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HOSPITAL GROUP PURCHASING: HOW TO MAINTAIN INNOVATION AND COST SAVINGS

HEARING

BEFORE THE

SUBCOMMITTEE ON ANTITRUST,
COMPETITION POLICY AND CONSUMER RIGHTS

OF THE

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UNITED STATES SENATE

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HOSPITAL GROUP PURCHASING: HOW TO MAINTAIN INNOVATION AND COST SAVINGS

TUESDAY, SEPTEMBER 14, 2004

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

The Subcommittee met, pursuant to notice, at 2:04 p.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 afternoon. We welcome you to the Antitrust Subcommittee hearing on hospital group purchasing organizations.

Senator Kohl and I have devoted substantial energy and time to exploring the allegations of questionable ethics and business practices in this industry. We have commissioned two General Accounting Office studies on this issue and this is our third hearing on the hospital group purchasing organizations, often referred to as GPOs.

The purpose of the hearing this afternoon is to look toward the future. Since our first hearing in April of 2002, I am pleased to say that many of the questionable practices in the industry have been voluntarily eradicated by the GPOs themselves. In particular, business practices such as GPOs owning stakes in their vendors or GPOs accepting ownership interest in the vendor in place of an administrative fee appear to have been ended.

The GPOs took these steps in response to the Subcommittee request for them to implement voluntary codes of conduct, and they deserve our thanks and applause for so doing. GPOs also have taken important voluntary steps to address certain controversial contracting practices that are of concern to both Senator Kohl and myself.

For example, GPO practices like the bundling of clinical preference products with commodity products, extremely high commitment levels, or sole-source contracting are often the focal point of debate within the medical community. Small manufacturers complain that these practices prevent fair market access to new, potentially innovative products, and as a result prevent improved patient care.

Larger incumbent manufacturers and GPOs often argue in response that these practices generate significant cost savings for

high-quality products without harming patient care at all. One GPO, for example, recently has pointed to an instance where it entered into a long-term, sole-source contract for surgical sutures and was able to save $55 million for its hospitals.

My sense is that both sides make some good points. In fact, these are business practices with the potential to save significant money in certain circumstances, but unfortunately they sometimes make it harder for legitimately innovative products to reach the market. Under these circumstances, it seems that the best result is one that maintains maximum flexibility in the market, and in some ways we may already have achieved that.

All the major GPOs have adopted codes that address these issues, but they vary in their details and how they are applied. As a result, it appears that we are seeing fewer long-term contracts, less bundling of clinical preference items, and less sole-sourcing, but that those contracting practices are still available in certain circumstances.

Unfortunately, however, the Subcommittee still hears complaints principally from small medical device manufacturers with arguably cutting-edge products, and they complain that they are unable to negotiate a contract with GPOs. Frankly, I will be honest. It is often difficult to really determine or to assess the credibility of certain complaints from medical device manufacturers, and also the GPOs' responses to such complaints.

On one hand, I certainly don't believe that every small medical device manufacturer that fails to win a contract with a GPO has a legitimate complaint. We all know that competition for contracts produces winners and losers, and sometimes sore losers as well. On the other hand, these complaints have been continuous and steady, and appear to have at least a degree of credibility. This makes me wonder if the GPOs indeed are all living up to their pledge to decrease or stop some of these controversial business practices.

So that brings us to where we are today, to explore where we should go from here. I know that Senator Kohl and I share a concern that if the Antitrust Subcommittee turns its oversight spotlight away from the GPO industry, there is a risk that there may be back-sliding. That means we need to decide if we can trust that the current reforms are sufficient, or if not, what pathway we can take to ensure that the current reforms are actively implemented and, in fact, long-lasting.

I think it is fair to say that we are at the crossroads, and sitting here today, I see at least three paths we could choose. I have made no decision, frankly, on which path is best, nor do I think we are necessarily limited to these three paths. But sitting here today, I think that these three paths are evident.

One path is to do no more, at least for now. We have studied the issue, held numerous meetings within the industry, commissioned studies and held three hearings in this Subcommittee. The GPOs, hospitals and manufacturers know all of our concerns and have acted on them to one degree or the other. Some would argue that we have done our job, and perhaps more importantly the GPOs have done their job by adopting the voluntary codes. Under that view, no more action would be needed.

Another path would be to formally transfer our oversight of the industry somewhere else. The primary example thus far of this approach is embodied in the staff discussion draft that has been circulated within the industry and provided to today's witnesses. If we followed this path, It would move the oversight role to the Department of Health and Human Services, which, as an executive agency, is arguably better equipped to oversee the activities in the GPO industry. The Department of Health and Human Services already has a degree of expertise in this area and it currently oversees the anti-kickback exemption upon which the entire GPO industry is built.

Another path would be for the GPO industry to build upon their work of setting up individual codes of conduct to create what I call a "voluntary plus" approach. Currently, existing voluntary codes are enforced by each company on its own, an approach which has both strengths and, of course, some weaknesses.

On the one hand, because it is voluntary and self-enforced, it provides maximum flexibility and does not hamstring the industry. But on the other hand, for those very same reasons, there is no absolute assurance that it will continue to be implemented in the future or that it always will be implemented actively. Most troubling is the fact that there is really no mechanism to discipline GPOs that don't follow their own code.

I welcome any proposals from the GPOs that would create this sort of "voluntary plus" approach, proposals that build upon the current voluntary codes, but add teeth, so that the Subcommittee can be assured that the reforms are made permanent and that if a GPO chooses to disregard its own code of conduct, it is disciplined in a way that has real consequences.

I have set out these three paths as what I see now, but I am not wedded to just these three paths. If there is a fourth pathway or a fifth out there that are products of this hearing, I look forward to considering them, also. We hope today to hear our witnesses comment not only on the strengths and weaknesses of the discussion draft, but on all these ideas and any others that may arise.

Before I turn to our ranking member, Senator Kohl, I would like to add that throughout our oversight of the GPO industry, I have tried to stay in close contact with the hospitals in my home State of Ohio to find out how they view GPOs. Of course, GPOs work as purchasing agents on behalf of these very hospitals. So it is really the hospitals that get the ultimate benefits of GPO activities.

I think it is fair to say that nearly all the hospitals that I have spoken to in Ohio are confident that their GPOs are saving them significant amounts of money. In this age of escalating health care costs, that is a very important outcome and one that we want to maintain. So I certainly believe that GPOs can provide significant benefits for hospitals. Ensuring that in the future GPOs both save money, but also allow for new technology and vigorous competition in health care products, is the goal of our hearing today, and been frankly the goal of this Subcommittee's work.

One final point. The Subcommittee first started investigating this issue in the fall of 2001 under the chairmanship of Senator Kohl. He has continued to work tirelessly on this very important issue, and I think it is fair to say that without his work, the Sub-

committee would not be holding this hearing today and the industry would not have progressed to where we are now without his very good efforts. So I thank him for that, and I turn now to him for his comments.

[The prepared statement of Senator DeWine appears as a submission for the record.]

Senator Kohl.

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

Senator KOHL. Mr. Chairman, I thank you for your continued efforts on this important issue and for holding this hearing today. The subject matter of this hearing centers on perhaps the most important work of our Subcommittee in the last few years, namely ensuring that physicians, patients and health care workers have access to the best and the safest medical devices, devices that literally make the difference in many cases between life and death.

With the cooperation of the industry, we have accomplished much over the past 2 years to reform the hospital purchasing system to make it better serve the interests of competition, of innovation and patients. The changes we have seen are real. We should all be proud that more patients are getting access to the best medical devices more often. So we must now find a way to ensure that these gains are maintained.

A review of the reforms shows how far we have come. Most significantly, six of the largest hospital groups, known as GPOs, agreed to fundamental reform by adopting codes of conduct governing their business activities and ethical responsibilities. These codes forbid anti-competitive business practices and ban conflicts of interest that interfere with the GPOs' mission of buying the best products at the lowest prices.

We commend the GPOs that worked cooperatively with us in the process. The actions of Premier and the other GPOs that followed its lead especially deserve praise. Premier acted first to clearly and unequivocally ban each of the most troublesome practices, and many of its competitors followed suit and the marketplace soon began to open.

We are pleased that we have made a real difference, but we also realize that two primary tasks remain. First, how can we be certain that these considerable gains will remain when the spotlight of a Senate hearing room fades away? The GPO codes of conduct are entirely voluntary and at present not backed with any sanctions or enforcement mechanisms. So we need to be sure that these reforms will not be reversed. Second, how can the industry continue to improve in those areas that still need work?

To answer these questions, we have drafted a legislative proposal which will assure that our reforms are truly permanent. This draft was only prepared after extensive discussions with the GPO industry over the last eight weeks, discussions at which we repeatedly solicited their suggestions.

Our draft legislation gives the Department of Health and Human Services the authority to forbid GPO business practices which are anti-competitive or unethical. The purpose of this legislation is simply to create a regulatory framework so that improper business

practices never return to this important industry. However, our proposal remains just that, a proposal. So we are anxious to hear the suggestions and views of today's panel regarding our ideas.

We are also happy to consider with an open mind any non-legislative proposal that the GPO industry or others may suggest. However, it is essential that any such measure have teeth. In other words, any industry plan must include a real and a meaningful sanction if any GPO violates ethical principles or the rules of free competition. In an industry as important to health and safety as the purchasing of medical equipment for critically ill patients, half measures which do not assure that the best medical devices are available for patients are not acceptable.

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

[The prepared statement of Senator Kohl appears as a submission for the record.]

Thank you, Mr. Chairman.

Chairman DEWINE. Senator Kohl, thank you very much.

Let me introduce our witnesses. Dr. Robert Betz is the President and CEO of the Health Industry Group Purchasing Association and has spent more than 20 years representing health care organizations. Additionally, Dr. Betz has worked for the American Hospital Association and the Louisiana Hospital Association.

Mr. Joe Kiani is the CEO and Chairman of the Board of Masimo Corporation, a provider of signal processing and sensor technology to the medical device industry. Additionally, he serves on the board of the Medical Device Manufacturers Association. He has testified before our Subcommittee in the past and we certainly welcome him back.

Mr. David Balto is a partner at Robins, Kaplan, Miller and Ciresi, specializing in antitrust litigation. Prior to joining that firm, he served as policy director of the Bureau of Competition at the Federal Trade Commission, and as attorney-advisor to the chairman.

Dr. Betz, we will start with you, and let me advise you all that we have a vote that is scheduled to begin at any moment. So I will break the testimony at some point. We are going to follow the five-minute rule, and we are going to follow that very religiously today, which means that you are going to get a four-minute warning when the light goes on. That means you have got a minute.

Dr. Betz, thank you.

STATEMENT OF ROBERT BETZ, PRESIDENT AND CHIEF EXECUTIVE OFFICER, HEALTH INDUSTRY GROUP PURCHASING ASSOCIATION, ARLINGTON, VIRGINIA

Mr. BETZ. I am Dr. Robert Betz, President and CEO of the Health Industry Group Purchasing Association. HIGPA represents over 150 health care supply organizations, including every major group purchasing organization in the United States, with the exception of two; also, many of the vendors with whom they do business. I appreciate the opportunity to submit testimony on behalf of the members of HIGPA.

We return to the Subcommittee again today, Mr. Chairman, not because hospitals and other health care providers are unhappy

with the current system of group purchasing. We are here today because some manufacturers aren't able to capture the sales they desire and/or think they should have. We believe we are here today because a small yet vocal group of medical device manufacturers would like to have Congress intervene in the marketplace in favor of small suppliers at the expense of health care providers and the patients they serve everyday.

I want to make three points, if I may, please. Number one, HIGPA, on behalf of the health care providers and patients that they serve, oppose the proposed legislation circulated to us by the Subcommittee staff. It is unnecessary, we believe. Furthermore, we believe this proposed legislation will lead to higher costs for health care in this country.

Number two, 2 years ago HIGPA developed a code of conduct, in collaboration with this Subcommittee, which focused on several areas, including the following: promoting competition and innovation, eliminating the potential for conflicts of interest, ensuring open communications between members and vendors, establishing guidelines for the use of contracting tools, and providing transparency by requiring full disclosure to members of all vendor payments.

Despite what the Subcommittee may be hearing from a vocal group of small manufacturers, HIGPA's code of conduct is working. Our industry continues to engage in vigorous examination of ways to improve and strengthen our certification and compliance process. We continue to do this because we believe strongly that the private sector compliance programs are the most efficient and effective way to advance best practices in hospital supply purchasing and ultimately strengthens our health care system.

Number three, at the request of some members of this Subcommittee, the Federal Trade Commission and the Department of Justice conducted a comprehensive examination of this industry. The agencies concluded in their July 2004, joint report on health care competition and policy that indeed they do have ample tools to assure competition in the GPO industry.

Additionally, the report states that it would be counterproductive to amend Health Care Statement 7, the policy statement that governs group purchasing organizations. Moreover, as you know, the FTC has historically demonstrated a preference for self-regulation in industries that offer self-compliance systems.

It is for these reasons HIGPA believes continued self-regulation is the viable compliance mechanism for the health care group purchasing industry. As always, you have our commitment. We offer to engage in productive dialogue with the Subcommittee to explore non-legislative approaches for assuring that the changes that have been made remain in place. Furthermore, our industry will remain vigilant in adapting its practices as the market continues to evolve.

The final point of the testimony I make today, Mr. Chairman and members of the Subcommittee, I make on behalf of all the health care providers in the United States. Make no mistake, if Congress weakens the ability of GPOs to negotiate the best deals for their provider members, as is proposed in the draft legislation, patients will not be better served. Rather, the cost of health care in this country will increase.

What will happen is manufacturers that would like to see GPOs severely weakened will surely realize greater financial profits. I urge the members of this Subcommittee not to weaken a crucial mechanism that helps providers reduce their purchasing costs, which allows them to commit more financial resources to patient care.

Mr. Chairman and members of the Subcommittee, thank you.

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

Chairman DEWINE. We are going to take a short break at this point. We have a vote that just started, so we should be back here, we hope, in about ten minutes. That is Senate time. Stay close.

[The Subcommittee was adjourned from 2:24 p.m. to 2:45 p.m.]

Chairman DEWINE. The hearing will come to order. Thank you very much for your patience.

I have a statement for the record from Senator Leahy and Senator Chambliss which, without objection, we will make a part of the record at this moment.

Mr. Kiani, you are next.

STATEMENT OF JOE KIANI, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, MASIMO CORPORATION, IRVINE, CALIFORNIA

Mr. KIANI. Thank you. Chairman DeWine, Senator Kohl, thank you so much for inviting me here to testify. I know that you and the other members of this Subcommittee want the best care for the patients in the U.S., especially children and infants. Your work over the last two-and-a-half years has yielded a lot of progress. Just alone with our piece of it, you should be happy to know that countless babies have vision that would have otherwise been impaired; their eyes have been saved. Because of competition, for the over 100 hospitals that we have converted since then, on average, each one of them has saved $100,000 a year.

Senator Kohl, after the last hearing that I was involved with, you remember I had the honor to meet with you. And at that meeting—and I know you felt the same way because we all want a free market—you asked me if legislation was needed. My response was I hope not; let's see if the code of conduct works. Well, 2 years later, I am here for you showing you examples, which hopefully I will be able to do, that show that these codes of conduct for the most part have not worked. Many GPOs continue to engage in anti-competitive practices such as bundling and sole-sourcing which get in the way of the best products getting into the patients' hands and the most competitive prices.

Today, I am convinced that the codes won't work, and I really believe we need oversight legislation. The discussion draft legislation that your staff has put together, I believe, is a great start. I believe that legislation bringing oversight should improve patient care, should reduce cost of care, and bring a robust competition to this industry.

I would like to give you an update of what has happened since my last testimony and since the codes of conduct. Two groundbreaking studies were published, the first one at the end of 2002 in the Critical Care Medicine Journal that showed that Masimo

Technology, the one that you guys with your oversight were able to put on a lot of contacts, can help reduce medical errors.

At the beginning of 2003, another ground-breaking study came out that showed, after 5 years at Cedars Sinai Hospital in Los Angeles, the rate of eye damage, known as retinopathy of prematurity, dropped from the national average of 12 percent to nearly zero percent. And this was because of Masimo's technology and a very sound protocol.

The other good news is that Premier did put us on contract and did stop their bundling with Tyco. As a result, over 1,600 hospitals and just about practically every children's hospital in this country being under Premier got access to Masimo's technology. And within 2 years, our reach of our technology getting to those patients has increased ten-fold.

You remember last time I was in front of you, we had not been able to convert one single Premier hospital to use our technology beyond the 10-percent limit that was imposed by Tyco and Premier. Today, 40 hospitals have converted hospital-wide to our technology.

The bad news is that there is talk at Premier about creating another means to drive sole-source to the dominant vendors, and the story of the two other GPOs I want to share with you today is even more disheartening. If I could show you something here, I have blown this up. This is actually an excerpt from a letter that was sent to Novation member hospitals. As you notice—I don't know if you can read that from there, but it says "The undersigned Novation member reconfirms as of 'x' 2003 a date that must be no later than October 31, 2003, that it intends to continue at its current commitment level of either 95 or 75 percent."

The next slide I want to put up for you even tells you the story better. This letter was sent to the member hospitals, despite the fact that we were added to the Novation contract just a day or 2 days before the last Senate hearing, and Tyco's patents were about to expire on the sensors that cost the hospitals in the U.S. about $300 million a year two weeks before the deadline for them to recommit.

Another example that I want to just share with you is that MedAssets, who is now the third largest GPO, has an active bundling program. Even though we were put on contract, they have a bundling program that they bundle over 100 products together.

I know I am running out of time and, if you like, I could either finish or take your questions afterwards.

Chairman DEWINE. Why don't we do it in questions? That would be good.

Mr. KIANI. Thank you.

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

Chairman DEWINE. Mr. Balto.

STATEMENT OF DAVID A. BALTO, ROBINS, KAPLAN, MILLER AND CIRESI LLP, WASHINGTON, D.C.

Mr. BALTO. Thank you, Chairman DeWine and Ranking Member Kohl. It is my privilege to speak before you today. I represent no one in the medical device industry, but I am here as a former antitrust enforcer who worked over a decade at the FTC in the Anti-

trust Division. In those roles, I helped to direct the FTC's non-merger enforcement efforts and acted frequently with Congress and other regulators on dealing with issues such as self-regulation.

There are three issues before the Subcommittee today. First, is there a need for regulation? Second, is self-regulation sufficient? And, third, would the proposed legislation be a sound approach?

I commend you and your Subcommittee staff for the hard work you have done in this area, but this Committee cannot be the regulator of the medical device industry. It is time to go and take that responsibility and give it to a responsible governmental entity, and the Inspector General's Office of Health and Human Services is the appropriate entity.

What you are dealing with is a serious gap in dealing with competitive issues in this industry. It is a gap because the Antitrust Division and the Department of Justice haven't acted. They have failed to amend their guidelines.

Let me just say as an aside, as somebody who was involved in the amendment of those health care guidelines in 1994 and 1996, the problems that Congress posed to us then were far less significant than the problems that Mr. Kiani and the other manufacturers are posing to you today. I was rather surprised that they said they couldn't address every problem and that was the reason for not issuing guidelines.

But even individual enforcement actions or individual litigation can only solve mere small episodes of anti-competitive problems. The Committee appropriately asked for self-regulation. I laud the self-regulatory efforts, but they will fail. They will fail for four reasons. They lack clear and unambiguous rules. There is no enforcement mechanism. There are no penalties for non-compliance and there is no procedural due process and transparency. Simply, this process lacks teeth.

Moreover, I am surprised that at the end of the last hearing you said there was more to do, Chairman DeWine, and these GPOs did not further amend or further strengthen their codes of conduct.

Now, one might suggest, well, the way to do this is to get all the competitors in a room together and have them come up with a stronger code of conduct. That would be the worst answer. It would be the worst answer because this is an environment in which collective action would lead to bad results.

Frequently, competitors act under the guise of self-regulation and engage in self-help. If you have a problem with the way the College Football Association deals with the Bowl Championship Series, you are going to have quite a problem if you get all of these folks together, well-meaning as they might be, to go and try and set things straight. Now, my testimony presents for you examples where Congress has said, self-regulation, nice try, good efforts, it is not enough, it is time to regulate. I think you can base what you do next on those models of self-regulation.

Let me answer two last questions. First, is the Health and Human Services' Inspector General's Office the right place to go? I think that is absolutely true. Although I don't represent medical device companies, I represent pharmaceutical manufacturers, and on a regular basis those clients call me up and they say we would like to do x, y, or z; tell me, does the HHS Inspector General's Of-

fice permit this. There is a body of not only regulations, but also staff opinion letters and other advice. The inspector general's office has a broad range of tools to go and advise the industry. So I think it is the right regulator to go and begin to address these problems.

Second, the Committee must consider seriously whether these actions will lead to higher costs and higher prices. I know there are people who will complain that they think this will lead to higher costs for hospitals. Let me just say that from over a decade as an antitrust enforcer involved in anti-competitive investigations through the years, my experience has taught me that the elimination of impediments to competition will bring the greatest long-term benefits. When these side payments or other types of anti-competitive practices are eliminated, you will see competition flourish and innovation and lower prices come about.

The GPOs' efforts at establishing voluntary codes of conduct fall far short of effective self-regulation. Their current system is insufficient to assure that anti-competitive activity is prohibited and consumers are protected. The time for effective self-regulation, I would submit, has passed. Congress should act to regulate anti-competitive activity to protect the consumer's right to a competitive marketplace.

Thank you.

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

Chairman DEWINE. Senator Kohl.

Senator KOHL. Thank you, Chairman DeWine.

Dr. Betz, we recognize that your industry has undertaken major efforts to reform through your voluntary codes of conduct and we certainly do commend you. We also appreciate and understand that you might oppose any government regulation of GPOs. However, we are reminded by multiple Federal and State investigations, as recently reported in the New York Times, that there is still much work to be done in the industry.

Since the industry codes of conduct are voluntary and have no mandatory enforcement mechanism, how can we be sure that GPOs will continue to comply with their codes of conduct, especially if the oversight of this Subcommittee ends?

Mr. BETZ. Senator Kohl, the compliance program that was put together by the Health Industry Group Purchasing Association for all of our industry members, have a couple of features I would like to call to your attention in answer to your question.

First of all, some of the permanent steps that were taken are that our bylaws were amended to include the requirement that all GPOs must adopt our code of conduct into their business model in order to be a member of the association, and then to continue to be in compliance to remain a member.

