Senate Committee on the Judiciary Subcommittee on Antitrust, Competition and Business and Consumer Rights
Hearing on

"HOSPITAL GROUP PURCHASING: HAS THE MARKET BECOME MORE OPEN TO COMPETITION?"

Thank you, Mr. Chairman. I want to thank you and Senator Kohl for holding this hearing, and for your continuing efforts to address a complex and critically important issue to our Nation -- how Group Purchasing Organizations, or "GPOs," affect the cost and quality of health care in America.

Let me take a moment here to commend specifically the efforts of Chairman DeWine and Ranking Member Kohl, and their staffs, for their tireless efforts in working with the GPO industry to address significant issues identified at the last year's hearing, particularly with respect to the GPO trade association's development and implementation of an industry code of conduct.

In addition, I would note that Chairman DeWine and Senator Kohl requested the Government Accounting Office to examine several significant issues relating to GPOs. I understand that the GAO is releasing a report today on some of these important issues. I look forward to reviewing that report as we continue to analyze and monitor GPO performance in the health care industry.

As I indicated at last year's hearing, there is widespread disagreement among news sources, commentators, economists and industry analysts as to whether the benefits of GPOs outweigh the potential for harm to hospitals, consumers and competition. These issues are complex and require careful analysis. On the one hand, GPOs may in some circumstances reduce the costs to hospitals, consumers and payers of medical care for a range of products, from basic commodities to high-technology medical devices. On the other hand, GPOs may in some circumstances create incentives which improperly exclude more efficient technologies and products from being used by hospitals.

Since last year's hearing, I understand that several GPOs have implemented new ethical codes of conduct. That is a welcome development, and I look forward to hearing today from witnesses about the implementation of these codes and the extent to which GPOs are adhering to these codes.

While much has been accomplished in this area to reform the ethical practices of GPOs, I am still concerned about potential anti-competitive business practices employed to varying degrees by GPOs. In particular, I am troubled by certain practices that may limit competition among small medical device manufacturers through the use of sole source contracting, bundling of products, high commitment contracts, private label programs and the administrative fees involved in GPO contracting decisions.

I look forward to hearing from the witnesses testifying here today, and I hope that they will address these important issues. I want to commend again Chairman DeWine and Senator Kohl for their commitment to this issue. I look forward to continuing to examine these complex issues which are so critical to our Nation's health care system.

# # #

United States Senate
Committee on Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights

"Hospital Group Purchasing: Has the Market Become More Open to Competition?"

Wednesday, July 16, 2003
2:30 p.m.
226 Dirksen Senate Office Building

Testimony Submitted by:
Robert Betz, Ph.D.,
President and CEO
Health Industry Group Purchasing Association
Arlington, Virginia

I. Introduction

I am Robert Betz, Ph.D., President and CEO of the Health Industry Group Purchasing Association (HIGPA). HIGPA represents 158 health care supply chain organizations, including nearly every major group purchasing organization (GPO) in the United States, and many of their trading partner members with whom they do business.

Today's hearing is to talk about how the health care group purchasing industry is changing in response to the concerns expressed by this Subcommittee in April 2002. This hearing will provide GPOs the opportunity to show how their contracting practices are transforming to accommodate small manufacturers to bring innovative products to the marketplace and how GPOs benefit health care providers. The industry is here to inform the subcommittee regarding the adoption and implementation of our Code of Conduct [See Appendix A], which establishes the highest ethical principles practiced in health care group purchasing.

II. Group Purchasing Industry Responds

At the April 30, 2002 hearing, concerns were raised by Subcommittee members and other stakeholders in the industry regarding the business practices of GPOs. Since that time, the industry has collectively responded with a HIGPA Code of Conduct, in addition to several individual GPOs addressing issues the HIGPA Code could not.

A. HIGPA's Code of Conduct Principles

HIGPA, with the support of its GPO members, developed a Code of Conduct in July 2002 with the purpose of strengthening and improving the delivery of products and services to health care providers. The GPO contracting process was already highly transparent to health care providers that purchase through GPO contracts. Nevertheless, the industry wanted to assure that it met the highest ethical standards. In developing the Code of Conduct, HIGPA focused on several areas, including: eliminating the potential for conflicts of interests; ensuring open communications

between members and vendors; establishing guidelines for the use of contracting tools; requiring full disclosure to members of all vendor payments; and, establishing reporting and educational programs, including surveys to quantify the value of GPOs.

The Code is unprecedented in the group purchasing industry. The Subcommittee's concerns regarding GPO contracting practices, conflicts of interest and cost savings were addressed in the HIGPA Code. Throughout the adoption of the Code, HIGPA members worked collaboratively and in a good faith effort with your Subcommittee to meet their concerns. The Code establishes baseline principles that individual GPOs have adopted to improve the group purchasing industry, while also recognizing that a one-size-fits-all approach would be counterproductive to ensuring a competitive GPO marketplace. If all GPOs had the same essential business models, health care providers would be unable to benefit from competition among GPOs. Following the adoption of the HIGPA Code, some individual GPOs adopted standards which exceeded, or were in addition to, the principles set forth in our Code. A majority of these companies adopted measures that HIGPA could not address due to antitrust laws.

1. Avoiding Antitrust Issues

There were specific issues pertaining to individual GPO business practices, such as the level of administrative fees, which HIGPA could not address in the Code without being in violation of federal antitrust laws.

In this regard, HIGPA asked one of the country's most respected antitrust scholars, Professor Herbert Hovenkamp, J.D., Ph.D., of the University of Iowa, College of Law, to provide an antitrust analysis regarding a Code of Conduct for the health care group purchasing industry. In a June 21, 2002 letter to HIGPA, Professor Hovenkamp detailed his concerns that the GPO Code of Conduct be lawful under the existing antitrust laws. Hovenkamp wrote:

> "Agreements fixing prices and related terms of sales are unlawful per se. Importantly, this rule applies to maximum price fixing as well as minimum price fixing. See Arizona v. Maricopa County Medical Society, 457 U.S. 332 (1982) (physicians' agreement setting maximum fees in context of health plan unlawful per se); see also Ratino v. Medical Services of D.C., 718 R.2d 1260 (4th Cir. 1983); Tom v. Hawaii Dental Service, 606 F.Supp. 584 (D. Haw. 1985) (dental plan setting fees unlawful per se). It also applies to brokerage fees as well as outright sales. See, e.g., McLain v. Real Estate Bd., 444 U.S. 232 (1980).
>
> "The per se rule also governs agreements fixing collateral terms such as signing bonuses, limiting or regulating the size of rebates, or specifying other price-related terms. Catalano v. Target Sales, 446 U.S. 643 (1980) (agreement to eliminate various forms of credit unlawful per se); National Society of Professional Engineers v. United States, 435 U.S. 679 (1978) (condemning agreement to refrain from competitive bidding); United States v. Aquafredda,

834 F.2d 915, 917 (11th Cir. 1987), cert. denied, 485 U.S. 980 (1988) (agreement eliminating discounts; criminal violations); Int'l. Assn. of Conference Interpreters, 5 Trade Reg. Rep. ¶24235 (FTC, 1997) (agreement fixing travel reimbursement rates and collateral charges unlawful); Personal Protective Armor Ass'n, 5 Trade Reg. Rep. (CCH) P 23,521 (FTC Mar. 17, 1994, consent order) (same; agreement stipulating insurance coverage).

"For these reasons competition among GPOs, rather than collusion via Code of Conduct, must determine the existence or size of administrative fees, signing bonuses, rebates and other collateral fees that GPOs charge for their services. Any provision that stipulates or even suggests a limit on such fees or prohibits a certain type of fee would be subject to antitrust challenge.

"This is not a situation where Congress or state law has granted GPOs immunity from the operation of the antitrust laws. Cf. Gordon v. New York Stock Exch., 422 U.S. 659 (1975) (federal securities law immunized commission setting by stock brokers from antitrust attack); 1A P. Areeda & H. Hovenkamp, Antitrust Law ¶243b (2d ed. 2000); and see Southern Motor Carriers Rate Conf. v. United States, 471 U.S. 48 (1985) (joint rate making by trucking firms immunized by state law); 1 Areeda & Hovenkamp, id. at ¶224.

"Nor is there any Noerr-Pennington immunity for petitions to the government. The petitioning immunity comes into play when joint actions are not instigated by private parties, but rather cast as a petition to the government for some action. Eastern R.R. Pres. Conf. v. Noerr Motor Freight, 365 U.S. 127 (1961); United Mine Workers v. Pennington, 381 U.S. 657 (1965). However, the immunity is invoked only when the joint action is proposed to the Government and contemplates government action, not when parties simply agree with each other to implement it on their own. See Superior Ct. Trial Lawyers Assn. v. FTC, 493 U.S. 411 (1990) (Noerr-Pennington immunity did not apply when lawyers simply set their own fees and imposed them.)

"In sum, if the GPOs acting without immunity agree to set maximum fees, rebates or other terms they would be incurring a significant risk of civil and perhaps even criminal violations of the federal antitrust laws."

By establishing baseline principles for all GPOs, the Code recognizes that both individual GPOs, and the industry as a whole, have important spheres of responsibility.

2. Compliance Process

Throughout the last quarter of 2002, HIGPA worked with its membership to develop a compliance process around which its GPOs began modeling their business practices with the industry-wide Code of Conduct. Part of this process was for members to certify to HIGPA their

compliance with the Code. In early 2003, HIGPA distributed to its GPO members the *2003 Survey of Compliance with Code of Conduct Principles* to report compliance with HIGPA's Code of Conduct. In turn, all 28 of HIGPA's American-based GPOs reported to the Association their compliance with the Code.

GPOs which have certified their compliance with the HIGPA Code of Conduct include: AllHealth; AmeriNet Central; AmeriNet, Inc.; CHAMPS Management Services; Child Health Corporation of America; Consorta, Inc.; Cooperative Services of Florida; Council Connections; GNYHA Venture, Inc.; Health Resource Services; Healthcare Purchasing Partners International, LLC; HSNE, Inc.; IHC/AmeriNet; Institutional Purchasing Services; International Oncology Network; Joint Purchasing Corporation; MAGNET; MedAssets HSCA Inc.; The MED Group; Metropolitan Chicago Healthcare Council; Managed Healthcare Associates; National Oncology Alliance, Inc.; Novation, LLC; Premier Purchasing Partners, L.P.; PRIME, Inc.; Shared Services Healthcare; SYNERNET, and; Vector.

3. What's Ahead

The HIGPA Code of Conduct is considered a "living" document and therefore can be updated and modified as necessary. Should the Code need improvements and modifications in the future, a revised Code would be adopted.

HIGPA would like to highlight that our Code of Conduct is the only Code in the health care industry that has a penalty for not complying with the principles. The penalty being, membership in the Association is revoked or denied if an Industry Member or prospective Industry Member fails to certify compliance with the Code. Moreover, HIGPA's Industry Members will be required to certify compliance each year to remain in good standing in the Association.

HIGPA's Bylaws will be amended at the Association's Annual Meeting in October to accommodate the adoption of the Code of Conduct, including the requirement that all GPO members (current and prospective) must adopt the HIGPA Code of Conduct into their business model in order to be a member of the Association.

The HIGPA Code also calls for a Web-Based Vendor Directory. This directory will allow vendors to post product information that is considered new and innovative. In the coming months HIGPA members will design this web site.

B. Industry's Response

The health care group purchasing industry is changing in many ways. Some examples include:

- Use of the so-called "contracting tools," such as sole sourcing and extended length of term, to ensure quality of patient care and cost-effectiveness.

- Enhanced procedures for new and innovative suppliers to access the contracting process.
- Outreach to medical device manufacturers to increase communication and understanding of the issues that are important to them, and new ways to collaborate.
- Greater operational transparency to their members.
- Adherence to the HIGPA Code provisions concerning conflicts of interest, including prohibitions on equity ownership in those companies with contracts, by both GPOs and their contracting employees.
- HIGPA's largest GPOs adopted additional business principles that the HIGPA Code could not address for antitrust reasons.

III. Role of GPOs in the Health Care Supply Chain

Most Americans are unfamiliar with the process health care providers – such as hospitals, nursing homes, and home health agencies – use to purchase necessary medical products and services. Group purchasing organizations are entities that help these providers achieve savings and efficiencies by aggregating purchasing volume and contracting functions to negotiate discounts with manufacturers, distributors and other vendors. Of all acute-care hospitals in the country, 96 percent use GPOs to help reduce their purchasing costs, as well as improve their supply chain management and quality of care. On average, hospitals utilize the services of at least two, and as many as four, GPOs per facility, according to a recent report by SMG Marketing.

The vast majority of products and services that health care providers need are available at a discounted price through a GPO contract – from pharmaceuticals, to medical devices, to dietary resources, to telecommunications services, to janitorial supplies. Industry-wide, approximately 72 percent of all hospital purchases are made via a GPO-negotiated contract, according to a March 2000 study by Muse & Associates. This level of utilization shows that GPOs have proven their ability to offer hospitals a valuable service, while also illustrating the fact that hospitals and other providers have the freedom to make purchases outside of their GPO relationships. Indeed, at the end of the day, the preferences of individual physicians, nurses and other clinicians are what drive purchasing decisions. Hospitals must listen to their front-line health care workers on what products they need to provide the highest quality of patient care, and GPOs in turn listen to hospitals.

GPOs are the agents of health care providers, not suppliers. They operate on behalf of their provider members, and negotiate contracts for products and services that those members desire. In many instances, GPOs are owned by their member-providers and in all instances are ultimately accountable to provide them with substantial value. If a GPO failed in this duty, it

would not survive as a business. GPOs do not purchase products or force the purchase of a particular product. Their value is based solely on offering providers access to desired products at reduced prices. Because most hospitals belong to multiple GPOs, each with a unique set of contracts, hospitals have choices – either choosing among GPO contracts or going directly to the supplier to purchase a particular product.

Group purchasing organizations are not a new phenomenon. They date back to 1909, when the Hospital Superintendents of New York first considered establishing a purchasing agent for laundry services. In 1910, the first GPO was created – the Hospital Bureau of New York. During the last quarter of the 20th century, the importance of GPOs grew as hospitals were faced with rising expenditures due to advances in care and an aging population, as well as declining reimbursement from the government and private sector payers.

A. Importance of GPOs to Hospitals and Other Health Care Providers

As an industry, GPOs save providers between 10 to 15 percent of what they would pay without the benefit of a GPO, according to an October 2002 industry report by Muse & Associates. Even when providers purchase directly from suppliers, they benefit from the GPO contracting process because suppliers who want to sell directly have to price their products to compete with annual GPO contracts. In an era when one-third of all hospitals have negative operating margins, reimbursements from private and public payers are falling, and overall expenditures are rising, this substantial cost saving is of critical importance. Quite simply, hospitals would be in far worse circumstances if GPOs did not exist. Very few hospitals could continue to properly serve their patients if GPOs did not empower them to purchase needed products at considerable discounts.

In addition to being able to get discounts in return for aggregating volume purchases, GPOs also reduce providers' administrative overhead costs, and offer supply chain efficiencies for health care providers in the procurement, standardization, and contracting functions. If group purchasing organizations did not exist, it would annually cost hospitals an average of $353,000 per facility to perform the same cost comparison and product standardization function as GPOs, according to a July 2000 study by a leading researcher at Arizona State University. This figure does not include the volume discounts GPOs provide, but rather benefits that result from taking out of the hospital much of the work that goes into identifying, tracking and performing due diligence on suppliers (*i.e.*, ensuring suppliers meet safety standards and can meet expected product demand), as well as negotiating, maintaining and updating contracts. Without GPOs, providers would have to increase the number of staff and resources to perform the same supply chain functions, essentially further fragmenting a sector of the economy that is already highly decentralized. Such a situation would have enormously harmful effects on providers, given that they do not have the luxury of adding non-clinical staff at a time when they are struggling to afford a sufficient level of staff needed for the direct provision of health care, such as nurses, doctors, and other clinicians.

In addition to cost-savings that result from group purchasing, hospitals and other health care providers are increasingly relying on GPOs for sophisticated supply chain solutions to help manage and streamline the complex system of health care purchasing. Many GPOs offer providers e-commerce solutions that reduce widely recognized inefficiencies in the health care supply chain. The GPO community is also a leader in the effort to reduce medical errors, through such efforts as standardizing product use within a facility to reduce unnecessary variation, educating clinicians on best practices, and leading the drive to institute bar coding for medical products.

GPOs help counter the balance of power in the health care supply chain that includes some of the largest and most successful companies in the United States. With the largest health care manufacturers and distributors reporting more than $360 billion in revenue in 2001 and the largest GPOs representing approximately $55 to $60 billion in purchasing volume, GPOs are increasingly important tools for health care providers to help adequately represent themselves in the health care supply chain.

B. Benefits of the GPO Business Model

Fundamentally, most GPOs are able to offer additional value to their provider-members because much of their operating revenue is generated through earning administrative fees paid by suppliers. This business model of sellers paying fees based upon sales is widely used in many sectors of the U.S. economy, such as the real estate industry. Moreover, buying cooperatives play an important role in other industries such as agriculture. This model has an established history of offering value to the ultimate recipient of a product or service. GPO administrative fees are earned only after providers utilize a contract and, typically, a substantial portion of this fee is returned to the provider-members after a GPO's administrative costs have been covered.

In the mid-1980s, Congress and the Department of Health and Human Services' Office of Inspector General recognized the value in allowing such fees, given that the alternative would be for hospitals to take money away from patient care. Indeed, in 1985 Richard P. Kusserow, the then 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."

What Mr. Kusserow and others recognized was that by allowing GPOs to earn administrative fees, hospitals and health care providers are able to dedicate more financial resources to the direct provision of patient care, such as employing additional doctors or nurses, purchasing the most advanced products, or a host of other goals to support patient care. In what could be the most supportive possible endorsement, the federal government uses many of the same contracting practices as GPOs, including earning administrative fees, for a variety of government agencies, such as the Department of Defense, General Services Administration and Department of Veterans Affairs.

It is also important to note suppliers can realize benefits by working with a GPO. For example, group purchasing offers a consolidated access point to a large group of health care providers dedicated to a common goal. For suppliers, the alternative to negotiating one contract that a large group of providers can access would be to negotiate individual contracts with each provider. A likely result of this would be higher costs for both the purchaser and the supplier as a result of streamlining the contracting and contract administration process. Suppliers would likely have to increase their sales, marketing and legal staff to make contact with each individual provider and to administer multiple contracts, and hospitals would lose the ability to obtain volume product discounts.

Such a system – where GPOs were unable to adequately represent the best interests of providers, and hospitals had to deal directly with manufacturers – would, I believe, favor larger suppliers over both their smaller counterparts and providers themselves. Purchasing contracts would still exist, as they do for any business, but they would have to be negotiated thousands of different times with each individual provider. This would tilt the marketplace in favor of larger suppliers because they would have a greater ability than smaller suppliers to fund the necessary operations to maintain such an extensive number of contracts. I do not believe this option to be beneficial to any entity in the health care supply chain, be it provider, GPO, or manufacturer.

IV. HIGPA Initiatives

In addition to addressing the Subcommittee's issues throughout 2002 – 2003, HIGPA members have pursued other initiatives of great importance to health care. The following are a few highlights:

A. Disaster Supply Formulary

In joint collaboration with the Association for Healthcare Resource & Materials Management (AHRMM) and the Health Industry Distributors Association (HIDA), HIGPA released results of a landmark, cooperative project on health care supply formulary for disaster readiness in March 2003. HIGPA and the other two associations created health care medical/surgical supply formularies in response to the ongoing issue of readiness for large-scale chemical, biological, radiological, nuclear and explosive (CRBNE) or natural disaster events. In the case of a large-scale event, a hospital may need to meet a community's needs for as long as 24-72 hours before the Federal Emergency Management Agency can provide relief. The formularies provide a starting place to devise a plan that would allow access to adequate medical/surgical supplies when needed. The supply formularies are based on information from multiple hospitals and health care systems. Intended as benchmarks for supply preparedness, the formularies can be customized to fit the needs of each hospital and community by working with internal staff and suppliers.

Like AHRMM and HIDA, the members of HIGPA play an integral role in the health care delivery system and its response to disaster events. The unique position of group purchasing

organizations (GPOs) allows them to communicate directly with hospitals and other health care providers to facilitate the planning and coordination of supplies in the event of a 'large scale' public health tragedy. Specifically, in the moments following the terrorist attacks on September 11, 2001, GPOs, distributors and suppliers (all HIGPA members) cohesively came together so that critical medical supplies could be transported to areas of need—health care providers.

The disaster supply formularies focus on adult and pediatric patient needs and provide a targeted supply formulary for each of the CBRNE events. It should be noted that the formularies do not cover radiology or pharmacy. It is anticipated that those departments will have input and involvement in the planning process and make amendments to these formularies at the hospital level.

B. HIGPA Pharmacy Working Group

In August of 2002, HIGPA created the Pharmacy Working Group in an effort to gather the leading minds of the industry to advise the Association on various pharmaceutical issues. Since the inception of this working group the members have worked on several different initiatives.

The initial project of the Working Group was to discuss pharmaceutical shortages and discuss tactics which could help mitigate these situations. The first component was to develop, from the perspective of GPOs and providers, the attributes of an effective program for pharmacy manufacturers to manage allocation programs when products are in short supply. The Working Group put a significant effort into this project, creating a paper entitled, "Pharmaceutical Manufacturer Allocation Program Attributes," which was endorsed by HIGPA's Board of Directors. This document has been forwarded to a HIGPA sister association, the Healthcare Distribution Management Association's (HDMA) "Drug Availability Task Force" (DATF). The DATF's goal is to publish a joint statement with HDMA, HIGPA and other organizations and industry groups concerning ways to alleviate and manage drug shortages. This document will candidly outline the contributing factors leading to product shortages and roles that stakeholders play in both the problem and the resolution. It will also focus on communication issues, which have been determined by the DATF to be one of the major requirements of an effectively managed product shortage occurrences.

C. HIGPA's Industry Research – GPOs Offer Value To Health Care Providers

For years, GPOs operated below the radar. This Subcommittee forced our industry to perform an evaluation of the benefits GPOs claimed they offered health care providers. Not surprisingly, this assessment supported the industry's claims.

According to a May 2003 Lewin Group research study on the health care group purchasing industry, GPOs provide measurable savings as well as non-financial benefits to hospitals and health systems. Lewin researchers reported that GPOs generate savings for health care providers in several ways:

- GPOs offer generally favorable pricing on goods purchased and they seem to influence suppliers to keep prices lower in the market overall;
- GPOs deliver patronage dividends and shareholder distributions; and,
- GPOs reduce purchasing administration expenses for many hospitals and health systems.

The study, entitled *Assessing the Value of Group Purchasing Organizations*, was conducted by The Lewin Group, a health care consulting and research firm based in Falls Church, Virginia. In their report, The Lewin Group conducted three separate analyses which all concluded that GPOs greatly benefit health care providers. The following are highlights of the report.

Interviews with Hospital Executives: Value GPO Relationships for Financial and Non-Financial Reasons

In the first analysis, Lewin researchers surveyed a national sample of hospital and health system supply-chain executives representing 183 hospitals in 33 states and the District of Columbia. The responses showed that these executives value their relationships with GPOs, for both financial and non-financial reasons.
Significant findings include:

- U.S. hospital and health system supply chain executives estimate that GPOs save their institutions an average 10.4 percent on supply costs, which includes price savings on goods purchased through GPOs, patronage dividends received from GPOs, and labor costs avoided by using GPOs.
- Ninety percent of hospital executives surveyed purchase between 60 and 90+ percent of their products on GPO contracts.
- Smaller hospitals or hospital systems typically purchase 20 percent more supplies through a GPO than a larger hospital system because of the cost savings. Larger hospital systems sometimes can negotiate on their own for better pricing using the GPO price as a base.
- Future reliance on GPOs will continue to be strong—with close to two-thirds of hospitals indicating an expected increase in purchases through GPO contracts.
- Approximately nine out of ten (87 percent) hospital and health system executives' responses indicated the absence of GPOs would lead to higher prices of between 10 and 35 percent for medical supplies—either industry-wide or within their own organizations.

- GPOs offer flexibility and commitment with contracts. Nearly 85 percent of respondents stated that they are not subject to a minimum level of compliance on GPO contracts.

- Based on the average number of full-time hospital staff the respondents said would be needed to supplant GPO services, if GPOs did not exist, Lewin researchers estimated that the direct costs of adding a purchasing staff would amount to $198,000 per organization.

- GPOs have helped to create a "Wal-Mart effect" in the health care supply chain, which means the GPO's best price makes prices lower for products not on GPO contract. An overwhelming four out of five respondents (82 percent) indicated that GPOs were effective in lowering medical supply prices on all or some items.