At the beginning of each year, as a second point, our American-based GPOs certify compliance with the code of conduct. HIGPA's ongoing compliance programs offer a solid example of the industry's good-faith efforts to address industry business practices now and in the future.

Our code of conduct also offers a web page that offers information about HIGPA's code of conduct principles for the world to see. The association's GPO compliance officers, that all GPOs are re-

quired under our code of conduct to have in place, and quite frankly something that is new—it is a new web-based vendor exchange program that was put in place.

We are tasked everyday with the difficult job of learning about new medical products and the direction of the health care provider members. In accordance with the association's code of conduct, we created this web-based exchange to enable health care manufacturers, whether currently contracting with a GPO or not, the ability to promote their new and innovative products directly to GPO members through HIGPA.

Upon accessing the submission forms, manufacturers are asked to provide information for the representative that is doing the marketing of this particular device or new technology, the product name, the detailed description, with the ability to upload any marketing or research materials that they want. As part of its commitment to the Subcommittee, the GPO industry reached out to small medical device manufacturers, to the community, to their trade association, to find ways to collaborate and facilitate communication among all players in the health care supply chain.

Finally, sir, in answer to your question, to be in compliance with HIGPA's code of conduct, each GPO must designate a compliance officer, and this compliance officer is known to anyone in the process—the hospitals, the manufacturer representatives, to this Committee, to the regulators. Anyone who has questions regarding the specifics of our compliance program can contact these compliance officers through our website. It is through these steps that we make our efforts and our successes and our ongoing commitment a part of a permanent process.

Senator KOHL. Mr. Betz, what is the remedy today if a GPO violates the code of conduct?

Mr. BETZ. Sir, as I said, it is mandatory that they have to be in compliance. We have the only mandatory compliance program in the whole entire health care supply chain. Manufacturers don't have it, distributors don't have it.

Senator KOHL. What is the remedy, that they go out of business?

Mr. BETZ. Sir, not being in compliance with the HIGPA code of conduct puts a burden, I would submit, on that group purchasing organization or that entity when they are in a contracting process with a manufacturer. That is one aspect of it. I think it also puts a burden, quite frankly, from the hospital perspective. Hospitals are constantly being approached by group purchasing organizations. It is not just one hospital that has one group purchasing organization. Many studies have shown that hospitals belong to more than one group purchasing organization and it is a constant, competitive marketplace. We believe that the hospitals are interested in who is in compliance with the code of conduct as well.

Senator KOHL. But isn't it true that even if you should expel them, which we could argue may or may not happen, a GPO could continue to do business?

Mr. BETZ. Yes, sir, they indeed could.

Senator KOHL. So in the absence of some legislation and oversight, continuing oversight by HHS, if you simply have a voluntary kind of a program, isn't it true that it would not be unreasonable for us to be quite worried, given the past history and our hearings

and where we are today, that in the absence of something concrete such as legislation that there isn't a chance—call it large or small—to come back in a year, or two, three, four or five, and we will pretty much back where we were before we commenced all this activity in this Subcommittee?

Mr. BETZ. I think that I would disagree with part of the basis of your observation, if I could, Senator. I think that there are current remedies that do exist in the Federal Trade Commission and the Department of Justice. Also, plaintiffs have the ability to get together and bring action singly or collectively in this area. Our codes of compliance also assure that the antitrust laws and the anti-kickback laws are being adhered to. If they violate our HIGPA code of conduct, they are subject to prosecution under current laws that exist.

One other point, too, is that we are very impressed that the Department of Justice and the Federal Trade Commission, again at the request of this Subcommittee, have looked at this area and told you the same thing they have told us. They think they have adequate enforcement capabilities as they currently exist.

So we think that that, married with the codes of conduct and the progress that the industry has made and on our ongoing commitment—Senator, everything you have asked of our association, everything you have asked of our industry, we have delivered. You asked us for a voluntary code. We delivered. You asked for 90 days. We have delivered.

We have gone beyond even that with the web-based exchange and with some other things that we currently have in the works. We have also committed to you that this is a living document, that this is a living process. We take it seriously and we think the system has been improved by it.

Senator KOHL. I thank you, Senator DeWine.

Chairman DEWINE. Well, let me just clarify a little bit in regard to your codes of conduct. Has any member been kicked out or disciplined for non-compliance?

Mr. BETZ. Sir, we have had one instance of one organization in Florida that we were getting ready to kick out and it was just that they didn't think we were serious about it. We had a conversation with the executive. They found out that we were serious about it. They took it to their board of directors and the board of directors told them to get in line. They did not want to be outside the industry code of conduct, so they did come back in. And I am pleased to report that all the GPO members of HIGPA are in compliance with our code. We have brought those certification documents on a regular basis to the Subcommittee staff.

Chairman DEWINE. What would be the real-world consequences to a GPO if it were kicked out?

Mr. BETZ. If they were kicked out?

Chairman DEWINE. Yes. How would it affect its business?

Mr. BETZ. Well, first of all, I would pray for them each and every day, Mr. Chairman. I believe that the reality of the situation is that they are going to face pressures in the marketplace, pressures from vendors. I mean, if you were a manufacturer, if I could, Mr. Chairman, who do you want to do business with? Who do you want

to do business with on a long-term basis? Do you want somebody that is open, in compliance with the industry code of conduct?

If you are a hospital, what do you want; what do you want of your GPO? Do you want to know that they have the highest ethical practices that they possibly can? And if you are a GPO exec, quite frankly, I think the competitive nature of the process is such that they are going to try to be more ethical than the others and take additional steps to try to impress the hospitals, the providers that they serve, and also the manufacturers.

Again, briefly, sir, the GPOs must certify compliance to the code to be a member of HIGPA. The association's bylaws reflect their membership requirement. The names of those in compliance are made public on a routine basis. And, finally, it allows hospitals and vendors to know which groups are operating within the best practices of the industry.

Chairman DEWINE. Mr. Kiani, your testimony makes really a compelling case for why we should all want competition in the marketplace. We all want that, so that the best and most cost-effective medical devices are used in patient care.

As I have told you, I have spoken to a lot of hospitals back in Ohio and they all tell me how important it is for them to keep the GPOs working for them and negotiating their contracts. They talk about money; that is the thing I hear. Certainly, these hospitals are very aware of the need to provide the best possible care. Surely, these doctors and nurses believe that they are using the best equipment and devices for their patients.

If GPOs were really, in fact, cutting off access to new and improved technology, why wouldn't these hospitals be demanding this technology? Why wouldn't they be complaining about that, or why wouldn't they just leave the GPO? Why don't I hear that from them? Are they just not aware of the technology out there, or what is the problem?

Mr. KIANI. Well, Chairman DeWine, first of all, I really wish maybe some of those hospitals were at these Senate hearings so they could for themselves see what the real issues are, and also understand the legislation you are seeking—

Chairman DEWINE. What does that mean?

Mr. KIANI. What I mean by that is that, unfortunately, I think they are misinformed, Chairman DeWine. I think they may believe that what we are seeking is to get rid of GPOs. All we want to do, and I think all your oversight is attempting to do is to make sure actually the GPOs are really working for the hospitals and not the dominant vendors.

So in our example that I gave you, Chairman DeWine, the competition that we are seeking and that your legislative oversight would create, hopefully, should reduce their costs. Nothing that we are asking for should increase the costs.

Chairman DEWINE. I appreciate what you are saying, but my point is a little different, and that is that they don't seem to have this concern about new technology not getting through that they are missing. Maybe you don't know what you are missing if you are missing it, I guess. I don't know. What is the deal here?

These are smart people, these are good people, these are people who care about their patients. They want the best for their pa-

tients. Why aren't they seeing what you see about the technology out there? Aren't they aware of this technology or what?

Mr. KIANI. Well, Chairman DeWine, I think for the most part they are not aware of the new technologies. For example, 2 years ago when I testified, I pointed out that the Novation contract actually imposed on the hospitals to not even look at a competing technology that competes with the incumbent vendor that is on the contract for what they call the opportunity program. The hospital wasn't even supposed to look at another technology. So I do believe it is what they don't know about that unfortunately makes them say what they say.

Now, we have been blessed mostly because of testifying in front of this Committee, and as a result we have been put on contract. But there are hundreds of companies that have not been lucky enough to testify and they are still having difficulties even letting their products—

Chairman DEWINE. That are as good as you that have got good stuff out there that are not getting through, is what your point is. They are not breaking through?

Mr. KIANI. That is correct, Senator. And as a member of the board of MDMA, I am aware of some of those. I know there is a booklet that has been handed to you that cites about 20 of those situations that deal with thousands of contracts.

Chairman DEWINE. Mr. Balto, several times during your written testimony you noted that the codes of conduct are not consistent throughout the industry. Some would say that that is an advantage. By allowing flexibility in the market, we assure that the market is more open than it otherwise would be.

For example, Mr. Kiani is selling his product to Premier hospitals even though he hasn't been successful with Novation hospitals. Isn't flexibility in that case a good thing?

Mr. BALTO. Well, sometimes flexibility can be positive. Let's step back a second and just think about the issue of self-regulation. The examples that I cite in my testimony are about issues such as privacy or telemarketing. They are not the issues of patients' health, about human beings' health that Mr. Kiani and other people have testified about before you. So as a first matter, Congress may be more reluctant to permit self-regulation in this instance than in other instances.

Second, in settings where you do want self-regulation to occur, allowing competing forms of self-regulation can be positive, and ultimately if it leads to a good enough threshold of compliance so that people are protected. But right now what we have is a highway of competition in the market, and somebody says it is 45 miles an hour and somebody says it is 65 miles an hour, but everybody knows there is no cop looking at how fast the cars are going. So long as there is no enforcement mechanism, this self-regulation isn't going to work.

Mr. KIANI. Could I add one thing to that, Mr. Chairman?

Chairman DEWINE. Sure.

Mr. KIANI. I have heard Mr. Betz say that if the GPOs don't comply with their code of conduct that they will take away their membership card. Also, if we want to have competition, we can all put ourselves on the website. The bottom line is I think either the

fourth or the fifth largest GPO in this industry does not belong to HIGPA, and that is HealthTrust.

One of the examples I was going to show you was actually HealthTrust, who, because they didn't have the oversight nor are they a member of HIGPA—in fact, if I could show you—

Chairman DEWINE. Sure, go ahead.

Mr. KIANI. The president, the CEO of HealthTrust wrote me this letter saying, "As our President says, you are either for us or against us in our fight against terrorism. You decide which side of the fight you are on. I will know by your support for this legislation." Now, the legislation this gentleman is talking about is the California legislation that was trying to deal with this GPO issue.

First of all, I thought we were all on the side of the patients. That is why we are all here today. But, secondly, this GPO who doesn't belong to HIGPA represents several hundred hospitals. Actually, we used to have a token contract with them before we initially testified, but as a result of our testimony they became irate and a few months later they took away our contract and gave a sole-source contract to Tyco.

Chairman DEWINE. Dr. Betz, when I talk to hospitals back in Ohio, as I said, they almost universally tell me that GPOs do, in fact, save money, and I have no reason to doubt them. They are in business to make those decisions. But here is my concern: I am wondering if it is possible that in the short run GPOs are saving money, but in the long run they may actually drive up costs.

Here is what I mean. If GPOs tend to contract with the large medical supply manufacturers and therefore lock out smaller innovative firms, then maybe these small firms will not ever enter the market. So in the long run, maybe it is conceivable that GPOs might unintentionally strengthen the market power of the large manufacturers.

If this is the case, in the long run the large manufacturer will be able to raise its prices. It has happened in other places and other industries.

Mr. BETZ. Yes, sir.

Chairman DEWINE. Why isn't that true here?

Mr. BETZ. Well, you again, I think, have to appreciate, in answer to your question, who is driving the train here?

Chairman DEWINE. Okay. Who is driving the train?

Mr. BETZ. Group purchasing organizations don't make decisions on clinical products that are being used. The providers, the doctors and the hospitals and the surgical nurses and others, make those decisions. But we believe in a phrase that was coined some time ago—that group purchasing organizations provide a sentinel effect. If you can imagine an economic band that would exist that is the result of group purchasing organizations' efforts to hold down costs for, say, a class of products, therein starts the processing.

I guess groups would like you to believe, or hospitals would like you to believe or others would like you to believe that they get the absolute best price in the marketplace. Quite frankly, my 34 years of experience in health care tells me, in the competitive realm that exists, in the ever-evolving area of health care procurement and supply, what happens is that someone will come in with a great price on a new product and then the sentinel effect begins. There

is a holding down of that price because of the contract that exists, and with that therein it becomes a negotiating point from which others go out and try to drive down the marketplace for that individual product.

In the short run, is it possible when a new product comes on the market—I think the economic literature might point you in the direction that it is not in the beginning that groups have their biggest impact; it is the long-term effect as that sentinel effect continues to put pressure on the system as it goes down, because as individuals go and get better prices, then the sentinel line begins to drop.

Chairman DEWINE. Mr. Balto, I was intrigued by one point in your written testimony. I believe you said that the threat of antitrust litigation is not sufficient to curb anti-competitive conduct in the GPO industry because it is too time-consuming and too cost-prohibitive for small start-up companies. Additionally, you say that antitrust litigation only addresses the specific conduct in question.

Couldn't you say the same for lots of other industries as well? What is unique about this industry that makes you conclude that the threat of antitrust litigation is not sufficient, so therefore we have to regulate?

Mr. BALTO. First of all, let me sort of say at the outset I had 10 years in the agency, having people come before us, including Congressional staff, saying should we regulate this? As a free marketer, that was the last thing I ever wanted to say. But I think there are certain instances where it is clear that the free market isn't working, the supposed free market isn't working, and it is appropriate for regulation to step in.

I am struck by the contrast between this industry and other health care industries such as pharmaceuticals, where the HHS IG office plays an active role in enforcing the anti-kickback and other statutes and preventing some of these kinds of payments. Certainly, the people who received the illegal payments in the TAP Pharmaceutical case were unhappy when those practices ceased, those entities that received those kinds of payments. But ultimately, by enforcing the anti-kickback statutes, the HHS Inspector General's office, I think, helps to make the market more competitive.

Chairman DEWINE. Well, let me ask you this. Do you think it is reasonable to expect HHS to write up regulations that are generally applicable? Wouldn't there be a tendency to draft regulations that are either highly specific, which could hamstring the industry, or are so vague that they are really of no use at all?

Mr. BALTO. That is an excellent question and I think that is something that HHS needs to address. Hopefully, with the active and supportive consultation of the antitrust enforcement agencies, Congress can go and provide further guidance in this area. But what you need is an active enforcement mechanism. HHS is serving that role in other health care contexts. I think they could serve that role in this health care context.

Chairman DEWINE. Mr. Kiani, do you want to take a shot at that question?

Mr. KIANI. Well, I am certainly not an expert in this area, but I think your question was do we think HHS will write something

that is good enough and doesn't create either too much burden or not enough. All I can tell you is that the code of conduct for the last 2 years has not worked and I would hate to see your oversight being taken away because you are dealing with a lot of other important issues and nobody else looking at this. I would hope that, together, we can give HHS some guidance to what works ultimately.

Mr. BALTO. Chairman DeWine, if I can just amplify.

Chairman DEWINE. Sure, Mr. Balto.

Mr. BALTO. I understand the concern that the hospitals are expressing to you. First of all, there isn't a soul in this room that thinks that group purchasing in and of itself is bad. No, there is nothing necessarily bad. Throughout every place in the economy, you see forms of group purchasing that help reduce costs and bring benefits to consumers.

However, there are different practices in this marketplace which may be superficially attractive to the buyers, such as the administrative fees and bundling, which actually at the end of the day may be anti-competitive. I am sure if we looked at the pharmaceutical settings in which the anti-kickback laws have been more aggressively enforced to drive out some kinds of practices that were clearly fraudulent and harmful to competition, we might see buyers who liked those things initially. But now that those practices are eliminated, we see a more competitive marketplace.

Mr. KIANI. Chairman DeWine, you earlier asked about what would happen to innovation, I believe, from Mr. Betz, and I think the analogy that I have been thinking a lot about is if group purchasing was buying word processors for industry, we would all be using IBM typewriters at $100 each.

I think Ms. Weatherman, representing the NVCA, stated very well that they don't look at investing in these sectors anymore because of the lack of competition. We hope your oversight that you will look to create will help GPOs be better in serving the hospitals and getting the most innovative products at the best prices.

Chairman DEWINE. Well, I want to thank the three of you. It has been very helpful. We appreciate it very much. Senator Kohl and I will continue to work together on this issue, and this Subcommittee will continue to stay interested in this and we will continue to monitor the situation.

Thank you very much.

[Whereupon, at 3:24 p.m., the Subcommittee was adjourned.]

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

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

QUESTIONS AND ANSWERS

Response of David A. Balto, Esq. to Post-Hearing Questions
"Hospital Group Purchasing: How to Maintain Innovation and Cost Savings"
September 14, 2003

Questions from Chairman DeWine

1) **In your testimony, you state that the GPO industry's voluntary codes of conducts "fall far short of any effective self-regulatory program." In your view, what are the essential ingredients for an effective self-regulatory program?**

As my testimony documents, in some instances self-regulation can be effective in addressing problems in the market. However, those are situations where a regulatory body establishes clear and unambiguous rules, there is an adversarial process to detect and report violations, there are penalties for violating the policy, and there is a transparent system of dispute resolution with due process. In many cases self-regulation is effective because the self-regulatory body can report violations to a government agency for enforcement. Clearly from the testimony at the hearing, the GPO industry and its trade association have failed to meet these minimum requirements in their efforts to create self-regulation.

Moreover, in this concentrated market, private self-regulation may be readily captured by industry pressure and give inadequate attention to the interests of smaller firms, new entrants, or the needs of the public. Moreover, because the number of competitors is small there is the threat that collective self-regulation could lead to collusion. In my opinion, the GPO industry cannot be expected to effectively police itself.

2) **Many antitrust lawyers are very skeptical of regulation because it can restrict competition and have unintended negative consequences. You have significant experience as an antitrust lawyer, both in government and in the private sector, so I am interested in why you prefer regulation in this instance. I would have expected your testimony to have been more skeptical of staff's discussion draft bill but you seem to endorse it without qualification. Tell me again why you aren't more skeptical of a regulatory approach? Don't you have any concerns?**

You are correct that many antitrust lawyers, including myself, are often skeptical of regulation and its consequences. However, in this instance, I believe regulation is ultimately necessary in order to correct the abuses and problems identified by this Subcommittee. GPOs have become much larger and more powerful than the industry and Congress contemplated when the exceptions to the anti-kickback laws were implemented. As the Subcommittee is aware, there are a variety of contracting practices that have raised competitive concerns, including sole source contracting, bundling, market share discounts, and tying. Sometimes one can hope antitrust litigation may address these kinds of competitive concerns, but such litigation is costly and time-consuming and addresses issues on a very episodic basis at best.

I do not have any major concerns because I do not believe regulations would be overly intrusive. Instead, they would look at and review a small subset of GPO practices. Also, I

feel that the Inspector General's Office of the Department of Health and Human Services has a proven record of effectively enforcing the anti-kickback provisions of the Act. Any new regulations on the activities of GPOs would provide minimal standards to address the abuses and conflicts of interest which have been uncovered by this Subcommittee. Thus, these regulations would build on an already existing regulatory foundation that exists via the Office of the Inspector General.

3) **Rather than transferring oversight to a regulatory agency, wouldn't it be better to build on the voluntary codes of conduct and put more "teeth" in them by creating something like a GPO accrediting entity? I have referred to this as the "voluntary plus" approach. So that, for example, if a GPO did not actively implement its code there could be serious consequences? Wouldn't this maintain the flexibility of the codes while creating accountability? At least as a next step?**

When first asked to testify on this matter before the Subcommittee I also initially gave thought to a more effective self-regulatory system which had some "teeth" to it because, as is clear from my written statement, self-regulation in certain environments can work. However, I became convinced that self-regulation cannot work in the GPO market.

First, accrediting entities sometimes can work to enforce self-regulatory schemes (the best examples involve professionals). However, those entities work because they can impose a significant penalty on their members, *e.g.*, the ability to practice their profession. A "voluntary plus" approach would have to be able to impose significant penalties for non-compliance. This might be no less intrusive than the proposed legislation. In fact, it might be less effective than the proposed legislation since the self-regulatory scheme may be captured by its members. As I have previously stated, the GPO market is heavily concentrated with just a handful of GPOs collectively accounting for more than 85 percent of all hospital purchases nationwide. Thus, the threat that collective self-regulation could lead to collusion is very real.

Second, self-regulation in this instance would not reduce the likelihood of private antitrust litigation against GPOs which has increased in the past several years; my written statement to the Subcommittee highlights several such cases. Any individual antitrust case only serves to address the conduct of specific companies with regard to market practices for a specific product which has adversely affected a specific plaintiff. Such litigation does not, and cannot, address problems on an industry-wide basis as could legislation and regulation. Third, the industry now has a history of anticompetitive behavior coupled with a continuing reluctance to further modify its practices.

The GPO industry is heavily concentrated and problems with GPOs are too widespread. What is being regulated by the GPOs are contractual arrangements that are critical to competition, a far different concern than self-regulating for deceptive conduct or false advertising. What is at issue is competitively sensitive and further self-regulation, while possibly adding "teeth", could quite easily lead to charges of collusion.

4) Since the Antitrust Subcommittee began investigating the GPO industry, I think things have largely improved in this market. It is not perfect but it is much better. Don't we risk throwing the baby out with the bathwater if we set up a regulatory regime? If not, how would we ensure that the regulatory regime is flexible?

As you indicate, things are better given the Subcommittee's focus on the GPO industry, but even with such close oversight, problems continue. Antitrust litigation against individual GPO practices is growing and we have seen several federal enforcement actions, including the Justice Department's recent initiation of a broad criminal investigation of the medical-supply industry.

I see no evidence that the efficiencies of the GPO market would be lost with the adoption of a regulatory regime. The Department of Health and Human Services' Office of Inspector General plays an active role in oversight and enforcement in other realms of the anti-kickback statute. Its system is flexible and could easily adapt to encompass the oversight of GPOs. The Inspector General could be charged with drafting regulations and once implemented could review on a case-by-case basis the competitive aspects of GPOs in the medical device and supply market. With its expertise in this area, the Inspector General could provide advice to the industry and work to ensure flexibility in the regime while at the same time ensuring that the market is open and competitive.

5) In your written testimony you say the following? "The relationships between medical device manufacturers and GPOs have also created incentives for the manufacturers to share profits with the GPO. As a GAO report noted GPOs acknowledged that 'a manufacturer dominant in a product line may contract with a GPO, or agree to a favorable contract, to preserve its market share and exclude competition.'" (emphasis added) But isn't that the whole point of GPO purchasing, to get a favorable deal for the hospital? Does it really matter what the motivation of the seller is?

The manufacturer's intent is relevant because it may suggest the ultimate effect of the conduct. So, the motivation of the dominant firm in entering into these agreements is relevant. GPO purchasing can be efficient, and the point of GPO purchasing is to get the best product at the best price for the hospital. But as some antitrust scholars have observed in many cases what occurs is that the GPO and a dominant manufacturer split supracompetitive profits. (*see* Prof. Einer Elhauge, "Antitrust Analysis of GPO Exclusionary Agreements" at pp. 23-28, submitted for the DOJ-FTC Hearings on GPOs, September 26, 2003). The GPO wins, the dominant manufacturer wins, but competition and consumers lose. Hospitals and consumers end up paying more for their medical products.

6) In your testimony you mention examples of industries where self regulation has failed. I was interested in your example from the telemarketing industry. You note a history where throughout the 1990s the telemarketing industry group advocated self-regulation but did not actually implement voluntary codes until 1998. Because complains continued over the next five years, Congress enacted the "Do-Not-Call Implementation Act in 2003."

The GPOs have had their voluntary codes in place a little over a year now. Isn't it too early to tell whether the codes have failed? Don't we need to wait at least five years, like Congress did with the telemarketers, before jumping to a regulatory framework? If not, why?

No. GPOs have been aware of the concerns in the marketplace since the late 1990s. Your Subcommittee began its inquiry over five years ago and the industry code went into effect in July 2002. I do not believe it is too early to determine whether the GPOs' voluntary codes of conduct will fail. Given my comments above on the increasing antitrust litigation and government investigations, given the concentration of the industry and the fact that it would be attempting to regulate competitively sensitive information, and given the lack of any enforcement mechanism in the current codes of conduct, I believe that it has become clear that self-regulation in this industry cannot work.

While I did provide the telemarketing industry's efforts at self-regulation as an example, there is one distinct difference. The effort to regulate telemarketers from making unwanted calls to consumers is much different than efforts to regulate anticompetitive behavior which can focus on sensitive pricing and commercial data in the GPO industry. Despite consumer complaints and demands for privacy in the telemarketing example, anticompetitive/antitrust issues were not a factor. In the GPO industry anticompetitive behavior and growing concern over antitrust issues is the key factor. Congress, in my opinion, cannot afford to wait five years to determine whether a regulatory framework is necessary.

In addition, I would argue that the medical device and supply industry, as well as hospitals and patients, cannot wait five years for action. Moreover, waiting five years means that the anticompetitive and deceptive practices at issue will continue unabated. In those five years many small and innovative firms will be driven out of business or have their competitive significance diminished. Several witnesses who have appeared before the Subcommittee have stressed the loss of advancement in medical technology and innovation by small companies who cannot compete. Consumers will lose by being denied choice and safer and more innovative products.

Many of the practices discussed by the Subcommittee and in the two related GAO reports suggest that GPOs have evolved from neutral buying units to "gateways" which permit dominant manufacturers to enter into arrangements that raise entry barriers, ultimately leading to higher prices and less innovation. There are serious questions which have been raised about the extent to which GPOs act as the agents of their hospital members or as the agents of the sellers that pay the GPOs' administrative fees.

As indicated in my written statement, there may be entities, especially hospitals, which fear that the enforcement of the safe harbor provisions will lead to higher prices. But my experience of over a decade as an antitrust enforcer involved in dozens of enforcement actions has shown that the elimination of impediments to competition will bring the greatest long-term benefits. Ultimately, restricting these anticompetitive practices will lead to more competition, lower prices and greater innovation. Everyone will benefit.

Questions from Senator Kohl

1(a). Do you believe that the Department of Health and Human Services is the right agency to oversee the hospital purchasing industry?

Yes. Specifically, the Department's Office of Inspector General.

1(b). Do you think the HHS is capable of writing rules to forbid unethical practices or those practices that impede the ability of needed medical devices to reach the hospital marketplace?

Yes, I think the Department of Health and Human Services already does this in many other health care environments. The anti-kickback statutes are already effectively administered by the Inspector General's office.

1(c). Which approach do you believe would be more effective – (i) giving HHS general authority to write regulations to prevent unethical practices and anticompetitive business practices, as envisioned by the current draft of our proposed legislation, or (ii) have specific standards of GPO conduct written into law?

Giving the Secretary of the Department of Health and Human Services and its Office of Inspector General the authority to write regulations as the current draft legislation proposes would be the more effective approach. This will provide some flexibility for more readily and easily revising and amending any regulations in the future should additional or new practices arise which give concern to anticompetitive practices.

2. At the hearing, you stated that without adoption of the draft legislation, the codes of conduct would "fail." Why do you believe this to be the case?

For the very same reasons you highlighted in your statement introducing the legislation - the codes of conduct are completely voluntary, they are not uniform, and they can be modified or even withdrawn by the GPOs. They have no enforcement mechanism or adversarial process, nor is there any manner to verify that they are being adhered to by the various GPOs. Also, there is no assurance that the current reforms undertaken solely as a result of this Subcommittee's investigation will not be abandoned or ignored once the spotlight is off the industry. Absent any meaningful enforcement mechanism and oversight by The Department of Health and Human Services, there is no guarantee that voluntary compliance to any of these GPOs' codes of conduct will remain effective for the long-term.

3. During the hearing, Dr. Betz of HIGPA acknowledged that the only sanction a GPO faces that fails to comply with the HIGPA code of conduct is expulsion from HIGPA. He further acknowledged at the hearing that a GPO that is expelled from HIGPA could continue to do business. In your view, is

the penalty of being expelled from HIGPA adequate assurance that a GPO will adhere to the terms of the HIGPA code of conduct.

No. Dr. Betz's testimony clearly explains why the penalty of being expelled is essentially meaningless – despite expulsion, a GPO may remain in business and, in fact, be quite successful. No real sanctions exist. As Joe Kiani's testimony indicated, GPOs do not even have to join HIGPA in order to be profitable or successful. HealthTrust Purchasing Group is not a member of HIGPA, yet it remains one of the largest GPOs in the nation. According to its own website, HealthTrust's membership has tripled since its inception in 1999, it supports approximately 1,200 facilities, it has annual purchasing volume approaching $6 billion and expects double digit annual percentage growth. Clearly, not being a member of HIGPA, and thus not adhering to its voluntary code of conduct, does not hinder a purchasing organization from being a successful GPO.

4. What do you believe will be the principal benefits should the draft legislation become law?

The Subcommittee is faced with a difficult problem. Its diligent efforts in focusing on harmful practices involving GPOs have created a certain level of reform within the industry. But once the spotlight of Congressional attention dims, the industry will revert to these practices. The Subcommittee cannot act as permanent regulator of the GPO marketplace.

The principal benefit of the proposed legislation will be a healthcare system that delivers quality care at an affordable price. The draft legislation will provide much needed oversight to an industry that has the *potential* to save the healthcare system millions of dollars. However, the current structure of some of the largest GPOs, coupled with the lack of oversight, has resulted in an environment where patients and caregivers do not have access to innovative, cost effective technologies.

In addition, the legislation will provide the proper framework for oversight and lasting reform. I recognize that one concern shared by you and Chairman DeWine is the potential for "back-sliding". This legislation will help ensure that once this Subcommittee moves on to other issues, the gains that have been made as a result of your efforts will not be lost.

5. Critics would argue that compliance with government oversight would create unforeseen costs to the GPO industry. How do you answer that concern?

There may be additional costs associated with compliance with government oversight by the GPO industry, but these would likely be offset by better clinical outcomes and cost savings achieved through an open and competitive marketplace. Initially, there would be certain additional costs. However, the bulk of these costs would be short-term and related to initial start-up and compliance expenditures (*i.e.*, costs of accounting and attorney fees, staff time needed to understand and comply with the regulations, implementing policies and programs to ensure compliance). After this initial and short-

term phase, costs would decrease substantially as officers and employees come to understand how the system functions. So long as GPOs remain in compliance with the regulations, I do not foresee how the impact of the regulations could, in the long-term, increase a GPO's overhead and operating costs, slow down its decisionmaking process, or reduce a GPO's ability to fulfill its main responsibility and purpose – to achieve efficiencies to benefit consumers and GPO hospital members by pooling the purchasing power to negotiate lower prices from vendors.

6. Are there other ideas, besides the ones in our draft legislation, that can work to ensure that the GPO reforms are permanent and lasting? What are minimum elements necessary for any self-regulatory mechanism to work?

At the moment, I am unable to come up with an alternative approach that would achieve the goals of this Subcommittee. This legislation would provide timely, effective and comprehensive reforms to address many of the concerns that arose out of the past three hearings.

In my opinion, the minimum elements necessary for any effective self-regulation to work are: (1) the creation of clear and unambiguous rules; (2) the existence of an enforcement entity; and, (3) allowing the entity to impose significant penalties for violations. Also, there must be a system of due process with transparent decisions. Although the GPOs efforts to self-regulate are laudable, they are clearly insufficient to cure the competitive problems in this market. Their efforts at self-regulation lack each of these critical elements. As I stated during my testimony, these voluntary codes of conduct have no teeth.

The absence of any accountability and enforcement mechanisms in such a concentrated industry should be of great concern to this Subcommittee. What is being regulated by the GPOs are contractual arrangements that are critical to competition; a far different concern than deceptive conduct or false advertising. Antitrust laws are replete with cases where firms have agreed to diminish competition, collude or raise entry barriers under the guise of "self-regulation." (*See* cases discussed at Appendix A of my September 14, 2004 written statement). This is why, even with additional elements for self-regulation, I ultimately see legislation and Department of Health and Human Services' regulations and oversight as necessary.

7. Without any legislation, the FTC and DOJ has the authority to investigate and prosecute wrongdoers. And private parties are free to bring private civil antitrust suits, as they have. Why isn't this sufficient to guard against future GPO misconduct?

It has been suggested that individual private litigation or government enforcement action challenging anticompetitive conduct on a case-by-case basis is the solution. As I indicated during my testimony, I disagree. The GPO industry is heavily concentrated and problems with GPOs are too widespread. What is at issue is competitively sensitive and

individual litigation or enforcement actions will not solve the overall problem of anticompetitive practices in the industry.

Private litigation is now proliferating with regard to the conduct of GPOs. My testimony provided several examples of recent court actions. Private litigation, however, is not the answer to the competitive problems in this market because it is too time-consuming and too cost-prohibitive. In addition, any individual antitrust case only serves to address the conduct of a specific GPO with regard to market practices for a specific product which have adversely affected a specific plaintiff. Such litigation does not, and cannot, address problems on an industry-wide basis as could legislation and regulation. Furthermore, undertaking such private litigation by plaintiffs, which are typically small, innovative companies, drains limited financial resources from such companies and can place them in a precarious financial situation while litigation drags out over several years. If such companies fail financially, the industry ultimately not only loses some of the benefits of a competitive market but also loses out on advancing new technology and innovation.

Government enforcement action is insufficient for many of the same reasons. The failure of the FTC and DOJ to take enforcement action or revise Statement 7 and the failure of the Department of Health and Human Services to regularly review and revise its safe harbor regulations have set an extremely lax standard. Even current news of DOJ investigations into the activities of certain GPOs makes it clear that the investigations are targeting individual GPOs for specific activities and conduct. Like private litigation, government enforcement actions will not address what is being increasingly described as an industry-wide problem. Furthermore, and unfortunately, one could easily assume from the FTC's and DOJ's lack of action in amending Health Care Statement 7 that those agencies do not have a strong desire to currently address the anticompetitive problems in the GPO industry.

8. You were involved in drafting revisions to the FTC/DOJ Statements of Policy in Health Care in 1994 and 1996. Do you believe Statement 7 of these Policy Statements, governing hospital purchasing, should be revised to protect competition and innovation? If so, what revisions would you propose?

At the time Statement 7 was originally prepared, it focused on the simple question of when a GPO may be too large or posed the threat of exercising monopsony power or facilitating collusion. As I indicated in my written statement submitted to the Subcommittee, it did not address the issues of exclusion that are the center of current anticompetitive concerns. As one of the collaborators in drafting these statements, I can state that at the time the FTC did not foresee the potential for GPOs to act to diminish competition and innovation in medical device market in the manner in which they are now doing.

I was disappointed when the DOJ and FTC declined to revise Statement 7. While I agree with their comment in the July 2004 report that "no statement is likely to cover every issue that could arise", I disagree with their assertion that amending the statement "to address some issues but not all potential issues, is likely to be counterproductive." (*See*

Improving Health Care: A Dose of Competition, A Report by the Federal Trade Commission and the Department of Justice; July 2004; p. 46). As stated in my testimony, even some additional guidance would be helpful to those in this industry. There are other examples where the agencies have given specific advice on contracting practices akin to those that raise concern in this market.

Not only should Statement 7 be revised to address many of the concerns raised by this Subcommittee, but legislation should be enacted to further regulate GPOs. Statement 7 should be revised to include a new section discussing those factors and arrangements which fall outside the antitrust safety zone and which raise antitrust concerns. This section could set forth many of the issues which have been raised before and investigated by this Subcommittee, including bundling, tying, sole source contracting, and other *de facto* exclusive-dealing relationships with medical manufacturers via long-term contracts, commitment level requirements, market share discounts, and rebate programs based on the volume purchased from a manufacturer. The revised statements could give specific examples to describe the mode of analysis (a similar approach is used in the Intellectual Property Guidelines). Moreover, the revised Guidelines should address several issues that frequently arise such as the degree of foreclosure, the analysis of efficiencies and the relevance of buyer support for the practices (*see* Prof. Einer Elhauge, "Antitrust Analysis of GPO Exclusionary Agreements" at pp. 45-46, submitted for the DOJ-FTC Hearings on GPOs, September 26, 2003).

As it currently exists, Statement 7 focuses on certain financial thresholds which must be breached before the agencies will challenge a joint purchasing arrangement. GPOs have greatly evolved since this statement was first implemented. It is time for Statement 7 to likewise evolve and to focus not only on the broader financial factors of GPO activities, but also the manner in which GPOs are engaging in relationships with medical device and supply manufactures.

Questions from Senator Leahy

1. **You cite in your testimony the July 2003 GAO report: "Group Purchasing Organizations: Use of Contracting Processes and Strategies to Award Contracts for Medical-Surgical Products." The conclusion of that report sates that an insufficient amount of time had elapsed to study the effectiveness of GPO codes of conduct between the adoption of voluntary codes of conduct by GPOs and the GAO study. Why do you believe Congress should act now, before GAO issues their next report on this issue and before it can be determined whether or not voluntary codes of conduct have in fact been successful in mitigating some of the concerns that existed prior to their adoption?**

I must respectfully disagree with the statement in the GAO report that an insufficient amount of time has elapsed in which to study the effectiveness of the current GPO codes of conduct. Despite continued criticism of their practices and federal investigations of their activities, GPOs and the Health Industry Group Purchasing Association do not appear to have further amended their voluntary codes of conduct since 2003. The GAO report also stated "some GPOs' conduct codes included exceptions and qualified language that could limit their potential to effect change." Therefore, time alone will not solve the problem. Legislation is required to achieve true and lasting reform.

In any event, these voluntary codes of conduct on their face are insufficient to guarantee success in mitigating the concerns of certain GPO behavior. As I indicated during my testimony, these codes of conduct lack any form of an enforcement mechanism. In order for any self-regulatory scheme to work, it must have as an integral component an adversarial enforcement system and process which is transparent and autonomous from the members of the industry whose business practices are under its purview.

I fully concur with members of the Subcommittee who have voiced concern that once the Subcommittee turns its oversight spotlight away from the GPO industry, there could be back-sliding. As the codes of conduct currently exist, with vague language, exceptions, and omissions on certain key issues, the GPO industry and its major association have shown that they will do as little as possible in the area of self-regulation and monitoring of industry practices in order to address anticompetitive concerns. Congress should act on this matter in order to ensure the integrity of this portion of the health care system and a competitive and open market in which hospitals, physicians and patients have access to the best and most advanced medical technology available.

2. **Are there circumstances where tying, bundling, and sole-source contracting can in fact be pro-competitive? If so, is it possible to preserve the benefits that these practices may offer while reining in what you characterize as anti-competitive practices? Does the draft legislation achieve this balance?**

Yes, such practices can be pro-competitive when used by a new firm attempting to enter a new market for its products. Bundling, tying and sole-source contracting can be more efficient and cost-effective for the manufacturer as well as the GPO member purchasing the goods. It is also an effective strategy for a manufacturer that wants to compete with rivals in the market. The mere existence of tying and bundling are not always indicative of a problem with anticompetitive behavior. Yet, in the concentrated GPO market, we have seen that it raises barriers to entry and expansion, and can be used in an exclusionary manner.

I believe it would be possible to preserve the benefits of such practices while reining in the anticompetitive practices engaged in by some GPOs. So long as the legislative history is clear regarding Congressional intent, the draft legislation could vest in the Department of Health and Human Services the necessary authority for the Office of Inspector General to draft regulations and review on a case-by-case basis the competitive aspects of GPOs in the medical device and supply market. The language of the current draft pertaining to the Secretary having to certify a GPOs compliance with the regulations is critical, as would regulatory language addressing methods of enforcement.

3. **The July 2003 GAO report on Group Purchasing Organizations includes some evidence that since the summer of 2002, GPOs have used fewer bundling arrangements. Do you believe this is the case? If so it would suggest that codes of conduct have in fact been effective in modifying GPOs' behavior. Is it possible that additional changes to the codes of conduct, short of legislation, could produce further positive results?**

My analysis for the Subcommittee relied, in part, upon the July 2003 GAO report and the evidence it set forth regarding changes in GPOs' practices since the issue was raised by this Subcommittee in 2002. I am not privy to any documentation which would either support or refute the GAO's conclusions. However, based upon general conversations, I do believe that GPO's (under the continued scrutiny of this Subcommittee) have used fewer bundling arrangements since 2002. If the Subcommittee desires more detailed information and documentation, I would initially refer you to the two major health organizations interested in this matter - Mr. Robert Betz, President and CEO of Health Industry Group Purchasing Association; and, Mark B. Leahey, Esq., Executive Director of the Medical Device Manufacturers Association.

Yes, it is possible that further changes to the codes of conduct would produce further positive results. However, I believe GPOs have shown a reluctance to undertake any further reform despite continuing criticism of their activities. As I stated during my testimony, the current codes of conduct lack teeth – there is no enforcement mechanism; there are no penalties for non-compliance; and, there is no procedural due process and transparency. At the hearing, Mr. Betz stated that violations of HIGPA's code of conduct would result in a GPO member being kicked out of the association and he asserted that this would negatively affect that GPO's ability to do business. Mr. Kiana accurately countered, however, that HealthTrust Purchasing Group is not a member of HIGPA, and yet remains one of the largest GPOs in the nation. Absent legislation, I remain very

concerned as to whether additional, meaningful and permanent changes to address this Subcommittee's concerns can be achieved.

4. **In a similar vein, the July 2003 GAO report on Group Purchasing Organizations notes that "some GPOs' conduct codes include exceptions and qualified language that can limit the potential of the conduct codes to effect change." You, too, argue that non-specific language in GPOs' conduct code limits their utility. Would clearer guidelines address some of your concerns, without the need for legislation?**

Yes, clearer guidelines would be superior than existing guidelines and could address some of the particular concerns raised by this Subcommittee, the GAO and the many medical device and supply manufacturers who have complained about the behavior of GPOs. Nevertheless, I believe a large anticompetitive problem would continue to exist. The GPO industry and its market are very concentrated and has a history of engaging in anticompetitive behavior. What is being regulated by the GPOs is contractual arrangements that are critical to competition; a far different concern than self-regulating for deceptive conduct or false advertising.

As I stated at the hearing, the Department of Health and Human Services' Office of Inspector General plays an active role in oversight and enforcement in many other health care markets. Legislation which would place regulatory oversight and enforcement in the hands of the Department of Health and Human Services' Office of Inspector General would ensure enforcement of the anti-kickback statute and help to make the GPO market more open and competitive.

HIGPA Responses to Questions from Chairman DeWine
Concerning Testimony from
Dr. Robert Betz on September 14, 2004
"Hospital Group Purchasing: How to Maintain Innovation and Cost Savings"

1) I am pleased that HIGPA created a code of conduct for all its members, and it appears to have been successful as far as it goes - - specifically, in greatly decreasing or even eliminating conflicts of interest and other potential ethical problems in the relationships between GPOs and manufacturers.

   However, for the most part the code is mute on the more difficult issues such as contracting practices like bundling, sole source contracts and long-term contracts. This limitation is understandable because, as we would be the first to agree, an industry-wide code that dealt too closely with price-related contracting practices might subject its members to antitrust scrutiny. So doesn't that argue for a more vigorous approach? In other words, since the industry would risk antitrust liability if it too closely self regulated itself, should it be "protected" by oversight from a federal agency?

   HIGPA Response:

   The group purchasing industry maintains that appropriate antitrust regulatory tools currently exist. The Federal Trade Commission and Department of Justice retain jurisdiction over any antitrust violations that may arise. These agencies concluded in their July 2004 report, "Improving Health Care: A Dose of Competition," that appropriate regulatory options currently exist to monitor health care group purchasing organization activities. Specifically, the agencies stated they would analyze criticized conduct on a case-by-case basis to determine whether it may violate the antitrust laws. Therefore, any additional regulatory protection, outside of present authority, would only add cost to health care while providing nothing new or additional to the current antitrust regulatory scope.

2) In your September 2, 2004 letter to the Subcommittee in anticipation of the hearing, you mentioned the National Association Securities Dealers, among other organizations, as an example of a business trade group that "rel(ies) on industry self-regulation to provide strong standards without reliance on government oversight." Of course, the NASD has significant powers to discipline members who do not abide by its rules and an appeals process to the Securities Exchange Commission and ultimately to the federal courts, if necessary.

   Obviously this degree of self regulation is not occurring in the GPO industry. Is your letter suggesting that HIGPA is willing to consider such a model of self regulation? If not, why?

HIGPA Response:

The Health Industry Group Purchasing Association shares parallels with the National Association of Securities Dealers and other self-regulating organizations in that each association subjects its members to a process whereby its membership is subjected to certain requirements to retain its standing within the organization. Like the NASD, HIGPA also retains the right to remove members from its organization and encourage federal agencies to take more serious action if necessary. HIGPA remains committed to finding ways to enhance the process of compliance with our Code of Conduct.