- In addition, non-financial services, such as professional education and technology assessment, contribute to the value of a hospital joining a GPO, over and above financial savings.

Those interviewed for this analysis were drawn from a random sample of purchasing executives representing hospitals and health systems across the nation. The results were compiled by researchers who solicited the following information: nature of GPO membership and participation, extent of savings on the costs of hospital goods by product type, additional rebates/discounts made available to GPO members, and the extent of non-financial value by type of service provided.

Comparative Pricing Study: Hospital GPO Contracts Produce Savings for Medical/Surgical, Laboratory and Pharmaceutical Supplies

In the second analysis, Lewin researchers compared GPO and non-GPO pricing across a subset of product models within three major product categories—medical/surgical supplies, laboratory products and pharmaceutical supplies—to estimate the dollar savings obtainable by hospitals through GPO contracting. The researchers concluded that the use of GPO contracts by health care providers saved money across all three product categories.

Significant findings include:

- Providers purchasing a set of top-selling medical/surgical, pharmaceutical and laboratory products from GPOs at the best price and the base price could save 26 to 17 percent, respectively. In many instances, providers contracting with GPOs received better prices regardless of whether purchases were made at best or base tier levels.

- Of all categories, pharmaceutical products had the smallest variation and laboratory products the highest variation between best and base tier, and non-GPO pricing.

- Providers purchasing 100 units of the selected pharmaceuticals at either base or best price could achieve overall cost savings of about 16 percent compared to wholesale acquisition cost.

- Purchasers of 100 units each of the products in the laboratory sample through a GPO contract could realize cost savings of 60 percent at best price and 10 percent at base price.

- Medical/surgical supplies purchased at 100 units of each could achieve cost savings of approximately 42 percent at best price and 29 percent at base price.

Efficiency Analysis: Hospital GPO Participation Yields Savings of up to 11 Percent

In the third analysis, to quantify the cost savings associated with the use of GPOs, researchers compared reported costs between hospitals relying on GPOs and those not using GPOs. Focusing on three classes of purchases—materials management, laboratory supplies and pharmacy products—the Lewin researchers found that participation in a GPO is associated with substantially lower hospital costs per case, yielding savings between eight and 11 percent. Of the hospitals in the national Medicare database of hospital costs that Lewin surveyed, those that participated in a pure GPO for all three categories saved $7.4 billion in total supply expenses.

Clearly the Lewin report demonstrates both the financial and non-financial benefits that group purchasing organizations bring to health care providers. Three separate analyses reach the same conclusion that the presence of GPOs in the health care marketplace is extremely valuable to hospitals and other health care institutions. GPOs value to health care providers is even more critical now then ever before. As hospitals' costs continue to rise due to lower Medicare reimbursement, implementation of federally mandated regulations, such as HIPAA, and increases in malpractice insurance and staffing costs, hospitals and other providers must be able to manage their expenses more efficiently and GPOs provide this critical service. Because non-labor costs comprise a sizable portion of a hospital's budget, group purchasing is a highly effective mechanism to control such expenses and, thus, to enhance a hospital's ability to manage its hard-pressed finances.

D. Health Care Providers Agree – GPOs Provide Benefits

Recent reaction by California health care providers in opposing California State Senate legislation (State Senate Bill 749), which attempts to weaken the GPO business model, highlights greatly the importance of GPOs to providers. Individual health care providers and the state hospital association, the California Healthcare Association, wrote and called state senators to state their opposition.

Below are excerpts from these letters:

Huntington Hospital, Pasadena, CA
Stephen A. Ralph, President and CEO
May 14, 2003

"The bill [SB 749] would restrict my organization's ability to purchase supplies in the most cost-effective manner and could ultimately cause us to pay more for the supplies we buy. If this bill were enacted, our supply costs would go up by at least $733,000 annually...Supplies represent a significant portion of our overall operating budget, second only to labor costs, and controlling supply costs through effective negotiations and efficient supply chain management practices is extremely important to maintaining quality health care. To do this, our not-for-profit health care organization works with group purchasing organizations (GPOs), which aggregate the purchases of hundreds of other community-based hospitals in California and across the nation to negotiate better supply contracts on our behalf. Industry studies have shown that GPOs provide greater savings on purchases than hospitals could obtain on their own, although each organization ultimately determines how and when it uses GPO services...If SB 749 restricts certain contracting practices of GPOs, such as sole-source contracting—a practice common in other industries—there is no question that community-owned, not-for-profit health care organizations would pay more for supplies. Only manufacturers would benefit from passage of SB 749."

California Healthcare Association, Sacramento, CA
Martin Gallegos, Senior Vice President and Chief Legislative Advocate
May 19, 2003

"There is a significant savings to both public and private hospitals, running in the millions of dollars, through participation in group purchasing organizations. These savings play a critical role in every hospital's effort to control the cost of health care in California. Hospitals and other health care providers voluntarily belong to group purchasing organizations and may choose to purchase a product through a competing group purchasing organization or directly from the manufacturer if the desired product is not available from their particular group purchasing organization. It is important to remember that group purchasing organizations are the agents of the providers of health care and their sole function is to meet the needs of the hospitals and other providers. May 13th amendments to SB 749 would restrict hospitals from negotiating the best price available for supplies being purchased and sets unrealistic limits on vendor remuneration which will certainly drive up the cost of supplies purchased by hospitals and other providers. SB 749 would prohibit the ability of group purchasing organizations to access and pass these savings to hospitals. Also, this bill would increase the cost of health care in California under

the cloak of regulation at the expense of every person who has to purchase health care."

The Corvallis Clinic, Corvallis, OR
Richard L. Eastburn, Laboratory Manager
May 27, 2003

"The competitive pricing structure of products available through our GPO also has the effect of bringing the cost of medical supplies down in those instances where we voluntarily choose to purchase an individual product off contract. It is my fear that the limitations placed upon GPOs in SB 749 will have the unintended consequence of increasing the cost of laboratory and medical supplies. Any increased cost for laboratory and medical supplies will have the added effect of reducing my overall operational budget including reductions in staff resources. Access to group purchasing organizations is an effective and necessary tool used by me to lower my laboratory expenses. Moreover the pooling mechanism of the GPO provides small rural clinics and hospitals access to competitive and cost effective medical supplies that would otherwise be unavailable."

V. Closing

We return to the Subcommittee today not because hospitals are unhappy with the current system of group purchasing, but because some manufacturers aren't able to capture the sales they desire. Indeed, the fact that approximately 96 percent of hospitals use GPOs, including all of the top hospitals as ranked by *U.S. News & World Report* is a testament to the tremendous value GPOs offer providers.

Make no mistake, if Congress weakens the ability of GPOs to negotiate contracts for their provider members, patients will not be better served. Rather, the cost of health care will increase and manufacturers that would like to see GPOs severely weakened will realize greater financial success.

The ripple effect of restricting GPO contracting practices will ultimately affect federal administered health care programs. According to an October 2002 Muse & Associates industry study, implementing additional restrictions on the GPO business model in CY 2002 would have resulted in an increase in expenditures in 2002 for several public health care programs. For every one percentage point decline in the rate of GPO-generated savings:

- **Medicare** – Expenditures would have increased by an additional $540 million to $641 million;
- **Medicaid** – Expenditures would have increased by an additional $395 million to $468 million;

- **Department of Veterans Affairs** – Health care expenditures would have increased by an additional $61 million and $73 million; and,

- **Department of Defense** – Health care expenditures would have increased by an additional $36 million to $73 million.

Providers, payers and ultimately, consumers will pay more for products and services purchased through GPOs if their ability to negotiate on behalf of their providers is curtailed by additional restrictions on the GPO contracting processes. Imposing such restrictions as taking away the essential contracting tools available to GPOs to get the best deals on products for their members would tilt the marketplace in favor of manufacturers and have a negative impact on pricing, discounts, and savings that GPOs attain for their member providers.

Some believe the current GPO examination is an antitrust issue. Hovenkamp, a leading antitrust expert argues that, "GPO group purchasing is a socially beneficial, pro-competitive activity that reduces costs by enabling sellers to bid for high volume sales." Additionally, in statement number 7 of the Department of Justice and Federal Trade Commission's "Statements of Antitrust Enforcement Policy in Health Care," it says health care joint purchasing arrangements "allow the participants [health care providers] to achieve efficiencies that will benefit consumers [patients]."

This is not an antitrust issue. Over the last 40 years the purpose of antitrust policy has been to protect consumer welfare, not competitors – such as medical device manufacturers represented on the panel today. GPOs enhance consumer welfare for their member health care providers by enabling hospitals, community clinics, nursing homes, surgical centers, oncology centers, blood centers, home health care and other providers to save money and help hold down health care costs. In addition to saving money, GPOs provide other services, such as contract negotiation, contract management, market surveying, and product evaluation that their members cannot perform as efficiently.

What we are talking about here is a health care policy issue: are patients getting the best products at the best prices? And they are. I urge members of this Subcommittee to act with caution and not weaken a crucial mechanism that helps providers reduce their purchasing costs which allows them to commit more financial resources to patient care.

Given that group purchasing empowers providers to negotiate discounts from suppliers at virtually no cost to those providers, GPOs are the real untold success story in health care.

Thank you.

Appendix A: HIGPA Code of Conduct Principles, adopted July 24, 2002.

Appendix A
Testimony of HIGPA President and CEO
Robert Betz, Ph.D.

HIGPA'S Code of Conduct Principles

Adopted by:
The Health Industry Group Purchasing Association
July 24, 2002

HEALTH INDUSTRY GROUP PURCHASING ASSOCIATION

CODE OF CONDUCT PRINCIPLES

INTRODUCTION

Hospitals and other health care providers have one principal objective: providing high quality care at an affordable price. Achieving this objective is always difficult, but it is particularly challenging now given a steady rise in the costs of health care items and services, and a sharp decline in payor reimbursement levels.

Group purchasing organizations (GPOs) — which enter into contracts with suppliers on behalf of their provider-members — help providers achieve their objectives of providing quality, affordable health care. GPOs do this in several ways. Most importantly, GPOs leverage purchasing power. That is, GPOs represent large numbers of providers and, as such, are able to negotiate lower prices with suppliers for a particular item than most individual providers, acting on their own, generally could.

GPOs also help their members avoid certain costs. For example, the process of procuring items and services — defining institutional needs, identifying quality products, preparing requests for proposal, analyzing responsive bids, and negotiating contract terms — requires specialized personnel, and is both time consuming and costly. GPOs, which are funded in large part by the fees that they receive from suppliers, are able to furnish those procurement services to their members at a minimal, or no, cost.

The services GPOs provide are of critical importance, especially during an era when providers are faced with a wide-range of challenges that put added constraints on the financial well-being of providers. The challenges include:

- More than 40 million Americans without health coverage;
- Severe hospital and health facility workforce shortages;
- Increasing administrative and regulatory burdens;
- Serious challenges in health care liability insurance;
- Skyrocketing costs for many critical new health care products and services;
- The increasing need for standardization of care and product use to improve patient safety, eliminate adverse events and reduce supply costs;
- Reimbursement systems that erect barriers to full deployment of new drugs and technologies;
- Rising costs and declining reimbursement; and
- A new emphasis on readiness in the wake of September 11.

In rising to these challenges, health care providers have pursued strategies to assure the highest level of uninterrupted care for their patients. At the same time, health systems have an obligation — imposed by public and private payers of care — to deliver such services in the most efficient,

cost-effective manner possible. In recognition and appreciation of this obligation, now more than ever before, health systems need access to the cost-saving tools and resources of group purchasing to manage growth in health care costs.

The Health Industry Group Purchasing Association (HIGPA) — in consultation with its member organizations — has prepared these Code of Conduct Principles to help ensure that providers have access to group purchasing organizations that offer necessary services at the lowest possible cost.* The principles cover several areas, including legal compliance, disclosure of vendor payments, conflicts of interest, product innovation, and a diverse manufacturer base with access to the GPO contracting process.

The organizations within HIGPA recognize that cooperation among health care providers is critical to ensure that patients' best interests are always served. Therefore, we collectively affirm our commitment to the following initiatives aimed at assuring patients' receipt of the highest quality care.

HIGPA's GPO Members are committed to observing these Principles, and to implementing company-specific compliance policies and procedures based upon each GPOs unique business structure and relationships. The Principles set forth below underscore the group purchasing industry's commitment to improving health care and advancing technological innovation at the most manageable cost to providers of care and their patients. These initiatives are designed to assure the operation of a thriving, innovative and competitive health care marketplace. Each GPO shall, at a minimum, incorporate these principles into its own Code of Conduct. Further, each GPO shall be committed to the full implementation of these Principles and shall not take any action that would be contrary to the intent and purpose of these Principles.

* These principles were developed through collaboration of HIGPA members and other trade association and industry members. The adoption of these principles affirms the best practices within the industry. Adoption of these principles reflects each GPO's commitment to the highest standards and is not a reflection upon any individual company's past actions or programs.

I. Principles

A. Compliance with Applicable Laws

Each GPO shall comply with applicable laws. Each GPO shall stay abreast of changes and new developments in the law and provide compliance training, guidance and education regarding applicable laws for directors, officers and employees.

B. Conflict of Interest Policies

1. *GPO Employees*

a. Each GPO shall implement internal policies to require that employees who are in a position to influence the GPO contracting decisions do not accept any gifts, entertainment, favors, honoraria or personal services payments (other than those of Nominal Value) from any Participating Vendor.

b. Each GPO shall implement internal policies to require that none of its employees who are in a position to influence the GPO contracting decisions for Participating Vendors have an Individual Equity Interest in such Participating Vendors.

2. *GPO Non-Employee Officers, Directors, or Advisors*

a. Each GPO shall implement internal policies to require that any non-employee officer, director, or member of an advisory board of a GPO, in a position to influence the GPO contracting decisions, who accepts any gifts, entertainment, favors, honoraria or personal services payments (other than those of Nominal Value) from any Participating Vendor discloses such transactions to the appropriate governance body and is recused from any negotiations or decisions relating to such Participating Vendor.

b. Each GPO shall implement internal policies that require that any non-employee officer, director or member of an advisory board or body of a GPO discloses Individual Equity Interests in any Participating Vendor to the appropriate governance body and is recused from any negotiations or decisions relating to such Participating Vendor.

3. *GPO Corporate Equity Interests*

a. Each GPO shall implement internal policies ensuring that the GPO does not have any Corporate Equity Interest in any Participating Vendor of Clinical Products or Services, unless the acquisition of such Corporate Equity Interest demonstrably benefits the GPO's Members by creating a source of a Clinical Product or Service where there is otherwise no other source, or very limited sources.

b. Each GPO that has a Corporate Equity Interest in a Participating Vendor shall disclose such equity interests to Members in writing. Each GPO in which a Participating Vendor has a Corporate Equity Interest shall disclose such equity interest to Members in writing. Such disclosure should be made (a) at the time the Corporate Equity Interest is obtained if the GPO already has a contract with the Vendor or (b) at the time the GPO enters into a contract with the Vendor if the GPO does not already have a contract with the Vendor, and in each case, at least annually thereafter. GPOs shall also publicly disclose such Corporate Equity Interests.

c. Each GPO that has a Corporate Equity Interest in a Participating Vendor will impose no obligation, commitment or other requirements or restrictions that in any way obligates any Member to purchase goods or services from such Participating Vendor.

C. Member Relations, Product Evaluation & Vendor Grievances

GPOs shall be committed to identifying and making available to Members innovative products and technologies in order to promote high quality and cost-effective health care, and to the free exchange of information relating to clinical, safety and technological and other innovations within the industry. Toward that end, each GPO shall incorporate the following principles in its contractual and business relationships with Vendors and Members:

1. *Member Communications & Relationships with Vendors*

a. Each GPO shall implement its policies and contracts in a manner that permits its Members to (a) communicate directly with Vendors, including Vendors that do not have current contracts with a Member's GPO, (b) assess Products or Services provided by a Vendor that does not have a contract with the GPO, and (c) purchase Clinical Preference Products or Services directly from Vendors that do not contract with the GPO.

b. Each GPO shall implement a contracting process that (a) informs potential Vendors of the process for seeking and obtaining contracts with the GPO and (b) provides any and all interested Vendors with the opportunity to solicit contracts, including but not limited to posting such information on a GPO's website and promptly responding to Vendor inquiries regarding contract opportunities.

2. *Innovative Product Evaluations*

Each GPO shall individually engage in or otherwise participate in processes and programs that routinely evaluate and provide opportunities to contract for innovative Clinical Products or Services.

3. ***Vendor Grievances***

Each GPO shall adopt policies and procedures that endeavor to address Vendor grievances related to access for innovative Clinical Products or Services.

D. Use of Contracting Tools

The goals of the GPO contracting process include promoting quality of patient care and achieving price savings and cost reduction for Members. In order to better achieve those ends, GPOs seek to foster competition among Vendors. To that end, GPOs have contracting tools that include sole source contracting, commitment level requirements, contract length and multi-product line discount arrangements. GPOs should use these tools either alone or in combination only in contracting arrangements that achieve the foregoing goals. These goals are most important in relation to Clinical Preference Products or Services. To the extent that multiple contracting tools are used in the contracting process, each GPO shall consider the following factors in each contractual arrangement to achieve the aforementioned goals: market share of the Participating Vendors, the size of the GPO, the number of Vendors available to provide the relevant product or service, ability of the Participating Vendor to meet the needs of the GPO's Members, and the occurrence of innovation in the relevant product or service category.

E. Compliance, Certification & Implementation

1. ***Compliance Officer***

Each GPO shall designate a compliance officer who will be responsible for overseeing compliance with the Code of Conduct adopted by the GPO and the fulfillment of the GPO's reporting requirements.

2. ***Certification***

The management of each GPO member of HIGPA shall certify annually to HIGPA that they are in compliance with the principles. HIGPA will publish an annual report identifying those HIGPA members that have certified their compliance. This certification shall constitute a requirement for membership in HIGPA.

3. ***Implementation, Transition & Updating***

a. Each GPO shall adopt a transition plan supervised by its compliance officer in keeping with these principles in the event (a) an entity becomes a Participating Vendor to a particular GPO, (b) an employee (i) is in a

position to influence the contracting decision for Participating Vendors and currently has an Individual Equity Interest in such Participating Vendors or (ii) is hired or transferred to a position in which the employee would influence the contracting decision for Participating Vendors and has an Individual Equity Interest in such Participating Vendors, or (c) other situations arise to which these principles apply. Each GPO shall seek regular, periodic and timely disclosure of information covered by these conflict of interest principles by directors, officers, employees and advisors.

b. HIGPA shall assess and update the principles consistent with newly identified best practices and as business practices change to ensure that the goals of avoiding conflicts of interest and promoting competition continue to be achieved.

F. Reporting & Education

1. ***Industry-Wide Survey***

To promote competition and to evaluate on an ongoing basis the benefits of group purchasing, HIGPA will evaluate and implement, consistent with the antitrust laws, periodic surveys and aggregate reporting of industry-wide information relating to value through cost savings and administrative efficiencies of GPO relationships.

2. ***Web-Based Vendor Directory***

In order to foster innovation, HIGPA, with the support of its GPO members, shall make available a web-based directory where Vendors can post product information, including information about products that the Vendors consider to be new and innovative.

3. ***Educational Programs***

HIGPA shall coordinate the development and implementation of industry-wide educational programs focusing on new developments related to clinical innovations, contracting processes and programs, patient safety, public policy, statutory and regulatory requirements and best practices regarding compliance and Code of Conduct principles. As part of this process, the industry will draw upon representatives of GPOs and any Vendors to promote processes and programs to assure availability of new and innovative products to Members through the GPO contracting process.

G. Disclosure of Vendor Payments

1. ***Written Agreement***

Each GPO shall have a written agreement with each Member or Member's agent that authorizes the GPO to act as a purchasing agent to negotiate contracts with Vendors to furnish goods or services to each Member.

2. ***Disclosure of Acceptance of Payments***

Each GPO shall disclose in writing to each Member or Member's agent that it receives Payments from Participating Vendors with respect to purchases made by or on behalf of such Member.

3. ***Disclosure of Payments Related to Purchases***

Each GPO shall annually report, or cause to be reported, to each Member or Member's agent the amount of all Vendor Payments received with respect to purchases made by or on behalf of the Member.

4. ***Disclosure of Payments Not Allocable to Actual Purchases***

Each GPO shall annually report, or cause to be reported, to each Member or Member's agent the amount of Payments received pursuant to a Vendor contract that was utilized by that Member, but is not allocable or otherwise reported with respect to the actual purchases of that or any other Member.

H. Safety, Cost-Reduction & Clinical Comparability

GPOs shall support programs and processes, such as displaying Universal Product Number ("UPN") or machine-readable bar codes at the unit-of-use level, or other programs and processes that provide for clinical comparability and improve and promote patient safety and supply-chain cost reduction.

I. Diversity

GPOs shall offer or participate in programs that promote diversity among Vendors to include women and minority-owned Vendors.

II. Definitions

A. **"Clinical Preference Products or Services"** shall mean those Clinical Products or Services which require substantial training to learn to use and which have a demonstrable effect on patient care outcomes. Accordingly, they are products or services for which a provider has a particular preference based on factors such as the provider's training and

experience, the performance or functionality of such products in a clinical setting and patient clinical outcomes.

B. **"Clinical Products or Services"** shall mean products or services used by providers directly in the provision of health care services to patients.

C. **"Corporate Equity Interest"** shall mean securities, options, warrants, debt instruments (including loans), or rights to acquire any of the foregoing.

D. **"GPO"** shall mean any entity that as all or part of its business activities is authorized to act as the agent of a provider of health care services to enter into contracts with Vendors ("Vendor Contracts"), pursuant to which Vendors agree to sell or furnish goods or services consistent with the terms set forth in the Vendor Contracts. GPOs do not typically take title to products.

E. **"Individual Equity Interest"** shall mean securities, options, warrants, debt instruments (including loans), or rights to acquire any of foregoing, provided, however that the term shall not include: (a) interests in mutual funds or (b) interests held in a blind trust in which all investment decisions are independently managed by a third party and the existence and trust terms are fully disclosed to the appropriate governing body to ensure that the neutrality of the GPO contracting decisions are protected.

F. **"Members"** shall mean any provider of health care services to patients that has an agreement (directly or through an authorized agent) which authorizes the GPO to act as the provider's purchasing agent to negotiate contracts with Vendors to furnish goods or services to the provider.

G. **"Nominal Value"** shall mean any item, service or other thing of value (not including cash or cash equivalents) that does not exceed $50 per instance or $100 in any given calendar year. Any item, service or other thing of value that costs $10 or less shall not be counted toward the $100 annual limit.

H. **"Participating Vendor"** shall mean, with respect to a particular GPO, a Vendor that has a contract or submits a formal bid or offer to contract with such GPO to provide goods or services to the GPO's members.

I. **"Payments"** shall mean all payments by a Vendor of goods or services to a GPO as part of any agreement to furnish goods or services to Members.

J. **"Vendors"** shall mean manufacturers, distributors, suppliers or other entities that sell goods or services to Members.

Statement of Gary Heiman
President and CEO, Standard Textile Co.
to the
U.S. Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights
July 16, 2003

Chairman DeWine, Ranking Member Kohl, and distinguished members of the subcommittee. Thank you very much for inviting me here today to provide my perspective as a vendor of hospital supplies who has extensive experience with the hospital supply chain.

I am the president and CEO of Standard Textile Company in Cincinnati, Ohio, a closely held, family-owned company that was founded by my grandfather in 1940. In the United States, we employ about 1,200 people, including 350 employees in Ohio and 600 workers in Georgia, where we have three manufacturing plants. Two of those plants – Thomaston Mills in Thomaston and the King Mill in Augusta – we rescued from bankruptcy proceedings by other companies.

Standard Textile produces reusable products for health care facilities ranging from surgical packs and gowns to incontinence products and bed sheets. We also supply some of the other fabrics that you see around hospitals, such as window coverings, cubicle curtains and upholstery fabric.

We began working with hospital group purchasing organizations about 20 years ago, competing against much larger companies – for example, Baxter International. Today, we have contracts with virtually all the GPOs, including AmeriNet, Broadlane, Consorta, Kaiser, MedAssets, Novation and Premier. About 75 percent of our revenue is generated through GPO contracts.

Using GPOs has helped us to reduce costs and increase the efficiency of our marketing, sales and customer service operations. Our bidding department used to be huge; today it has only three people. We have been able to cut our sales force by 15 to 20 percent. And while our prices have dropped substantially under GPO contracts, we have the benefit of much greater volume. Today, we are still a medium-sized company competing against Goliaths, but we are seven times larger than we were 20 years ago.