3) In Mr. Kiani's written testimony he states "[t]he GPOs as a whole will be better off [with legislation] because they will no longer be subject to the pressure exerted by the largest vendors who threaten to take their fees away if they don't get the exclusionary contracts they want." Do you agree with that?

HIGPA Response:

No. The group purchasing marketplace is an extremely competitive and dynamic marketplace. This market is driven by the end-user hospitals and health care practitioners that ultimately make purchasing decisions. It is these end-users that make the decisions of which GPOs to utilize, which vendors to purchase from, and what products to provide to patients. Therefore, any vendors that wish to reach the hospital marketplace must provide a product that has a demand in the hospitals. If hospitals do not demand a product or wish to contract for a product, regardless of the desires of any GPO or any vendor, that product cannot be forced into that hospital for use. Neither the group purchasing industry nor the vendors drive this demand. Ultimately, the demand is driven by doctors, patients, and hospital preference.

HIGPA Responses to Questions from Senator Kohl

1) As you know, Congress granted your industry a special exemption from the anti-kickback law. Doesn't that fact make it appropriate that government oversee the industry to monitor that this exemption is not abused?

HIGPA Response:

The Department of Health and Human Services (HHS) has oversight and enforcement authority under the anti-kickback law. In order to fit within the safe harbor, a GPO has to meet requirements, including the following: If an administrative fee in a GPO contract is greater than three percent, the agreement must state the specific amount of the fee, expressed either as a fixed sum or as a fixed percentage of the value of the purchases made from the vendor. When the entity that received the goods or services from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Department of Health and Human Services upon request, the amount received from each vendor with respect of purchases made by or on behalf of the entity. The OIG regularly includes oversight authority over GPOs in its annual work plan.

2) Do you believe that the Department of Health and Human Services is a suitable agency in the federal government to have oversight over hospital purchasing? If not, explain why not and specify which agency would be better and why.

HIGPA Response:

Please see response to question #1.

3) Dr. Betz, page two of your written testimony notes that you have received legal advice that it would be contrary to antitrust law for a private organization such as yours to enforce restrictions on its members' business practices. Doesn't this legal advice to mean that there is no private sector enforcement mechanism possible consistent with the antitrust laws?

HIGPA Response:

No. The most important private sector enforcement mechanism of the group purchasing industry is the marketplace itself. The GPOs provide their member hospitals and vendors with the HIGPA Code of Conduct. This is done to educate the entire health care supply chain on the compliance issues of the industry. By certifying compliance with the HIGPA Code of Conduct and providing it to all contracting partners, the GPO is, in essence, making a pledge to its partners to operate within these principles. Any party that has a grievance can complain to the Justice Department and the Federal Trade Commission as well as bringing a private

civil action.

4) As we have asked your organization repeatedly over the past two months, are there other ideas or mechanisms, besides the ones in our draft legislation, that you would propose which will ensure that the GPO reforms are permanent and lasting, or do we have to trust that the industry's promises will be enough? If you have additional ideas, please be as specific as possible.

HIGPA Response:

HIGPA's Board of Director's recently approved the formation of a Working Group comprised of one representative from each of HIGPA's Industry Member organizations (health care purchasing organization) to examine the following:

- **Possible changes or enhancements to the HIGPA Code of Conduct Principles**
- **Changes in the manner in which Industry members certify compliance with the Code, or strengthened verification of compliance, such as third party certification.**
- **Enhanced enforcement of compliance, either from within HIGPA, or from other players in the supply chain – especially providers.**
- **Consideration of ways to extend the reach of the Code to other players in the supply chain.**

The Working Group's recommendation is expected to be presented to the HIGPA Board of Directors in January 2005, allowing HIGPA to meet with Senate staff early in the year to discuss the industry's selected approach.

5) During your testimony at the hearing you stated that the GPOs' codes of conduct were "living" documents. What is the consequence of this fact? Doesn't this suggest that the GPOs and HIGPA can change or modify their codes as they see fit? Doesn't the fact that the codes are "living" documents subject to modification support the idea of finding a mechanism to ensure that the reforms are not withdrawn in the future?

HIGPA Response:

The HIGPA Code of Conduct has been created and implemented by the group purchasing industry. It, like other industry self-regulation or government regulation, necessitates changes, enhancements, and improvements as market conditions warrant. A static document does little to encourage improvement and promote efficiencies within the industry. Therefore, the industry must constantly reevaluate itself. However, changes to the Code of Conduct are not to be taken lightly or without extensive research, investigation, and consultation by the member of HIGPA and industry experts. Any enhancements require consensus among the industry membership.

6) As you acknowledged at the hearing, the only sanction a GPO faces that fails to comply with the HIGPA code of conduct is expulsion from HIGPA. You further acknowledged at the hearing that a GPO that is expelled from HIGPA could continue to do business. Is the penalty of expelled from HIGPA adequate assurance that a GPO will adhere to the terms of the HIGPA code of conduct?

HIGPA Response:

When a GPO certifies compliance with the code, it is certifying not only to the association, but to all its contracting partners – vendors, distributors, and hospital end-users. Were a member to be expelled for failure to adhere to the terms in the HIGPA code of conduct, its HIGPA membership would be terminated. This expulsion is a message to its contracting partners and health care provider members that the GPO does not follow the industry standard practices and does not certify that it is in compliance with the industry's rules.

7) Describe all steps HIGPA undertakes to verify a GPO's assertion that it is in compliance with the HIGPA code of conduct.

HIGPA Response:

Following the Code's adoption in July of 2002, in the first quarter of each year HIGPA sends to its members a "Compliance Survey," which requests the Association's Industry Members to self-certify compliance with the HIGPA Code. The chief executive and compliance officers are required to attest to the GPO's survey responses. Upon completing this survey, the Industry Member returns it to HIGPA. Copies of these surveys are then sent to the Senate Judiciary Antitrust Subcommittee for its records.

8) Can HIGPA take any action against a GPO that violates that GPO's own code of conduct? Does HIGPA even monitor whether GPOs are complying with their own individual codes of conduct? Would it be possible for a GPO to fail to comply with its own code of conduct yet still be complying with HIGPA's code of conduct?

HIGPA Response:

All GPO members of HIGPA must be in compliance with the principles in the HIGPA Code of Conduct in order to retain membership in the association. However, individual GPO members also have company-specific codes that incorporate the HIGPA principles, as well as other issues tailored to their business model. To assist in the monitoring efforts, HIGPA, through its website, offers any individual or company the opportunity to contact HIGPA's Industry Member Compliance Officers to report or highlight compliance concerns. These are routed to both HIGPA and the specific GPO of concern.

HIGPA Responses to Questions from Senator Graham

1) How do GPOs benefit member hospitals?

HIGPA Response:

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.

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.

2) Do most hospitals belong to more than one GPO, and if so, how does that benefit the hospitals?

HIGPA Response:

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. Because most hospitals belong to multiple GPOs, each with a unique set of contracts, hospitals have choices – either choosing among GPO contracts or bypassing the GPO process and going directly to the supplier to purchase a particular product.

3) Please explain the role of GPO member hospitals in the selection of products for contract.

HIGPA Response:

Please see attachment: "The Clinical Review Process Conducted by Group Purchasing Organizations and Health Systems," The Lewin Group, April 2002.

4) Please explain how GPOs integrate new technologies into their contracts. Please provide examples of innovative technology being used in GPO contracts in the last two years.

HIGPA Response:

In section C.2. of HIGPA's Code of Conduct, adopted in July 2002, it states "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."

Additionally, in accordance with HIGPA's Code of Conduct Principles, the Association created the web-based *Vendor Information Exchange*, which allows every health care manufacturer the ability to promote their "new and innovative" products by accessing the top U.S. based group purchasing organizations (GPOs) in HIGPA's membership. HIGPA created this exchange to enable any manufacturer to submit information about their product to the key players in the health care supply chain—the purchasing organizations. Group purchasing organizations are tasked daily with the difficult job of selecting medical products for their health care

provider members. In turn, HIGPA has created this information exchange to further HIGPA's Industry Members' commitments in providing the best products at the best price to the patients they ultimately serve.

The exchange (*http://www.higpa.org/vendorinformationexchange/*) is an open forum for any manufacturer, whether currently contracting with a purchasing organization or not, to provide detailed information about their new product to HIGPA's members. Upon accessing the submission form, manufacturers are asked to provide contact information for the representative marketing the new technology, product name and a detailed description, with the ability to upload marketing documents. Individual GPO Compliance Officers receive this information and then determine the proper course of action.

HIGPA Responses to Questions from Senator Leahy

1. You note in your statement that HIGPA has created an Internet-based "Exchange" whereby medical device manufacturers may promote their goods online, whether or not they contract with a GPO. However, the extent to which this initiative allows smaller device manufacturers the opportunity to do business with your member organizations would seem to be limited by both bundling and sole-source agreements. Has this program been effective? How many medical device manufacturers – large and small – that had not previously contracted with GPOs have obtained business through this program?

   HIGPA Response:

   The Internet-based "Vendor Information Exchange" was developed in order to provide a simplified tool for medical device manufacturers, or other companies, to promote their new or innovative products to the GPOs. The system has only been in place for less than three months after discussions with interested parties to improve and enhance the tool itself. At this time, the system will need to function for several months in order to determine its effectiveness and develop further refinements. HIGPA plans to follow-up with both the GPOs and the medical device manufacturers in the upcoming months to seek feedback and modify as necessary.

2. Some have expressed the concern that GPOs have an incentive to act as agents on behalf of medical device manufacturers rather than hospitals because GPOs' profits are derived as a percentage of the overall amount of the contract. Is this true? Are their economic incentives that would ensure that GPOs negotiate the best possible prices for participating hospitals as opposed to obtaining the best possible deals for device manufacturers?

   HIGPA Response:

   GPOs are the agents of providers, not suppliers. They operate at the request of their health care 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, and because most hospitals belong to multiple GPOs, each with a unique set of contracts, hospitals have choices in deciding which GPO's contract to use for a particular product.

3. I also have heard concerns about the practice of "private labeling" by GPOs and the high administrative fees that seem to accompany this branding. The Government Accountability Office's July 2003 report notes that while most GPOs did not exceed the 3-percent threshold established by Department of Health and Human Services regulations, private label products were an exception: on average manufacturers paid a 5-percent administrative fee for these products. In one case, the maximum administrative fee was 18-percent. Please explain this disparity.

HIGPA Response:

As the trade association, HIGPA has a policy not to comment on the specific contracting practices of individual GPOs. Such questions should be directed to those organizations practicing private labeling.

4. The July 2003 GAO report on Group Purchasing Organizations notes that "some GPOs' conduct codes include exceptions and qualified language that can limit the potential of the conduct codes to effect change." Has ambiguous or vague language limited the effectiveness of these codes? Are clearer guidelines needed?

HIGPA Response:

We believe the HIGPA's Code of Conduct is working. If there is a concern related to the HIGPA Code, they can be directed through HIGPA's web site by contacting the Compliance Officers of HIGPA's member organizations at http://www.higpa.org/complianceofficers/.

Answers to Questions from Chairman DeWine

1. Yes, our company is in much better position than it was in April 2002 but it is still necessary to move forward with legislation. The position of a single company such as Masimo should not be the basis upon which to legislation is enacted. Masimo's improved position in the market is due, in part to the Code of Conduct, which cannot be expected to continue indefinitely on a voluntary basis. There are clear indications that without comprehensive, lasting and enforceable reforms, any gains made as a result of this Committee's activities will be short lived because of the following 2 reasons:

   I. Codes of Conduct are voluntary and can be changed or interpreted subjectively. Without a real enforcement mechanism, there is no way to ensure that the GPOs will have adequate codes of conduct, follow their codes of conduct, or not alter their codes of conduct once the Senate scrutiny is off. Here are some examples where a GPO either never set up a code of conduct, or set up one, but altered it later, or interpreted its own code of conduct to benefit itself:

   - **HealthTrust Purchasing Group (HPG)-** HPG is one of the top five GPOs, yet they never adopted or followed a code of conduct to deal with the Committee's issues. In fact, they sent Masimo a notice of non-renewal and created a sole source contract with Tyco-Nellcor last year, a year after the Committee's first hearing and a few months after the second hearing.

   - **MedAssets-** MedAssets, the third largest GPO, adopted a code of conduct in February 2003 which dealt with several of the issues that this Committee was concerned about, including a commitment that it would not bundle clinical preference items. In October 2003, MedAssets adopted a new code of conduct, which not only removed this pledge, but also removed all specifics regarding anti-competitive contracting practices. As far as we can tell, MedAssets made this change without consulting this Committee, HIGPA or anybody else. MedAssets put Masimo on contract prior to the second hearing, but kept a bundling agreement with Tyco-Nellcor that effectively shut us out.

   - **Novation-** Novation is the market leading GPO. Their code of conduct has many loopholes in it. For example, instead of giving ordinary meaning to clinical preference items as Premier did, Novation has no clear criteria for what is a clinical preference item. In fact, Novation told us that they think pulse oximetry is not a clinical preference item even though Premier describes it as a clinical preference item in their code of conduct and it is prescribed by doctors. Novation also stated that it could terminate all of its supplier agreements with 90 days notice and that it would prospectively abolish bundling and sole sourcing of clinical preference items. Yet over two years has passed, and Novation still has not terminated its bundling program, called Opportunity, and has only cancelled a handful of contracts in order to allow multiple sourcing for clinical preference items. In Masimo's example, even though Novation created its code of conduct one week after Premier, Novation put Masimo on contract one year after Premier, and sent a letter to its members asking them to recommit to Tyco-Nellcor after we were put on contract.

   - **Premier-** Premier, the second largest GPO, was the only GPO to adopt a code of conduct that came close to being comprehensive. The rest of the GPO codes were inconsistent, incomplete and full of modifying language. However, we have information that Premier has begun implementing what they call a "Second Event", which is a way to discretely move back to sole source contracts.

II. Retaliation is expected for those who testified against the GPOs anti-competitive tactics and self-dealings. There is a strong indication that absent ongoing oversight, the GPOs will retaliate if and when this Committee turns its attention elsewhere. Our testimony includes an email from the CEO of HPG, the fourth largest GPO, who threatened us for promoting legislation and later followed through by not renewing our contract and entered into a sole source contract with Tyco-Nellcor for pulse oximetry, a clinical preference product.

In summary, several of the GPOs went through the motions of adopting codes and even putting Masimo on contract, but these contracts are temporary and already have proven to be insincere. Premier is talking about moving back to sole source agreements. Other GPOs, including Novation, the market share leader, continue to act in an anticompetitive fashion, preventing patients and caregivers from accessing the most innovative, cost-effective pulse oximetry technology. Also, by being vocal regarding reform, we are vulnerable to backlash.

And as for why not to take things more slowly, we could spend years working on devising new and better codes of conduct, but patients, caregivers and taxpayers cannot wait that long. We have already been waiting for years. As I mentioned at our last hearing, I was also one who was hoping the codes of conduct would sufficiently remedy the problems. However, after over 2 years of seeing how the codes can be manipulated, I am convinced that without legislative action, there will be no true reform. The government must facilitate a more comprehensive and lasting approach. If this does not occur, any progress that has been made will be short lived and we will end up back where we started or even worse. Once this Committee turns its attention away, the GPOs will revert back to their old ways because there are huge economic incentives for them to do so. The largest vendors will always be anxious to work with the GPOs to devise ways of closing out their competitors. In fact, we have already seen this with Premier's "Second Event Program." Additionally, MedAssets, the third largest GPO has also been "backsliding" with their Code within the first seven months. Novation interprets its code to meet its own financial needs, and HPG retaliated against Masimo for speaking out against anticompetitive practices.

2. We do favor free markets, but that is not what we have today. In a free market, vendors don't pay third party buyers (GPOs) who are supposed to represent their members. As the CEO, Director, and the Chairman of the Board of Masimo, I couldn't sleep at night if our vendors were paying Masimo's purchasing department. I would worry that the purchasing department would be serving the interest of our vendors and not Masimo's shareholders. Unfortunately, hospital CEOs and directors seem to be able to sleep fine, apparently unknowingly allowing their Group Purchasing Organizations to be paid up to 30% of the dollar amount their hospitals purchase from vendors. This is the situation in most of our hospitals in the US. GPOs are negotiating long term committed contracts with vendors and are paid a percentage of the total amount purchased by the GPO members, while the vendors are being encouraged by the GPOs to be creative in the amount they pay for getting such contracts. The conditions that exist today were caused by allowing GPOs to depart from the free market in the first place and allowing an exemption from our anti kickback laws. This special status created a ripple in the free market that has now turned into a tidal wave crushing our healthcare system. It created an opportunity for the vendors to buy market share from the GPOs. GPOs engage in self-dealing instead of looking after their member hospitals. There's only one true way to get back to a free market; repeal of the safe harbor status granted to GPOs. Short of repealing the Safe Harbor, GPOs must be regulated to ensure that corruption is minimized and that the special status is used to benefit hospitals not GPOs.

As for the risk of unintended consequences, yes, there is the risk of unintended consequences. However, if we leave things the way they are, we are living with a known, terrible, unintended

consequence from the safe harbor granted to GPOs, where everyday patients, caregivers and innovations are being harmed. Perhaps when the GPOs were granted the safe harbor, more time should have been spent discussing the intent of the exemption and not the specific rules similar to our constitution. So this time, to minimize unintended consequences, the legislation has to be carefully drafted, the intentions must be clear and there should be a mechanism for evolution based on feedback and proper oversight.

3. The industry has not evolved much since the GPOs and dominant vendors became as large as they are. The top seven GPOs and ten dominant vendors make up over 80% of hospital purchases. With this bill, the industry will hopefully evolve as fast as it did in the 1970's and 1980's. Evolution in other industries, such as the computer industry, has brought amazing progress to the world. In anticipation of a freer market, as stated above, care must be taken in the drafting of the bill. The intention of the legislation must be stated clearly and mechanisms for evolution must be provided. I believe the current bill provides for both. The intentions are clear and the HHS is given the opportunity to adapt with the evolving industry. Fortunately, the basic issues regarding free competition and promoting innovation do not change. Adopting regulations to prevent the GPOs from engaging in anticompetitive contracts can only increase competition and innovation, which will result in lower prices and better care.

Answers to Questions from Senator Kohl

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In summary, several of the GPOs went through the motions of adopting codes and even putting Masimo on contract, but these contracts are temporary and already have proven to be insincere. Premier is talking about moving back to sole source agreements. Other GPOs, including Novation, the market share leader, continue to act in an anticompetitive fashion, preventing patients and caregivers from accessing the most innovative, cost-effective pulse oximetry technology. Also, by being vocal regarding reform, we are vulnerable to backlash.

4. Yes, we do believe that the Department of Health and Human Services (HHS) is the suitable agency to have oversight over Group Purchasing Organizations. HHS currently has the authority over the hospital group purchasing industry related to the safe harbor of the anti-kickback statute. In fact, the HHS OIG has issued reports stating that some GPOs were not in compliance with the safe harbor requirements. Therefore, there is precedent and an understanding within HHS of this industry.

5. If your bill becomes law, we believe that competition will increase and as a result, health care costs will be reduced and health care will improve for patients in the US. In addition, the medical technology sector will remain vibrant and continue to outpace other industries in terms of export. The exemptions from anti kickback laws created an irresistible opportunity for self-dealing by the GPOs and a way for incumbent manufacturers to shut out the US hospital market from their competition. The largest vendors were more than happy to pay large fees, well over the 3% that was anticipated, if they were granted sole source contracts and the GPOs devised schemes, such as tying discounts to bundling of unrelated products, to keep their competition out. Note that we didn't say the dominant vendors gave their best price to get sole source contracts, but rather negotiated for higher fees (administrative, marketing, private labeling, bundling, ... fees) paid to the GPO to become the sole provider of the products they had to offer. Negotiating for long-term sole source contracting, even for immediate discounts by itself would hamper long-term competition in a market. But to have these long term sole source contracts be granted for more fees to the GPOs only benefits the GPOs and dominant vendor.

   The 3% hard cap on vendor fees will significantly reduce these incentives. In addition, carefully drafted regulations regarding anticompetitive contracting practices will increase competition, resulting in lower prices and better products. And with clear rules and known penalties, GPOs are less likely to become tools for monopolies to maintain their dominant market positions.

6. Without comprehensive and uniform principles, third-party oversight, and real penalties for non-compliance, the GPO industry will continue to engage in practices that harm patients, caregivers and innovation. Like David Balto, I am a free market person. However, the free market was interrupted when Congress granted GPOs a special "safe harbor" from the anti-kickback statute. This opened the door for GPO self-dealings and many of the problems we currently find today. Therefore we believe your proposed legislation is an effective way to mend and not end the GPO system.

Another alternative would be the elimination of the safe harbor. If hospitals saw value in their GPO, they would pay a membership fee.

7. We believe that industry self-regulation can't work in this instance because the safe harbor created such significant economic incentives for abuse. There will always be large suppliers willing to work with the GPOs to shut out their competition and as long as the GPOs are allowed to, they will cooperate.

Answers to Questions from Senator Leahy

1. The Medical Device Manufacturers Association did not refuse to review HIGPA's Internet exchange program. In fact, MDMA met with HIGPA representatives about this exchange. During the course of these conversations, MDMA stated that the goal of promoting innovative, cost effective technologies would be better served if HIGPA proactively addressed the anticompetitive issues within their membership. Without real reform, the website would be ineffective. For example, it would not do a vendor any good to have their product listed on a website if the underlying GPO contract prevented the hospital from purchasing the product.

   HIGPA, like MDMA is a trade association, without any way to reward or punish behavior. HIGPA can serve to bring forth their members' issues, but can't dictate to their members how to behave. Unlike Boards that certify doctors, HIGPA cannot certify or decertify their GPO members. So if a GPO doesn't follow HIGPA's code, which is very empty and doesn't address any of the issues that have been raised at your hearings, or a GPO doesn't follow their own code, HIGPA can't take away the GPO's certification. It should be noted that although most of the GPOs have not followed their own codes of conduct, none of them have been kicked out of the HIGPA trade association. In addition, HPG, the 4th largest GPO is not even a member of HIGPA. So the GPOs who violate their own code of conduct have no risk of losing the safe harbor granted to them by congress. Members must, on their own, practice good conduct. Unfortunately to date, as stated above, HIGPA's code of conduct does not address the continued anticompetitive practices of its members in a real and substantive way. Still, MDMA remains open to discussing the "exchange" program with HIGPA. However, "promoting" such a program without HIGPA's members first addressing the anticompetitive issues would not change the conditions in the marketplace. In fact, the program may even serve as a costly distraction from the real issues facing the HIGPA membership.

2. As far as the industry environment is concerned, Elizabeth Weatherman, Vice Chair of the Medical Group at the National Venture Capital Association and Managing Director of Warburg Pincus, described the market conditions in her previous testimonies before this Committee. She said, "GPO roadblocks have greatly diminished the attractiveness of medical device and biotechnology investments because they reduce the confidence of venture capitalists that they will have fair access to medical markets and thereby will achieve a return on very risky investments." She went on to say, "One of the reasons for this relative decline in investment is a lack of market access brought about by business practices and the increasing power of GPOs. GPO practices such as contract exclusivity, substantial fee structures, and product bundling, if allowed to continue, will so constrict potential markets that product segments where these practices are widely adopted will simply not be considered for venture capital backing. This investment drain will result in stagnation of product innovation and stymie improved patient care across these product sectors."

3. Yes, we have seen a scale back in bundling by some GPOs. But, while some GPOs may have scaled back their bundling programs, other GPOs continue to bundle unrelated products and even multiple dominant manufacturers' unrelated products. In fact, certain GPOs have expanded their bundling programs over the past year. Novation, the country's largest GPO and MedAssets, the nation's 3rd largest GPO, continue to promote programs, which bundle products from unrelated companies. In addition, both GPOs continue to bundle unrelated products from the same vendor as well.

We believe unrelated products should not be bundled together, at any level. We believe that each product should succeed or fail based on the merits of the individual product. Tying products together prevents an equally efficient rival with a clinically equivalent or superior product or lower priced product from competing in the marketplace. This will negatively impact long term patient care, innovation and cost of health care.

Once you allow a handful of GPO's who control over 80% of the hospitals in the US to bundle unrelated products and companies together, the effect is catastrophic. GPOs, who enjoy the special government "safe harbor" should not be allowed to dictate what products are used in hospitals. Yet that is what the sole source and bundling programs do. These programs reduce competition, increase prices, stifle the innovation process, and compromise the overall quality of care.

4. Yes, ambiguous and vague language has limited the effectiveness of the codes. We have witnessed for ourselves how Novation has allowed its own appointed panels to decide what product is considered a "clinical preference" item. Most, if not the entire Novation code of conduct applies to clinical preference products. So, if Novation's self appointed panels decide that stents, pulse oximeters, pacemakers, ... are not clinical preference products, then Novation can enter into sole source contracts, bundling, ... for these products. In fact, right before your second hearing, Masimo was almost not granted a contract with Novation, since Novation's self appointed panel considered pulse oximetry not as a clinical preference item.

   As the GAO reported, "some GPOs' conduct codes include exemptions and qualified language that can limit the potential of the conduct codes to effect change." In addition, contrary to what Mr. Betz stated in his September 2, 2004 letter to Senators DeWine and Kohl, the HIGPA code is not mandatory. There are multiple multibillion-dollar GPOs who do not comply with the "industry code". Furthermore, Mr. Betz testified last year that the code was the only one in healthcare with a penalty for noncompliance. However, during this year's hearing it came out that the penalty for noncompliance was a loss of membership to HIGPA. Given the fact that there are multibillion-dollar GPOs that don't belong to HIGPA, I do not think this penalty serves as an adequate disincentive. Unless and until the GPOs risk the loss of the special government "safe harbor" from the anti-kickback statute, their behavior will not change.

   Clearer guidelines would be a good first step, but without third party oversight and real penalties for noncompliance, the guidelines alone would have no real impact. That is why this legislation is needed. It would provide clearer guidelines, real oversight and proper penalties for noncompliance.

5. While certain GPOs may have taken the first step in informing vendors of the timing of the bids, the structure of the bids are still closed. There aren't open forums by the GPOs to state why a company was not granted a contract and others were. Until the underlying elements of the bid process are reformed to prevent excessive fee payments, the bundling of products, the award of sole-source contracts, and long-term contracts, the process will remain flawed.

   The real question is not how many companies have received contracts. Some GPOs are notorious for awarding "token contracts" with multiple vendors. Only to then do their best to channel the business to one vendor, e.g., Novation's letter to their member to recommit to Nellcor, after we were put on contract, or MedAssets's Select program, which bundles their favorite vendors' products together and ties the member's purchases to the discounts, forcing their members to buy from the incumbent vendors.

   More transparency is required to ensure that contract decisions are made for the patient's best interest, not the financial best interest of the GPO.

SUBMISSIONS FOR THE RECORD

September 10, 2004

Mr. Seth Bloom
US Senate Subcommittee on Anti-Trust

VIA E-MAIL

Dear Mr. Bloom:

I am writing to comment on the sub-committee's upcoming hearing regarding various oversight and regulatory considerations involving hospital Group Purchasing Organizations or GPOs.

A diverse array of problematic business practices and possible anti-competitive activity involving these businesses have been the topic of various media reports as well as investigations by a number of government agencies. It is not my purpose to indict the GPO industry, which I believe has the potential to enhance the efficiency of the medical supply chain by aggregating the contracting activity, but to suggest what I believe from over 30 years experience in the industry, may be a positive and constructive solution.

While the arrays of problems reported to be associated with the business practices of GPOs may appear diverse, I am convinced they have a single root cause. That is the conflict of interest created by the fact that all GPOs collect fees from the vendors with whom they negotiate contracts on behalf of hospitals. This fundamental conflict of interest (e.g. GPOs actually earn more when prices are higher) creates such perverse economic incentives that over time they resist even the most stringent regulatory and oversight efforts both voluntary and from outside the industry. These fees are of such amount that they also allow the payment of participation dividends to hospitals, further distorting the competitive market and raising issues of Medicare cost reporting.. Any solution with a reasonable expectation of permanence would require that fees from vendors be prohibited in favor of fees from the hospitals who receive the services of GPOs.

I am aware that GPOs claim that hospitals cannot afford their services. I am suggesting that if the GPOs simply required that their contract holders net the fees out of the "price at the pump" that hospitals (and other healthcare providers) pay, then they could partially offset that windfall with a concurrent bill for their contracting services. It is difficult to understand why this simple process wouldn't rectify the flaw in the business model that has caused such controversy.

I have been Board Chairman of the Health Industry Distributors Association, the Health Industry Business Communications Council, and a not for profit Hospital although these opinions are my own. My company is a healthcare distributor and contractor to most of the major GPOs. As such we value these business relationships and intend these comments only toward a solution of the seemingly intractable problems which have

afflicted the efficiency of the medical supply chain and embarrassed its many hard working and earnest participants.

Thanks for your consideration of these comments and please feel free to contact me at your convenience if you require further information or have questions.

Regards,

Ted Almon, President, CEO
Claflin Co.
800-343-7776 X3102

Testimony of
David A. Balto
before the
United States Senate Committee on the Judiciary
Subcommittee on Antitrust, Business Rights and Competition
September 14, 2004

Chairman DeWine, Ranking Member Kohl and other distinguished members of the Subcommittee, thank you for this opportunity to appear before you today regarding a matter of great importance concerning the cost and quality of health care in America. The issue of how Group Purchasing Organizations, or "GPOs," negotiate contracts with vendors of medical supplies and devices on behalf of its members deserves the close and careful scrutiny which this Subcommittee, the General Accounting Office, the Federal Trade Commission and the Department of Justice have devoted to the matter over the past two years.

I have practiced antitrust law for over 20 years both in the government and in private practice. Prior to entering private practice, I was the Assistant Director of the Office of Policy and Evaluation for the Bureau of Competition of the Federal Trade Commission and attorney advisor to Chairman Robert Pitofsky.[1] In these positions, I was a senior advisor in the FTC's merger and non-merger enforcement program. I was involved in the drafting and issuance of the FTC and DOJ Statements of Antitrust Enforcement Policy in Healthcare. I also assisted in the litigation of numerous monopolization cases as well as challenges to anticompetitive and exclusionary conduct by several health care companies.

My purpose before you today is to address three issues which have clearly arisen out of the extensive review of GPOs by this Subcommittee, the GAO, the FTC and the Department of Justice. First, is there a need for regulation of GPOs? Second, is self-regulation of the market sufficient to cure the problems identified by your prior hearings? Third, would the proposed legislation before us today be a sound approach to the problem?

Before I discuss each issue in more detail, allow me to offer a summary conclusion: There have been significant competitive problems in the GPO market. While I applaud this Subcommittee's success in working with GPOs to create and implement codes of conduct which attempt to address these anticompetitive concerns, these codes of conduct are inadequate for three main reasons: (1) they are not consistent industry wide and they are ambiguous; (2) there are no enforcement mechanisms for noncompliance; and, (3) there is no enforcement entity. Thus, enacting legislation to give the Department of Health and Human Services the power to regulate GPOs is appropriate.

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[1] I am a Partner at Robins, Kaplan, Miller & Ciresi L.L.P. This testimony solely reflects my own views and not those of the firm or any firm client. I testify today at the request of the Committee and not on behalf of any hospital, GPO, or medical supply or device manufacturer.

Competitive Concerns

The past hearings on this issue document that competitive problems have existed and still exist with regard to GPO practices. The original purpose for GPOs was to allow them to act as collective bargaining purchasing agents on behalf of member hospitals. By pooling their purchases, member hospitals would be able to negotiate lower prices from medical supply and device vendors. This Subcommittee's prior hearings into the activities of GPOs raise serious questions as to whether GPOs continue to truly operate in this fashion, or whether they have used the safe harbor provisions of the anti-kickback statute to evolve into far more powerful entities with monopoly and monopsony powers which reduce competition, create barriers to market entry, and impede the functioning of a free market.

As the Subcommittee is aware there are a variety of contracting practices that have raised competitive concerns, including sole source contracting, bundling, market share discounts, and tying. As the GAO reports suggest GPOs have evolved from neutral buying units to "gateways" which permit manufacturers to enter into arrangements that may raise entry barriers, ultimately leading to higher prices and less innovation. The relationships between medical device manufacturers and GPOs have also created incentives for the manufacturers to share profits with a GPO. As a GAO report noted GPOs acknowledged that "a manufacturer dominant in a product line may contract with a GPO, or agree to a favorable contract, to preserve its market share and exclude competition."[2]

Sole-source contracts, exclusive-dealing relationships and bundling or rebate programs are not necessary for hospitals to obtain costs savings and can cause market inefficiencies. In fact, the GAO found in its 2002 pilot study that in a number of instances "GPOs' prices were not always lower and were often higher than prices paid by hospitals negotiating with vendors directly."[3] The GAO's follow-up report in 2003 concluded that "when used by GPOs with a large market share, these contracting strategies have the potential to reduce competition .... [and] discourage other manufacturers from entering the market."[4]

Anti-Kickback Statute

Various aspects of GPOs' operations are regulated by federal statute and regulations. While anti-kickback provisions do exist under the Social Security Act, the Act also contains an exception for amounts paid by vendors of goods or services to a GPO. 42 U.S.C. Section 1320a-7b(b) states in part that provisions regarding illegal remunerations shall not apply to: "any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if," there is a written contract with the GPO disclosing the amount to be

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[2] GAO, *Group Purchasing Organizations: Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices*; GAO-02-690T, at 9; April 30, 2002.

[3] *Id.* at 3.

[4] GAO, *Group Purchasing Organizations: Use of Contracting Process and Strategies to Award Contracts for Medical-Surgical Products*; GAO-03-998T, at 6; July 16, 2003.

paid, and the GPO discloses in writing to the member hospital, medical facility or agency at least annually the amount received from each vendor supplier with respect to purchases made by or on behalf of the member.

This statutory language is the result of Section 14 of Public Law 100-93, which required the promulgation of regulations specifying the types of practices which would not be subject to criminal prosecution under Section 1128B of the Social Security Act and which would not serve as the basis for an exclusion under Section 1128(b)(7) of the Act. In implementing this legislation, Congress acknowledged that the anti-kickback statutory language was broad, had created uncertainty among health care providers, and needed to remain relevant in light of changes in the health care industry.[5] The purpose in directing the Secretary of the Department of Health and Human Services was the recognition that such regulations were necessary to limit confusion among health care providers as to which commercial arrangements were legitimate and which were proscribed.[6]

As a result, in 1991 the Department of Health and Human Services established a series of regulations setting forth various proposed business and payment practices, or "safe harbors" that would not be treated as criminal offenses under the Act.[7]

FTC/DOJ Guidelines

Shortly thereafter, in 1993, the Department of Justice and FTC issued their joint *Statements of Antitrust Enforcement Policy in Health Care.* These policy statements were designed to advise the health care community in a time of tremendous change and attempted to address any uncertainty concerning the Agencies' enforcement policy. These statements were revised and expanded in 1994 and 1996.

Statement 7 sets forth the Agencies' enforcement policy on joint purchasing arrangements among health care providers, including the formation of GPOs. It states that "[m]ost joint purchasing arrangements among hospitals or other health care providers do not raise antitrust concerns. Such collaborative activities typically allow the participants to achieve efficiencies that will benefit consumers." It sets forth the following specific guidelines:

> Joint purchasing arrangements are unlikely to raise antitrust concerns unless (1) the arrangement accounts for so large a portion of the purchases of a product or service that it can effectively exercise market power in the purchase of the product or service, or (2) the products or services being purchased jointly account for so large a proportion of the total cost of the services being sold by the participants that the joint purchasing arrangement may facilitate price fixing or otherwise reduce competition. If

[5] House Rep. No. 100-85 (Part I) at 27, (Part II) at 27 (1987); Senate Rep. No. 100-109, at 27 (1987).

[6] *Id.*

[7] 42 C.F.R. Part 1001.952

neither factor is present, the joint purchasing arrangement will not present competitive concerns.[8]

This statement sets forth an "antitrust safety zone" that describes joint purchasing arrangements among health care providers that "will not be challenged, absent extraordinary circumstances, by the Agencies under the antitrust laws."[9]

Statement 7 was focused on the simple question of when a GPO may be too large or posed the threat of exercising monopsony power or facilitating collusion. It did not address the issues of exclusion that are the center of today's competitive concerns. As one of the collaborators in drafting these statements, we did not foresee the potential for GPOs to act to diminish competition and innovation in medical device market.

I am aware that certain members of this Subcommittee requested that the DOJ and the FTC revise Statement 7. In their joint healthcare report of July 2004,[10] the FTC and DOJ declined to do so. While I agree with their comment that "no statement is likely to cover every issue that could arise," I disagree with their assertion that amending the statement "to address some issues but not all potential issues, is likely to be counterproductive."[11] Even some additional guidance would be helpful. There are numerous examples of where the Agencies have provided specific guidance on marketing and contracting practices through Guidelines in the past.[12]

It would appear that since the FTC and DOJ are not currently prepared to revise any guidelines, or that since the Secretary of HHS has not indicated any intention to formally re-evaluate the anti-kickback regulations, that it is time for Congress to step in and give these Agencies some direction. Not only should Statement 7 be revised to address many of the concerns raised by this Subcommittee, but legislation should be enacted to further regulate GPOs.

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[8] Statement 7 - "Joint Purchasing Arrangements Among Health Care Providers"; *Statements of Antitrust Enforcement Policy in Health Care*; Federal Trade Commission and Department of Justice; at 54 (August 1996).

[9] *Id.*

[10] *Improving Health Care: A Dose of Competition*; Federal Trade Commission and Department of Justice; July 2004.

[11] *Id.* at 46.

[12] *See Antitrust Guidelines For Collaborations Among Competitors*, Federal Trade Commission and the Department of Justice, April 2000; *Antitrust Guidelines for the Licensing of Intellectual Property*, Federal Trade Commission and the Department of Justice, April 6, 1995.

Evolution and Growth of GPOs

Allow me to briefly address the growth of GPOs and the current debate over their proper role in the medical supply/purchasing market sector. It is clear that the hospital and health care supply industries are greatly different today than they were when the safe harbor provisions were created in 1986. There have been significant changes. GPOs are no longer regional entities or small buying groups. In the 1990s, there was tremendous consolidation which created the large groups that dominate the hospital supply buying market today. I believe that GPOs have become much larger and more powerful than the industry, and Congress, contemplated when the exceptions to the anti-kickback laws were implemented.

As recent GAO reports and the July 2004 DOJ/FTC report indicate, this growth has been tremendous. As the GAO previously testified just seven of these GPOs collectively accounted for more than 85 percent of all hospital purchases nationwide mad through GPO contracts.[13] More importantly, the two largest GPOs account for approximately 66 percent of total GPO purchasing.[14]

This growth and the increasing allegations of abuses rightfully lead this Subcommittee to initiate this ongoing investigation. GPOs have evolved from their intended purpose of acting as a collective bargaining agent on behalf of hospitals in order to lower prices and reduce costs into an unhealthy hybrid which increasingly answers to the suppliers of medical supplies and devices which pay the administrative fees rather than their member hospitals. If left unchecked and unregulated, competition will continue to be harmed to the detriment of the cost and quality of patient health and medical innovation.

The Subcommittee's previous hearings on this topic have provided evidence of abuses which were never intended or contemplated at the time the anti-kickback exceptions were implemented. Testimony has been presented regarding clear conflicts of interest by employees of GPOs, the bundling of products and high contract commitment levels mandated in order to obtain discounts and higher administrative fees, the issuance of sole-source contracts which reduce choice, restrict entry into the market and inhibit innovation, and the payment of administrative fees by in order to capture market share and dissuade the GPOs from doing business with competitors. There are serious questions raised about the extent to which GPOs act as the agents of their hospital members or as the agents of the sellers that pay the GPOs' administrative fees.

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[13] GAO, *Group Purchasing Organizations: Use of Contracting Process and Strategies to Award Contracts for Medical-Surgical Products*; GAO-03-998T, at 4; July 16, 2003.

[14] *Id.*

Self-Regulation Is Not Working

While it is laudable that the GPOs have created and implemented voluntary codes of conduct which attempt to address these anticompetitive concerns, these codes are inadequate. While the Health Industry Group Purchasing Association ("HIGPA") and some GPOs have adopted codes of conduct for GPO business practices, as the GAO has reported, the codes established by the individual GPOs are not uniform and they include diverse qualifying language and exceptions.[15] There are no requirements for external accountability, and none of the codes of conduct I reviewed contained any enforcement mechanisms or dispute resolution procedures. Moreover, while this Subcommittee probably expected these codes to "evolve" and become more expansive they have not changed since the last hearing of this Subcommittee.

Let me provide several examples. Among the top four GPOs,[16] their policies on sole-source contracting are inconsistent – with one making no statement at all on this topic, and another making only the generic statement that all contracts "should" be multi-source. No code of conduct entirely precludes sole source contracts. In spite of promises on sole source contracts, the GAO has found that for Premier and Novation, "the shares of dollar purchasing volume accounted for by sole-source contracts were 19 percent and 42 percent."[17]

Many GPOs have also created *de facto* exclusive-dealing relationships with medical manufacturers via long-term contracts, commitment level requirements and rebate programs based on the volume purchased made from a manufacturer.[18] The codes of conduct do not prevent such activity which can have the same effect as the restrictions of a sole-source contract.[19] Another manner in which GPOs restrict competition comes in the form of bundling of products which also can be anticompetitive.[20] As the GAO reported, "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."[21]

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[15] *Id.* at 15-19.

[16] Novation, Premier, AmeriNet, and Med Assets.

[17] GAO, *Group Purchasing Organizations: Use of Contracting Process and Strategies to Award Contracts for Medical-Surgical Products*; GAO-03-998T, at 11-12; July 16, 2003. The GAO noted that these "levels of sole-source contracting are worth noting, given the sizable market shares of these two GPOs."

[18] *Id.* at 11-12, 14 and 19.

[19] *See LePage's, Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003) (en banc), *cert. denied*, 2004 U.S. LEXIS 4768 (May 28, 2004); Willard K. Tom, David A. Balto, Neil W. Averitt, *Anticompetitive Aspects of Market Share Discounts and Other Incentives to Exclusive Dealing*, 67 Antitrust L .J. 615 (2000); David A. Balto, *Networks and Exclusivity: Antitrust Analysis to Promote Network Competition*, 7 George Mason L. Rev. 523 (1999) (describing anticompetitive effects of various forms of de facto exclusivity).

[20] GAO, *Group Purchasing Organizations: Use of Contracting Process and Strategies to Award Contracts for Medical-Surgical Products*; GAO-03-998T, at 18-19.

[21] *Id.* at 13-14 and 18-19.

Self-regulation may work in several environments. However, there are several critical elements which must be present for self-regulation to work. First, there must be clear and unambiguous rules. Second, there must be an enforcement entity. Third, the entity must be able to impose significant penalties. Finally, there must be a system of due process with transparent decisions.[22] Although the GPOs efforts to self regulate may be laudable, they are clearly insufficient to cure the competitive problems in the market. Their efforts at self-regulation lack each of these critical elements. Simply put, these voluntary codes of conduct have no teeth.

The anti-kickback exceptions and safe harbor provisions, as implemented, have failed to provide for any oversight or enforceable compliance measures. Now, efforts at self-regulation have also failed to provide for these measures. Current news reports regarding a broad criminal investigation into the medical supply industry and its apparent relationship with various GPOs only heighten the need for this Subcommittee to seriously consider legislation to address this problem.

Finally, I want to raise a concern of whether *private* self-regulation is appropriate for the types of problems faced in this industry. Self-regulation may be appropriate where what is being regulated is not an important dimension of competition between competitors. For example, self-regulation of deceptive conduct raises few competitive concerns. But what is being regulated by the GPOs is contractual arrangements that are critical to competition. he antitrust laws are replete with cases where firms have agreed to diminish competition, collude or raise entry barriers under the guise of "self-regulation."[23] As former Assistant Attorney General of the Antitrust Division Donald Baker once observed "self-regulators often combine – and sometimes confuse – self-regulation with self-service."[24] Private self-regulation in this market may be readily captured by industry pressure and give inadequate attention to the interests of smaller firms, new entrants, or the needs of the public. Moreover, because the number of competitors are small there is the threat that collective self-regulation could lead to collusion. Simply, one cannot expect this market to police itself.

Selective Enforcement Will Not Work

It has been suggested that individual private litigation or government enforcement action challenging anticompetitive conduct on a case-by-case basis is the solution. I disagree. The problems with GPOs are too widespread.