I'd like to give you one example of how GPOs helped us as a medium-sized manufacturer … and also helped hospitals to adopt a technically innovative product that greatly enhanced safety and efficiency.

In 1990, Standard Textile developed a patented, proprietary fabric that we use to manufacture surgical packs and gowns and sterile wraps, a Class II medical device, for operating rooms and other clinical procedures. This fabric has greater barrier resistance to fluids and viral penetration, and, as such, enhances safety. It's also more cost-effective

and environmentally friendly than disposable products, because it creates less medical waste.

When we developed these products, VHA (one of Novation's owners) already had a contract for disposable products with a much larger, publicly traded competitor, Kimberly-Clark. It would have been easy for VHA to turn down a small company like ours. But they didn't. Not only did they clinically evaluate our products, they brought in a third party – Deloitte and Touche – to analyze our financial model and determined that we could create overall cost savings for hospitals.

Standard Textile doesn't always win the GPO contracts that we bid on. At times, we've been defeated by other companies. As a supplier, we of course never like to lose, but the GPO committees that evaluate these contracts are representative of the hospital industry, are qualified and are fair. We may not always agree with their conclusions, but we believe the process is open, fair and honest.

I can also say that whenever I have encountered a hospital or clinician who wanted to use my product, regardless of whether it was listed on their GPO contract, I have never had a problem getting it into their hands. They always have the freedom to buy directly from manufacturers.

In addition to being a supplier, I can also speak from a hospital perspective about the benefits of GPOs. I am the board chairman of the Jewish Hospital of Cincinnati, a medium-sized, tertiary, not-for-profit hospital with about 200 beds … and growing. In 1998, the hospital was running an annual deficit of approximately $5 million. To help reverse that situation, the hospital made many significant operating changes, including greater utilization of GPOs to assist in managing costs. This year, I am pleased to say that the hospital will report a net gain from operations of $12 to $13 million.

I have been following with interest the recent discussions about GPOs. I think it's commendable that this subcommittee has taken an active interest in the topic, and I believe many of the changes in the GPO industry since your first hearing have been positive.

But speaking as both a hospital supplier and a hospital board chairman, I think the existing GPO system brings enormous value to the health care system, and I hope it remains that way.

Again, thank you very much for inviting me to share my views at this hearing, and I welcome any of your questions.

Gary Heiman
President and CEO
Standard Textile Co.
Cincinnati, Ohio
Phone 513 761-9255
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Statement of

Mr. Said Hilal

President and Chief Executive Officer
Applied Medical Resources Corporation

Before the Subcommittee on Antitrust
of the Judiciary Committee of the United States Senate

July 16, 2003

I. INTRODUCTION

I am Said Hilal, and I offer this statement on behalf of Applied Medical Resources Corporation, a medical device company that has been committed to a motto of "Better Medicine, Better Value" from its founding in 1987. We have achieved that combination through innovations in technologies and practices. Based on an independent national study, in 2002, *Inc. Magazine* identified Applied as one of the top 50 most innovative companies in the United States with revenues less than $100 million.

Applied invests heavily in entirely new technologies as well as more efficient and less expensive ways to implement established technologies. True to the "Better Medicine, Better Value" motto, both forms of innovation improve the quality and affordability of health care. We are absolutely committed to having Applied's products incorporate advanced and unique technologies and, at the same time, considerable savings over competitors' products – in many cases we offer as much as 40 percent to 60 percent savings.

Our company offers fourteen different lines of innovative products used primarily by surgeons. One of our product lines is "trocars." Trocars are tubes with openings covered by advanced seals through which a surgeon inserts surgical instruments while maintaining pressure within the body cavity of a patient undergoing "minimally invasive" surgery. This type of surgery, using trocars, also is referred to as "keyhole" surgery, because the hole made by the trocar is about the size of an old-fashioned keyhole. Typically, the trocar provides a half-inch or smaller aperture for surgical instruments and a television camera to negate the need for large, open

incisions and the lengthier recovery time typically associated with large, open incisions.

Because surgeons use our products, our products are sold to hospitals. We therefore are very much affected by and interested in the practices and policies of hospital Group Purchasing Organizations ("GPOs"), especially Premier and Novation. If GPOs were fulfilling their original purpose – enabling hospitals to acquire the best products at the lowest cost – there would be no need for these hearings. Unfortunately, GPOs have mutated from their intended role as collective bargaining purchasing agents, acting on behalf of member hospitals, into sales agents protecting the interest of a select group of large and dominant multi-product suppliers of medical devices. This mutation is the product of incentives built into the current business relationships between GPOs and those dominant suppliers. By becoming economically dependent on payments from a few dominant sellers, the GPOs essentially have become commissioned sales representatives for these dominant suppliers, boasting their ability to "move market share." The GPOs inevitably allow, adopt and endorse the suppliers' use of bundling and related practices to freeze out innovation and cost savings of specialized suppliers like Applied, and thus negatively impact the quality and cost of health care for all Americans.

Applied repeatedly has been advised by hospitals that, even though they believe that Applied's products are superior to those of dominant suppliers such as Johnson & Johnson, they are compelled to purchase inferior and more costly products from the dominant supplier who could inflict serious economic penalties on the hospitals through a combination of GPO connections and bundling practices. In other cases, hospitals have been prevented by a GPO's threats of economic sanctions from even trying Applied's products. Some of these instances are described below.

Applied enthusiastically supports the efforts of this subcommittee to address these problems and to encourage others in the federal government – particularly the antitrust enforcement officials at the Federal Trade Commission and the Department of Justice – to pay attention to them as well. We also appreciate the efforts of members of this subcommittee to bring these issues to the attention of the Secretary of Defense.

In recent months, perhaps in anticipation of this hearing, some GPOs have shown improved willingness to purchase products based on their merits and their value. This, however, may be temporary. Congress needs to change

the rules governing GPO and dominant supplier relationships to ensure that GPOs are able and willing to purchase the best products and value from vendors, large and small, without fearing the continuing ability of dominant suppliers to inflict economic penalties on them and their hospitals. To effect meaningful changes, enforcement and additional legislation will be required, to eliminate sole-source, bundling and minimum purchase requirements that currently handicap and blind collective purchasing.

In the following pages, we will describe our company, its experiences, and why we have come to these conclusions.

II. APPLIED IS AN INNOVATOR IN SEVERAL SURGICAL FIELDS

Founded in 1987 and headquartered in Orange County, California, Applied designs, develops, manufactures, licenses, markets, and sells fourteen lines of specialized devices for cardiovascular, vascular, laparoscopy, urology and general surgery. Our products are 99 percent manufactured in the United States.

At its inception, Applied recognized that the national trend of rapidly escalating healthcare costs would reach 20 percent of GDP within a decade. This presented a serious national problem and an opportunity for innovative companies that could affect improved clinical and financial outcomes concurrently. Accordingly, Applied's business strategy has been to develop products and practices that enhance performance while reducing the cost of products and procedures. Since 1988, Applied has evolved as a prolific developer of products and technologies that fulfill this dual requirement, resulting in 380 pending and issued medical device patents worldwide.

Our products have been safely, successfully, and satisfactorily used in many hospitals throughout the globe and for many years. Hundreds of thousands of our devices have been sold and used as testament to their acceptance and performance. Our outstanding record with the FDA also attests to the quality and performance of our products.

Applied maintains one of the highest commitments to innovation and quality in its industry. Over the past decade, Applied has spent 22 percent of its revenues on R&D, resulting in impressive clinical results and financial savings. One example of the results of Applied's investment is our Acucise® product, which is used to treat ureteral strictures. Peer-reviewed clinical

papers attest to the fact that the Acucise® product eliminated hospital stay, reduced costs by $14,000 per procedure and replaced a 210-minute surgery under anesthesia with a 42-minute minimally invasive procedure under sedative and achieved a hundred percent success rates in secondary procedures. Applied also has introduced new generations of atraumatic, minimally invasive surgical devices for occluding blood vessels and grasping tissue, and has eliminated sometimes life-threatening latex from its products.

Applied's trocar seal technologies set the standard for seals used in minimally invasive surgery and are utilized in the majority of trocars currently on the market. The Applied trocars were the first to accommodate instruments with a wide range of diameters to traverse the seal without adaptors, leakage or excessive friction. The patented seal technologies developed by Applied have resulted in real improvements in patient care in minimally invasive surgery by reducing time in the operating room and improving surgeon control during the procedure.

More recently, Applied introduced the GelPort™ product in the rapidly expanding field of minimally invasive hand access surgery. We were awarded *Innovation of the Year 2002* by The Society of Laparoendoscopic Surgeons. Applied offers the GelPort™ product in a kit including Applied's trocars and clip appliers, instruments used to close off blood vessels and arteries in minimally invasive surgical procedures. And, this year, Applied introduced the Separator™ product, a new generation of access products that uniquely separates the abdominal wall layers along their natural lines without the use of traumatic plastic or metal blades.

Despite these innovations, Applied has been prevented from obtaining more than 1 to 2 percent market share based on dollars (or 2 to 3 percent based on units sold) of the $300 million U.S. trocar market. This limited success is the result of practices that arise from the anticompetitive and exclusionary economic relationships between GPOs and the dominant multi-product vendors with which Applied attempts to compete. The dominant supplier in the trocar market, Johnson & Johnson, has and exercises the power to exclude Applied and its products and to exact penalties from hospitals that seek to purchase Applied's products.

In addition to using GPO fees in excess of the statutorily authorized 3 percent cap by disguising them as non-administrative fees or private label agreements, some of the tools used by the dominant supplier and GPOs to

effect this exclusion include: bundling of unrelated products; sole-source contracting; high minimum purchase requirements to obtain discounts; prohibition of evaluations of competitive products; delayed payment of incentives; and forfeiture of rebates for being "out of compliance" with the GPO contract.

The practice of tying or bundling purchases of trocars to purchases of sutures and other minimally invasive surgical products is especially anticompetitive because of Johnson & Johnson's market share. Johnson & Johnson, through two subsidiaries, has an 80 to 85 percent share in the suture market, a 65 to 70 percent share of the trocar market, and an estimated market share for other minimally invasive surgical products exceeding 50 to 60 percent. Johnson & Johnson and its two subsidiaries have joint sole-source contracts with Novation, Premier and other GPOs, and thus have tied up the market.

As a result of these market conditions, patient care is suffering because clinicians are blocked from the best product and value for their patients. And, despite Applied's diligent efforts to persuade GPOs to make Applied's products available to their member hospitals and save up to 40 percent or more, Applied's products remain unavailable in GPO-affiliated hospitals and the costs of trocars and certain other minimally invasive surgical products are maintained at artificial, supra-competitive prices.

III. CLINICIANS PRAISE AND PREFER APPLIED'S TECHNOLOGY

Applied offers a minimally invasive surgery abdominal access system that is advanced, complete, and interchangeable. It comes in disposable or reusable systems, and consists of advanced ports, cannulas, obturators, separators and seals. All configurations can be combined and interchanged. In the minimally invasive surgical devices field, Applied also offers clip appliers to close off blood vessels and arteries, and, as noted above, GelPort™ hand-access devices.

During documented evaluations in hospitals considering Applied's technology, surgeons have ranked Applied's trocars equal or superior to Johnson & Johnson's trocars, which are the only trocars on contract with Premier and Novation. Applied is aware of many customers who would prefer to purchase Applied's trocars if not for the GPO contracts, but they refrain from doing so solely because they have a sole-source GPO contract.

Despite its recognized superior innovation, highly focused sales and marketing efforts, and the 40 percent cost savings, Applied has found that a majority of GPO member hospitals are unwilling even to speak with Applied about Applied trocar and clip applier products. The common given reason is the perceived sole-source contract in place and the fear of falling "out of compliance" with a GPO contract, and thereby risking forfeiture of rebates and discounts on bundled products.

We understand that GPO contracts are held confidentially and not available to hospitals to review and confirm or maximize savings. Hospitals instead depend on the suppliers to estimate and report the cost savings. The analyses conducted by the supplier, however, typically are flawed and purposely intended to mislead the hospital and prevent any conversion to a competitor's product. The ultimate judge of the hospital's compliance with the GPO contract is the sole contracted supplier, who often goes beyond the language of the GPO contract to ensure that the fear works in the supplier's favor.

At no time was this more evident than in May 2002, just after the original hearings held last year by this subcommittee, when Applied launched what we called a "May Day" campaign. We blanketed GPO accounts across the country and offered them a trocar kit at 60 percent savings compared to Johnson & Johnson's identical kit. We did not get one single account as a result of that effort. The common reason given was that the hospital had a sole-source contract and they were fearful of being penalized for failing to meet purchase percentage requirements under their GPOs' contracts with Johnson & Johnson. Avoidance of penalties was more important than cost savings or clinician preference.

IV. THE GPOs ARE PREVENTING COMPETITION

In progressive European and other foreign markets that do not have GPO exclusionary contracts, Applied's market share is approximately 15 percent of the total available trocar market. In 2002, Applied's sales of trocars in those markets grew by approximately 45 percent compared to perhaps 5 percent in the U.S. It is worth noting that 90 percent of our selling and marketing budget is aimed at the U.S. market. However, more than 50 percent of our overall trocar business is generated overseas. This is in stark contrast to the rest of our business, which is at 80 percent U.S. and 20 percent outside of the U.S.

In the U.S., GPOs are the dominant means by which minimally invasive surgical devices are sold to hospitals, who are the dominant users of such devices. Novation in Irving, Texas and Premier in San Diego, California are the two largest GPOs, contracting for about two-thirds or more of hospitals in the U.S. Johnson & Johnson and two of its subdivisions have joint sole-source contracts with each of Novation and Premier.

Setting aside the issue of whether sole-sourcing, bundling, and minimum purchase requirements are appropriate in the first place, leaving the assessment of cost savings to the dominant supplier and the GPOs is a fox-in-the-hen-house problem. One example of Johnson & Johnson's "calculation" of compliance was documented recently. A customer supplied Applied with documents that presented Johnson & Johnson's flawed analysis of compliance with the Premier GPO contract. Exhibit. The first page says that if Applied product is purchased then compliance will fall below 80 percent, and the discount from the list price will drop from 47 percent to 24 percent on Johnson & Johnson's minimally invasive surgery products, including trocars, representing more than a 40 percent price increase. The document also says that there will be a 12.5 percent increase on Johnson & Johnson's suture pricing.

The numbers, however, do not support these "out of compliance" claims. The first page of the document says that the hospital currently purchases 5 percent from competitors. The second page indicates that $586,901 (about $587,000) represents 95 percent of the hospital's purchases under the Premier contract – so 100 percent of purchases is about $618,000. Excluding $94,000 in trocar purchases (see line item in "Current Spend") from the $618,000 total purchases yields $524,000 in trocar and other minimally invasive surgical products purchased under the Premier contract with Johnson & Johnson. Because the hospital then would spend $50,000 purchasing trocars from Applied and continue to purchase another $30,000 or so from other competitors, the total purchases would be about $604,000 ($524,000 + $50,000 + $30,000). $524,000 is 87 percent of $604,000, thus the hospital would be in compliance.

Johnson & Johnson and Premier thus had no basis for threatening to pull the hospital's discount. Still, that is exactly what was threatened using the GPO contract. This is not an isolated instance.

In similar instances, not until hospitals challenged the calculation of compliance and the matter escalated did Johnson & Johnson and Novation

stop beating the "out of compliance" drum. In one specific instance, not until the matter escalated to the President of Johnson & Johnson's subdivision Ethicon Endo-Surgery and Lee Taylor, a Novation Senior Product Manager, was the math accepted to be wrong. Applied now is selling to that hospital.

We are seeing the very same tactics used in government-funded hospitals as well. In one instance, an army hospital in Texas was threatened with loss of discounts from the list price for bundled sutures, trocars and other minimally invasive surgery products under the Federal Supply Schedule in effect until March 2005 if the hospital purchased product from Applied. The army hospital was told that it was at 85 percent compliance and received a warning that erosion of its purchases from Johnson & Johnson to less than 80 percent would cost the hospital discounts as well as rebates directly from Johnson & Johnson.

Even in the few instances when these episodes end with Applied getting business from the hospital, that occurs only after months of delays and sales costs that are far higher, as a percentage of revenue, than are borne by Applied's competitors. While Applied's costs pile up, customers continue to pay twice as much and Johnson & Johnson piles up the profits.

This kind of "raising rivals' costs" strategy is well recognized in the economics literature. It is not economically practical to correct this situation one hospital at a time. The rules need to be changed by legislation to prevent this problem.

In order to give surgeons the opportunity to try Applied's trocars and other minimally invasive surgical devices, Applied has included these products for free in kits containing its unique and highly desired GelPort™ products. Still the fear of penalties for non-compliance under GPO contracts has caused contracting hospitals to discard the free products from GelPort™ kits and then to purchase Johnson & Johnson contract products to replace the discarded products at additional cost to the hospital. The customers literally feared that the free trocars would cause them to be out of compliance with the Novation/Johnson & Johnson contract. Applied has documented at least twenty instances of this product dumping in several states, including Alabama, California, Florida, Massachusetts, Minnesota, New York, North Carolina, Texas and Washington. Such wasteful dumping does not reflect surgeon preference for the competing products but rather simple fear of "out

of compliance" penalties. This waste is especially disheartening because many, if not most, of these hospitals are publicly funded, teaching hospitals.

Outside of GPO-controlled hospitals, where the playing field is somewhat more level, Applied enjoys much more success. The majority (over 60 percent) of Applied's 3 percent of the trocar market comes from hospitals outside of the Premier and Novation contracts. Although Premier and Novation make up over two-thirds of the market potential, they constitute only about 30 percent of Applied's 3 percent market share of trocar customers. Surgery centers, rural hospitals, and VA hospitals make up only 5 percent of the overall market potential, but are responsible for over 20 percent of Applied's current trocar business. Surgery centers, rural hospitals, and VA hospitals can more freely choose their products, because they are not held to the same unreasonable restrictions on product choice ("compliance requirements") to which the Premier/Novation members are held. Decision makers at these institutions have a clear understanding of the financial and clinical merits of these products and make their business decisions accordingly.

Another example of Applied's success outside of GPO-controlled markets involves the atraumatic occlusion market, in which we sell surgical clips and clamps. In or around 1990, when we entered the market, Baxter had about a 98 percent market share. By the mid-1990s, Applied had nearly 50 percent market share, and now has over 70 percent market share. During the past ten years, we have obsoleted our own product twice in the interest of bringing innovation to patients.

The impact of the dominant supplier/GPO enforcement efforts also can be appreciated by reviewing Applied's trocar business over a seven-year period. In the mid-1990's, Premier and Novation affiliated hospitals represented about 42 percent of Applied's business and Applied had no Premier or Novation contract. Hospitals simply preferred the Applied products and value. Surgery centers, rural hospitals, and VA hospitals then represented 10 percent of Applied's business, which is much closer to their proportion of the total hospital population (5 percent). In the late-1990s, Premier and Novation became more aggressive in enforcing the exclusionary provisions of their contracts. As this effort built up, Applied's share in GPO accounts was obliterated. The GPOs moved market share from Applied to Johnson & Johnson. Applied was forced to concentrate its efforts in the smaller market segments outside of the GPO dominance. Over the last two years, almost 50 percent of Applied's new trocar business has been

generated from surgery centers, rural hospitals, and VA hospitals. These hospitals represent only 5 percent of the overall market potential. Applied's market share continues to decrease in the Premier/Novation affiliated hospitals as the enforcement of compliance requirements continues to exclude other suppliers. In spite of continued investment in innovation, quality, value, and service, the majority of the market is not able to benefit from the latest technology and cost savings offered by Applied. It is clear that the more stringent enforcement by Premier and Novation has created a more limited marketplace. Today, with 4 to 5 times the sales people, the ratio of Applied's business in Premier and Novation member hospitals has been reduced from about 42 percent to less than about 25 percent while in non-Premier/Novation hospitals this ratio has grown from about 10 percent to about 50 percent.

Had Applied been able to compete on a level playing field, we believe that we would be growing faster in the U.S. than we are internationally, where our 45 percent growth rate in 2002 is testament to the power of innovation in a free market. We also believe that the real market price of products offered to GPO members would be considerably lower than the artificially inflated prices currently offered under GPO contracts. We echo the concerns expressed by Masimo Corporation before this subcommittee last year that other young, innovative medical device companies are being excluded from the market and investors are becoming increasingly unwilling to support breakthrough products and companies because of the major supplier/GPO-related threats to investors' opportunity to recoup investments.

V. APPLIED DILIGENTLY HAS TRIED TO GET A GPO CONTRACT FOR APPLIED'S TROCARS

Applied believes that recent changes in Novation's and Premier's responsiveness is a direct result of last year's hearings before this subcommittee. While both Novation and Premier recently have promised to seriously consider putting Applied's trocars on contract, to date neither has put Applied's trocar or other minimally invasive surgical products on contract or agreed to cease enforcement of their sole-source contracts with Johnson & Johnson. We are concerned therefore that Novation and Premier may be extending mere courtesies as opposed to real change. A brief summary of Applied's experiences with Novation and Premier follows:

A. Novation

Until recent months, Applied's efforts to get a contract with Novation were largely ignored. In 2000, Applied was invited to bid on the Novation contract for sutures, trocars and other minimally invasive surgical devices – a $2 billion contract nationwide. Applied offered a $150 price on laparoscopic cholecystectomy kits typically used for gall bladder removal. Johnson & Johnson offered a $250 price for the same kits. Our bid was dismissed. It took months to get an audience with Novation, at which time we were unceremoniously told that we did not have the rest of the products that Johnson & Johnson and Tyco bundled with the trocars. There is no legitimate business justification for bundling the purchase or sale of trocars with sutures; such bundling is obviously designed to exclude Applied's products from competition on the merits. We pointed out that Novation knew we did not offer sutures or bundle at the time we were invited to bid. We asked how we could ever stand a chance of winning the next bid and Novation's answer was: "Perhaps you shouldn't bid."

Having "lost" the 2000 bid, we believed that the three-year contract signed in 2000 would be up for re-bid in July 2003 and Applied would have an opportunity to bid on a new contract. Recently, however, we learned that just one year into the three-year term, Novation and Johnson & Johnson extended the contract by an additional two years without any re-bidding or additional discounts. This was especially alarming because we also learned the contract includes the following additional exclusionary provisions:

- high minimum purchase requirements for qualification for discounts and rebates, e.g., 80 to 95 percent;
- bundling of unrelated products (suture products, trocars and other minimally invasive surgical products);
- bundling of rebates and discounts (four-tier pricing structure with best prices going to hospitals buying 90 percent of their suture products and 80 percent of certain minimally invasive surgical products from Johnson & Johnson, and $750,000 or more in suture products annually – they get an additional 2 percent rebate if they buy 95 percent of suture products and 85 percent of certain minimally invasive surgical products from Johnson & Johnson); and
- prohibition on evaluation of competing products.

The covert extension of the contract yielded Novation members no benefits of which we are aware. Novation members did not secure additional

discounts or lower prices. The contract simply extended Johnson & Johnson's chokehold on a $2 billion market by two years. It is a testament to Johnson & Johnson's power over GPOs and hospitals that these buyers believe that the best prices they can ever get are prices that go up in single digits. In today's economy, buyers should not have to accept price increases as inevitable.

Even more disconcerting is the fact that Novation also bundles rebates for Johnson & Johnson's products with the products of other large suppliers on contract with Novation under the guise of the Novation Spectrum Program. To qualify for 5 to 7 percent in rebates, the Spectrum Program requires members to purchase at least 95 percent of all products from five vendors. While this rebate is paid to the hospital, the hospital must be "in compliance for the full term of the Spectrum Program – through March 2005 – otherwise the hospital risks forfeiture of rebates, even rebates already received by the hospital. We have seen at least one check exceeding $1,000,000.00 from Novation to a Spectrum Program participant. This is no small sum for a hospital to forfeit. The threat of such forfeitures is unreasonably exclusionary and anticompetitive. Such threats have the purpose and effect of canceling the otherwise attractive cost savings that suppliers like Applied can offer to hospitals and their patients.

Late last year, our efforts with Novation on another product met the same fate – rejection. Applied had submitted a bid on latex-free catheters. Even though the bid was unopposed, without explanation, Novation rejected the bid that was offered. They instead chose to award the contract to no one.

Only in the recent months preceding this hearing, and only in response to Applied's repeated direct and indirect requests to speak with Novation, has Novation engaged in meaningful discussions with Applied.

During meetings in late March and then May of this year, Applied asked Novation to terminate the sole-source contract with Johnson & Johnson in which sutures, trocars and other minimally invasive surgical products are bundled and to accept a bid from Applied on trocars. Novation initially refused, but more recently, in June, agreed to entertain a bid on Applied's trocars and a couple of other products. We do not believe that this opportunity would have materialized but for the efforts of your subcommittee to focus attention on these practices. We hold high hopes but as yet have not had any trocar bid accepted. Novation also has rectified the latex-free catheter situation, and we now have a contract on that product.