It appears that private litigation is proliferating with regard to the conduct of GPOs. Applied Medical Resources Corporation, a manufacturer of medical devices used in minimally

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[22] *See* Angela J. Campbell, *Self-Regulation and the Media*, 31 Fed. Comm. L.J. 711 (1999); Douglas C. Michael, *Federal Agency Use of Audited Self-Regulation as a Regulatory Technique*, 47 Admin. L. Rev. 171 (1995); Remarks of Robert Pitofsky, Chairman, Federal Trade Commission, before the D.C. Bar Association Symposium, "Self Regulation and Antitrust," February 18, 1998. Available at www.ftc.gov/speeches/pitofsky/self4.htm.

[23] *See* cases discussed at Appendix A.

[24] Donald I. Baker and W. Todd Miller, Privacy, Antitrust and the National Information Infrastructure, in *Privacy and Self-Regulation in the Information Age* (NTIA 1997).

invasive surgery, in 2003 sued Johnson & Johnson and Novation for allegedly employing anticompetitive business practices.[25] The lawsuit alleges that Johnson & Johnson harmed Applied's sales of two medical products through exclusionary practices "designed to obtain and maintain (J&J's) monopoly power" in the market.

In addition, ConMed Corporation has also sued Johnson & Johnson alleging that it engaged in anticompetitive conduct with respect to sales of products used in endoscopic surgery, resulting in higher prices to consumers and the exclusion of competition.[26] The lawsuit alleges that ConMed's ability to sell its surgical products has been stifled by J&J's practices, which include entering into exclusive contracts with hospitals, tying and bundling the price of products to a hospital's agreement to buy a very high percentage of their specific J&J products, and imposing financial penalties on hospitals if they purchased competitive products such as those provided by ConMed. Rochester Medical Corporation, in March of this year, also filed suit against a number of medical device companies and GPOs charging the companies with anticompetitive practices to keep it out of the urological products and hospital markets.[27]

I would also note the recent case of *Kinetic Concepts, Inc., et al. v. Hillenbrand Industries, Inc.*[28] While this antitrust case did not directly involve a GPO, it certainly serves as another example of the impact various exclusionary practices can have in the medical supply market. Kinetic Concepts, Inc. ("KCI") sued Hillenbrand Industries and several of its subsidiaries for antitrust violations involving the manufacture and rental of specialty hospital beds and surfaces designed for patients suffering from burns, spinal injuries, pneumonia and other medical conditions. KCI alleged that Hillenbrand was bundling its specialty beds with its standard hospital beds, conditioning additional discounts on the standard beds to exclusive dealing commitments on rental of its specialty beds. Much of the evidence revolved around GPOs, their contracting policies, their relationships with hospitals, and the harm to competition. Ultimately, the jury returned a verdict in favor of the plaintiff in the amount of over $170 million.[29]

Private litigation, however, is not the answer for the competitive problems in this market because it is too time-consuming and too cost-prohibitive. In addition, any individual antitrust case only serves only to address the conduct of specific companies with regard to market practices for a specific product which have adversely affected a specific plaintiff. Such litigation does not, and cannot, address problems on an industry-wide basis as could legislation and regulation.

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[25] *Applied Medical Resources Corp. v. Johnson & Johnson, et al.*, U.S. District Court for the Central District of California (Southern Division), Case No. 8:03-cv-01329-JVS-MLG.

[26] *ConMed Corp. v. Johnson & Johnson, et al.*, U.S. District Court for the Southern District of New York, Case No. 1:03-cv-08800-JES.

[27] *Rochester Medical Corp. v. C.R. Bard, Inc. et al.*, U.S. District Court for the Eastern District of Texas, Case No. 5:04-cv-00060-DF.

[28] U.S. District Court for the Western District of Texas, Case No. 95-cv-0755.

[29] The case settled prior to the formal entry of this judgment.

Antitrust challenges and/or enforcement actions by either the FTC or DOJ might rein in certain egregious behavior. However, the antitrust Agencies have taken no enforcement actions in this area in spite of these complaints. The failure of these Agencies to take enforcement action or revise Statement 7 and the failure of the Department of Health and Human Services to regularly review and revise its safe harbor regulations have set an extremely lax standard. In any event, agency enforcement actions are not the answer as such individual actions, just as with private litigation, will not lead to industry-wide changes.

As this Subcommittee knows, the Justice Department has initiated a broad criminal investigation of the medical-supply industry, apparently to determine whether hospitals and other medical care providers are fraudulently overcharging Medicare and other federal and state health programs.[30] Based on the federal codes cited in the subpoenas, it appears that investigators are seeking evidence of health care fraud, conspiracy to defraud the United States, theft or bribery involving programs receiving federal funds, obstruction of investigations, and other possible violations. Given the very early stages of this investigation, we do not know whether any antitrust or consumer protection issues will arise. Nevertheless, this new criminal investigation, along with this Subcommittee's investigation, provides a clear indication that the GPO industry is in need of some form of oversight and regulation. GPOs and their hospital members should welcome this oversight and the accompanying regulations as a means to clarify what could be considered as anticompetitive behavior.

Effective Oversight and Enforcement is Necessary

In 1986, when the safe harbor provisions were created the healthcare supply industry was much different from what it is today. Today, GPOs need some form of oversight and regulation for anticompetitive concerns; and, consumers as well as medical device and supply manufacturers need a forum in which their interests can be represented. While the FTC has recognized that self-regulation can serve an important role, the current voluntary GPOs' codes of conduct are not sufficient.

As I have stressed today, it is regulatory oversight and ability to undertake enforcement action which is missing from the GPOs' current self-regulatory efforts via their codes of conduct. Self-regulation can be successful when there are consistent and uniform standards industry-wide; when there is an enforcement mechanism in place; and, when the relevant federal agency and, if necessary, the courts have a role in any necessary enforcement. Let me provide several examples:

The National Association of Securities Dealers ("NASD") registers member firms, writes rules to govern their behavior, examines them for compliance and disciplines those that fail to comply. It has uniform policy guidelines and rules established for its members and takes disciplinary actions against firms and individuals for violations of those rules and federal securities laws and regulations. It has also established the National Adjudicatory Council ("NAC"), a national Subcommittee that reviews initial decisions rendered in NASD disciplinary

[30] *See* Mary Williams Walsh, "Wide U.S. Inquiry Into Purchasing for Health Care", *New York Times*, August 21, 2004.

proceedings. NAC decisions may be appealed to the Security and Exchange Commission which may affirm, modify, or set aside any of the findings made by the NAC, or remand the matter for further proceedings; and may also affirm, reduce, or set aside the sanctions imposed by the NAC. In addition to the SEC's role, a matter may be further appealed to a U.S. Court of Appeals for review.

Similarly, the advertising industry has an effective self-regulatory program which, when necessary, refers matters to the FTC for investigation and possible enforcement action. The National Advertising Review Council ("NARC") was established to provide guidance and set standards of truth and accuracy for national advertisers. NARC sets the policies for the National Advertising Division ("NAD") which investigates complaints against advertisers brought by consumers and other advertisers. The review process by NAD is known to be quick, fair, and a less-costly form of dispute resolution. Compliance with NAD is voluntary, however, an advertiser who disagrees with a NAD recommendation may appeal it to the National Advertising Review Board ("NARB"). NARB is the second part of the advertising industry's self-regulatory process. When an advertiser or challenger disagrees with a NAD finding, the decision can be appealed to NARB for additional review. When an advertiser refuses to comply by a NAD decision, the matter can be referred to the FTC for further investigation and action.

These self-regulatory methods are effective not simply because they have uniform standards and enforcement mechanisms, but also because both the consumers and industry may participate and because the enforcement process is transparent (*i.e.*, decisions and reports are made public). Such provisions are necessary in order to enhance the credibility of any self-regulatory program. None of this is present in the GPOs' efforts at self-regulation. Instead, they appear to have undertaken a haphazard and inadequate effort in a mad dash to avoid further scrutiny by this Subcommittee and the possibility of the implementation of additional regulations.

Additional Regulations are Necessary for GPOs in Order to Ensure Competition

The current situation is not what Congress envisioned or intended when it implemented safe harbors in Medicare's anti-kickback provisions for GPOs. Something is amiss in the hospital, GPO, medical device and supply market. The relationships and markets have evolved beyond the original purpose of allowing hospitals to form GPOs to aggregate their purchasing power to benefit consumers through lower prices.

The legislative history for Public Law 100-93 indicates that the House Committee on Ways and Means foresaw the need for periodic review and public input to ensure that the anti-kickback regulations remained relevant in light of industry changes. House Report 100-85 states: "Accordingly, the Subcommittee expects that the Secretary will formally re-evaluate the anti-kickback regulations on a periodic basis and, in so doing, will solicit public comment at the outset of the review process."[31] Therefore, I would submit that the Department of Health and Human Services has the ability to effectively modify existing regulations, and to adopt and enforce new regulations. In any event, if legislation is necessary Congress clearly has the

[31] House Rep. No. 100-85 (Part II) at 27 (1987).

authority to move beyond self-regulation and require the federal government to implement and enforce regulations upon an industry.

There are several examples where Congress has decided to regulate after self-regulation has failed. Here are two examples:

The history of telemarketing gives an excellent example of how self-regulation failed to protect consumers and how Congress moved to implement and enforce regulations. In 1991, Congress passed the Telephone Consumer Protection Act[32] requiring the Federal Communications Commission ("FCC") to prescribe regulations to implement methods and procedures for protecting the privacy rights of consumers. While setting forth specific offensive and prohibited practices, the legislation only stated that the FCC "may" require the establishment of a single national "do-not-call" database. The FCC decided against the idea of such a database, preferring company-specific do-not-call lists which required consumers to inform companies to put them on a do-not-call list.

In response to continued abuses and telemarketing fraud, Congress in 1994 enacted the Telemarketing and Consumer Fraud Abuse Prevention Act[33] which empowered the FTC to issue the Telemarketing Sales Rule[34] prohibiting deceptive and abusive acts or practices. The Act also authorized State attorneys general and private persons to bring civil actions in federal district court to enforce compliance with the FTC Rule.[35]

There were significant efforts at self-regulation. Throughout the 1990s, the Direct Marketing Association ("DMA") advocated self-regulation. But, not until 1998 did DMA establish mandatory compliance programs requiring its members, as a condition of membership, to provide their customers with notice and the right to opt-out. However, the DMA applied sanctions only against its members, and there remained telemarketers who took advantage of consumer confusion and committed fraud. Despite these self-regulatory efforts, telemarketing complaints continued to rise.

Therefore, in 2003, the FTC implemented a national do-not-call list,[36] and Congress enacted the "Do-Not-Call Implementation Act"[37] which allowed the FTC to collect fees to implement and enforce the provisions of the Telemarketing Sales Rule. To date, the regulations and do-not-call registry have withstood legal challenges brought by telemarketers.[38]

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[32] Public Law 102-243; 47 U.S.C. Section 227.

[33] Public Law 103-297; 15 U.S.C. Sections 6101-6108.

[34] 16 C.F.R. Part 310.

[35] 15 U.S.C. Section 6103.

[36] Final Rule, 68 Fed. Reg. 4580-4679 (January 29, 2003).

[37] Public Law 108-10.

[38] On February 17, 2004 the U.S. Court of Appeals for the 10th Circuit upheld the law; *see Mainstream Marketing Services, Inc. v. FTC*; Case No. 03-1429.

Another instance where Congress has gone beyond self-regulation is in protecting the privacy of children. During the 1990s there were significant concerns raised about the protection of children's privacy on the Internet. Self-regulatory efforts did not diminish these concerns. In response in 1998, Congress enacted the Children's Online Privacy Protection Act[39] ("COPPA") and the FTC implemented rules (the Children's Online Privacy Protection Rule) enforcing the Act.[40] The Act was passed in response to a growing awareness of Internet marketing techniques that targeted children and collected their personal information from web sites without any parental notification.

COPPA and the FTC Rule provide that industry groups or others can create self-regulatory guidelines to govern participants' compliance with the FTC's Rule. These guidelines must include independent monitoring and disciplinary procedures and must be submitted to the FTC for approval. The FTC then publishes the guidelines and seeks public comment in considering whether to approve the guidelines. An operator's compliance with FTC-approved self-regulatory guidelines will generally serve as a safe harbor in any enforcement action for violations of the COPPA. To be entitled for a safe harbor treatment, the operator's guidelines must contain requirements that are substantially similar to COPPA, a mechanism for evaluation of the operators' compliance with the FTC Rule, and incentives for compliance.[41]

I use these examples to highlight the fact that Congress has the authority to step in and regulate an industry when self-regulation is failing to protect the interests of consumers. I believe the proposed GPO legislation is a sound step in the right direction. The Inspector General's Office of HHS has a proven record of effectively enforcing the anti-kickback provisions of the Act. As for any regulations on the activities of GPOs, any new regulations should provide minimal standards to address the abuses and conflicts of interest which have been uncovered by this Subcommittee. I would suggest efforts towards additional regulations concentrate on more clearly defining abusive acts or practices, and the implementation of some form of clear and fair procedures to give parties affected by the regulations an opportunity bring complaints and/or defend against complaints of anticompetitive behavior. And, the statute should be amended so that GPOs do not automatically enjoy the special status of a government safe harbor. The safe harbor should be earned and granted only after sufficient oversight and approval by the Department of Health and Human Services.

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[39] Public Law No. 105-277; 15 U.S.C. Sections 6501-6505.

[40] 16 C.F.R. Part 312.

[41] In addition, the FTC retains the authority to bring enforcement actions and impose civil penalties for violations of the Rule. Anyone who violates the Rule may be liable for civil penalties up to $11,000 per violation, as well as injury caused to consumers.

Conclusion

Let me close with an important thought. There may be entities, especially hospitals, that may fear that the enforcement of the safe harbor provisions will lead to higher prices. But my experience of over a decade as an antitrust enforcer involved in dozens of enforcement actions has shown that the elimination of impediments to competition will bring the greatest long-term benefits. Ultimately, restricting these anticompetitive practices will lead to more competition, lower prices and greater innovation. Everyone will benefit.

The GPO industry's efforts at establishing voluntary codes of conduct fall far short of any effective self-regulatory program. The current system, including the voluntary codes of conduct, is insufficient to ensure that anticompetitive activity is prohibited and that consumers are protected. The time for effective self-regulation has passed and Congress should act to regulate anticompetitive activity to protect the consumers' right to a competitive marketplace.

Thank you for allowing me to testify before the Subcommittee today.

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Appendix A -- Past Antitrust Cases Involving Anticompetitive Self-Regulation

In *Fashion Originators' Guild v. Federal Trade Commission,* 312 U.S. 457 (1941), the Supreme Court struck down a self-regulatory scheme -- implemented by a group of high-priced dress designers designed to exclude those who would copy the dress designs of the high-price firms. The Defendant organized a boycott scheme whereby each "originator" agreed not to deal with the outlets to which the "pirates" sold their goods. The Supreme Court condemned the boycott observing that, "the combination is in reality an extra-governmental agency, which prescribes rules for the regulation and restraint of interstate commerce, and provides extra-judicial tribunals for determination and punishment of violations, and thus, 'trenches upon the power of the national legislature.'" (citation omitted).

In *Goldfarb v. Virginia State Bar,* 421 U.S. 773 (1975), the Supreme Court struck down a local county bar associations rules prescribing the minimum prices that lawyers could charge for real estate services.

In *National Society of Professional Engineers v. United States,* 435 U.S. 679 (1979), the Supreme Court struck down an association's ethical rules that prevented the negotiation over fees for engineering service until after the engineer had been selected for the job. The defendants attempted to justify the restraint on the grounds that ruinous price competition would lead to unsafe structures. The Court rejected the defense explaining that "the [analysis of restraints under the Sherman Act] does not support a defense based on the assumption that competition itself is unreasonable."

In *U.S. v. National Association of Broadcasters,* 1982-83 Trade Cas. (CCH) ¶ 65,049 (D.D.C. 1982) (consent decree), the Department of Justice successfully challenged a self-regulatory scheme limiting the number of minutes of advertising that a TV broadcaster could run in any particular hour. The Department asserted that this arrangement was simply an output limitation that would be likely to result in higher prices for TV advertising.

Board of Regents of the Univ. of Okla. v. NCAA, 468 U.S. 85 (1984), involved the NCAA's efforts to maintain a "level playing field" among football-playing colleges by restricting the number of college football broadcasts to one a week. The rule prevented each individual member from going out and selling its own TV rights. The Supreme Court found this an unreasonable restraint of trade, rejecting the defense that TV broadcasts would diminish attendance for less popular teams.

In *FTC v. Indiana Federation of Dentists,* 476 U.S. 447 (1986), the FTC challenged an effort by an association of dentists to prevent members from providing X-rays to insurance companies on the ground that it was inconsistent with professional standards. The Court found this self-regulatory effort interfered with the workings of a free market.

United States Senate
Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights

"Hospital Group Purchasing – How to Maintain Innovation and Cost Savings"

Tuesday, September 14, 2004
2:00 PM
Room 226 – Dirksen Senate Office Building

Testimony Submitted by
Robert Betz, Ph.D.
President and CEO
Health Industry Group Purchasing Association
Arlington, VA

Introduction

I am Robert Betz, Ph.D., President and CEO of the Health Industry Group Purchasing Association (HIGPA). HIGPA represents over 150 health care supply chain organizations, including nearly every major group purchasing organization (GPO) in the United States, and many of the vendors with whom they do business.

Today's hearing allows both policy makers and the public to learn of the industry's efforts and accomplishments over the past two years and share our thoughts with the Subcommittee about maintaining a GPO industry that helps hospitals realize significant savings on the best products for their patients. I appreciate the opportunity to submit testimony on behalf of the members of HIGPA.

At the outset, I would like to highlight the following points:

1. Two years ago, HIGPA developed a Code of Conduct which focused on several areas, including: promoting competition and innovation; eliminating the potential for conflicts of interests; ensuring open communications between members and vendors; establishing guidelines for the use of contracting tools; and providing transparency by requiring full disclosure to members of all vendor payments. Our Code has provided greater accountability to hospitals and other providers.

2. Since 2002, this industry has undergone a full review by the U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC), and they found there was no need for additional regulation of the industry. As they have indicated in their July 2004 joint report on health care competition and policy, the current tools available to them are sufficient to oversee the industry, and assure continued competition.

3. We offer to engage in productive dialogue with the Subcommittee to explore non-legislative approaches for assuring the changes that have been made remain in place, and the industry is always vigilant in adapting its practices as the market continues to evolve.

HIGPA's Code of Conduct Principles

In 2002, with the assistance and guidance of your Subcommittee, HIGPA cooperatively developed a Code of Conduct Principles for its GPO membership – designed to strengthen the delivery of health care products and services by creating a set of principles for GPOs to incorporate into their businesses.

HIGPA's Code is unprecedented in the health care supply chain industry, and the only mandatory one within the industry. The adoption and implementation of the Code underscores 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. Ultimately, it has provided greater accountability to hospitals and other providers.

Our 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. We maintain that if all GPOs had the same essential business models, health care providers would be unable to benefit from competition among GPOs. 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.[1]

Throughout the adoption and implementation of the Code, HIGPA has always stated that our Code was to be considered a "living" document. Specifically in the public release, the Association stated, "HIGPA's Code of Conduct Principles is intended to be a document that is updated and modified as necessary." This principle shows that the industry allows for modifications to the Code when circumstances warrant. Therefore, it is imperative the industry continue to use tools such as codes of conduct and certification programs to ensure prompt, flexible, and effective industry regulation.

Highlights of HIGPA's compliance program include the following:

- HIGPA's Bylaws were amended to include the requirement that all GPO members must adopt the HIGPA Code of Conduct into their business model in order to be a member of the Association, and then continue to be in compliance to remain a member.

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[1] As the Code was being developed, some members of the Subcommittee staff wanted more restrictions, including consideration of a cap on fees, and limitations on certain contracting tools, and they suggested we should seek a Business Advisory Review from the DOJ Antitrust Division.

The industry discussed this with antitrust legal counsel, and HIGPA was advised to seek guidance from one of the country's most respected antitrust scholars, Professor Herbert Hovenkamp, J.D., Ph.D., of the University of Iowa, College of Law. In a June 21, 2002 letter to HIGPA, Professor Hovenkamp expressed his concerns that the GPO Code of Conduct be lawful under the existing antitrust laws. In his conclusion, Hovenkamp wrote:

> "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."

- At the beginning of each year, HIGPA's American-based GPOs certify compliance with our Code of Conduct. HIGPA's ongoing compliance program offers a solid example of the industry's good faith effort to address industry business practices, now and for the future.

- HIGPA's new "Code of Conduct" web page offers information about HIGPA's Code of Conduct Principles, the Association's GPO Compliance Officers and the new web-based "Vendor Information Exchange."

- GPOs are tasked daily with the difficult job of learning about new medical products at the direction of their health care provider members. In accordance with the Association's Code of Conduct Principles, HIGPA created our web-based "Exchange" to enable every health care manufacturer, whether currently contracting with a GPO or not, the ability to promote their "new and innovative" products directly to GPO members of HIGPA. Upon accessing the submission form, manufacturers are asked to provide contact information for the representative marketing the new technology, product name and a detailed description, with the ability to upload marketing documents. As part of its commitment to the Subcommittee, the GPO industry reached out to the small medical device manufacturers' community to find ways to collaborate and facilitate communication among all players in the health care supply chain.[2]

- To be in compliance with the HIGPA Code of Conduct, each GPO must designate a Compliance Officer to assure that their respective purchasing organization is abiding by the provisions set forth in the Code. Anyone who has questions regarding a specific GPO's compliance can contact that GPO's Compliance Officer through HIGPA's web site.

Antitrust Compliance

In July 2004, the FTC and the DOJ produced a joint report on health care competition and policy, titled, "Improving Health Care: A Dose of Competition" (hereinafter, 2004 FTC/DOJ Report). This report was issued after significant scrutiny of the industry, including a workshop in September 2002 and a hearing in September 2003. The FTC and DOJ ultimately concluded the agencies have ample tools to assure continued competition in the GPO industry. Additionally, the 2004 FTC/DOJ Report states Health Care Statement Seven, the policy statement that governs GPOs, provides the FTC and DOJ with the ability to review group purchasing organizations' business practices at any point:

> "Health Care Statement 7 and its safety zone aim to address monopsony and oligopoly concerns with the formation of a GPO. This statement does not address all potential

[2] HIGPA intends to request many national associations, organizations and coalitions to help in the Association's commitment to optimize its new web-based Exchange to provide the best health care products to hospitals and other providers. Before asking these organizations to promote this new HIGPA program, the Association requested feedback from the Medical Device Manufacturers Association (MDMA), given that their membership could be the one to most benefit from such a capability. After numerous requests on behalf of HIGPA for MDMA to review and support such a program, the MDMA declined to provide HIGPA with constructive feedback, let alone agree to promote this capability to their members.