Unfortunately, we have no understanding from Novation as to whether they will cease sole-source contracts, minimum purchase requirements, bundling, or other anticompetitive practices. They have provided no transparency in this regard. Even if they do award a trocar contract to Applied, i.e., permit multi-source, without cessation of the minimum purchase requirements and bundling, any such contract would be meaningless. We hope that this subcommittee will draft and that Congress will enact legislation putting an end to these practices.

Aside from the bidding, sole-source, bundling and purchase requirement issues, one additional issue concerning Novation that we believe is important to address is its relationship with Neoforma, which operates as Marketplace@Novation as Novation's exclusive e-commerce partner. Neoforma's May 2003 Form 10-Q discloses, "Novation agreed to act as our exclusive agent to negotiate agreements with suppliers to offer their equipment, products, supplies and services through marketplaces sponsored by Novation or HPPI, including Marketplace@Novation." Novation is comprised of the 2,400 members of VHA Inc. and the University HealthSystem Consortium. The Form 10-Q further discloses, "In connection with the initial version of the outsourcing and operating agreement we entered into with Novation, VHA, UHC and HPPI, or the Outsourcing Agreement, we issued approximately 4.6 million shares of our common stock to VHA, representing approximately 36% of our then outstanding common stock, and approximately 1.1 million shares of our common stock to UHC, representing approximately 9% of our then outstanding common stock." Thus, Novation owns at least 45 percent of Neoforma. The Form 10-Q also discloses that Novation's shares may be increased even further if Novation members meet certain performance targets: "We also issued warrants to VHA and UHC, allowing VHA and UHC the opportunity to earn up to approximately 3.1 million and approximately 800,000 additional shares of our common stock, respectively, over a four-year period by meeting specified performance targets. These performance targets are based upon the historical purchasing volume of VHA and UHC member healthcare organizations that sign up to use Marketplace@Novation, which is available only to the patrons and members of VHA, UHC and HPPI. The targets increase annually to a level equivalent to total healthcare organizations representing $22 billion of combined purchasing volume at the end of 2004."

During recent discussions, Novation told us that to get a Novation Supplier Agreement we also must agree to use Neoforma. Applied repeatedly asked Novation not to require Applied to sign a Neoforma agreement as a condition of obtaining a contract. After much discussion, we have agreed that if a member requests to use Neoforma then Applied may accommodate that member. We remain of the belief, however, that Novation should sever its relationship with Neoforma and refrain from further involvement, including funneling business to Neoforma, since these relationships appear to increase costs with no corresponding increase in benefits to suppliers, hospitals, or patients.

B. Premier

Until recently, and subsequent to last year's hearings, Premier had never allowed Applied to submit a bid on any product. Despite repeated efforts, we couldn't get their attention.

In June 2002, Premier endorsed HIGPA's code of conduct, which we believe was a good first step. In August 2002, Premier's CEO Mr. Richard Norling submitted a letter to Senators Kohl and DeWine committing Premier to take additional actions above those under the HIGPA code.

As a result of Premier implementing some of these commitments, in April 2003, we did reach agreement on one product, our GelPort™ hand access product. We remain concerned, however, about serious implementation of these commitments. We understand that Premier shortly will be accepting bids on sutures, trocars and other minimally invasive surgical products. According to its web site, Premier has separated bidding for trocars from bidding for other products. Thus, while they appear to intend to unbundle trocars, they also appear to be continuing to bundle sutures themselves and sutures with certain minimally invasive surgical products. This evidence of only partial compliance with the commitments it made last year shows the continuing power of the major suppliers to deter the GPOs from acting in the best interests of their member hospitals and the hospitals' patients.

Premier and other GPO's will only act in the best interests of their member hospitals when economic incentives and threats to do otherwise are banned. Legislation restoring GPOs to their proper roles as purchasing agents for the hospitals rather than sales agents and market-share movers for major suppliers is necessary if GPOs are to fulfill the purposes for which they were authorized to exist in the first place.

C. Other GPOs

The practices of other GPOs contracting for the one-third of the nation's hospitals not under either the Novation or Premier umbrella should not be ignored. In some instances, the contracting practices of these other GPOs are even more worrisome. For example, in recent months, in response to a customer request, Applied has attempted to get a trocar contract with Broadlane, which contracts for 540 acute care hospitals and another 1,735 sub-acute care facilities. To date, however, Broadlane has been largely unresponsive and refused to disclose to Applied the criteria for obtaining a contract. Applied understands that members must fill out a lengthy request for the GPO to consider Applied's products, yet Broadlane will not tell Applied what the criteria for consideration are. What one Broadlane administrator recently told us is that her job is to drive compliance with their current supplier to 98 percent regardless of cost savings to the member hospitals. We understand that the minimum purchase requirement for Broadlane members is 90 percent.

VI. SOLUTIONS/CONCLUSION

By holding hearings last year and this year and thereby focusing attention on the problems inherent in GPOs' relationships with major suppliers, this subcommittee has made a constructive contribution to the quality and cost-effectiveness of health care. Applied is very grateful for that effort. We urge you to push forward with efforts to draft and enact legislation that permanently reforms behavior in this area and restores GPOs to their proper and constructive role in the procurement process, for the sake of patients and hospitals, healthcare providers, and the continuing competitiveness of innovative U.S. suppliers in world markets. We also urge you to exercise your oversight responsibilities to encourage enforcement of the existing laws by the Federal Trade Commission and Department of Justice and at the same time as you act to strengthen those existing laws.

This nation has led the world in many fields where as capabilities increased, cost decreased, and, as volumes went up, so did availability and choices and competitive spirit. Consumers have more computing power for less, more telephone providers vying for the business unbundled. Local calls can be purchased separate from long distance, international, or cellular services.

But these trends in the economy generally have been frustrated in the markets for medical devices and supplies, where products are

anticompetitively bundled and, as volumes go up, so does the cost. As the devices remain more or less the same, they become more expensive. Prices are contracted as discounts off a list price and suppliers change the list price once or twice a year, hardly ever downward.

My company and I urge you to return free market conditions and fair and open competition to the markets for medical devices and supplies.

Thank you.

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ALNKO S RIVERPARK 7758511606 001

Daren Sox

Kaweah Delta District Hospital Cost Analysis Summary

Currently, KDDH enjoys a 47% discount on EES products on ESD69 (3 price books back).

By converting to Applied Medical trocars alone, KDDH's Premier contract penetration level drops below 80%. You have about 5% of competitive volume now(nothing significant). Once this occurs, Premier puts KDDH on ESD70 – 24%. The difference between ESD69 & ESD70 is approximately 3-4%. This is a 26% increase on all Ethicon- Endo products. KDDH will also have a 12.5% increase in suture because of the combined agreement.

Please Keep in mind, these are not my rules or EES rules. These penetration requirements were made in combination with Premiers Buying group, the participating hospitals and EES & Ethicon Inc. The requirements were established to price protect you and give the deepest discounts possible to hospitals that are compliant.

Kaweah Delta Cost Analysis
2002 Year-End Usage

Current Spend

Category	$ Spend
Trocars	$94,040
Clip Appliers	$21,139
Trays	$134,853
Circular Staplers	$21,329
Ligation	$24,361
Linear Cutters	$72,834
Staplers	$24,740
Skin Stapling	$32,779
Roticulating Stapler	$4,313
Endocutters	$63,938
Endo Instruments	$9,241
EndoPouch	$26,262
Endostapling	$2,689
Endo Suture	$3,003
Handoscopy	$2,640
Energy	$48,740
Total	**$586,901**

Spend with EES without Trocars (If you convert to Applied)

Category	$ Spend
Clip Appliers	$26,635
Trays	$169,915
Circular Staplers	$26,875
Ligation	$30,695
Linear Cutters	$91,771
Staplers	$31,172
Skin Stapling	$33,285
Roticulating Stapler	$5,434
Endocutters	$80,562
Endo Instruments	$11,644
EndoPouch	$33,090
Endostapling	$3,388
Endo Suture	$3,784
Handoscopy	$3,326
Energy	$48,740
Total	**$600,316**

Statement of
The Honorable Patrick Leahy
United States Senator
Vermont

July 16, 2003

PRINTABLE VERSION

Statement of Senator Patrick Leahy
at the Senate Antitrust Subcommittee Hearing on
"Hospital Group Purchasing:
Has the Market Become More Open to Competition?"
July 16, 2003

Last April, when the Antirust Subcommittee held its first hearing on Group Purchasing Organizations, or GPOs, everyone was concerned with the escalating costs of health care. Those concerns have only been exacerbated in the intervening months, in the Senate and across the nation. Efforts to keep the cost of health care as low as possible, while ensuring that the quality of the care is as high as possible, is the Herculean task confronting our nation's health care providers. GPOs allow hospitals to aggregate their buying power in making purchases from suppliers of medical equipment, pharmaceuticals, and the plethora of more ordinary products necessary for the daily functions of any hospital. The idea is that, by purchasing in bulk, the hospitals should save significant sums, and because the GPOs handle much of the administrative burden of dealing with the suppliers, the hospitals would be relieved of those tasks as well.

The first hearing followed in the wake of press and industry commentary suggesting that there were serious issues we needed to address in the context of GPO purchasing. That hearing provided a real education, for the Judiciary Committee and for the public, allowing us all to learn more about how GPOs work, how they benefit hospitals, and whether there are any changes that could improve their operations. We began the difficult task of addressing complicated issues concerning, among other things: GPO funding structures and purchasing procedures, relationships between GPO employees and the suppliers under GPO contracts, statutory fee limits on administrative fees assessed by GPOS against their member hospitals, accusations that GPOs deny innovative and small manufacturers effective access to member hospitals, and -- perhaps most importantly -- assertions that GPOs do not actually save their member hospitals money.

In addition to providing all of us with a wealth of information, last April's hearing led the two largest GPOs, Premier and Novation, to adopt "codes of conduct." These codes are an attempt to address some of the claims that were

explored in that first hearing, and they certainly seem to be a step in the right direction. Today's hearing should allow us to assess the effectiveness of that step, and also determine what other efforts we need to make -- or to demand -- in our on-going project of lowering the cost, and raising the quality, of the healthcare available to our citizens. A robust competitive process should ensure the best possible health care for patients at the most reasonable price.

I look forward to continuing to explore this issue, with the help of the Subcommittee and today's witnesses. 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. Their unfailing cooperation, and their refusal to bow to partisan pettiness in their Subcommittee work, is an example for all of us in the Senate.

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PRINTER FRIENDLY VERSION

LSL Industries, Inc.

Manufacturers of Quality Medical Devices & Disposable Kits

Background

My name is Ash Luthra and I am President of LSL Industries, Inc. located in Chicago, Illinois. We are a **manufacturer** of disposable medical devices and are classified as a small minority manufacturer. We employ about 48 people and are located in the enterprise zone in the City of Chicago. Most of our production workers are hired from the local low-income population.

After I received my Masters degree in Engineering and MBA from the University of Chicago Business School I worked for 6 years and then started LSL in 1983 with my brother. For the first 15 years we were primarily private labeling, supplying components to some of the nation's leading healthcare multibillion-dollar companies and supplying to the Department of Veterans Affairs and the Department of Defense (under open competition against some of the nation's largest companies). Although we have been in business for the last 20 years, we started dealing with GPOs only about 5 years ago. In these five years we have had our share of disappointments and successes.

Our first big break came when Consorta Catholic Resources awarded us a contract for IV Start Kits on a **sole source basis** in February 2001. This was a very important test for us since our predecessor was a multibillion-dollar market leader – Becton Dickinson. However the key here was that we were awarded the contract based on the sole source. LSL is one of the small manufacturers in the nation that has the capabilities to manufacture a broad range of disposable medical devices. LSL has the unique capabilities of manufacturing products very competitively while keeping the quality at its highest since we are used to manufacturing for the large companies very cost effectively.

LSL's Performance

We have had tremendous success with this first contract awarded by Consorta to us. The main reason for the **success- it was a sole source contract**. As I said earlier, a small business like LSL can manufacture cost effectively with consistently high quality but can't match the sales force power of 500+ people of the large companies. Slowly, over a period of time we have achieved annual sales of over a million dollars in this category with Consorta members. We not only lowered their acquisition cost but also gained confidence that a small company can manufacturer and deliver cost effectively. This would not have been possible if we had a dual source contract and were fighting the selling power of a multibillion-dollar company. Another reason for our success was that Consorta is wholly owned and operated for the benefit of thirteen catholic health care systems and these members were highly involved in the decision making progress,

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leading them to be more committed to making the sole source contract a success for them and for us.

Since then we have had additional GPO contracts awarded to us as a dual source, but we have been less successful. Even though our prices are lower, we can't match the selling power of large companies with hundreds of sales people calling on each account everyday. This obviously keeps our market share limited, harms us and drives up the cost to the end user by them going to the alternate sources who the hospital is used to ordering from. A very vivid example of our success has been with the Federal Government (VA) where we were awarded 14 national contracts 3 years ago. These contracts were awarded strictly based on quality and price in open competition. Company size or Name brands were not given any preference. VA's Clinical User committee (consisting of professionals including Doctors) approved the products even before the prices were requested.

Concerns

Our major concern is that if GPOs are not allowed to or choose not to award sole source contracts to small businesses, it will be detrimental to small businesses. An exception should be made for awards to small **manufacturing** businesses only, on a sole source basis. The GPO and their members should decide this.

Secondly, for small businesses, the length of the contract awards should be longer and the contracts renewable for a similar term without having to go out for competitive bid again unless there is another small business competing. This is very important from the small business standpoint for two reasons:

First, it takes a while to switch the business (normally with a large business) due to the limited number of sales force personnel a small company may have.

Secondly, at the renewal time large companies come in with a slightly lower (token reduction) price just to edge out the small business, since the large companies know what the incumbent's pricing was. At the time of the renewal, if the GPO determines that the small business' pricing remains competitive, they should be able to renew the contract or negotiate the price down.

We respectfully request and hope that our concerns are given due consideration by the subcommittee. If heeded, this will certainly make the small businesses more viable and continue to make a contribution in keeping our nation's healthcare costs down.

*SBA 8(a) Certified Mfr • **Minority Owned, SDB Certified, Small Business Concern** • Enterprise Zone, Labor Surplus Area Manufacturer*

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Testimony of Masimo Corporation Before the Antitrust, Business Rights and Competition Subcommittee of the U.S. Senate Judiciary Committee
July 17, 2003

We would like to thank the Subcommittee Members and Staff for the time that they have spent over the last two years to bring about change in the practices of hospital Group Purchasing Organizations (GPOs). Since the mandate delivered during last year's hearing, all of the leading GPOs have published their own codes of conduct to reform their business practices and we have seen some examples of GPOs opening doors that were previously shut. However, more needs to be done to create a truly open and transparent marketplace where GPOs select products based on the best interest of the hospitals and patients, not the financial well being of the GPO.

Masimo Corporation has been a direct beneficiary of this progress. Since last year's hearing, we have been awarded contracts by 3 GPOs, including Premier, one of the nation's largest. And while this contract does not guarantee Masimo any sales, we are thankful for the opportunity to offer our products to more of our Nation's hospitals. Our business has grown in Premier hospitals by over 350% in less than a year and 18 Premier hospitals have converted fully to Masimo SET, compared to zero before Premier eliminated their bundling and sole source contract with Tyco-Nellcor. As a result more patients have access to Masimo SET, the technology that has now been linked to significant reduction of eye injuries in babies[i]. And as reported by many hospitals, including George Washington University Hospital, Masimo SET has helped reduce the cost of care; in many cases the cost of pulse oximetry to hospitals has been reduced by over 30%[ii],[iii].

While we are thankful for the progress that has been made, we believe that much more remains to be done. Most of the codes of conduct did not fully address key problems and most did not require the GPOs to immediately amend their contracts and arrangements with medical products suppliers that have stifled competition, but rather to deal with these issues as contracts expired. In addition, we do not believe that voluntary codes of conduct can truly solve the problem on a permanent basis. Without a clear set of enforceable rules, we fear that the positive impacts of these reforms may only be temporary in nature.

GPOs were granted certain exclusions from anti-kickback laws for the purpose of helping hospitals lower their costs. This was the expected outcome of aggregating purchasing power and consolidating contracting services. The unintended consequence of the exemptions is that vendors became the GPO's primary source of revenue and their partners. Some of the largest vendors quickly realized the power that they had and they used it to persuade the GPOs to make arrangements that limit competition. We believe that the reduced competition has kept hospitals and

patients from getting not only the best clinical products, but also the best pricing possible and the GAO's study supports this belief.

We believe that legislation; elimination of the safe harbors or some other type of enforceable measure needs to be enacted to solve these problems on an immediate and permanent basis. Incentives for GPOs to favor certain vendors over other vendors on bases other than quality and cost must be removed. These measures should restore the notion that GPOs work for their members in getting the lowest prices on the products that they need. We believe that the restoration of competition will result in new and better quality products and lower average product pricing being made available to hospital members.

In closing, we would once again like to thank the Members of the Subcommittee for their leadership on this difficult issue. Access to innovative technologies and more cost efficient alternatives must not be delayed any longer. We hope that the Subcommittee considers taking additional steps leading to enacting enforceable measures to restore competition in hospital purchasing.

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[i] Lily C. Chow, MD, Kenneth W. Wright, MD, Agusto Sola, MD, "Can Changes in Clinical Practice Decrease the Incidence of Retinopathy of Prematurity in Very Low Birth Weight Infants? February 2003 issue of *PEDIATRICS* (Vol.111 No. 2 February 2003).

[ii] Thomas Erler, MD, Stefan Avenarius, MD, Esther Wischniewski, MD, Katerina Schmidt, MD, Hans-Georg Klaber, MD. 'Longevity of Masimo and Nellcor Pulse Oximeter Sensors in the Care of Infants', (*Journal of Perinatology* 2003; (23)2; 133-135)

[iii] Charles Durbin, MD 'More reliable oximetry reduces the frequency of Arterial Blood Gas analysis and hastens oxygen weaning following cardiac surgery: A prospective randomized trial of the clinical impact of a new technology,' (*Critical Care Med.* 2002;(30)8:1735-1740)

STATEMENT OF MARK MCKENNA
PRESIDENT
NOVATION, LLC

BEFORE THE

UNITED STATES SENATE COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

JULY 16, 2003

Good afternoon Chairman DeWine, Ranking Member Kohl, and distinguished members of the Committee. It is my pleasure to be with you once again to discuss the benefits that Novation's group purchasing program provides to more than 2,200 health care organizations in all 50 states and the District of Columbia. As you know, these organizations include many of our nation's finest community-based, not-for-profit hospitals and a majority of its academic medical centers, many of them state-owned.

Last year, Novation exchanged a wealth of information with the Subcommittee about hospital group purchasing in general and about Novation's business practices in particular. We emphasized three things.

First, that Novation's owners — VHA and UHC — are cooperatives created by hospitals, owned by hospitals, and governed by hospitals. That distinguishes Novation's group purchasing program in two important ways: it is (and always has been) entirely member-driven, and it is (and always has been) entirely voluntary. When Novation enters into a vendor contract, the only party that makes a commitment is the vendor. The vendor commits to sell its products to hospital members at agreed-upon prices. The members commit to nothing. They are under no obligation to buy anything at anytime from anyone.

Second, we emphasized that member hospitals receive tremendous financial and clinical benefits by participating in Novation's group purchasing program. We estimate that in 2003 alone, the discounts and rebates negotiated by Novation will save participating hospitals over $1 billion. And, in addition, because VHA and UHC are cooperatives, member hospitals receive substantial cash distributions each year that further reduce their purchasing costs. Between 1997 and 2002, for example, VHA returned more than $400 million in cash to its member hospitals.

Third, Novation emphasized that our competitive bidding and vendor contracting process is open, fair, flexible and — once again — member-driven.

Recognizing Novation's unique offerings and market leadership, the Subcommittee urged Novation to take the lead in helping develop an industry code of conduct, promoting best practices, and making certain changes in its operations. You

made it clear that you wanted to ensure that smaller vendors had an opportunity to participate in group purchasing programs, and that member hospitals had ready access to innovative technology. We heard you. Novation's goals have always been consistent with those of the Subcommittee: to offer hospital members the freedom to choose among a wide variety of high quality products at favorable prices and to give all vendors, regardless of size, a full and fair opportunity to participate in Novation's group purchasing program.

In close collaboration with the Subcommittee, Novation adopted a comprehensive, progressive set of Operating Principles last August. We agreed to make significant changes in seven core areas:

- Innovative Technology;
- Sole, Dual and Multi-Source Contracts;
- Commitment;
- Contract Term;
- Private Label;
- Vendor Fees; and
- Code of Conduct and Compliance.

Today, less than one year later, I am proud to report that Novation has made substantial progress in all seven areas. Indeed, in many cases, we have taken steps that are not only consistent with the letter of the Operating Principles, but go well beyond its four corners. Before turning to Novation's progress in each of the seven areas covered by the Operating Principles, I would like to take a moment or two to put this progress into context.

Background

As I noted at the outset, Novation is owned by two legal cooperatives: VHA and UHC. VHA is a cooperative that is owned, governed and controlled by non-profit community hospitals; and UHC is a cooperative that is owned, governed and controlled by academic medical centers, including many state-owned institutions. Together, VHA and UHC represent over 2,200 health care organizations in all 50 states and the District of Columbia.

VHA and UHC are idea-generating and information-disseminating enterprises that help their members pool resources, create economies of scale, and improve clinical operating efficiency. Consistent with this mission, VHA and UHC offer their members group purchasing programs. For purposes of these programs, VHA and UHC act both directly and through Novation, which was created by them to increase the purchasing power of their members.

Vendor Contracting

Novation's group purchasing program generally work as follows. First, using a wide variety of VHA and UHC member surveys, as well as substantial input from Novation's 23 member councils (comprised of clinicians and health care professionals from member hospitals), Novation identifies those health care items and services that are needed by VHA and UHC member hospitals. Novation then obtains bids from vendors using a competitive bidding process. This process is well-publicized within the vendor community and is designed to comply with the stringent requirements of the state academic medical centers that belong to UHC. After responsive bids are received, they are rigorously evaluated by Novation — both in terms of quality and cost — with extensive input once again from VHA and UHC member hospitals through councils, task forces and surveys. Finally, the winning bidders are selected and the resulting contracts are executed.

As I will discuss in a few moments, in addition to this traditional process, which occurs during regularly scheduled bid cycles, Novation has developed mechanisms that are designed to ensure two things. First, they are designed to ensure that where new and innovative technology enters the market, VHA and UHC members are made aware of this technology in an expedited fashion. Second, they are designed to ensure that if requested by a vendor and approved by the relevant Novation member council, such technology is placed under contract by Novation regardless of whether Novation is in, or is between, its regular bid cycles.

Member Access to Contracts

Once a contract with a particular vendor has been executed, VHA and UHC members may "access" that contract. That is, member hospitals may purchase the items and services covered by the contract directly from the vendor at issue at the prices agreed upon in the contract. Importantly, VHA and UHC members are not required — as a condition of membership or otherwise — to purchase goods or services under any Novation-vendor contract. To the contrary, members are free to purchase all, some or none of their supplies and services under such contracts.

I would like to use a very simple hypothetical, which I will return to again later, to help demonstrate this extremely important point. Assume that there is a bed sheet vendor, which we will call Vendor A. Vendor A enters into a three-year contract with Novation on January 1, 2003. Under this contract, Vendor A agrees to sell bed sheets to VHA and UHC members for $10 each. Now assume that six months later, a second vendor, Vendor B — which does not have a contract with Novation — offers bed sheets directly to a UHC member hospital for $9 each. The UHC hospital is free to purchase such sheets from Vendor B. The hospital also is free, of course, to purchase bed sheets from Vendor A, or, for that matter, from any other vendor of bed sheets.

At Novation, this is true regardless of the product, regardless of the vendor, and regardless of the contract. And this is true regardless of whether the contract is or is not included in (1) Novation's OPPORTUNITY program, (2) Novation's NOVAPLUS private-label program, or (3) any other Novation program.

Benefits to Members

Of course, because Novation represents thousands of health care organizations, it typically is able to negotiate better prices from a given vendor for a particular product than any individual hospital, acting on its own, could obtain. As I mentioned a moment ago, Novation estimates that this year alone, the discounts and rebates negotiated by Novation will save participating hospitals over $1 billion.

I should emphasize, however, that aggregating purchasing power is not the only way that Novation saves member hospitals money. Developing and drafting invitations to bid, soliciting responsive bids from prospective vendors, analyzing bids to determine which offer the best combination of clinical value and price, and negotiating contract terms with successful bidders, is a complex process that requires specialized personnel. It also is time consuming and costly. Hospitals avoid these considerable costs by having Novation furnish these various services on their behalf.

Hospitals are able to avoid these costs because VHA and UHC are funded, in large part, through the administrative fees that vendors pay to VHA and UHC under Novation-vendor contracts. These administrative fees, which usually are based on a percentage of the value of member hospital purchases, cover Novation's clinical evaluation and contract bidding, analysis and negotiation costs — costs, once again, that member hospitals would otherwise be forced to incur. This funding structure enables hospitals to apply precious resources — resources that would otherwise be diverted to cover supply chain management costs — to patient care.

In addition, as I mentioned a moment ago, VHA and UHC are cooperatives. It is common for cooperatives to be funded by fees paid by vendors wishing to do business with cooperative members and to return their net revenue to these members. UHC and VHA are good examples. Each year, VHA and UHC distribute 100 percent of their net revenue — the vast majority of which is generated by administrative fees — to their hospital members. These distributions, which take the form of cash and patronage equity certificates, serve to further reduce the overall supply chain management costs of member hospitals.

Group Purchasing in Non-Health Care and Public Sectors

Not surprisingly, given the benefits involved, group purchasing is not unique to health care. It is common, for example, in the farming, building, hardware, restaurant and other industries. Nor is group purchasing unique to the private sector. Indeed, the benefits of aggregating purchasing power are well-recognized by both state and federal governments.

For example, at the state level, there have been dozens of recent group purchasing initiatives involving pharmaceuticals. The Minnesota Multistate Contracting Alliance for Pharmacy, for example, is a coalition of over 40 states seeking to standardize, consolidate and competitively bid for state requirements for pharmaceutical supplies and services. Similarly, at the federal level, the Departments of Veterans Affairs and Defense have combined their purchasing power to jointly contract for drugs and, according to the General Accounting Office, they have been

able to procure significant discounts as a result. See DOD and VA Health Care, Jointly Buying and Mailing Out Pharmaceuticals Could Save Millions of Dollars, GAO/T-HEHS-00-121 (May 25, 2000).

Novation Operating Principles

With this background in mind, let's turn now to Novation's Operating Principles and the progress that Novation has made over the last year in implementing them. As I noted a moment ago, the Operating Principles address seven areas. Let's start with innovative technology.

Innovative Technology

As the Operating Principles correctly observe, VHA and UHC members "expect and deserve access to the most innovative and cost-effective medical technology." In order to ensure such access, the Operating Principles note that Novation is "always searching for ways to better serve VHA and UHC members, and is committed to becoming a leader in enabling the development, awareness and utilization of innovative health care technology."

I am happy to report that Novation has lived up to this commitment, and then some. Shortly after adopting the Operating Principles, Novation created a new department dedicated solely to the identification and evaluation of new and emerging technology. Several months later, Novation launched its web-based "Technology Forum." The Forum invites vendors to post information about their new products and devices on Novation's web site. In this way, both VHA and UHC members, as well the general public, have access to continually-updated descriptions of new products. The Forum also permits a vendor, between Novation's regular bid cycles, to ask Novation to place its product under contract.

Novation also has been reaching out to vendors of potentially innovative technology proactively, both during and between bid cycles. Through its technology pipeline program, Novation monitors the marketplace for emerging medical technology. Where we identify such technology, we contact the vendor and encourage it to do two things. First, we encourage the vendor to post information about its product on the Technology Forum. Second, in appropriate cases, we encourage the vendor to submit a request for contract consideration to Novation.

I am pleased to report that in just seven months, vendors have posted information on the Technology Forum relating to more than 50 different products. In addition, between the Technology Forum and Novation's technology pipeline outreach program, Novation has entered into 19 contracts with vendors outside of the regular bidding cycle and a dozen more contracts are currently under review.

Novation also has developed and implemented a more defined and objective process for addressing vendor grievances. Today, Novation immediately acknowledges receipt of all grievances and provides a detailed response within 90 days. This process has yielded meaningful results. For example, one vendor filed a grievance when it did not receive a contract for its product. Novation's review of this grievance gave rise to a more complete exchange of information and, ultimately, a contract award for a

technologically innovative product.

Sole, Dual & Multisource Contracts

The next section of the Operating Principles concerns sole, dual and multisource contracts. Novation made two basic commitments in this area.

First, Novation agreed that, on a prospective basis, it would not award a sole-source contract for a clinical preference product unless two conditions were met: one, there had to be no alternative product that offered incremental patient care or safety benefits; and two, any sole source contract had to be reviewed and approved by the appropriate Novation clinical counsel or task force.

Novation has complied with this provision in full. Since adopting the Operating Principles, Novation has awarded just one sole-source contract for a clinical preference product — IV catheters. In that case, Novation determined that there were no alternative products offering incremental patient care or safety benefits and the award was reviewed and approved by Novation's Nursing Council and IV Catheter Task Force. In addition, Novation previewed the award with members of the Subcommittee's staff. I should also note that the successful bidder in this case offered prices that, in the aggregate, were more than 28 percent lower than the next lowest bid.

Second, Novation agreed that, on a prospective basis, it would re-bid a product category or make a dual or multisource award if, in the view of the relevant Novation clinical council or task force, a new product had entered the market that offered incremental patient care or safety benefits. On 10 occasions since the Operating Principles were adopted, Novation has made a dual or multisource award for a clinical preference product because a new product entered the market that offered incremental patient care or safety benefits. Significantly, in six of these cases, the product category had been sole-sourced prior to adoption of the Operating Principles.

Commitment

The third section of the Operating Principles relates primarily to Novation's OPPORTUNITY program and, more specifically, to Novation's OPPORTUNITY Spectrum Portfolios. Before turning to Novation's progress in this area, I would like to spend a moment or two putting the discussion of the OPPORTUNITY program into context.

The OPPORTUNITY program was created in 1996 at the request of member hospitals. These hospitals were seeking greater cost savings in order to compete locally with for-profit hospital chains. In particular, smaller hospitals were looking for ways to earn additional price reductions that were not driven by volume. The OPPORTUNITY program provides such a mechanism by tying price reductions not to the volume of purchases that a member makes from a particular vendor but to the proportion of such purchases in comparison to purchases from vendors that do not participate in the OPPORTUNITY program.

I would like to emphasize, as I did earlier, that no VHA or UHC member is required to purchase any product from any vendor under any Novation contract. With

respect to the OPPORTUNITY program, this bedrock principle manifests itself in two ways. First, no VHA or UHC member is required to participate in the OPPORTUNITY program in the first instance. Second, if a member chooses to participate in the OPPORTUNITY program, the member is not required to purchase any product under any contract that Novation has negotiated with any vendor participating in the program.

Once again, I would like to use a simple hypothetical to help demonstrate this important point. Let's assume, once again, that there are two vendors of hospital bed sheets, Vendor A and Vendor B. Both normally sell their products for $10 each. Vendor A enters into a contract with Novation. Under the contract, Vendor A agrees to sell bed sheets to VHA and UHC members at a discounted price of $9. Under these circumstances, as we have discussed, the only party that has committed to do anything is Vendor A, which has agreed to sell bed sheets to members of VHA and UHC for $9 apiece. The members of VHA and UHC, on the other hand, have committed to nothing.

Now let's assume that Vendor A decides to participate in the OPPORTUNITY program. As part of its participation, Vendor A agrees that if a VHA or UHC member chooses to purchase 75 percent of its bed sheets from Vendor A, that member will get an additional $1 discount off the already discounted $9 price. Under these circumstances, VHA and UHC members simply have one more option. That is, if a member chooses to participate in the OPPORTUNITY program, the member not only is eligible for the discounted $9 price for bed sheets (under the base contract between Novation and Vendor A), but the member also is eligible for the further discounted $8 price if the member chooses to purchase 75 percent of its bed sheets from Vendor A.

Again, however, by choosing to participate in the OPPORTUNITY program, a member has not committed to do anything. Once again, the only party that has committed to do anything is Vendor A, which has agreed not only to sell bed sheets to all VHA and UHC members for $9 apiece, but also to sell bed sheets for $8 apiece to any VHA or UHC member that, one, chooses to participate in the OPPORTUNITY program and, two, chooses to purchase 75 percent of its bed sheets from Vendor A.

Now let's turn to the OPPORTUNITY Spectrum Portfolios, specifically. These Portfolios were assembled from Novation's existing contract base. The selection process was handled by a special task force comprised of representatives from VHA and UHC member hospitals. This task force included a Chief Financial Officer, directors of materials management, and senior personnel from various nursing, pharmacy, radiology and laboratory departments. The process was guided by a value analysis facilitator, three separate member surveys, and feedback from the Novation Nursing, Materials and Peri-operative Councils. The task force considered a wide variety of options over a several month period before making its final selection. In general, member hospitals expressed a strong preference for the inclusion of highly utilized contracts in order to permit cost savings without the extensive disruptions and expenses often associated with product conversions.

With this background in mind, let's turn back now to the Operating Principles, which include four provisions relating either to Novation's OPPORTUNITY Spectrum Portfolios or to related issues.

First, the Operating Principles provide that Novation will impose no commitment requirements as a condition of participating in any base vendor contracts or as a condition of membership or continued membership in VHA or UHC. Novation has complied with this provision of the Operating Principles and will continue to do so.

Second, the Operating Principles provide that any vendor proposal that offers additional discounts in exchange for commitment levels in excess of 75 percent on clinical preference products will be reviewed and approved by the relevant Novation clinical council or task force before going into effect. Novation also has complied with this provision of the Operating Principles and will continue to do so.

Third, the Operating Principles provide (1) that hospital participation in OPPORTUNITY Spectrum Portfolios will be voluntary, (2) that such participation will not be a precondition to a hospital joining or maintaining membership in VHA or UHC, and (3) that the price discounts offered by Novation under its base vendor contracts will continue to be available to any member whether or not the member makes any purchasing commitment or participates in OPPORTUNITY Spectrum Portfolios. Once again, Novation has complied with this provision of the Operating Principles and will continue to do so.

Fourth, and finally, the Operating Principles provide that, on a prospective basis, Novation will:

- review its OPPORTUNITY Spectrum Portfolio descriptions and contracts to eliminate language that could be construed as anti-competitive;
- eliminate combinations of clinical and non-clinical preference products in the OPPORTUNITY Spectrum Portfolios;
- eliminate combinations of capital equipment and consumable products in the OPPORTUNITY Spectrum Portfolios;
- increase the percentage of dual and multisource vendor contracts in the OPPORTUNITY Spectrum Portfolios; and
- pursue the implementation of lower purchasing commitment levels within the OPPORTUNITY Spectrum Portfolios.

By their terms, the OPPORTUNITY Spectrum Portfolios are set to expire in early 2005. Novation has decided, however, to implement a replacement for this program next year. The new program will comply with all of the above provisions of the Operating Principles. Furthermore, although the Operating Principles only require Novation to act on a prospective basis, since August of last year, Novation has made several changes to the existing OPPORTUNITY Spectrum Portfolios.

In March 2003, for example, Novation notified all members and vendors participating in the OPPORTUNITY Spectrum Portfolios that, effective immediately, Novation was proactively removing any language in any member or supplier participation agreements that might be construed as anti-competitive.

Also in March 2003, Novation notified all participating GPO members that, effective April 1, 2003, Novation was eliminating the requirement that members participating in the OPPORTUNITY Spectrum Portfolios purchase capital equipment in order to meet the requirements of the program.

Two months later, in May 2003, Novation notified all participating GPO members that, effective immediately, Novation was eliminating any penalties associated with a member dropping out of the program and, as a result, would no longer require restitution of previously earned incentives.

Finally, Novation's member councils have reviewed all contracts in the current OPPORTUNITY Spectrum Portfolios and determined which, if any, cover clinical preference products. With respect to two of these products — specialty interventional urology and pulse oximetry products — Novation has added lower, 75 percent purchasing levels to the portfolios.

Contract Term

The next section of the Operating Principles concerns the term of Novation-vendor contracts. This section imposes five obligations on Novation.

First, the Operating Principles provide that Novation will preserve its existing contracting flexibility by ensuring that all of its vendor contracts permit contract termination without cause upon 90 days written notice. Every new contract that Novation has executed since adoption of the Operating Principles has included a 90-day termination without cause provision, and Novation will continue to include this provision in each of its vendor contracts.

Second, the Operating Principles provide that Novation will preserve its existing contracting flexibility by including a provision in vendor contracts permitting Novation to add vendors or terminate and re-bid the contract if Novation identifies a product that offers incremental patient care or safety benefits. Every contract that Novation has executed since adoption of the Operating Principles has included this provision, and Novation will continue to include this provision in each of its vendor contracts. I would also note that both during and between regular bid cycles Novation's new Technology Forum and pipeline outreach programs — which I discussed a few moments ago — not only permit, they encourage, the consideration of products that offer incremental patient care or safety benefits.

Third, the Operating Principles provide that, on a prospective basis, Novation will limit vendor contracts to an initial term of three years or less. Since August 2002, Novation has not entered into any contracts with an initial term of more than three years.

Fourth, the Operating Principles provide that, on a prospective basis, Novation will thoroughly and objectively evaluate alternative technologies before exercising any option to renew a vendor contract. Since adopting the Operating Principles, Novation has developed and is implementing policies to ensure the thorough and objective evaluation of alternative technologies before Novation enters into or extends any vendor contract.

Fifth, and finally, the Operating Principles provide that "[a]s necessary and appropriate," and on a prospective basis, Novation will modify contracts that have terms that "erect a barrier (or a perceived barrier) to member access to innovative technology." Following the adoption of the Operating Principles, Novation set up a process designed to ensure that all new contracts, as well as contracts coming up for extension, do not have language that erects such a barrier. In addition, as I discussed a few moments ago, Novation has proactively removed such language from OPPORTUNITY Spectrum Portfolio documents.

Private Label

The next section of the Operating Principles concerns Novation's NOVAPLUS private label program. Once again, before turning to these provisions, I would like to take a moment to provide some background information on this program.

The NOVAPLUS portfolio, which is the only brand of health care products developed by hospitals for their own financial benefit, includes approximately 1,500 commodity items, such as disposable pillows, elastic bandages and ice packs. These products have three distinguishing characteristics: one, they are identical to their supplier-branded equivalents; two, they are used by VHA and UHC members in large volumes; and three, they are offered at extremely favorable prices.

Novation also places a premium on the quality of the products in the NOVAPLUS portfolio. Toward this end, Novation carefully selects its NOVAPLUS manufacturing partners and evaluates their products and services through a rigorous quality assurance process. For example, Novation's quality assurance/regulatory affairs team conducts regular inspections of vendor manufacturing plants for all NOVAPLUS products.

Finally, the NOVAPLUS program does not benefit only VHA and UHC members. The brand also has helped smaller manufacturers, with less market recognition, to compete effectively with manufacturers many times their size. Indeed, in several cases, NOVAPLUS products have eclipsed leading national brands as the market share leader within VHA and UHC member organizations.

With this background in mind, let's turn back to the Operating Principles, which impose three basic obligations on Novation with respect to the NOVAPLUS program.

First, Novation agreed, on a prospective basis, to limit the NOVAPLUS program to commodity products. Novation has complied with this provision. In addition, although not required by the Operating Principles, Novation has reviewed each and every existing medical-surgical contract in the NOVAPLUS program portfolio, identified three that cover clinical preference products, and arranged to have these products removed from the program.

Second, Novation agreed, also on a prospective basis, to reduce NOVAPLUS vendor fees while achieving equal value to members through improved price reductions or other member incentives. Since adopting the Operating Principles, all new NOVAPLUS program contracts and contract extensions have provided for, or, in a handful of cases, have been amended to provide for, combined administrative and licensing fees of six percent or less.

In addition, although not required by the Operating Principles, Novation is reviewing all NOVAPLUS program contracts that were executed prior to August 8, 2002 and have not come up for re-bid or extension. Where such a contract calls for a fee of greater than six percent, Novation is working with the relevant vendor to reduce the fee to six percent (or less). To date, Novation has reduced the fees in nine such agreements, and an additional six amendments are awaiting signature.

Third, Novation agreed, again on a prospective basis, to take further steps to document and communicate to member hospitals the benefits of the NOVAPLUS program. For example, after adopting the Operating Principles, Novation undertook 26 price studies covering 511 medical-surgical products. Novation compared the prices that hospitals were paying for these products to what they would have paid under the NOVAPLUS program. Novation found that participating hospitals would have saved, on average, 14 percent had they purchased the products at issue through NOVAPLUS.

Novation has communicated the results of these studies to VHA and UHC members. In addition, through its maintenance of Novation's robust web site, which includes a section devoted to the NOVAPLUS program, as well as other publications and outreach efforts, Novation is ensuring that VHA and UHC members are aware of the program's benefits.

Vendor Fees

The next section of the Operating Principles addresses the vendor fees that are paid to Novation. As I discussed at the outset, these fees serve two critical cost-saving functions for VHA and UHC members.

First, they fund the vast array of supply chain management services that Novation furnishes to member hospitals. Indeed, every dollar in fees that vendors pay to Novation is a dollar in costs that member hospitals do not have to expend on supply chain management and, therefore, is a dollar freed-up to improve patient care.

Second, because VHA and UHC are cooperatives, the difference between the amount of vendor fees that Novation receives and Novation's supply chain management costs is returned to VHA and UHC member hospitals, further reducing their supply costs. As I mentioned at the outset, between 1997 and 2001, VHA alone returned $250 million in cash to its member hospitals.

With this in mind, let's turn now to Novation's implementation of the five provisions in the Operating Principles relating to vendor fees.

First, Novation agreed, on a prospective basis, that it would not accept vendor fees prior to the inception of a contract or in the form of vendor equity. Novation has complied with these provisions and will continue to do so.

Second, Novation agreed, on a prospective basis, that it would take steps to further ensure that vendor fees are not a determinative factor in the award of contracts under Novation's competitive bidding process, except in those situations where the quality and pricing of competing products is essentially the same. After adopting the Operating Principles, Novation modified its bid assessment process to conduct two

decision criteria award matrix — or "DCAM" — assessments per bid. The first assessment includes vendor fees as an evaluated factor; and the second assessment does not. This revised process ensures that fees will only be a factor where, consistent with the requirements of the Operating Principles, the quality and pricing of competing products are essentially the same.

Third, the Operating Principles provide that Novation will explore ways to make fee disclosures to VHA and UHC members even more transparent and user-friendly. Toward this end, Novation and the GPOs have spent months developing secure internet databases listing vendor contract fee provisions that are not fixed at three percent or less. These databases, which are being rolled out in phases, will be updated on an ongoing basis and are available to GPO members 24 hours a day, 365 days a year.

Fourth, the Operating Principles provide that with respect to clinical preference products, Novation, on a prospective basis, will reduce administrative fees that are above three percent to three percent, while achieving equal value to members through improved price reductions or other member incentives. Since adopting the Operating Principles, Novation has not entered into any contract for a clinical preference product providing for vendor fees in excess of three percent.

In addition, although not required by the Operating Principles, Novation is reviewing vendor contracts that were executed prior to August 8, 2002. To date, Novation has reviewed contracts in 408 out of a total of 468 medical-surgical product categories and will complete its review of the contracts in the remaining 60 categories on or before December 31, 2003. Where Novation determines that such a contract includes a clinical preference product and provides for fees in excess of three percent, Novation is contacting the relevant vendor to negotiate additional price reductions or other member incentives, along with a reduction of the fee.

Fifth, and finally, the Operating Principles provide that with respect to clinical preference products, Novation will not accept other forms of contract-related marketing fees and that vendor participation in any additional programs for which fees may be charged (such as trade shows or advertising) will be voluntary and a vendor's participation (or non-participation) will have no bearing upon contracting decisions.

With respect to the first point, none of the clinical preference product contracts in the 408 product categories that Novation has reviewed include marketing fees of the type covered by this provision. Novation will determine whether any of the contracts in the remaining 60 product categories provide for such fees and, if so, the contracts will be amended to eliminate such fees. With respect to the second point, since adoption of the Operating Principles, vendor participation in programs for which fees have been charged has been entirely voluntary and such participation (or non-participation) has had no bearing upon contracting decisions.

Novation Code of Conduct & Compliance Program

The final section of the Operating Principles concerns Novation's compliance program. As Novation noted in the Operating Principles, at the time they were adopted

Novation's compliance program was being reviewed, enhanced and customized. Toward this end, in the Fall of 2002, Novation appointed a Corporate Compliance Officer and Novation's Board of Directors appointed a Board-level Corporate Compliance Committee.

The Compliance Officer and Corporate Compliance Committee, together with Novation's Board of Directors and senior management, have taken an active and energetic role in ensuring the implementation of the Operating Principles. Among other things, Novation has (1) designated a Compliance Manager in nine different areas (including each of the areas addressed in the Operating Principles), (2) trained every employee with respect to Novation's revised business ethics policies, and (3) trained every employee involved in vendor contracting with respect to the Operating Principles and the various policies and procedures that Novation has developed relating to the Principles.

Finally, the Operating Principles provide that Novation will prohibit Novation and its employees and directors from owning certain types of equity interests. These provisions, which go beyond those required by the HIGPA Code of Conduct, have been implemented through a written certification process involving all Novation employees and all members of Novation's Board.

Conclusion

In conclusion, let me say that I am quite proud of the progress that Novation has made in implementing the Operating Principles that the company adopted less than one year ago. We have opened up new doors to innovative technology. We have increased the flexibility of our contracting process. We have expanded and enriched Novation's product offerings. We have eliminated perceived barriers to member choice. And we have emphasized and reemphasized that such choice is a bedrock Novation principle.

Although I am proud of this progress, I should make it clear that we at Novation recognize that our job is not done. Not by a long shot. Implementing the Operating Principles has required, and will continue to require resolve, structure, resources and, above all else, diligence. On behalf of VHA and UHC members, I can promise you that Novation has the resolve, is developing the structure, will devote the resources, and is committed to doing whatever it takes to get the job done.

Thank you.

Novation
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July 23, 2003

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The Honorable Mike DeWine
Chairman
United States Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights
United States Senate
224 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Herbert H. Kohl
Ranking Member
United States Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights
United States Senate
224 Dirksen Senate Office Building
Washington, D.C. 20510

RE: Novation, LLC

Dear Chairman DeWine and Senator Kohl:

On behalf of Novation, LLC, thank you for the recent opportunity to submit information to and testify before the United States Senate Committee on the Judiciary, Subcommittee on Antitrust, Competition Policy, and Consumer Rights. On the whole, Novation found the July 16, 2003 hearing a helpful and constructive continuation of the dialogue among the Subcommittee, Novation and others concerning the merits of hospital group purchasing. There were, however, several statements that were made in connection with the hearing that Novation believes either were inaccurate or incomplete. Novation does not propose to identify and address each and every one of these statements, believing instead that Novation's numerous submissions to the Subcommittee and record of accomplishments speak largely for themselves.

There is one particularly important issue, however, that arose during the hearing and that we believe does warrant clarification in writing. Indeed, we would ask that this letter be included in the official record of the July 16, 2003 hearing. Specifically, we would like to address the statement by Senator Kohl that although Novation pledged in its August 2002 Operating Principles to terminate its "bundling" program, Novation has not done so. The term "bundling" does not, in fact, appear in the Operating Principles. Since there is no commonly accepted definition of product "bundling," the adoption of principles, practices or procedures relating to "bundling" can be difficult to effectively apply and monitor.

Although Novation did not address "bundling" in the Operating Principles, Novation did make several specific commitments relating to its "OPPORTUNITY Program" and, more specifically, to one set of contract "portfolios" that are included in this Program, the "Spectrum Portfolios." As described in some detail in its submissions both before and at the July 16 hearing, Novation has lived up to these commitments, and then some.

As the Subcommittee knows, the OPPORTUNITY Program was created by and for the hospital members of VHA Inc. and University HealthSystem Consortium (UHC). Novation believes that the Program continues to provide valuable savings to those VHA and UHC hospitals that choose to participate in the Program, particularly smaller, community. not-for-profit hospitals that have difficulty achieving savings through high-volume purchasing.

We also should reemphasize that no VHA or UHC member is required to purchase any product from any vendor under any Novation contract. With respect to the OPPORTUNITY Program, this principle manifests itself in two ways. First, no VHA or UHC member is required to participate in the OPPORTUNITY Program. Second, there are no adverse consequences — relating to membership status, penalties or otherwise — if a member chooses to withdraw from the Program.