> issues that GPOs may raise. The Agencies believe amending the statement to address some, but not all potential issues, is likely to be counterproductive. Health Care Statement 7 does not preclude Agency action challenging anticompetitive contracting practices that may occur in connection with GPOs. The Agencies will examine, on a case-by-case basis, the facts of any alleged anticompetitive contracting practice to determine whether it violates the antitrust laws."

Indeed, this report reveals that existing law and policy provide the necessary tools to prevent anti-competitive behavior by GPOs and that changes would be counterproductive. It is for these reasons continued self-regulation is a viable compliance option for the health care group purchasing industry.

The Value of Compliance Programs

Moreover, the Federal Trade Commission has demonstrated a preference for self-regulation in industries that offer efficient self-compliance systems. As former Chairman of the Federal Trade Commission (1995-2001), Robert Pitofsky, wrote:

> "From a public policy perspective, self-regulation offers several advantages over government regulation or legislation. It often is more prompt, flexible, and effective than government regulation. Self-regulation can bring the accumulated judgment and experience of an industry to bear on issues that are sometimes difficult for the government to define with bright line rules. Finally, government resources are limited and unlikely to grow in the future. Thus, many government agencies, like the FTC, have sought to leverage their limited resources by promoting and encouraging self-regulation." (February 18, 1998)

Numerous industries, in addition to the GPO sector, recognize the benefits of self-regulation to manage issues, which are similar to group purchasing. Business trades, including the American National Standards Institute (ANSI), financial rating services such as Moody's, the National Association of Securities Dealers (NASD), and certifications for kosher and halal food, among many others, rely on industry self-regulation to provide strong standards without reliance on government oversight. Time has proven that the well-placed trust by consumers in self-regulation offers them the best value.

Potential Legislation

There is absolutely no need for legislation. Through HIGPA, the industry reiterates the point made in its September 2, 2004 letter to the Subcommittee and strongly opposes any effort to impose new restrictions on the group purchasing industry that are unnecessary and harmful to our health care provider members.

Draft legislation has been provided to HIGPA by the Subcommittee's staff. The GPOs of HIGPA are alarmed at this Subcommittee's consideration of legislation that would ultimately restrain health care providers' ability to control one of the few budget items it can—supply costs.

So, without going through each of the elements of the legislation, allow me to highlight some of the more serious concerns it raises:

- Although the draft legislation is entitled the Medical Device Competition Act of 2004, it actually extends to all products and services sold to health care providers.

- The reach of the definition of "purchasing agent" would clearly include group purchasing organizations (GPOs) and integrated delivery networks (IDNs), but also potentially pharmacy benefit managers (PBMs), distributors, wholesalers, and even providers as well as employees of these entities who work in the procurement chain.

- The draft legislation requires the Secretary of HHS to promulgate procedures for annual certification that a purchasing agent is in compliance with all regulations promulgated by the Secretary.

  No other segment of the health industry is currently subjected to any such government certification process. The certification process could entail seeking information from other parties, such as vendors and providers, which could significantly exacerbate the burden and expense to all participants in the health care supply chain.

- A three percent cap on vendor payments was expressly rejected by Congress when it enacted the current statutory exception. Placing a cap on fees raises numerous issues regarding how fees are calculated. For example, how do you calculate the fee if it is fixed in the aggregate (which is authorized by the statutory exception and current safe harbor)? Is it an average of three percent and, if so, over what period of time?

- Many of the congressional findings in the draft legislation regarding contracting practices of "purchasing agents" are directly contradictory of the conclusions set forth in the 2004 FTC/DOJ Report. This report concluded the current regulations governing the GPO industry are sufficient for the FTC and DOJ to monitor the industry.

- The draft legislation refers to anti-competitive practices, including tying, bundling or sole source contracting, but fails to define, or otherwise reference, any source to define these practices or the circumstances under which these practices are anti-competitive. There is significant established law, as demonstrated by Professor Herbert Hovenkamp, in his antitrust analyses regarding GPOs, and Robert Bloch, partner at Mayer, Brown, Rowe and Maw, ("An Analysis of Group Purchasing Organizations' Contracting Practices Under the Antitrust Laws: Myth and Reality")[3], that defines these practices, and demonstrates they are often pro-competitive, such that each must be analyzed on a case-by-case basis – as recommended by the FTC and DOJ.

[3] Both analyses were heavily cited in the 2004 FTC/DOJ Report.

- For these reasons, promulgation of regulations that apply to multiple, very different parties and relationships, as well as to extremely variable factual scenarios is virtually unworkable and risks stymieing competition and cost savings in the industry.

These are just some of the major concerns about the proposed legislation. They alone persuade HIGPA that this proposed legislation is far-reaching, unwarranted, and potentially harmful to the fight to hold down health care costs.

Our industry continues to engage in a vigorous examination of ways to improve and strengthen our certification and compliance process. We do this because we believe strongly that private sector compliance programs are the most efficient and effective way to advance best practices in hospital supply purchasing and strengthen our health care system. We offer to engage in productive dialogue with the Subcommittee to explore non-legislative approaches for assuring the changes that have been made remain in place, and the industry is always vigilant in adapting its practices as the market continues to evolve.

Closing

Over the last 40 years the purpose of antitrust policy has been to protect consumer welfare, not competitors. In any event, the concerns raised against the GPO industry do not create an antitrust issue.

We return to the Subcommittee again 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. We are here today because a small, yet vocal, group of medical device manufacturers would like to have Congress intervene in the marketplace in favor of "small" suppliers, at the expense of health care providers and the patients they serve every day.

We are here today because these manufacturers and their trade association cloak their arguments as being in the best interests of patients. They would have you believe that patients, and even health care workers, are being harmed because hospitals are being denied the ability to purchase their products. This is simply not true. It is the clinicians making decisions about the most appropriate medical devices to use – through the GPO process – that are the real advocates for patients.

At the end of the day, GPOs are responsible to their member providers, not to for-profit suppliers. What some self-interested, profit-maximizing companies are urging is to give hospitals less power in the procurement and supply chain.

Make no mistake, if Congress weakens the ability of GPOs to negotiate the best deals for their provider members – as is proposed in the draft legislation – 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.

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. 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.

I urge members of this Subcommittee not to weaken a crucial mechanism that helps providers reduce their purchasing costs which allows them to commit more financial resources to patient care.

Thank you.

Survey Report:

The Clinical Review Process Conducted by Group Purchasing Organizations and Health Systems

Prepared for:

The Health Industry Group Purchasing Association

April 2002

The information provided in this report is based upon interviews conducted by The Lewin Group with representatives of selected group purchasing organizations (GPOs) and health systems. This approach is consistent with the terms of the engagement requested by the Health Industry Group Purchasing Association. The scope of this study did not include on-site audits or other independent confirmation of the findings of the interviews.

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EXECUTIVE SUMMARY

On behalf of the Health Industry Group Purchasing Association, The Lewin Group conducted a survey to determine the extent to which group purchasing organizations (GPOs) and health systems employ clinical review processes to inform technology decision-making. HIGPA's central question to Lewin was whether these clinical review processes support timely adoption and evidence-based, cost-effective use of health care technology.

Five health systems and six major GPOs—an illustrative sample—were contacted during February and March 2002. This survey revealed that GPOs and health systems conduct extensive and rigorous clinical reviews when deciding which health care technologies will be listed in purchasing contracts and made available for use. The exact locus of the clinical review process can vary – sometimes more is done at the GPO level, and sometimes more is done at the health system level – but in any event these processes employ widely accepted methods for assessing the clinical value of health care technologies. Notable findings include:

- Clinical review processes of health systems and GPOs rely upon comprehensive systems of expert committees.
- Recognized independent technology assessment resources are used.
- Health systems and GPOs have functions for monitoring and incorporating "breakthrough" and other novel technologies.
- Mechanisms for ongoing review are in place. Some GPOs have in place "perpetual" review of new technologies as part of their regular contracting process.
- Information is shared among clinical review functions. Certain separate clinical review functions related to review of clinical practices and technologies are linked within health systems and GPOs, which serves to strengthen them.
- GPOs can facilitate clinical trials.

Most health systems use a decentralized approach for identifying products and technologies for review, coming often from their centers of excellence, specialty areas, and departments. GPOs surveyed do not generally contract for experimental or investigational technologies, but they have mechanisms for monitoring what is in the pipeline, through continuous market assessment. Staff contract directors are expected to stay current and bring products to review to the appropriate subcommittees, which are normally organized around service lines.

Pharmaceuticals, particularly, are monitored closely from the experimental phase through the standard-of-care phase. A GPO will examine the whole range of therapeutic agents, even though it may not contract for the whole range. Certain GPOs do not perform clinical reviews, but act as the prime contractor for other member GPOs, who have direct contact with health systems and alternate care sites that constitute their membership.

Health systems and GPOs identified the following comprehensive list of attributes and impacts of technologies that generally are incorporated into the clinical review process:

- Technical properties and performance
- Safety and risk to patients and health care workers
- Efficacy and effectiveness
- Economic attributes
- Acceptability to patients and clinicians (comfort, ease of use, utility)
- Risk of liability
- Potential for standardization
- Impact on market share/competitiveness
- Requirements for facility modification/work flow
- Manufacturer reputation and support
- Capacity of vendor to provide sufficient and reliable supply.

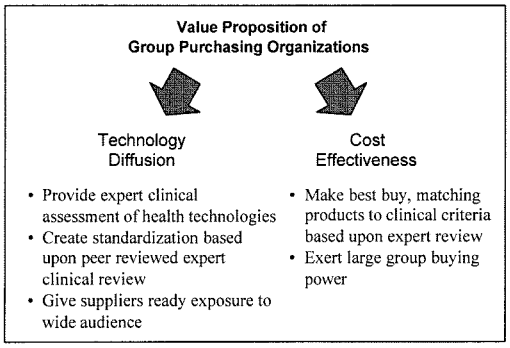
For both health systems and GPOs, reporting mechanisms range from standard change-of-product forms (for commodities) to white papers and formal reports (mostly for pharmaceutical and therapeutic products) to reports containing extensive analysis for capital equipment.

Health systems and GPOs expressed that there are many mechanisms to acquire technology beyond the GPO, and that these avenues are increasing. This is leading GPOs to offer new programs and services and to modify existing ones in order to remain the preferred purchasing channel.

I. BACKGROUND AND OBJECTIVE

The Lewin Group was engaged to assist the Health Industry Group Purchasing Association (HIGPA) in determining the extent to which group purchasing organizations (GPOs) and health systems employ clinical review processes to inform technology decision-making. Of particular interest was whether these clinical review processes support timely adoption and evidence-based, cost-effective use of health care technology. For the purposes of this study, "clinical review" refers to processes to assess or examine attributes of health care technologies, particularly pharmaceuticals, medical-surgical devices, and equipment, for the purpose of making acquisition decisions.

As requested by HIGPA, Lewin performed a survey to accumulate evidence to examine objectively selected aspects of the value proposition offered by GPOs in the context of these processes, as depicted below.



II. METHODOLOGY

Five health systems and six major GPOs were surveyed during February and March 2002. The interview sample is not considered to be statistically representative, but rather, illustrative. Health system interviewees were purchasing managers, administrative officers, and medical officers. GPO representatives interviewed were clinical operations directors, chief executives, or other senior company executives. The interviews were conducted by telephone, using a detailed interview guide (see Appendix A) which was sent to all participants in advance of the calls. The Lewin Group developed the guide with input and comments by HIGPA.

In cooperation with HIGPA and executive staff at these organizations, Lewin sought to identify interviewees who would be most familiar with the clinical review processes and their roles in technology acquisition. In general, interviewees were knowledgeable and forthcoming with information pertaining to the topics discussed during the telephone discussions. Most interviewees appeared to have reviewed the interview guide prior to their call and were prepared to respond to questions. Consistent with the content of the interview guide, proprietary aspects such as contract terms, financial arrangements, and business tactics, were not discussed during the interviews; however, non-proprietary attributes of and approaches to the clinical review process were addressed.

Table 1 below provides information about the characteristics of hospital/health system participants and GPO participants. The health systems were promised that they would not be identified by name. Table 2 illustrates significant characteristics of the GPOs that participated in the survey.

Table 1
Characteristics of Surveyed Hospitals and Health Systems

Hospital	System	Location	Teaching
A	4-hospital regional system 1 large, 3 small hospitals	Mid-size city Midwest	Yes (medical school affiliate)
B	One hospital was interviewed; part of a 52-hospital Catholic System, 442 beds	Urban/suburban East	No
C	2-hospital academic medical center system, 775 beds & numerous clinics	Large urban/ suburban West	Yes (own medical school)
D	Major System: 19 hospitals & health plan	Urban/suburban East	Yes (own medical school)
E	Stand-alone, 399 beds & 18 clinics	Urban–"almost inner city" Midwest	No

Table 2
Characteristics of Surveyed GPOs

GPO	Size	Purchasing Focus	Ownership Structure
AmeriNet	14,315 members: 1,924 hospitals, 3,840 clinics 1,086 ambulatory surgery centers, 1,806 Long-term care centers 103 integrated delivery networks 4,814 physicians (hospital based) 863 other $5.2 billion/year	Full range of products	Cooperative Three Shareholders: AmeriNet Central, Warrendale, PA, Intermountain Health Care, Salt Lake City, UT and Vector, Providence, RI
Consorta Catholic Resource Partners	2,000 sites: 455 hospitals 1,500 other facilities	Full range of products	Cooperative Owned by 12 Catholic health systems; each holds equal shares
Magnet	Primarily the NE quadrant of the US; represents 7 other GPOs	Capital equipment and niche products (surgical instruments, food service mgmt., IV infusion pumps, uniforms). Does not handle pharmaceuticals.	"Group of groups"; unique umbrella role for 7 other GPOs

GPO	Size	Purchasing Focus	Ownership Structure
Novation	2,200 health care organizations (VHA) 78 major academic medical center organizations plus affiliates (UHC)	Full range of products	Supply chain management company for and owned by VHA (75%) and University Health System Consortium (25%)
Premier	203 health systems composed of 892 hospitals plus 669 hospital purchasing affiliates Many additional "alternate sites" purchase through Provider Select	Full range of products	Owned by 203 health systems
Shared Services, Healthcare Inc.	1,000 members $330 m in sales 10 SE states	Full range of products	Cooperative Members pay a nominal annual fee to become shareholders. Members comprise board and advisory board

III. FINDINGS

This study revealed that GPOs and health systems conduct extensive and rigorous clinical reviews when deciding which health care technologies will be listed in purchasing contracts and made available for use. The exact locus of the clinical review process can vary – sometimes more is done at the GPO level, and sometimes more is done at the health system level – but in any event these processes employ widely accepted methods for assessing the clinical value of health care technologies.

Specific elements of clinical review processes that prevailed in the organizations interviewed are summarized below.

Clinical review processes of health systems and GPOs rely upon comprehensive systems of expert committees. These committees cover a broad array of clinical and administrative areas, and comprise a range of clinicians, technicians, managers, and others drawn from the member health systems themselves and outside experts.

Recognized independent technology assessment resources are used. Information gathering for the clinical review processes tends to draw upon many of the same widely recognized sources used by other types of technology evaluation processes present in the health care sector, including independent assessment groups such as ECRI and Hayes, and databases of peer-reviewed literature such as MEDLINE. For example, Premier makes extensive use of assessment reports and related services of ECRI, and Consorta provides access to Hayes assessments for its member institutions.

Health systems and GPOs have functions for monitoring and incorporating "breakthrough" and other novel technologies. Although much of their purchasing activity is devoted to acquisition of "commodity" products of demonstrated quality, most health systems and GPOs have dedicated functions or other provisions for incorporating new and unique technologies into their purchasing contracts. These functions include the capacity to respond to initiatives from technology companies/vendors, as well as actively seeking out novel technologies with the potential to be added to contracts or supplant technologies under contract. Consideration of such technologies is subject to the demonstrated safety, effectiveness, cost-effectiveness, reliability of supply, and other attributes that pertain to other technologies.

Mechanisms for ongoing review are in place. Some GPOs conduct ongoing or "perpetual" reviews of new technologies as part of their regular contracting process. In addition to reviewing technologies as part of their regular contracting cycles (typically three to five years), these contracts often have provisions for replacing/upgrading these technologies in mid-contract when a vendor places a new model on the market or when a GPO identifies a preferable alternative.

Information is shared among clinical review functions. Certain separate functions related to review of clinical practices and technologies are linked within health systems and GPOs, which serves to strengthen them. For example, one of the surveyed GPOs has a clinical technology service that undertakes repair, maintenance, and upgrading for many types of capital equipment. The GPO arranges for the clinical technology service to provide its practical field experience with capital equipment to the GPO's technology assessment process and its technology contracting process.

The breakthrough technology function of one of the GPOs is linked to the broader technology assessment group, so that information about breakthroughs can be fed into considerations of technology choices. In turn, the technology assessment group can provide information resources and expertise in support of analyses of the breakthrough technology function.

GPOs can facilitate clinical trials. A separate avenue by which GPOs can support clinical research involving health care innovation is by helping to facilitate clinical trials. One of the surveyed GPOs has a clinical trials index that serves to link technology companies (and other research interests) that want to conduct clinical trials with provider institutions interested in serving as trial sites.

IV. SUMMARY BY TOPIC

A. Structure and Role of the Clinical Review Process

Health systems and GPOs were queried about steps in the technology review process for medical/surgical devices, pharmaceutical products, and capital equipment, and the extent to which the process was used to support or inform the acquisition, procurement, or use of health care technology.

Health Systems

Regarding the process, the response of one hospital executive is representative of the entire sample:

> ***"The process is similar in all three cases (devices, pharmaceuticals, capital equipment). The end users are after a change or a new product, and pass their requests through the various committees. The process is stimulated by physicians, front-line staff, or by an outside entity like a manufacturer or vendor."***

Similarly, health systems were largely consistent with regard to the structure of relevant committees, as follows.

- **Medical-surgical devices** are handled through a product evaluation committee, value analysis committee, product acquisition management committee, or comparable entity. The committee may be specific to particular clinical specialties or departments, or may have multi-disciplinary oversight over the entire health system's acquisitions. There are other types of specialized committees devoted to particular products or aspects of certain types of products, such as sharps committees for reviewing products that present a risk of percutaneous injury from contaminated hypodermic syringes and other sharp medical devices. Task forces with outside experts may be formed to assess specific products and report their findings to these committees. There is usually a dollar limit to the unit costs of products addressed by the product evaluation/value analysis committee; products whose costs exceed a set threshold fall under the purview of a capital committee.

- **Pharmaceuticals** are typically handled through a pharmacy and therapeutics (P&T) committee, typically chaired by the director of pharmacy and comprising primarily clinicians and pharmacists. P&T committees perform independent reviews of pharmaceuticals being considered for the formulary. P&T committees in multi-hospital systems involve members from across those institutions.

- **Capital equipment** is managed by capital committees that primarily review and assess technologies having high unit costs such as radiology equipment, or large multi-item purchases such as movable bedside equipment, taking into consideration the impact of acquisition on space and facility requirements, personnel, patient flow, and other institutional impacts. Capital committee assessments provide input to the capital purchasing and annual budgeting processes.

Table 3 provides an overview of the committee structure as reported by health systems in the survey sample.

Table 3
Health Systems' Committee Structures for Clinical Review

Health System	Category of Technology		
	Med/Surg Devices	Pharmaceuticals	Capital Equipment
A	Value Analysis Committee	P&T Committee, chaired by pharmacy director	Capital Committee
B	Product Evaluation Committee	Pharmacy Department/ P&T Committee	Capital Committee
C	<$1m: Value Analysis Committee >$1m: Executive Committee Clinical Services Committee contributes to process	P&T Committee	Capital Purchasing, Budget Committee (all items >$50,000)
D	Each subspecialty has a multi-disciplinary Product Acquisition Management (PAM) Committee. Each hospital in system has an equal vote.	P&T Committee for each hospital system	PAM Committees for each subspecialty
E	Product Standards Committee involved in all purchases Sharps Committee also reviews certain products	P&T Committee	Total Quality Management teams focus on large multi-item purchases or new technologies. Representatives are mostly clinical staff.

Group Purchasing Organizations

The surveyed GPOs have established comprehensive committee structures and related processes to review new products. Committee members are generally drawn from the clinical, pharmacy and technical staff of GPO member institutions, supplemented by GPO staff and other outside experts. Numerous committees, typically arranged by clinical specialty areas, pharmaceutical products, capital equipment, and others, evaluate contract opportunities and formulate recommendations to the governing committee (e.g. a contract and program committee). In general, committees are charged to evaluate clinical and related technical properties first. If these elements are consistent with expectations for quality, then the committees consider relevant economic and other impacts of a product.

Aside from evaluating commodity technologies, GPOs have provisions for monitoring breakthrough technologies and for incorporating these technologies in purchasing contracts when they meet the relevant purchasing/acquisition criteria. For example, one GPO described how its breakthrough technology function evaluated the "camera pill," a new diagnostic technology from a small company. Approved by the FDA in 2001 and available by prescription only, the device is used to visualize the inside of the small intestine to detect polyps, cancer, or causes of bleeding and anemia. The FDA cleared the device for use in conjunction with, not as a substitute for, other endoscopic and radiological evaluations of the small intestine. Despite its considerable unit cost, the GPO conducted an analysis that determined that it can be cost-effective. In deciding to include this type of technology in its purchasing contracts, the GPO can serve as a means for widespread diffusion of the technology.