In the Operating Principles, Novation agreed that — on a prospective basis — it would:

- review its OPPORTUNITY Spectrum Portfolio descriptions and contracts to eliminate language that could be construed as anti-competitive;
- eliminate combinations of clinical preference products and non-clinical preference items in OPPORTUNITY Spectrum Portfolios;
- eliminate combinations of capital equipment and consumable products in OPPORTUNITY Spectrum Portfolios;
- increase the percentage of dual and multisource vendor contracts in OPPORTUNITY Spectrum Portfolios; and
- pursue the implementation of lower purchasing commitment levels within the OPPORTUNITY Spectrum Portfolios.

As noted above, Novation has lived up to these commitments. As we also indicated on July 16 — and this may be where some of the confusion lies — whereas the OPPORTUNITY Spectrum Portfolios currently are set to expire in 2005, in which case Novation would have been required by the Operating Principles to ensure that these next-generation Spectrum Portfolios were consistent with the above-listed commitments in 2005, Novation has decided to accelerate this process by introducing a

parallel set of similar portfolios in 2004. Of course, this parallel set of portfolios must, and will, be consistent with the requirements of the Operating Principles.

Please note, however, that Novation has never committed — in the Operating Principles or elsewhere — to terminate its OPPORTUNITY Program in general or the Spectrum Portfolios specifically. What Novation has agreed to do is to live by its Operating Principles. This, Novation has done and will continue to do.

* * *

We hope that this clarification is helpful and we look forward to continuing our work with the Subcommittee to achieve our joint goal: ensuring the delivery of high quality, low cost health care in a manner that is open, fair and consistent with the legitimate interests of hospitals, patients and vendors alike.

Sincerely,

Mark McKenna
President
Novation, LLC

cc: Senator Saxby Chambliss
Senator John Edwards
Senator Russell Feingold
Senator Lindsey Graham
Senator Orrin Hatch
Senator Patrick Leahy
Senator Arlen Specter

Statement of:

Mark B. Leahey, Esq.
Executive Director
Medical Device Manufacturers Association

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

July 16, 2003

The Medical Device Manufacturers Association (MDMA) is pleased to submit testimony to the Senate Judiciary Subcommittee on Antitrust, Competition, and Business and Consumer Rights concerning the effect of Group Purchasing Organizations (GPOs) on innovation in the health care marketplace.

MDMA is a national trade association representing the innovative and entrepreneurial sector of the medical device marketplace. More than 160 device manufacturers comprise our membership, including makers of medical devices, diagnostic products, and health care information systems. MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of innovative products in the marketplace.

Summary

The Subcommittee's hearing in April 2002, "Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation," raised a number of important questions related to the business and contracting practices of certain GPOs. In addition, the GAO released a pilot study suggesting that "large buying groups do not always offer hospitals lower prices." More than a year later, this Subcommittee convened to see what, if any, measurable changes the GPOs have made related to their ethical, business and contracting practices.

Immediately following the 2002 hearing, the Members of this Subcommittee and the staff worked tirelessly with certain GPOs to develop codes of conduct that were intended to prevent many of the questionable practices reported by the *New York Times* and discussed at the hearing from occurring in the future. We applaud the efforts of the Subcommittee for this work and we believe it was an important first step on the road to an open and fair health care marketplace.

However, as the GAO reported in its July 16, 2003, report, many of the conduct codes "include exceptions and qualified language that could limit their potential to effect change."

If patients and caregivers are to have access to quality medical products at competitive prices, the codes must be comprehensive in scope, implemented completely, mandated industry wide and enforced by the government.

The code presented by Premier, one of the two largest GPOs, minus its exceptions and qualified language, may be a good place to start. The code committed to the following:

- prohibit administrative fees over 3 percent
- prohibit marketing or any other fees
- prohibit the bundling of unrelated products
- prohibit the bundling of vendors
- prohibit private label programs
- limit the contract period to three years

However, MDMA believes the codes also should include, but not limited to, the following:

- prohibit "sole-source" contracts
- prohibit GPOs from investing in for-profit ventures
- require GPOs to base the administrative fee on what it actually costs to negotiate the contract, nothing more.

Unfortunately, because the codes developed by Premier and the other GPOs are merely voluntary, GPOs cannot be held to the limited reforms they themselves propose. Therefore, without legislation or government certification of a uniform, verifiable and comprehensive code (similar to above), we fear certain GPOs will never implement the changes necessary to improve patient care and foster innovation.

This concern was shared at the hearing by Elizabeth Weatherman, Vice Chair, Medical Group, National Venture Capital Association and Managing Director, Warburg Pincus LLC. She spoke of the unsuccessful California State Senate's attempt to legislate the codes. Similar to the qualified language that Premier added to their codes, the GPOs mobilized in California and added qualifying language that eviscerated any real reforms.

Actions Speak Louder Than Codes

We agree with the GPOs that the codes of conduct should be given time to work. In fact, the codes have been given ample time (almost a year) and to date little has changed on the contracting front. As Senator Kohl mentioned during the hearing, every GPO has a 90 day "without cause" termination clause which they may execute. Yet, the GPOs continue to state that they need more time to enact reform. It is our belief that if they truly wanted reform by now, greater steps could have been taken.

The pace of reform has been far too slow. While we understand that terminating thousands of contracts would have been difficult over the course of the last year, GPOs have not dedicated fully to this effort. We are not asking GPOs to revisit every contract.

However, those Med/Surg contracts where a manufacturer has identified themselves as a "locked out" participant need to be reopened immediately to the bid process. Once this occurs and a comprehensive GPO code is implemented, true reform may be possible.

MDMA recognizes that the GPO industry has taken some steps at reform, but in too many cases these measures are token rather than systemic reforms. Granting purchasing contracts to the GPOs' most vocal critics in the manufacturing industry merely serves to quiet individual critics without fixing the underlying problem. It should not take constant Congressional oversight for device manufacturers to be able to sell their products to hospitals.

Anti-competitive GPO Practices that Continue Today

1) Bundling of Unrelated Vendors

Today, Novation continues their Spectrum Opportunity Program which bundles unrelated products and unrelated vendors. In order to qualify for "rebates" a hospital must buy upwards of 95% of product from each of the 12 product categories from different vendors, according to the GAO. If a hospital does not meet both the compliance percentage and purchase from all the vendors in the Spectrum bundle, it does not receive the "rebates." As a result, hospitals are effectively forced to purchase less desirable products in order to receive the program's "rebates." It is also worth noting that hospitals accrue the "rebates" on a quarterly basis, but they do not earn the "rebates" until the completion of the five-year program. As a result, a hospital who has accrued "rebates" over a three year period and then wants to purchase a product outside the Spectrum bundle because it is clinically preferable or available at a lower price, it is free to do so, but will forfeit ALL the "rebates" accrued to date. Said Hilal, CEO of Applied Medical Resources, testified that his product could save a given hospital $400,000 on a $1,000,000 purchase. The hospital wanted to contract with Applied because of the quality of the product and the cost savings, but ended up staying with the incumbent vendor because they would have forfeited $600,000 in rebates.

Senator Kohl asked during the hearing, "why should patients who benefit from products outside the Spectrum bundle have to wait another year or two?" Mark McKenna, stated that "hospitals are not forced to buy" the products. However, the GPO has structured certain programs in such a way that the hospitals are not always free to choose because of the severe financial penalties.

Senator Kohl also asked the question, "why not offer maximum discounts without bundling?" This was an excellent question that needs a thorough response. The Spectrum program ties "rebates" to compliance across vendors. Why should "Vendor A" in the Spectrum program care if a hospital buys "Vendor C's" product. This practice must cease immediately because the punitive structure of the program is penalizing both hospitals and manufacturers who can offer competitive products at competitive prices. Mr. McKenna stated that the program is voluntary and hospitals can opt out. Does this mean they can opt out of certain product lines within the Spectrum bundle or is it an all or nothing proposition? Why do GPOs refuse to open up the contracts and re-bid

immediately, as Senator Kohl suggested? As was noted above, Mr. Hilal stated he could offer his product at 40% savings to the current contracted product. It would seem that patients and hospitals would be best served if the contracts were re-bid. Who are the GPOs serving by resisting these needed reforms?

2) Bundling of Unrelated Products

Many GPOs continue to utilize the practice of bundling unrelated products from a single vendor. This practice unfairly disadvantages a young, innovative company with a limited portfolio of product. Under the current system, many products which are clinically preferred and can be offered at competitive prices, cannot get a GPO contract because they do not have a relationship established with the GPO or cannot offer as wide a product line. Each GPO contract should take an individual product and judge it on the quality and price of that product alone and not on the price that a manufacturer is willing to offer if products are "bundled" together. In addition, it has been reported that certain large manufacturers will raise the price of a product if it is not bundled with another product. This behavior again penalizes the smaller, innovative companies with a limited product line. As I will discuss later, the need to foster innovation in this marketplace is critical to improving patient care. This practice must be examined very carefully, especially in light of the GAO report documenting the revenues generated by GPOs through these contracts.

3) Sole Source Agreements, High Compliance and Long Term Contracts

As the GAO recently reported, industry observers felt that "when GPOs with substantial market shares award long-term sole-source contracts to large well-established manufacturers, some newer, single-product manufacturers—left to compete with other manufacturers for a significantly reduced share of the market—may lose business and be forced to exit the market altogether." Furthermore, the GAO reported that "one of the two largest [GPOs] used sole source contracting extensively" and that "for one of the two largest GPOs, clinical preference products accounted for the bulk--82 percent--of its sole-source dollar purchasing volume." These practices only serve the financial interests of GPOs and must be terminated.

4) Excessive Administrative Fees

The largest GPO, Novation, continues to collect administrative fees in excess of the three percent originally intended in the safe harbor legislation, albeit mostly for products that are not deemed "clinically preferred" by Novation. While Novation claims to not "require" a manufacturer to pay these fees, they also will not refuse the fees. This creates a clear conflict of interest, which Novation must avoid.

The current Novation practice presents a problem because certain vendors willing to pay higher fees on "non-clinical" preference products may have their "clinical preference" products viewed more favorably based on the financial relationship between the GPO and the vendor. Every decision a GPO makes regarding product selection should be free from any financial interests. Novation's current policy does not foster this environment.

Beyond excessive fees, the GPOs financial incentives under the current administrative fee system should be examined. Today, GPOs actually receive more money, the higher the bid price is. This perverse incentive structure must be examined. Perhaps hospitals paying a GPO based on a percentage of savings would ensure that GPOs select the best products at the best price.

5) Conflicts of Interest

Although many GPOs have adopted codes to address the conflicts of interest related to investments in medical supply vendors, there still remains a conflict that needs to be addressed. Novation's interest in the e-commerce company, Neoforma, is troubling and must be dealt with.

Neoforma is a publicly traded company that Novation has a substantial interest in. Much of the revenue Neoforma generates comes as a direct result of its relationship with Novation. Novation's supplier agreements (through May of this year) require that the vendor MUST agree to sign up for Neoforma in order for a vendor to be awarded a contract to sell to Novation hospitals through traditional methods. The fees for Neoforma often exceed $100,000. Irrespective of whether a vendor plans to sell via Neoforma, they must participate. In fact, most clinical preference products are not sold via e-commerce because of the need for service, training, etc., so participation in Neoforma would add no value to these vendors.

This presents yet another conflict (similar to the excessive fee example above) of a GPO having the potential to award a contract based on their financial well being without regard to clinicians' preferences. If a vendor was not willing to pay the fee for Neoforma and another vendor was, would the two still be viewed objectively? I am not claming that Novation would base their decision solely on a vendor's willingness to participate in Neoforma, but the potential for conflict does exist and it should be eliminated.

6) Private Labeling

The practice of private labeling continues today by two GPOs, Novation and AmeriNet. Novation publicly stated that its hospitals purchased over $1 billion in private label products alone in 2002. AmeriNet does substantially less, under $50 million.
These programs are another way in which GPOs generate revenue from the vendor without adding value to the end user. When MDMA asked Novation officials the reason for a private label program, they stated that there were three main "drivers." First, they said smaller companies without a sales force, marketing, etc. would benefit. After a review of the Novaplus products, most seemed to be private labels of large vendor's products. Second, they stated that the Novaplus named carried the "branding advantage" within their hospitals. With all due respect, J&J, 3M, etc. have pretty good name recognition and would not reasonably benefit from the Novaplus label. Finally, Novation claimed that they "drove compliance" with the private label so vendors "see value". However, Novation claims to only private label "commodity" products. Novation typically uses "sole-source" contracts for commodity products and as a result, the vendor would enjoy "compliance" due to the fact that they were the only ones on contract. To date, we have been unable to determine a reason for the private label program other than

another means of extracting fees from a vendor outside the traditional "administrative fee" and in doing so generating hundreds of millions of dollars for certain GPOs in the process. The GAO report stated that one GPO charged 18% on a private label product. This cannot result in cost savings for the system.

7) Other Concerns

There have been other conflicts that have arisen in recent weeks. It has been reported that both Broadlane and MedAssets plan to have public offerings. MDMA does not believe that the revenues collected by GPOs from manufacturers under a government safe harbor were intended to build the infrastructure for a publicly traded company. If a GPO wants to go public, that is acceptable, as long as it funds itself and does not derive monies from a government safe harbor.

Premier Inc., the parent of Premier Purchasing Group, recently announced a partnership with CMS to evaluate hospital performance and award the top hospitals with additional Medicare reimbursement dollars. While MDMA applauds CMS's concept of rewarding top performing hospitals, the use of Premier's proprietary system, on the surface, is troubling. This system did not appear overnight and MDMA questions whether the monies generated from the administrative fees from manufacturers helped to develop the proprietary system. If this program is adopted nationwide, Premier has the potential for a financial windfall because every hospital who wanted to participate would have to pay Premier for the system. Furthermore, if a hospital is willing to pay thousands of dollars for a chance to increase Medicare payments, should they not be willing to pay the GPO for contracting services. Both are value propositions. Let the market decide how much a hospital is willing to pay a GPO. A model based on a percentage of savings would be a true incentive to lower health care costs in this country.

Next Steps

The manufacturers who testified before you discussed their experiences since the codes have taken effect. Although some progress by certain GPOs has been made, the largest GPO in the nation continues to operate in the same manner that was called into question at last year's hearing. It continues to accept fees well above the 3 percent level Congress intended when establishing the Safe Harbor (See. H. Conf. Rep. 1012. 99th Cong., 2d Sess.310-11(1986)), including licensing fees, marketing fees, private label fees, etc. In addition, it continues to promote programs that bundle unrelated companies together (see Novation's Spectrum Opportunity Contract), bundle unrelated products, promote private label programs and require vendors to sign up and pay fees to a for-profit e-commerce company in which it owns a substantial interest. These practices cannot be allowed to continue. It is not fair to those GPOs who truly want to reform and those GPOs that were never acting in this manner.

Last year, Senator Kohl stated, "Without quick and effective self-regulation, we will have to consider Congressional action." At that time, MDMA agreed with the Subcommittee's decision for a self-imposed code. However, self-regulation may have come quick, but it

is not comprehensive and has yet to be truly effective. In fact, most GPOs fail to commit to the practices listed earlier and those that do so state that these are "prospective" and do not pertain to existing contracts. This can hardly be described as "quick and effective," and it is clearly not in the best interest of patients, caregivers, or innovative small businesses.

MDMA believes that the safe harbor status granted to GPOs was well intended. Curbing health care costs was necessary when the safe harbor was granted and is even more critical today. However, due to massive consolidation in the marketplace over the past decade, and certain business and contracting practices of some GPOs, the savings Congress intended to generate have not been realized and innovation is suffering. Congress must provide greater oversight to ensure the GPOs act in the best interests of the hospitals they serve and not in the best interest of their own financial well being.

MDMA is encouraged with Chairman's DeWine's statement, "our work in this area is not complete" and his commitment to further hearings. In addition, Senator Kohl's letter to HHS Secretary Thompson calling for an officer to oversee the GPO industry and for HHS to "strengthen" its regulations governing the Medicare safe harbor which GPOs operate" is commendable and necessary for true, lasting reform to occur. In addition, MDMA urges this Subcommittee to act immediately to require GPOs seeking to enjoy the safe harbor to comply with a verifiable, uniform and comprehensive code of conduct. Failure to do so should result in a GPO no longer qualifying for the safe harbor. This system will reward GPOs that promote open and fair access to the marketplace while punishing those GPOs who have their own self-interest ahead of patients and the members they claim to serve.

We also ask you take any legislative steps you deem necessary to restore competitive principles to this marketplace to ensure the continued health and safety of our people. 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.

Why the Need for Reform?

Medical Technology Innovation Drives Health Care

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 dramatic advances in modern medicine and surgery.

The free market system that underlies our economy protects the ability of innovative, entrepreneurial manufacturers to research and develop new products. Our antitrust laws safeguard that system. 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 thank the Subcommittee for its continued oversight of this issue and we encourage your continued attention, and, if necessary, a corrective legislative remedy.

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.

Since 1992, MDMA has been the chief advocate of the research-based entrepreneurial sector of the medical device industry. We represent more than 160 innovators and manufacturers of medical devices, diagnostic products and health care information systems.

Together, we represent the future of medical technology in America. 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).

Unlike other industries, medical devices see constant updating and improvements. At any given time, 60 percent of the medical products sold are less than 12 months old. The life cycle of a typical medical device is only 18 months. This continuous innovation has traditionally been the hallmark of the entrepreneurial medical device industry.

The large manufacturers are important to the continuity of supply of quality product. They themselves were 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 are 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. To gain regulatory approval, manufacturers must gather a vast array of laboratory, animal, and human test results, as well as secure adequate funding to endure the long process. Next, a manufacturer must navigate the Medicare and private pay reimbursement mazes. Yet, once a device has cleared these hurdles, significant barriers exist that limit the ability for many manufacturers to compete in an open, fair marketplace.

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.

The current situation has unintended health care consequences, which flow from the antitrust exemptions in question, including:

- "Administrative fees" paid to GPOs by manufacturers are often excessive and are not reliably passed along to hospitals as savings.

- 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. Current GPO contracting practices act as a significant barrier to market entry by entrepreneurial medical technology companies.

- Improper bundling/tying practices 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.

MDMA appreciates the efforts of the Subcommittee's Chairman and Ranking Member, to investigate this important issue and hold GPOs accountable. Last April, the Subcommittee held a hearing on this issue. In addition, an exhaustive series in *The New York Times* shed necessary light on this previously "hidden" problem. Now, the Subcommittee is again calling on the group purchasing industry to explain their actions and hold them accountable for carrying out their mission, which is to help hospitals save money while ensuring availability of a wide array of new and innovative technologies in the marketplace.

Over the past few years, a situation has evolved through rational strategic business decisions made in response to the opportunities the antitrust exemptions provided. However, we believe this evolution has led to a situation that is inconsistent with a free and open competitive market.

Anticompetitive Behavior Limits Innovation and Raises Health Care Costs

The business practices of the large GPOs that dominate the health care purchasing market continue to stifle innovation and entrepreneurship. Recent 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. Indeed, the largest two GPOs control purchasing for 70 percent of American hospital beds. As a result, larger device manufacturers, now able to focus their sales attention on just a few purchasers, have paid 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, these contracts effectively prevent any hospital affiliated with a GPO from making purchases from other product manufacturers, regardless of quality, safety, cost, or physician preference.

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.**

In many cases, GPO member hospitals are 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. 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 was not what Congress envisioned in granting the GPO industry the safe harbor.

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

Certain GPOs bundle multiple product lines (even unrelated products made by different manufacturers) together under committed-volume GPO contracts. The contracts can require hospitals actually to pay higher prices for products where competition is great in order to receive preferred pricing, rebates, and other discounts on products in markets without significant competition. These 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 bundling arrangements create significant incentives for hospitals to avoid the 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 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.

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

GPOs claim that their long-term contracts do not exclude any manufacturer from competing for business from member hospitals. Indeed, GPOs 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.

GPOs devised a 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." The name is 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.

In reality, GPOs frequently decide what constitutes 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.

For example, one GPO "breakthrough program" included a review of the request by the competing manufacturer that currently holds the contract and required their consent. This sort of activity demonstrates 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 continues to include contracts with exorbitant "administrative fees", "licensing fees", and other charges, is a barrier to market entry and secures the position of incumbent, dominant manufacturers.**

GPOs continue to 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 GPOs. Some GPOs are known to charge additional administrative fees, above the 3% allowance contemplated by Congress.

These additional fees, which include private label licensing fees, payments to for-profit enterprises, and other excessive fees, amount to coerced payments that unduly influence GPOs' purchasing decisions. In a system designed to save hospitals money, these extra fees only increase the cost of devices without any noticeable benefit.

Additional fees are 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 bundling program. This practice protects GPO-sponsored manufacturers from targeted competition from small and entrepreneurial manufacturers with innovative technologies.

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.

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

For-profit GPOs 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. GPOs 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 article of its series 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 do not 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 GPOs to do as much business as possible with as few manufacturers as possible, thereby helping GPOs maximize their profits while minimizing their own administrative costs.

➢ ***GPO*s are unable to demonstrate actual savings and may actually cost the health care system more money.**

As you are no doubt aware, health care costs are dramatically on the upswing again. A recent Joint Economic Committee hearing revealed that while health sector cost increases

slowed in the mid 1990s, since 1999, annual per capita spending has grown 4.5 percent faster than inflation. By 2002, health care spending was 14 percent of the nation's GDP.

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.

GPOs claim to save money for their hospital customers, but anticompetitive practices limit the ability of the free market to control costs. In addition, excessive fees paid to GPOs by manufacturers needlessly add to the overall cost of health care.

There is no evidence that GPOs are holding down health care costs. In fact, the only true independent study to date conducted by the GAO concluded that GPOs often do not save money. 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 context in *The New York Times* series.

In addition, there is more to the equation than simply the upfront cost of medical products. 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. In other words, many other factors must be considered when evaluating savings related to purchasing decisions.

The 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.

GPO decision-making is notoriously opaque. 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.

Again, we thank Chairman DeWine, Ranking Member Kohl and the Subcommittee for their continued efforts to ensure that patients and doctors have access to the best medical products the competitive prices.

Thank you.

Mark Leahey
Executive Director
Medical Device Manufacturers Association

Memorial Hermann

FOR YOUR WHOLE LIFE.

July 14, 2003

The Honorable Mike DeWine, Chairman
U.S. Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights
224 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator DeWine:

My organization has relationships with several group purchasing organizations, most notably, Novation, and I am told your subcommittee will be holding a hearing on July 16 on the hospital group purchasing industry. I would appreciate this opportunity to comment for the record. I believe the hearing is titled, "Hospital Group Purchasing: Has the Market Become More Open to Competition?"

Memorial Hermann Healthcare System is a not-for-profit community health care system with eleven hospitals serving the Greater Houston area. We provide 120,000 inpatient admissions, 380,000 emergency room visits, and over 1,000,000 outpatient services on an annual basis. Memorial Hermann must leverage the purchasing power of Novation in order to maximize our resources and enable us to better serve our patients.

Numerous industry studies have validated the benefits of group purchasing, which is common in many large and small industries. As you know, health care organizations across the country are struggling with rising costs, falling insurance reimbursements and reduced state and federal support. Group purchasing is an effective tool to help us contain costs and make health care more affordable.

We annually purchase $233 million in supplies through Novation and other Group Purchasing Organizations (GPOs). One of the unique programs that Novation offers is its private label, NOVAPLUS. This private label is estimated to save Novation members approximately $180 million each year, in comparison to branded products. As with other private labels, such as the grocery and retail industries, we have the assurance that we are getting the best prices on high quality commodity products. In many cases, we saved as much as 15 percent on these purchases – much more than we could if we purchased these items on our own. And frankly, it doesn't make sense for us to spend time negotiating prices on commodity products. Novation does that for us.

In addition to lowering the cost of commodities, Novation makes ordering easier and less expensive by providing one-stop shopping for a huge range of medical-surgical, pharmaceutical,

Executive Offices
Memorial Hermann Healthcare System
7737 SOUTHWEST FREEWAY ■ HOUSTON, TEXAS 77074

radiology, laboratory and other products. Novation also increases patient safety by standardizing commodity products – reducing the risk of human error.

Any additional changes in the GPO industry could push beyond the point of useful government oversight and move towards harmful interference into a system that provides enormous benefit to health care organizations across the nation. I believe the changes GPOs have already made are reasonable.

Sincerely,

Dan

Dan Wolterman
President/CEO

DJW:pm

cc: The Honorable Herbert Kohl, Ranking Member
The Honorable John Cornyn
The Honorable Kay Bailey Hutchison

Testimony of Richard A. Norling
Chairman and CEO
Premier, Inc.

Before the
Subcommittee on Antitrust, Competition, and Business and Consumer Rights
Committee on the Judiciary
United States Senate
July 16, 2003

Introduction

Good afternoon, Chairman DeWine, Senator Kohl, and members of the Subcommittee. My name is Richard Norling and I am Chairman and CEO of Premier, Inc. I appreciate having the opportunity to appear once again before this Subcommittee. As you know, Premier Inc. and its group purchasing affiliate, Premier Purchasing Partners, are owned and governed by 198 not-for-profit hospitals and healthcare systems and count as members approximately 1,500 of the leading hospitals in all 50 states, serving some 130 million patients every year.

As stated at last year's hearing, if there is an opportunity to improve, Premier will take it. Last year, we made commitments and I am pleased to tell this Subcommittee today that those commitments were kept. I would also like to take this opportunity to point out the valuable contributions that Premier continues to make to our owner and member hospitals, and to the communities and patients they serve as well as to the broader healthcare marketplace.

Proactive Steps Taken

In response to your challenge to improve business practices at Premier and throughout the industry, we supported the Health Industry Group Purchasing Association (HIGPA) in its adoption of an industry-wide code of conduct. This Industry Code provides key guidelines for conduct in major areas including conflict of interest and contracting practices.

But we went farther when, in August 2002, we adopted 13 additional principles that raised the bar even higher and addressed several important contracting and fee-related issues that the Industry Code could not address.

In October, we took an additional and very important step with Premier's adoption of the Hanson report and its 50 recommended best ethical practices for GPOs. This was the groundbreaking work of Professor Kirk Hanson, Executive Director of the Markkula Center for Applied Ethics at Santa Clara University in California and distinguished business ethicist. By embracing the Hanson report and its recommendations, we have provided assurance of our commitment to the highest ethical standards in order to respond to the concerns of this Subcommittee and other interested parties. At the same time, we believe strongly that these principles make sound business and strategic sense for Premier, other GPOs and the other participants in the healthcare marketplace.

With the adoption and implementation of our Code of Conduct:

- We contract for physician preference products on a multi-source basis with no GPO commitment levels or "bundling" with unrelated products. For example, in the last year, we re-bid pulse oximetry products – which had been raised as an area of concern at your previous hearing. We sent out requests for proposals to all suppliers in this area. We reviewed these submissions and contracted with three different manufacturers. These contracts contain no GPO commitment levels and no bundling with unrelated products.

  Another good example is our contracting for medical-surgical products that hospitals use in neurosurgery. Previously, these products were all grouped in one contract area. With our hospital members' input, we broke these products into eleven separate product categories and put all eleven out for bid on a multi-source, unbundled basis without GPO commitment levels. As a result, we added two new suppliers in this area, including Integra NeuroSciences, a small

innovative manufacturer of implants, instruments and monitors used in neurosurgery and intensive care units.

- We substantially revised and improved our Technology Assessment and Technology Breakthroughs programs to further assure that they operate in a fair, timely, confidential and unbiased manner. We placed these programs under the direction of Jack Cox, M.D., and supplemented our assessment activities by outsourcing functions to several highly qualified external firms. Those firms include:

    - the Health Technology Center (a non-profit research and education organization that provides strategic information and resources);
    - the Institute of the Future (a non-profit research firm specializing in long-term forecasting);
    - SG-2 (a firm that identifies and analyzes changes in the technology and business of health care); and
    - ECRI (formerly the Emergency Care Research Institute, a health services research agency).

  In addition, we entered into an agreement with ECRI to support our assessment for our Technology Breakthroughs program. ECRI, a not-for-profit health services research agency, has a sterling reputation in this field and is adding much to our efforts to bring innovative products to our members. Further, we worked to reduce the cycle time of Technology Breakthroughs reviews. In the early days of this program, reviews took longer than any of us would have liked – not surprising in a new effort. But substantial improvements have been made. We have gone from a review process of more than eight months to one that takes only four months from the time Premier receives a completed application to the time a recommendation is made.

- We incorporated our Code into our policies and procedures, including our conflict of interest policies. Every single employee and advisory committee member received training on the Code and our updated policies, and each has certified compliance. Further, we have applied our conflict standards to all employees, not just those directly involved in contracting, and prohibited all employees from holding equity stakes in any participating vendors.

- We continue to limit administrative fees to 3%, and our average fee is 2.1%. We do not charge "upfront" fees or marketing fees, and we do not accept administrative fees in the form of vendor equity or require vendor participation in any additional services for which fees may be charged. In addition, we have begun the process of standardizing administrative fees for each bid process and product category. This major innovation was recommended by Professor Hanson to eliminate the potential or perception that fees or fee levels impact product selection.

- We continued our practice of not private-labeling products.

- We contract for 3 years or less, with limited exceptions.

- We continue to seek out small and woman- and minority-owned suppliers for contracts. At present, approximately 30% of our suppliers are small companies as defined by the Small Business Administration and a number of these companies are also woman- and minority-owned businesses.

- We continue to focus on environmental issues, an effort which was recently recognized when the Hospitals for a Healthy Environment, H2E, awarded Premier the Champion for Change Award for our efforts to contract for the most environmentally safe products.

- At the close of this calendar year, our Ethics and Compliance officer will make publicly available a report on Premier's compliance with our Code. This report will be in addition to the Certification of Industry Code Compliance that we made earlier this year.

When we introduced our Code, Senators DeWine and Kohl called it "the most significant reform to the hospital purchasing system since the development of...group purchasing...." On other occasions, Senator Kohl was kind enough to describe our efforts as setting the "gold standard" for the industry and to cite us as "the industry leader." We are greatly encouraged by the response to our Code and are committed to working with you and the other members of the Subcommittee in a good faith and productive way to continue to improve our industry and healthcare in America.

The Value of Premier

Premier is a healthcare alliance that is owned by non-profit hospitals and healthcare systems. Our core purpose is to improve the health of communities by helping our members improve quality and cost effectiveness. Group purchasing is a vitally important part of that purpose, but it is only one of several cornerstones of a broader strategy to support our owners' and members' efforts to improve their performance. Others include an ongoing effort to help improve the quality of care by using the wealth of comparative data on clinical performance Premier has accumulated, and by enhancing our capabilities to manage hospitals' enormously complex supply chain processes and assess new and existing technologies. We also provide insurance and risk management services that enable our member hospitals to better manage the major risks inherent our industry. I would like to bring you up to date on key successes in these cornerstones of Premier's operations.

Since I testified before this Subcommittee in April 2002, Premier has continued to be highly successful in helping its hospital members control costs. One of our most notable

achievements in this effort has been the adoption of a strategy known as strategic sourcing.

At its basic level, following this strategy allows suppliers with products that are focused in specific product categories to compete with suppliers that offer a broader line of offerings. A terrific example of this strategy in action is in custom sterile procedure trays (these are trays of medical/surgical supplies customized for a particular procedure) where we moved from a sole-source award to contracts with four suppliers including one woman-owned company. Our owners and members benefit from this strategy because it introduces additional competition into categories that would otherwise be dominated by a major supplier, and our entire healthcare system benefits because it fosters greater competition within vital supply categories.

As part of our strategic sourcing effort, we have also adopted advanced tools that allow us to conduct reverse auctions for certain types of products. This approach has proven successful in other industries, and Premier is leading the effort to utilize this approach within the healthcare industry. We started using this technology in the last year, and have now completed auctions for 16 product categories representing $434.5 million of historical spending, and have achieved a total savings opportunity of over $103.5 million vs. our previously contracted pricing. In fact, this tool has been so rewarding that we are currently working to implement the reverse auctions in ten additional categories over the course of the next several weeks.

Examples of cost savings opportunities we have achieved through the use of reverse auctions include:

- Amiodarone (pharmaceutical) – 61.7%
- Patient Aids – 35.3%
- Waterless Hand Gels and Solutions – 33%
- Vital Sign Monitors/Cuffs – 30.6%
- Surgeon Gloves – 30%

- Salad Dressing & Sauces – 26.4%
- Soaps and Lotions – 26%
- Lap Sponges and OR Towels – 26%
- Textiles and Textile Services – 25.2%
- Exam Gloves – 25%
- Standard Surgical Set-up Kits and OR Access – 24%
- Personal Protective Apparel – 21.0%
- Disposable Anesthesia – 14%
- Surgical Hand Scrubs – 11%
- Patient Warming – 5%
- Wound Drainage - 3%

Widening the focus to GPOs as a whole, over the past year, the evidence of the tremendous value we deliver to hospitals and their patients has continued to build. In one major study conducted by Muse & Associates for HIGPA and released in October 2002, healthcare institutions reported that they saved from 10% to 15% of their non-labor costs by channeling their purchases through GPOs. That translates into savings for the U.S. healthcare system in 2002 of between $19.0 billion and $33.7 billion each year.

According to a May 2003 study by The Lewin Group, GPOs save their member institutions an average of 10.4% of their total supply costs. Savings of this magnitude are critical to the ability of many hospitals to confront the powerful squeeze between increasingly restrictive insurance reimbursement and the challenge of uninsured patients on the one hand, and rising labor and supply costs on the other. Of course, hospitals experience enormous cost pressures and can, therefore, benefit significantly by each dollar saved. For not-for-profit hospitals, the money saved can be dedicated to help cover the medical costs of the under- and uninsured, augment stretched hospital staffs, increase bioterrorism readiness and/or pay for costly medical liability insurance.

Controlling the costs of supplies is an area in which hospitals can make a significant difference. If GPOs were to operate within a significantly more restrictive business

model, these savings might be drastically cut to the detriment of hospitals and their patients. According to Muse & Associates, under a more restrictive model, public and private expenditures for healthcare services and supplies would increase by approximately $2 billion, and that's with only a 1% increase in the cost of medical supplies. That would mean more than $1 billion in higher costs to the Medicare and Medicaid programs alone.

It is clear that, for many hospitals, GPOs like Premier Purchasing Partners are much more than a convenience or a tool of purchasing management. The economies of scale they provide play a crucial role in sustaining vital medical services. A significant drop in those savings could have devastating effects – especially for the not-for-profit hospitals that own Premier. Still, even with the benefit accrued from our cost control measures, we have witnessed an acceleration of healthcare costs in several areas that should be of great concern to all those present here today.

Turning to Premier's role as a performance-improvement organization, we help our hospitals undertake initiatives to improve clinical performance and supply chain value by using the vast reservoir of collected knowledge and experience contained within our databases. Drawing on the experience of thousands of healthcare professionals in hundreds of hospitals, Premier's databases are among the most comprehensive and accurate sources of clinical, financial and operational metrics available anywhere. Through our Healthcare Informatics programs, member and non-member hospitals are able to apply detailed, comparative data and performance-improvement expertise in their continuing efforts to improve quality.

Premier hospitals continue to achieve important performance improvements through initiatives assisted by Premier data in a wide range of clinical treatment areas, including acute myocardial infarction, congestive heart failure, coronary bypass grafts, community acquired pneumonia, hip- and knee-replacement, spinal surgery, pregnancy and related conditions, and stroke.

We are especially pleased that the federal Centers for Medicare and Medicaid Services (CMS) has chosen our database system, Perspective, as the foundation of a three-year demonstration project to recognize and reward high-performing hospitals through increased reimbursements. As you know, this effort is a key step toward putting the weight of the major federal health insurance programs behind the growing movement toward encouraging quality of care. The hospitals across the nation that will voluntarily participate in this pilot program are being drawn from among the approximately 525 hospitals that already participate in the Perspective program. By submitting clinical and financial data to Premier, we generate regular clinical performance reports that the hospitals will use in their own planning for improvement. This data will provide the basis for Medicare to reward hospitals that provide the highest quality of care with higher reimbursements and will pave the way for a wider national effort to enable healthcare providers and payers to work together on an agenda of healthcare quality.

Several Premier members committed publicly to the project on the first day – among them Aurora Health Care of Wisconsin and Kettering Medical Center of Kettering, Ohio – and we were pleased that Kettering CEO Frank Perez was able to participate in the July 10, 2003 news conference in Washington, D.C. announcing this program. In addition, according to the July 10 *Milwaukee Journal Sentinel,* Aurora President Ed Howe said that the idea behind the experiment is that hospitals with better quality should be able to save the government "significant amounts of money."

Another important service we provide to our not-for-profit hospitals, unrelated to group purchasing, is insurance. Through Premier Insurance Management Services (PIMS), we help hospitals manage their insurance costs while improving risk management and claims capabilities. In these days of skyrocketing insurance costs to cover the risks inherent in delivering healthcare services, liability coverage can be very expensive or even difficult to obtain in many areas. Working with PIMS, hospitals have come together to create insurance pools (that they own) to reduce cost, manage risk and improve clinical performance. PIMS is able to help hospitals share information on best practices and network solutions. Increasingly, we hope to be able to use the tremendous power of Premier's clinical databases to analyze the relationships between insurance claims and

clinical outcomes. Our goal is to help hospitals focus on risk prevention, so they can improve outcomes for patients and bring down the costs of insurance claims simultaneously.

In addition to lowering costs for all our members, we have paid attention to special needs by setting up, on behalf of our more than 60 children's hospitals, dedicated committees that specialize in evaluating and contracting for pediatric medical products.

To sum up Premier's value, our contribution to hospitals' efforts to control costs through group purchasing contracts alone is a substantial one; without it, many not-for-profit hospitals would have no choice but to make significant cuts in staffing or services. But the value we contribute as a performance-improvement organization to the quality and effectiveness of Premier hospitals and the nation's healthcare system is also very significant and we will continue to look for new and exciting ways to provide meaningful value.

Conclusion

Premier has long proved its value to the healthcare system and continues to play a critical role in helping hospitals keep costs down and maintain the quality of healthcare. We at Premier have rolled-up our sleeves and plunged into the job of creating a set of practices and principles that will ensure the highest standards of ethical conduct. We made a strong commitment to set the pace of leadership for our industry. We lived up to that commitment by adopting the tough, comprehensive principles embodied in the Industry Code, the Premier additional principles, and the recommendations included in the Hanson report.

While I want to emphasize that you can count on our continuing cooperation and support, we believe that the time is right to encourage others to do their part in an ongoing effort to ensure the quality and effectiveness of our nation's healthcare system.

Everyone involved in the healthcare system in this country should be working towards the same mission: to provide the best quality care and access to that care for every individual. Organizations such as Premier play a valuable but discrete role in the healthcare system. Going forward, we must ensure that every participant in healthcare commits to the highest standards. At Premier, we are committed to doing our part.

###

FORREST GENERAL HOSPITAL
Medical Excellence. Community Loyalty.
WILLIAM C. OLIVER
President

July 14, 2003

The Honorable Mike DeWine, Chairman
United States Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy
and Consumer Rights
224 Dirksen Senate Office Building
Washington, DC 20510

VIA FACSIMILE 202-228-0463

Dear Senator DeWine:

I have learned that the Subcommittee on Antitrust, Competition Policy and Consumer Rights will be holding a hearing on July 16 on the hospital group purchasing industry. I want to voice my support for the GPO industry in general, and Novation specifically, and ask that my comments be entered into the official record for the hearing: "Hospital Group Purchasing: Has the Market Become More Open to Competition?"

I'm sure many of my peers in the industry have written you expressing their concern and dismay at the Senate's interest in this topic. Many of them have probably highlighted the savings they achieve through GPOs. I want to highlight the potential increase in costs for federal healthcare programs that would result if you created legislative barriers that hindered GPO activities.

Specifically, *for every one percentage point decline in the rate of GPO-generated savings:*

- *Medicare expenditures would increase annually by an additional $540 million to $641 million.*
- *Medicaid expenditures would increase annually by an additional $395 million to $468 million.*
- *Workers' Compensation healthcare expenditures would increase annually by an additional $32 million to $39 million.*

Hospitals across the nation are already struggling to cope with lower federal funding. To compound their problems by limiting the ability of GPOs to help them manage costs and create situations that would increase the charges they send to the federal government

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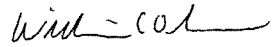
www.forrestgeneral.com

and state for Medicare and Medicaid patients would not be good medicine for healthcare.

At Forrest General Hospital we have made serious cutbacks to our staff. Without the savings from GPO efforts, many more hundreds of positions would be affected—which would also affect the thousands of patients we serve.

I urge you to take conservative measures when considering any further demands on the GPO industry. I believe the industry acted responsibly to last year's request for changes in behavior. Please consider that progress as an opportunity to allow the industry to regulate itself.

Sincerely,



William C. Oliver, CPA, FHFMA
President

lck

pc: The Honorable Herbert Kohl, Ranking Member
The Honorable Thad Cochran
The Honorable Trent Lott

HEALTHCARE SYSTEM
800 N.E. Glen Oak Avenue, Peoria, Illinois 61603-3200 Phone (309) 655-2850

July 14, 2003

The Honorable Mike DeWine
United States Senator
140 Russell Senate Office Building
Washington, D.C. 20510

Re: Judiciary "Antitrust, Competition Policy and Consumer Rights" Subcommittee Hearings on Group Purchasing Organizations – July 16, 2003

Dear Mr. Chairman:

We respectfully request that the following written remarks be included in the official record of the Subcommittee Hearing on July 16, 2003.

OSF Healthcare System is a large Catholic system doing business primarily in Central Illinois. We operate five OSF hospitals in Illinois, and provide support to another seventeen (17) affiliated hospitals throughout Central Illinois.

The Senate Judiciary Subcommittee on "Antitrust, Competition Policy and Consumer Rights" has held hearings over the last year on the operational aspects of GPO's. Based upon those hearings, some positive changes have already occurred regarding GPO operations and ethical codes of conduct. However, more hearings such as those scheduled for July 16, 2003, will be held and OSF is concerned that the Senate may go too far in creating new operational restrictions on GPO's that would severely limit their effectiveness and value to healthcare providers.

OSF is a member of AmeriNet, a well run GPO based in St. Louis, MO. When properly structured, GPO's are able to offer health care facilities significant cost savings in the purchase of products and supplies because they buy in large bulk quantities at much lower prices from suppliers.

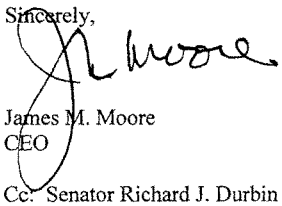
Business practices that are common to all industries are also used by healthcare GPO's, and they are essential to lowering our supply costs. Such practices include:

- Sole source contracts, private label arrangements, and committed volume agreements. Such arrangements enable our GPO to greatly reduce our supply costs. Please allow these to continue.

- Administrative Fees paid by suppliers to GPO's are also a legitimate business practice. Suppliers derive a substantial cost benefit using GPO's to reach their customers vs. the mass advertising and individual contracting they would otherwise have to do to reach customers. These fees do not reduce competition or access to new products in the market when the GPO operates ethically. New products are essential to medical providers, and GPO's must offer them or lose their value to their members.

Please do not punish an entire GPO system for the bad behavior of a few.

Sincerely,



James M. Moore
CEO

Cc: Senator Richard J. Durbin
Mark Keam, Chief Counsel to Senator Durbin

Premier Health Partners

Office of the President
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Dayton, Ohio 45409
Telephone: 937-208-2101
Fax: 937-208-6300

July 11, 2003

RECEIVED JUL 23 2003

The Honorable Mike DeWine, Chairman
Subcommittee on Antitrust, Competition Policy and Consumer Rights
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator DeWine:

We have learned that your Subcommittee has scheduled a hearing on group purchasing ("Hospital Group Purchasing: Has the Market Become More Open to Competition?"), and I would like to comment for the record on the role of GPOs as they relate to new technology. It is also important for us to hold down costs and ensure that we're getting the best equipment for the money.

GPOs – in our case, Novation – helps us do in two ways:

1) By combining our purchasing power with other hospitals, they can negotiate more effectively with manufacturers.
2) Equally important is their use of clinical councils that include representatives from member hospitals to evaluate new technology products and give us unbiased information.

We also have been pleased with Novation's commitment in the past year to ensure that members have timely access to new and innovative technologies by limiting the initial length of contracts, re-bidding or adding suppliers when new technology becomes available and creating new communications tools to inform us about innovative technology.

However, while technology is important hospitals choose to standardize. It's ineffective and wasteful to multi-source all contracts. GPOs like Novation are essential to help us buy the most appropriate products at the lowest possible costs. Therefore, we oppose any restrictions on GPOs that would limit their ability to evaluate technology and award appropriate contracts.

We support your Subcommittee's efforts to make sure that health care systems have access to new technology, but we think GPOs are already doing that. We have seen significant improvements in the past year, and we believe the current system works well.

Please let me know if I can be of assistance, and I would respectively request that this letter become a part of your official record.

Sincerely,

Thomas G. Breitenbach
President and Chief Executive Officer

bsw

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*

Hearing on

"Hospital Group Purchasing: Has the Market Become More Open to Competition?"

July 16, 2003

***All of the statements and allegations contained in this testimony can be substantiated by affidavits, sworn statements, and other documents.**

On behalf of my colleagues at Retractable Technologies and other small medical device makers, I'd like to thank you once again for the opportunity to present our views on the current competitive environment in the medical device industry. Most of all, I want to commend Senators DeWine and Kohl and the other Members of this Subcommittee and staff for their dedication over the last two years to investigating and eliminating the barriers to free market competition in this critical industry sector. Before last year's hearing, I had just about given up hope that a small, entrepreneurial company like ours could get more than lip service and a handshake in Washington when faced with powerful, deep-pocketed monopolies. Your obviously sincere commitment to assuring that hundreds of small, innovative device makers get a fair shake in the marketplace has not only rekindled the hopes and dreams of many small companies like ours, but also those of medical innovators for years to come. Even more importantly, your concern holds out the promise that patients and healthcare workers will get the benefit of the best, safest medical technology American ingenuity can devise.

The purpose of this hearing, as I understand it, is to determine whether any progress has been made since last year's hearing in freeing the marketplace from the anticompetitive, unethical, and we believe, illegal practices of the large group purchasing organizations and the dominant medical device manufacturers. As you may recall, I presented written testimony on April 30, 2002 that explained in detail our long and unsuccessful efforts to overcome the hurdles these behemoths created to block us from introducing our lifesaving automated retraction needle devices into America's hospitals---or even demonstrating them to clinicians. So rather than repeat myself, I'll try to focus on the present and the future rather than on the past.

Before proceeding further, I should point out that although Retractable Technologies is just one of hundreds of small companies that have been blocked by these questionable arrangements, our situation is unique in one important respect. On May 7, 2003, we announced settlement agreements with three of the four defendants in our longstanding federal antitrust lawsuit. They are Novation and Premier, the two largest GPOs, and Tyco International, the second largest needle maker. As we stated in our press release, specific terms are confidential, but the settlement includes "provisions that are intended to facilitate the sale" of our VanishPoint® products to Premier and Novation facilities. Becton Dickinson, the dominant needle maker, is the sole remaining defendant, and we look forward to seeing them in February 2004 in Federal District Court in Texarkana, Texas, where we are hopeful that justice will finally prevail.

With this as backdrop, I'd like to make three observations.

First, if it were not for our settlement agreement, we would not expect any improvement in access to GPO member hospitals as long as the current system remains in place. That's because the GPOs have become no more than front men for the monopolistic manufacturers. Indeed, I believe this Subcommittee should now focus its attention on the role of the big medical device suppliers in this corrupt system.

Second, even if small companies like ours ultimately gain unfettered access to America's private acute care hospitals, that alone will not remedy the perverse economics of the current system and the GPOs' role in the system. This system will continue to drive up healthcare costs for all Americans. Under the current arrangement, in which suppliers pay various fees to the GPOs, there is no incentive for suppliers to reduce ***prices*** or for GPOs and hospitals to reduce ***costs***. Suppliers, not hospitals, are the GPOs' real

customers. As a result, medical supply costs will continue to rise far in excess of the rate of inflation.

Finally, all this leads me to one inescapable conclusion: that voluntary codes of conduct will not fix the flaws of the current system. The ill-conceived "safe harbor" from federal anti-kickback statutes that Congress, with the best of intentions, passed in the early 1990's has instead become a "pirate's cove" for big companies with inferior products seeking to avoid the rigors of fair competition. Accordingly, we believe Congress must now pass corrective legislation that 1) repeals the ill-conceived "safe harbor"; 2) prohibits the payment of fees, administrative or otherwise, by manufacturers to GPOs; 3) reinstates criminal penalties for companies, GPOs and individuals who pay or receive kickbacks in any form for granting a contract to a vendor; and 4) prohibits tying and bundling, sole source contracting, and other contracting and purchasing abuses.

I'll elaborate on each of these points in turn.

First, we're hopeful that our legal settlement will ultimately pry open the doors of America's hospitals to our salespeople and our products. In fact, I'm convinced that this settlement would not have happened if this Subcommittee and *The New York Times* had not brought this matter into the court of public opinion.

That said, since last year's hearing, we've seen no material change in access to these hospitals for manufacturers with innovative technology. The GPOs have clearly been stung by the ongoing public disclosures of corruption and wrongdoing. But our market sources tell us that they expect to return to business as usual once this panel and *The New York Times* lose interest in this issue. Although they have made high-sounding statements about their intention of following the codes of conduct forced on them by this Subcommittee, we

see little evidence that they intend to walk the walk. The reason: the business model of the big GPOs is entirely dependent on payments from major manufacturers such as Becton Dickinson. This is why I believe this Subcommittee should now focus on the role of the monopolistic manufacturer side of the equation.

As an example of our current predicament, consider the case of New York's Montefiore Medical Center, a major Premier shareholder facility. In my opinion, the relationships between Becton Dickinson, Montefiore, and Premier illustrate the evils of the GPO system as they existed last year and still exist today. On April 8, just shy of the first anniversary of this Subcommittee's hearing, more than 12 courageous Montefiore physicians, aided by the Committee of Interns and Residents, signed their names to a complaint filed with the U. S. Occupational Safety and Health Administration (OSHA) alleging that the facility was in flagrant violation of U. S. bloodborne pathogen standards and the Needlestick Safety and Prevention Act of 2000. Over a period of three years, from 2000 through 2002, the complaint shows, accidental needlestick injuries continued at intolerable levels. Citing the ties between Montefiore, Premier, and Becton Dickinson, the complaint indicated that the facility had made no attempt to purchase or evaluate safety engineered needle devices for its healthcare workers and blocked highly rated safer products made by smaller manufacturers.

Unfortunately for America's healthcare workers, there are many more Montefiore hospitals out there flouting the law and the findings of this Subcommittee.

Further indication that nothing has changed is the fact that Abbott Laboratories, our marketing partner, recently informed us that their ability to show our products to clinicians was still restricted and that they did not foresee any improvement. Incredibly, one Abbott

executive told me that he was so convinced that the current GPO system would remain intact that he believed Abbott would never have to compete in other product areas in which it held exclusive GPO contracts. But Abbott is not a major player in the needle market. Becton Dickinson owns that business, and even Abbott is not permitted to tread there.

Simply put, the current GPO business model cannot survive if the Retractable Technologies of the world are allowed in. In this system, GPOs are nothing more than shills for the major manufacturers. The GPOs protect them from competition. There is little hope for small, innovative manufacturers like Retractable because there is no arms length dealing between the GPOs and the dominant manufacturers.

This absence of arms length dealing is especially egregious because billions of Medicare and Medicaid dollars are being used to pay for the supplies and devices purchased through GPO contracts. The federal government is not monitoring this process to make sure this money is being used to buy the best products at the best prices. Although the government requires a competitive bid system whenever taxpayer dollars are used to buy pencils and erasers for the Department of Defense, it apparently does not when billions in Medicare and Medicaid funds are used to buy needles, pacemakers, defibrillators, and surgical gloves. Many potential sellers are shut out of the current system, while others have withdrawn from contention because they regard the current system as a farce.

Right now, under the current corrupt system, companies like ours have three options, none of them satisfactory:

1) We can turn over to major manufacturers for a pittance the technology and patents we've spent years developing; or

2) We can try to work within this system, scratching for handouts at the doors of institutions that are run by unethical corporate chieftains who specialize in stealing from the government and taxpayers; or
3) We can struggle along, focusing on small, niche markets that are not controlled by the GPOs or manufacturers, while continually faced with cash flow crises and the prospect of bankruptcy.

But even if the doors to the hospital suddenly swung open to welcome Retractable Technologies and hundreds of other small, innovative medical device makers, this still would not fix the fatally flawed economics and financial incentives embedded in the current system, which brings me to my second point.

The GPOs would like you to believe they are saving hospitals money, but the opposite is in fact the case. The General Accounting Office, in the report it issued last year, confirmed what every participant in the healthcare supply chain already knew: that the presence of yet another high maintenance middleman who is paid by big manufacturers results in higher, not lower, healthcare costs.

That's because under this system, in which big manufacturers pay group purchasing organizations a potpourri of administrative fees, rebates, prebates, marketing fees, and other monetary payments, no one really has any incentive to reduce prices. Manufacturers pay the GPOs to deliver market share, and, in many cases, exclusive access to GPO member hospitals, so they, not the hospitals, are the GPOs' real customers. Manufacturers want to lower their ***costs,*** but they have no incentive to lower their ***prices***. Of course, higher manufacturers' prices generate higher GPO revenues.

In a truly arms length relationship, GPOs and manufacturers would spar with each other over prices. In fact, the GPOs have helped boost manufacturers' profits by eliminating the need for spending on R&D, advertising, and marketing. So you can be sure that no major manufacturer with established market control will ever come forward to complain to this Subcommittee that its survival is threatened because the GPOs are driving its margins down to razor-thin levels. Their silence is deafening.

Meanwhile, hospital administrators submit ever increasing reimbursement claims to Medicare and Medicaid and are rewarded by the GPOs for boosting compliance with GPO contracts. The only parties who genuinely welcome lower healthcare costs are the hapless patient and taxpayer, who may be paying health insurance premiums of more than $800 a month, if they can afford insurance at all. But until this Subcommittee stepped in, no one was listening to them. So at a time when the rate of inflation is the lowest in decades, healthcare costs continue to surge at double-digit levels. If the GPOs really achieved the savings for member hospitals that they claim, hospitals should be delighted to use a portion of these putative savings to fund the GPOs' operations. In fact, GPO claims of cost savings are a total fiction.

It's also interesting to me that healthcare executives and other so-called experts typically attempt to explain the dichotomy between low inflation in the economy generally and double-digit costs increases in the healthcare economy by attributing it to the higher costs of new medical technology. If that's the case, why is it that the application of state-of-the-art technology in every other sector of the U. S. economy leads to lower operating costs? The reason is that the GPO-run healthcare supply chain is the only segment of the

economy that operates according to the old Soviet model. There is no competition. There is one buyer and one seller. And the contracting process is closed and secretive.

So, finally, I'm convinced that Congress has no choice but to repeal the so-called "safe harbor" provision of the anti-kickback statutes that apply to GPOs---which helped created this mess in the first place---and to impose safeguards against the abuses that this Subcommittee and *The New York Times* have uncovered. It is now clear for all to see that this safe harbor, which was created by Congress in the early 1990's to permit the payment of administrative and other fees by manufacturers to GPOs, has in fact become a pirate's cove for a motley fleet of sophisticated pirate ships operated by monopolist manufacturers. It is a safe harbor created by the government that allows these corporate pirates to rob the government. It is a safe harbor that enables them to loot the American healthcare system. It is a safe harbor from having to spend money on research and development for new technology. It is a safe harbor from having to spend money on advertising and marketing. And it is a safe harbor from free enterprise and fair competition. Since the inception of the safe harbor, America has lost much of its competitive edge in medical device technology. We will never know how many inventors opted not to devote their talents to developing lifesaving medical devices because they realized they could never find a market for them under the current system. In both human and financial terms, the cost of this lost technology is incalculable.

I should add that I believed last year and still believe today that your efforts to impose a voluntary code of conduct on the GPOs was a useful first step. But while I am an entrepreneurial manufacturer who believes in America's free market system, I think the events of the last few years demonstrate that Corporate America needs more government

policing, not less. Indeed, the healthcare industry arguably needs more policing than any other. One recent study found that the healthcare business leads American industry in the percentage of Qui Tam, or whistleblower suits, that have been filed against it.

The good news is that your work on the voluntary code of conduct was time well spent. Now it can serve as a road map for legislation to end the abuses of the current GPO system, eliminate the stranglehold of the GPOs and the monopolistic manufacturers on the healthcare supply chain, and introduce free market competition into this industry.

Companies like ours can no longer afford to wait and see if the GPOs and their big company partners will do the right thing on their own. Healthcare workers, who suffer hundreds of thousands of potentially fatal needlestick injuries each year, can't wait any longer. And America's patients can't wait any longer. Senators, our patience with the current system has run out. I appeal to you to introduce legislation that would repeal the safe harbor, abolish administrative and other questionable fees, impose criminal penalties for wrongdoing, and prohibit tying and bundling, sole source contracting and other abuses before they inflict more damage on patients, healthcare workers, innovation, and the American healthcare economy.

Once again, thank you all very much for all your good work and kind attention.

###

Jul-10-2003 10:21am From-ST LUKES HOSP EXEC +8169325990 T-390 P 001/001 F-244

G. Richard Hastings, FACHE
President & Chief Executive Officer

July 10, 2003

The Honorable Mike DeWine, Chairman
U.S. Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights
224 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator:

I am told that the Subcommittee on Antitrust, Competition Policy and Consumer Rights is holding a hearing on July 16 on the group purchasing industry for health care. I'm writing to express my organization's support for group purchasing and to express my disagreement with comments that you apparently are receiving from the Medical Device Manufacturers Association. Please include this letter in the official record of the hearing, titled: "Hospital Group Purchasing: Has the Market Become More Open to Competition?"

Saint Luke's Health System is one of the largest not-for-profit health care organizations in Missouri. We see over 400,000 patients every year. I have watched with growing concern over the last year as federal and state government bodies have shown interest in restricting operations of the group purchasing industry. Some oversight is valuable, and I believe the changes that the GPO industry enacted after your subcommittee hearing last year are positive.

But I believe it is a gross exaggeration for medical device manufacturers to blame GPOs if they aren't selling every product to every hospital. Frankly, even if GPOs didn't exist, we wouldn't buy every product on the market--we would still have to make choices, and GPOs help us make the best choices. No single hospital can possibly evaluate all the new devices that come on the market, so the clinical councils of Novation, drawing on the pooled resources of member hospitals, do the job for us. GPOs aren't the problem--GPOs are the solution.

We also are concerned about the MDMA's criticism of administrative fees paid to GPOs. Frankly, shifting those fees to hospitals wouldn't do us a favor. In any group purchasing operation, somebody has to pay the cost of evaluating products and performing contracting work; we believe the existing business model works well--as it does in many other industries where group purchasing is used. Also, even if vendors no longer had to pay fees, there is no guarantee they would lower prices to compensate hospitals for the additional expense associated with supporting GPOs themselves.

Ensuring an open marketplace, especially for something as important as health care, is an important function of government. However, do not side with for-profit manufacturers at the expense of not-for-profit hospitals. Higher prices for their products mean higher costs for us, which means more expensive health care for patients. Thank you for your interest in this issue.

Sincerely,

Rich Hastings

G. Richard Hastings

By fax
cc: The Honorable Herbert Kohl, Ranking Member
The Honorable Christopher Bond
The Honorable James Talent

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Senator Mike DeWine
Chairman
Subcommittee on Antitrust, Competition Policy and Consumer Rights
United States Senate
224 Dirksen Senate Office Building
Washington, D.C. 20510

July 16, 2003

Dear Chairman DeWine:

I am writing on behalf of Shelby County Myrtue Memorial Hospital ("Myrtue Memorial Hospital"), a small, 50-bed county-owned hospital, located in rural western Iowa. I understand you will be holding a hearing on July 16, 2003, on hospital group purchasing, and, as the CEO of Myrtue Memorial Hospital, I would like to give my perspective on this important topic.

As you know, Iowa has the highest percentage of residents in the nation over age 85, and our county is one of the top three in that category. As such, approximately 65 percent of our patient revenue comes from Medicare, requiring us to manage our costs very carefully in order to ensure that Myrtue Memorial Hospital is able to continue to provide quality patient care.

Controlling our costs also is critical because Myrtue Memorial Hospital provides indigent care and a reduced fee program for lower-income residents. As a county hospital, we provide those services regardless of the financial impact. However, if we can't manage our expenses, we may be compelled to turn to the taxpayers, who already subsidize us at a rate of $450,000 annually. That is a lot of money in a farming county of 13,200 people.

That is why we use a group purchasing program – in our case, primarily Novation, through our membership in VHA. Myrtue Memorial Hospital receives many benefits from participating in Novation's group purchasing program, both financial and non-financial. Below I briefly summarize these benefits.

First, Novation gives us access to lower prices from medical supply companies that we would never receive by ourselves because of our modest purchasing volume (our total expense budget is only $15 million annually. I would estimate that roughly 75 to 80 percent of our purchases are through Novation, which gets us prices much closer to what a larger hospital group would pay.

1213 Garfield Avenue Harlan, Iowa 51537 (712) 755-5161

However, I also want to emphasize that because our membership in VHA and participation in Novation is entirely voluntary, we are always free to buy off-contract – and we do. For example, if an orthopedic surgeon needs a specific type of pin for a hip, and Novation does not have that product on contract, we negotiate our own contract with the vendor. We don't even think twice about the fact that we are buying an item that is not included in a Novation contract. Similarly, Myrtue Memorial Hospital likes to support local industry, and therefore we purchase many items from local vendors (and not through Novation contracts).

Though we have the freedom to buy products from a wide-variety of vendors, and as noted above, do use this freedom, we have found that for the vast majority of items Novation has contracts across the product lines that our physicians and clinicians want to use. And, if Novation wasn't consistently meeting our needs, we would have no problem with switching to another GPO. That's how a competitive marketplace is supposed to work.

Second, being a small hospital, we don't have the expertise, personnel, time or money to negotiate with vendors or to do our own comparative evaluations of new technology. Our purchasing agent is a very dedicated professional with 24 years of experience, but her main focus is on managing inventory. She doesn't have time to research every safety needle on the market, for example, to ensure that we comply with OSHA guidelines. Similarly, our purchasing agent does not have the time or technical skills to overhaul our technology infrastructure. We recently needed to update all of our information technology systems and relied almost exclusively on our GPO to guide us through this complicated and time-consuming process. Without this type of support, we would not be able to offer our patients the benefits of such technological advances. Without our ability to buy the necessary equipment and supplies to stay current with the latest medical developments, our patients would have to go elsewhere. Thus, not only does Novation help us avoid the costs of doing a variety of contracting-related tasks ourselves, we are able to accomplish things we would otherwise not be able to accomplish.

Third, being a GPO member has helped us move toward standardization, which can help lower costs, make training easier, and has the potential to reduce medical errors. Novation helped us realize, for example, that we were probably ordering more types and sizes of different needles than was really necessary. In the long run, this helps us save money, which we can use for patient care instead.

Fourth, we appreciate the patronage dividend that we get back from VHA and Novation, based on the volume of our purchases.

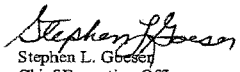
We also receive many non-financial benefits from Novation and VHA. For example, through VHA, we work with clinical improvement groups, including one on patient safety, and another that provided information on safety needles.

Ultimately, we belong to a GPO to get lower prices on high-quality products that ensure we remain a going concern, and not a burden on taxpayers. We also belong to a GPO

because by avoiding costs we would otherwise be forced to incur, we are able to further our mission to deliver quality health care to our patients. We choose to belong to VHA and to use Novation's purchasing program, because they are the people that we know and respect. In the long run, I believe that anything that harms the ability of GPOs to negotiate effectively with manufacturers will ultimately harm hospitals and patients. Therefore, I appreciate this opportunity to provide you with information about our experience with Novation.

In closing, while I was disappointed that the Committee could not hear my testimony, I respectfully ask that you make this letter part of your official record. Hospitals (and their patients) will be directly impacted by any action the Committee may decide to take. Therefore, I hope I have adequately explained that group purchasing programs, like the one offered by Novation, are essential to the success — and perhaps even the survival — of small rural hospitals such as Myrtue Memorial Hospital. Please feel free to contact me anytime if you have questions or would like additional information.

Sincerely,



Stephen L. Goesen
Chief Executive Officer
Shelby County Myrtue Memorial Hospital

Cc:
Senator Herb Kohl
Senator Saxby Chambliss
Senator John Edwards
Senator Russell Feingold
Senator Lindsey Graham
Senator Orrin Hatch
Senator Patrick Leahy
Senator Arlen Specter

JUL-11-03 FRI 09:40 AM UNIV OF UT HOSP ADMIN FAX NO. 8015855280 P. 01

University of Utah Health System
HOSPITALS & CLINICS

Medical innovation for UHC
July 11, 2003

The Honorable Mike DeWine, Chairman
The Honorable Herbert Kohl, Ranking Member
U.S. Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights
224 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senators,

I have learned that your Subcommittee has scheduled a hearing on group purchasing in mid-July, and I would like to comment on the role GPOs play in the health care industry.

As an academic medical institution, we are at the forefront of clinical medicine, often testing new drugs and medical devices in clinical studies. We value clinical innovation. At the same time, we are not immune to the financial realities that face health care organizations. We have to be wise stewards of our resources.

Because of that objective, we take advantage of the benefits group purchasing can provide, even to an organization of our size. I have heard that certain medical device manufacturers have argued that GPOs keep innovative medical products from reaching the marketplace. We test many of these devices, so we understand the benefits, but we also understand the financial balance that has to be maintained by many health care organizations, and we do not believe that GPOs hinder access to medical innovations. In fact, GPOs can be a conduit for rapidly pushing many innovations into the marketplace, if manufacturers are willing to work with the GPOs, and if the innovations represent true improvements. This is the point where debate begins, but the debate should be between clinicians and manufacturers, not manufacturers and GPOs. I know that several of Utah's administrators and clinicians sit on review committees for Novation, the GPO that The University of Utah Hospitals and Clinics use, and have extensive input into the product selection process.

GPOs help health care providers evaluate and incorporate innovative products into their portfolio of agreements. The result is better care for patients at the lowest possible cost. I respectfully ask that you include my comments for the record at your upcoming hearing.

Sincerely,

Richard A. Fullmer
Executive Director
University of Utah Hospitals & Clinics

Hospital Administration
50 N. Medical Dr.
Salt Lake City, Utah 84132-1507
(801) 581-2350

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

BEFORE THE ANTITRUST, BUSINESS RIGHTS AND COMPETITION SUBCOMMITTEE
OF THE U.S. SENATE JUDICIARY COMMITTEE

JULY 16, 2003

Good Morning. My name is Bess Weatherman. As Vice Chair of the Medical Industry Group of the National Venture Capital Organization, I am honored to have the opportunity, once again, to address this committee on behalf of over 500 professional venture capital and private equity firms dedicated to the successful development of innovative technologies and services. Collectively, our members have invested more than $240 billion over the past 21 years, funding nearly all the most important technological breakthroughs of this period. A substantial number of our firms invest heavily in the life sciences field, including biotechnology, drug delivery, medical devices and diagnostics. Over the last 12 months alone, the venture capital community has invested more than $3.5 billion in new and emerging medical technologies.

1655 North Fort Myer Drive • Suite 850 • Arlington, Virginia 22209 • 703.524.2549 • Fax 703.524.3940 • www.nvca.org

First, I would like to thank the Committee, with Senators DeWine and Kohl at the helm, for their tremendous efforts toward creating a climate where nascent life sciences companies can pursue the development of groundbreaking technologies that will ease pain, reduce suffering, lower the cost of care, and improve and extend lives.

Young life sciences companies are dependent on venture investors because their capital needs are so large, and their path to market is so long and sometimes tortuous, that they are unable to access bank financing or other more traditional sources of capital. Without patient investment from the venture capital community, the life sciences industry would be virtually nonexistent. Venture capital has financed the development of such breakthrough medical technologies as MR imaging, ultrasound, angioplasty, implantable defibrillators, spinal implants and pulse oximetry; as well as drugs for a whole host of previously incurable diseases, not to mention therapeutics to treat such major killers as heart disease and cancer. These advancements have had a huge and enduring impact on improving the lives of Americans, from geriatrics to newborns.

As I reported to you last year, the venture capital industry exists, in part, because the antitrust philosophy of the United States prevents entrenched, unmovable 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 telecommunications or medicine, are inevitably threats to some existing larger competitor who will use all means at its disposal to defend itself.

New medical technology companies, in particular, face a daunting course as it is, in order to get their products to patients. Venture investing in new medical technology is risky enough without the potential for encountering a GPO roadblock.

The possibility of anti-competitive practices on the part of GPOs serves to erode venture capital confidence in fair access to medical markets, and unnecessarily increases the risk that a new medical technology will fail to run what is already frequently a fatal gauntlet to market.

By shining a spotlight on the GPO industry's business models, practices and ethics, this committee has initiated a process that could prove to be vital to ensuring that anticompetitive business practices will not artificially limit access to medical markets for young companies. We applaud your efforts and achievements thus far. However, we remain concerned that the voluntary adoption by GPOs of non-uniform Codes of Conduct will not be enough. And worse yet, that the GPO's willingness to adhere to them will not last once the oversight by this committee is gone.

Last year, the Group Purchasing Organizations industry responded to your call to action by creating a Code of Conduct for its members that addressed the Committee's concerns about ethics and conflicts of interest. Standard industry-wide practices were established. Unfortunately, from our perspective, the concept of 'standard practices' allows too much latitude for interpretation by individual GPOs -- many of whom have not impressed us in the past with their ability to police themselves.

Every individual's notion of what is 'ethical' is different. Every corporate culture is different. We believe that creating, adopting and implementing a Code of Conduct to varying degrees in an industry that has escaped scrutiny for so long is not enough, and is not in the best interest of the life sciences industry, nor the American public. The GPOs may appear to be adhering to the "letter" of your April 2002 request, but we fear that the "spirit" is still lacking in some.

Senators DeWine and Kohl, I am sure you are aware of the efforts of California State Senator Eschutia to bring forth legislation to adopt several uniform rules that GPOs had agreed to in their Code of Conduct, such as no sole source contracts, and no bundling of unrelated products. Yet the GPOs have lobbied hard against that legislation. This makes us wary.

We believe a more definitive Code of Conduct must be created that goes beyond the industry's current version. And, it must be stringently enforced across the entire GPO industry. We would like to see reforms that are consistent with promoting and fostering healthy competition for all GPOs -- not only for those companies, like Premier, who have gone beyond the industry's own Code of Conduct. Once implemented, newly launched best policies and practices must be monitored via clear benchmarks and disclosure requirements.

More definitive policy change is necessary to assure that the unintended consequences of the antitrust exemptions previously granted to GPOs are corrected. As long as the financial incentives exist for GPOs to benefit from selling restricted market access, they will continue to find ways to do it. Accordingly, if all that results from your hard work on this issue are voluntary reforms, we have little hope that any gains achieved thus far will last.

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 vast and meaningful technological innovation. The temptation for GPOs to return to their previously collusive and anticompetitive activities with larger medical companies (if indeed they have all truly shed them, which we doubt), threatens obvious benefits for the American public, not only in healthcare, but across the entire economy.

On behalf of the venture community, I would like to thank the Committee again for its diligent efforts in this area. We would strongly encourage the Committee to consider legislation to correct past abuses on the part of GPOs. In no other sector would abuses of this sort be tolerated, and healthcare should be no exception. In health care, reform is not just a matter of dollars and cents, but of life and death.

JUL-10-03 15:45 FROM-administration 12293124115 T-485 P.002/003 F-551

VIA FACSIMILE 202-224-0103

July 10, 2003

The Honorable Saxby Chambliss
U.S. Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights
224 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Chambliss,

I understand that the Senate Subcommittee on Antitrust, Competition Policy and Consumer Rights is holding a meeting on July 16 on the hospital group purchasing industry. I would like to officially weigh in on this topic and ask you to enter my comments into the record for the hearing.

As a member of VHA, we work with one of the leading GPOs, Novation. We have quantified the value we receive through that GPO relationship, and it is substantial – both in terms of price savings and access to other services that make our organization better.

One frequently overlooked benefit in the discussion about GPOs is the issue of cost avoidance. By relying on GPOs to perform certain purchasing functions, our organization reduces the administrative burden, creating more time for staff to engage clinical personnel on topics like contract utilization and other performance improvement initiatives that could save money or enhance patient care. The cost avoidance benefit for our organization has been calculated at about ($300,000 per year per hospital). That's substantial for any health care organization.

Many studies by third-party experts and academics have also confirmed the measurable hard-dollar savings and other non-financial benefits of health care GPOs. For example, total direct cost savings to customers of Novation are estimated to exceed $1 billion this year.

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The Honorable Saxby Chambliss
July 10, 2003
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I hope the subcommittee exercises restraint before considering any further restrictions on group purchasing organizations. The GPO industry isn't well understood by outsiders, and GPOs certainly aren't liked by suppliers, because they help keep a lid on prices. But those are not appropriate reasons for additional government intervention. GPOs have an important mission: to lower the cost of medical supplies, to help us reduce internal administrative costs, and to help us make better purchasing decisions. Please do not push for additional changes in regulatory statutes that would hinder their ability to serve our health care organization.

Thanks

Sincerely,

Joel Wernick, FACHE
President/CEO

JW/aa

cc: The Honorable Mike DeWine, Chairman
The Honorable Herbert Kohl, Ranking Member
The Honorable Zell Miller