Table 4
Structure of Clinical Review Process in GPOs

GPO	Features of Clinical Review Process		
	Process	Constituents	Comments
AmeriNet	Five **Program Development Teams** manage and review specific contract categories. Each team manages **Centers of Excellence** staffed by contract managers or market experts.	Program Development Team Constituents: GPO and Shareholder staff specific to the contract category.	Areas of purchasing covered: 12 Centers of Excellence: • Administrative services • Diagnostic imaging • Environmental services • Information resources • IV solutions and supplies • Laboratory • Medical supplies • Nutrition • Office supplies • Pharmacy • Plant engineering • Surgical supplies
	Member Advisory Groups seek health system input, experience, and advice.	Select Member Health Systems	Provide member input, experience and advice
Consorta	**Contract and Program Committee** receives recommendations from nine **clinical subcommittees**. Separate **Pharmaceutical Advisory Committee** (PAC).		Medical devices reviewed by clinical subcommittees or task forces; results go to Contract and Program Committee, then contract strategy and bid process begins 80% of pharmaceutical portfolio is rebid every other year, looking at clinical effects and potential for substitution. Remaining 20% (mostly products in use a long-term use) is reviewed more in depth, with white papers distributed throughout the membership.
Magnet	No internal technical review process; receives input from members regarding equipment and devices.	N/A	Role is to determine what they can offer to their member groups in terms of better price **for a set product** chosen by the health systems.
Novation	Formal 8-step review process for all products going out for bid.	Multiple committees	Steps: 1. Identify member needs 2. Develop bid/define product and evaluation criteria 3. Bid analysis 4. Decision-making based on non-financial and financial factors 5. Resolution and clarification of issues 6. Finalize the award; develop launch package 7. Launch phase 8. Record retention

GPO	Features of Clinical Review Process		
	Process	Constituents	Comments
Premier	**Member Committee** structure for medical/surgical devices for each major product category (e.g., med/surg, pharmacy and equipment).	Member health systems (including clinicians and supply chain executives)	**Member Committee** makes final decision on whether to contract for a product
	Clinical Technology Assessment Group looks at products going on contract. Reports to appropriate Member Committee.	Bioengineers and technicians	
	Separate **Breakthrough Technology Group** looks at "challenges" to existing products. Scans proactively for new technologies.	Member health systems	
	Strategic Advisory Committee works on overall strategy for group purchasing services.	Member health systems	
Shared Services, Inc.	Seven **Advisory Committees** review products under 3 scenarios: • Vendors present new products • Committees bring needs to SSI • Existing products come up for review	Clinical, technical, and administrative staff from member health systems	Types of purchases covered: • Pharmacy • Laboratory • OR • Radiology • Dietary • Materials management and services

B. Identification, Responsibility, and Locus for Review

The Lewin Group asked respondent health systems and GPOs to describe the way in which their clinical review process identifies and accommodates technologies to assess the types of technologies that are considered, and whether the review is conducted internally or externally. In addition, the participants were asked to identify the types of staff and experts who become involved in the process.

"Types of technologies" were defined by their physical nature (pharmaceuticals, devices, etc.) as well as in terms of their maturity:

- Experimental: undergoing laboratory or animal testing
- Investigational: undergoing clinical studies; prior to FDA approval

- Established: standard approach, in mainstream use
- Potentially obsolete/outmoded.

Another distinction was made among:

- Pure commodities, where price is the main difference among alternatives
- "Me too" products largely similar to others but which may have certain distinguishing characteristics (e.g., differing side-effect profiles among drugs of similar molecular structure in the same class)
- Breakthrough products where there is no alternative having the same effects.

Health Systems

Most health systems have a decentralized methodology for identifying products and technologies for review, coming often from their centers of excellence, specialty areas, and departments. They rely on physicians and other clinicians as well as technicians and business partners to define the agendas of the collective groups of committees that perform the review. Each teaching and research hospital surveyed reported that they review the full range of products, from experimental to potentially obsolete or outmoded. One hospital representative stated that "Obsolete technology is a function of default; it becomes apparent during the review process."

Little of clinical review activity concerns experimental technology. Particularly at hospitals that have major research programs, some clinical review activity involves investigational technologies, including clinical trials of products that are not FDA-approved or that are FDA-approved but being investigated for new indications. Much of the clinical review is devoted to pharmaceuticals, devices, and other products that are recently FDA-approved, or whose approval is imminent. Regarding established technologies, products to be reviewed are often identified by the "value added" potential of the product. One example cited was new models of CT scanners. During the previous year, a health system "purchased new CT scanners which performed in 14 seconds what the old CT scanners used to do in 45 minutes, resulting in less trauma for the patient, better imaging, and more equipment time for patients."

One hospital medical director stated that the distinctions between commodities, "me too" products, and breakthrough technologies are often made *de facto*, as follows.

> ***"Mostly, we see breakthrough products – the latest and greatest. The pulse oximetry device is kind of a commodity – but a new feature could make it a me-too or a breakthrough. The committee's job is to distinguish among these. Me-toos are usually not worth it."***

This medical director went on to state:

> ***"Every single case involves an extensive financial analysis. It used to be that the analysis was not rigorous; most products were looked at as replacements. But most are not one-on-one replacements. They require focus on how they change care, payer mix, and the program impact."***

Across the sample, most reviews are conducted internally, with the use of benchmark data from external sources. In the larger health systems, a member of the responsible value analysis committee is designated as the internal reviewer, often leading a special task force. Vendor-supplied information is always validated against external review sources and internal expertise.

Most clinical review processes involve people who bring differing types of expertise. Managers, clinicians, pharmacists, laboratory and radiology technicians, clinical/biomedical engineers, risk managers, and attorneys are consistently represented on committees and task forces charged with clinical review. Economists, epidemiologists/biostatisticians, and ethicists participate on occasion. Patients and community representatives are less commonly included.

GPOs

GPOs surveyed do not generally contract for experimental or investigational (i.e., prior to FDA approval) technologies, but they have mechanisms for monitoring what is in the pipeline, through continuous market assessment. Staff contract directors are expected to stay current and bring products to review to the appropriate subcommittees, which are normally organized around service lines. Most contracts have terms ranging from three to five years, but if membership wants to look at a product in the middle of a contract (particularly something that looks like a promising breakthrough product), the GPO will reexamine the product or service line. Thus, the three-to-five-year duration of these contracts provides continuity of purchasing and supply while enabling GPOs to track availability of upgrades and emerging technologies, and to amend their product lists if appropriate within the scope of the current contracts or at the time of contract renewal.

Pharmaceuticals, particularly, are monitored closely from the experimental phase through the standard-of-care phase. A GPO will look at the whole range of therapeutic agents, even though it may not contract for the whole range. New brand names of drugs as well as those going off patent will be reviewed, and GPOs often produce their own papers or other reviews of specific drugs that may have significant clinical or economic impacts.

GPOs often will contract on a line-item basis, not for bundles of products. Each GPO that carries out clinical reviews reported that it has developed written analytical tools, which are employed to determine if products are clinically equivalent.

Certain GPOs do not perform clinical reviews, but act as the prime contractor for other member GPOs, who have direct contact with health systems and alternate care sites that constitute their membership. These GPOs deal only with products that are already on the market, and depend on the health system/hospital community for the locus of clinical review. They look for best practices among their membership and make this information available to their membership on their websites. While some GPOs maintain extensive internal databases regarding utilization and repair histories, all GPOs surveyed commonly use external sources of technology assessments and related evaluations, such as ECRI, Hayes, and Zynx Health as well as other sources for utilization and other market research data, health outcomes, and other input to their clinical review processes.

Similar to health systems, a full range of staff and outside experts are involved in the GPO review process. Participants include internal executives and managers, physicians, nurses, and other clinicians, pharmacists, technicians, clinical/biomedical engineers, economists, attorneys, and others.

C. Attributes Evaluated

The Lewin Group asked health system and GPO respondents to describe the types of attributes that are commonly evaluated for each category of technology that is assessed (medical/surgical devices, pharmaceutical products, and capital equipment). These attributes may be characteristic of the product itself or may result from the product's use.

Health Systems

Health systems identified the following comprehensive list of attributes and impacts of technologies that generally are incorporated into the clinical review process:

- Technical properties and performance
- Safety and risk to patients and health care workers
- Efficacy and effectiveness
- Economic attributes
- Acceptability to patients and clinicians (comfort, ease of use, utility)
- Risk of liability
- Potential for standardization
- Impact on market share/competitiveness
- Requirements for facility modification/work flow
- Manufacturer reputation and support
- Capacity of vendor to provide sufficient and reliable supply.

Each of these factors is used to differentiate products if other aspects are similar when conducting a review. Sometimes the risk of liability is explicitly considered; for example, a lower infection rate associated with a product can offset a high unit cost. The potential for standardization was mentioned consistently, especially by multi-hospital systems, as the need to have a unified organizational approach becomes necessary.

The performance capacity of manufacturers "is critical" and "key." The longitudinal impact of the manufacturer's reputation and relationship as a supplier are important factors. Any doubts regarding the ability of a vendor to provide a reliable adequate supply of a product diminish the likelihood of that product being listed in a contract, even if the product itself is comparable in quality to others that are listed.

GPOs

GPOs surveyed gave responses that were consistent with those of health systems/hospitals with regard to attributes assessed during the clinical review process. In addition, GPOs mentioned "green" (i.e., environmentally friendly) sources and products as a sought-after attribute, such as in the use and disposal of mercury and the use of latex. Product conversion strategies were mentioned as an enhancement to the potential for standardization when considering a product. Most contracts with manufacturers contain performance criteria specific to a product, as well as indemnification clauses, which protect one party from a failure of performance by the other party.

D. Reporting and Link Between Review and Purchasing Action

Interviewees were asked about the reporting mechanisms that are used to communicate findings of technology reviews to decision-makers and about the link between the clinical review findings and the purchasing action to follow.

For both health systems and GPOs, reporting mechanisms range from standard change-of-product forms (for commodities) to white papers and formal reports (mostly for pharmaceutical and therapeutic products) to reports containing extensive analysis for capital equipment. Committee minutes and reports of proceedings are distributed to the parties involved and the leadership of the organization. One hospital stated,"We make a serious systematic attempt at reporting—it's not haphazard—but there is no template. Each application has a core set of reported material."

Table 5 summarizes GPOs' reporting mechanisms, and the linkage between the results of a review and the purchasing or contracting action taken as follow-up. If a supply item is on the list of products carried by a GPO, the purchasing health system is expected to purchase from the list (some lists distinguish "preferred" and "acceptable" products). Health systems consider the financial implications of choosing "acceptable" versus "preferred" products, as well as going off the list, i.e., purchasing products directly from vendors, if enough evidence exists about the capabilities of unlisted products.

As the industry changes, particularly with large multi-facility systems, health systems go directly to manufacturers and suppliers. "Just because it's the GPO doesn't mean you always get the best price," said one health system. This health system reported that it goes through a prime distributor for medical supplies and also has a wholesaler for pharmaceutical products; the GPO is their first source, then the prime distributor, and then the manufacturer.

Table 5
GPOs' Reporting Mechanisms and Linkages between Clinical Reviews and Contracting Activities

GPO	Reporting	Link Between Technology Review and Contracting Action
AmeriNet, Inc.	Reports on research and member input as described in Table 4 are directed to the appropriate Program Development Team for evaluation and consideration in portfolio development.	AmeriNet welcomes opportunities to evaluate new technologies. Members are free to access product outside AmeriNet contracts, however, AmeriNet encourages members to bring new technologies to their attention for evaluation and possible portfolio inclusion.
Consorta Catholic Resource Partners	Information from technology reviews is transmitted to decision-makers via: e-mails, website (posts relevant clinical information), meeting minutes, benchmarking studies, white papers, and newsletters	Health systems are free to purchase items through other sources. Consorta generally has two types of contracts—preferred contracts and committed contracts. In the preferred contracts, it is recommended that the health system purchase a certain product or pharmaceutical from a particular vendor, but it is not a requirement. Even in a committed contract, hospital systems have some flexibility in purchasing items from non-committed entities. Consorta also encourages members to bring new technologies or products to their attention. If there is enough interest among hospitals systems to change product contracting, Consorta will do so.
Magnet	As noted above, Magnet does not have a technology review process (they rely on their members' review processes)	If a member wants an item that is not under contract, most likely Magnet will not be able to get the product immediately, but they will look into contracting with the suggested vendor at the time of renewal. However, the hospital/health system is free to go outside the GPO and purchase the item.
Novation	Nonfinancial and financial decision criteria are measured and reported through the decision criteria award matrix, customized for each bid and with input by members.	Invitations to bid are made public; if new technology has come to market, Novation will evaluate it. New technology clauses are present in contracts, subject to the award cycle.
Premier	Information from technology reviews is transmitted to decision-makers via: in-depth written reports (white papers) and meeting minutes. The Pharmacy Group does a worldwide literature search and detailed review to decide if they should more forward with a contract. This information is made available to members as well.	Premier's contracts do not require that members buy 100% through Premier, but they typically consider buying through Premier first Members are encouraged to come to Premier with suggestions for new products.
Shared Services, Healthcare Inc.	Minutes and reports from advisory committees.	Members are free to acquire items through other sources, but they can often get a better price if they commit to buying a certain quantity from a vendor under contract. These members will not be penalized if they choose to buy from an off-contract vendor.

Health systems and GPOs expressed that there are many mechanisms to acquire technology beyond the GPO, and that these avenues are increasing. This is leading GPOs to offer new programs and services and to modify existing ones in order to remain the preferred purchasing channel. One medical director of a health system characterized the relationship among GPOs, health systems, and manufacturers as follows.

> ***"GPOs are not locking out 'newer cusp' technologies. Together with health systems, they evaluate products on the merits, they do a trade-off of costs and effectiveness, and they use best evidence. Purchasing consortia get the best price on command, and they don't make it so innovation cannot occur."***

Written Testimony of Novation Submitted for the Record of the Senate Judiciary Subcommittee on Antitrust Hearing of September 14, 2004 "Hospital Group Purchasing – How to Maintain Innovation and Cost Savings

Introduction

Novation, along with the other members of the Health Industry Group Purchasing Association (HIGPA), opposes the proposed legislative options for regulating the group purchasing industry. It is our view that legislation is not necessary because the industry's system of self-regulation is having the intended effects. Additionally, legislation would negatively impact the nation's health care organizations by increasing their supply costs and burdening their organizations with added administrative activities.

Novation believes that any legislation would have the unintended effect of creating uniform business practices that would stifle innovation and competition in the group purchasing industry. Instead of promoting self-regulation, the proposed legislation would instead create a new regulatory regime, imposing substantial administrative burdens on the healthcare industry. Rather than focusing scarce resources on innovation and development of new products and services that would directly benefit patients, GPOs, providers and suppliers would instead be forced to focus on responding to and implementing these new regulatory demands.

Unfortunately, the testimony presented by other witnesses at the hearing offered inaccurate and misleading information about group purchasing and Novation in an apparent effort to bolster their demands for the Senate to move forward with legislation. In the course of offering this testimony, GPO critics presented old information and industry examples as if depicting existing market conditions in an attempt to sway the subcommittee members. It is important that the subcommittee receives accurate and complete information about Novation. Therefore, we offer this testimony to provide the subcommittee with a correct and complete record.

Novation

Novation is a health care supply services company jointly owned by VHA Inc. and the University HealthSystem Consortium (UHC). VHA is a national cooperative comprised of more than 2,200 non-profit hospitals and health care organizations. UHC is a cooperative that is owned and governed by its 91 academic medical center members and has an additional 120 associate members. GPOs like Novation utilize the combined purchasing power of participating members to obtain lower prices for quality medical supplies. GPOs also help member hospitals avoid significant costs associated with procuring products and services by providing centralized procurement services and expert personnel at minimal cost to members. Suppliers willingly offer fees to GPOs for the value they receive: aggregated volume, reduced sales costs and increased overall contracting efficiencies.

New Federal Legislation is Unnecessary

Today, there is enormous competition in the GPO industry. Hospitals are struggling financially and are scrutinizing their GPO relationships very carefully to assure they are getting the best products and prices through their GPOs. These hospitals cannot afford the additional administrative burden of new government regulation or the higher prices that would result from new government limits on GPO business practices. Such regulation would reduce rather than enhance competition and savings. The current competitive environment allows GPOs to provide value for both suppliers and member hospitals.

The Department of Justice and the Federal Trade Commission recently have reviewed GPO practices under the so-called "safe harbor" for administrative fees paid from vendors to GPOs and determined that no new laws or regulatory changes are warranted. These enforcement agencies have sufficient authority to address potential problems in the GPO industry on a case-by-case basis. Similarly, the Department of Health and Human Services already has ample regulatory authority to oversee GPOs. HHS is also able to provide additional guidance to the GPO industry through advisory opinions.

The changes implemented through the codes of conduct have been absorbed and institutionalized by the industry such that compliance with them has become the normal course of business for most GPOs. In an intensely competitive marketplace, failure to comply with these established codes would not be tolerated by hospital members and suppliers.

GPO Codes of Conduct

In 2002, the subcommittee focused attention on certain GPO practices, such as investments by GPO executives in companies the GPOs did business with and advance vendor payments to GPOs as part of some vendor contracts. Since then, the GPO industry has adopted a strict voluntary code of conduct that forbids these activities and mandates the highest ethical standards in the health care industry.

Novation complies with all requirements of the HIGPA Code of Conduct. In addition, on August 8, 2002, Novation supplemented the HIGPA Code of Conduct with a progressive, comprehensive set of Operating Principles to enhance innovation and savings to member hospitals in seven core areas: (1) innovative technology, (2) sole, dual, and multi-source contracts; (3) commitment; (4) contract term; (5) private label; (6) vendor fees; and (7) Code of Conduct and Compliance.

The implementation of the Voluntary Code of Conduct already has resulted in significant progress in the way GPOs do business. HIGPA continues to examine and refine the Code of Conduct. This is a time for this subcommittee to let the voluntary code and the market work to enhance quality and competition in this critical area of health care purchasing.

Corporate Governance

GPOs are regulated by the federal government in a number of respects and self-regulated in others. They have in place voluntary ethical guidelines that govern a wide range of issues, including conflicts of interest. HIGPA, the trade group for more than two-dozen national GPOs

and other smaller ones, as well as various manufacturers, has developed a code of conduct for GPOs. In addition to that code, Novation has adopted and implemented one of most stringent business ethics and conflict of interest policies governing all employees, council members and the board of directors.

Nearly all the large national GPOs have made changes in their business practices to comply with the code, and some have moved well beyond the code's standards in areas such as disclosure practices and ethics policies.

Specifically, Novation has:

- Increased its focus on identifying new and innovative technology and, since August of 2002, has awarded agreements to 22 innovative technology companies for 27 products. Another 10 contracts are pending and 15 are currently under review.
- Created a website that can be used by small companies to post information about their products that can be viewed by Novation customers, regardless of whether the firms have agreements with Novation.
- Established a formal grievance process that enables manufacturers that did not win a contract through the competitive bidding process to request reconsideration by Novation member councils.
- Reduced the number of sole source agreements it signs for clinical preference products and has moved towards dual- and multi-source arrangements for almost all of these types of products.
- Reduced commitment levels for its committed purchasing programs.
- Focused its medical-surgical private label program, NOVAPLUS, exclusively on commodity products and standardized fees.
- Reduced vendor fees overall, especially for clinical preference products.
- Appointed a compliance officer accountable to the board of directors to ensure adherence to the commitments that were made to the U.S. Senate.

Points of Clarification

Masimo

An important omission in the testimony presented by Mr. Kiani is that Masimo currently holds a contract with Novation for its pulse oximetry products. That contract was initiated on September 1, 2003, and is on track to generate significant sales in 2004.

A letter from March 2003 was entered into the record as an exhibit by the Masimo executive. The purpose and intent of this letter was grossly mischaracterized. Masimo management reviewed the letter before signing off on their agreement with Novation, yet it was offered at the hearing as an example of egregious behavior by Novation. The letter was a routine communication designed to make member hospitals aware of programmatic changes, including the opportunity to reduce commitment levels if desired, the availability of a new product under contract, and to reinforce that member hospitals can purchase products from any supplier. These changes were made voluntarily and proactively by Novation two years prior to the company's commitment in its operating principles. Ultimately the decision to purchase Masimo products is the members', with or without a Novation contract.

A statement was made that Novation tells hospitals to turn away manufacturers that do not have a Novation contract. This is inaccurate. Participation in Novation contracts is completely voluntary. Additionally, hospitals are free to examine new products and new technology without penalty, sanctions or other consequences.

During the course of the testimony offered by GPO critics, it was stated that hospitals are uninformed about new technology and their GPO's contracting activities. In actuality hospital representatives are actively involved in Novation's contracting process. Novation contract award recommendations are made by more than 30 member councils and task forces, composed of representatives from more than 300 member organizations. These purchasing executives and clinicians help shape Novation's product portfolios. Members are also surveyed regularly regarding their clinical and quality requirements, product and service expectations, and preference for new technologies. Members determine the criteria by which contracts are bid and awarded. Contrary to Mr. Kiani's testimony, administrative fees are not the determinative factor in the decision-making criteria used to determine contract awards. In any event, the fees, collected by Novation, after operating expenses, are ultimately returned to the member hospitals, helping them reduce their operating costs.

Service Employees International Union

Testimony submitted by the SEIU inaccurately stated that the Safe Harbor established a 3 percent ceiling on fees GPOs could collect. The Safe Harbor allows for GPOs to accept fees above 3 percent so long as this information is reported to participating hospitals. Novation acts in full compliance with the Safe Harbor and all other industry regulations. The average fee accepted by Novation is just under 2.2 percent. Any fees over 3 percent are disclosed to member hospitals through a Web-based system.

Claims that Novation limits provider choices also have no factual basis. Member hospitals participate in Novation contracts on a voluntary basis. This is evidenced by the fact that on average VHA and UHC members purchase only 50 percent of their supplies through Novation contracts, and most U.S. hospitals belong to two or more GPOs.

Novation, VHA and UHC are governed by boards largely comprised of hospital representatives who abide by strict conflict of interest policies. These board members serve without compensation and do not have influence over the selection of suppliers and products, nor

do they benefit financially from these decisions. Additionally, Novation, VHA, and UHC have never had any individual shareholders. VHA and UHC are owned by not-for-profit hospitals; Novation is owned by alliances of not-for-profit hospitals.

Contrary to the SEIU's assertion, manufacturers do not have to pay a fee to Neoforma to get a Novation contract, they are simply asked to make their contracted products available through the online Novation Contract Catalog on Marketplace@Novation, Novation's members'only Web site. Then, they may freely choose to purchase additional reporting tools. Fees for these services go directly to Neoforma; Novation does not receive any portion of these fees.

The VHA Health Foundation, a 501(c)(3), 509A-1 organization, is governed by a 16-person board. In 2004, the Foundation will distribute more than $1.9 million in grants to support community health improvement projects. The VHA Health Foundation receives most of its funds from VHA, not individual suppliers, and VHA's funding of the Foundation was approved by the VHA Board of Directors. Even so, the Foundation does not influence contract awards at Novation, nor is it in any way connected to the contracting process. Furthermore, VHA Foundation grants can be awarded to VHA members, as well as health care organizations that do not belong to VHA. The Health Foundation is staffed by one dedicated, full-time VHA employee with support from other employees in the form of a few hours a week. The statement in SEIU's testimony that one VHA employee receives his entire annual salary as compensation for four hours of foundation work per week is false. The referenced employee is a full-time senior executive with significant management responsibility.

The SEIU also suggests that Novation does not maintain transparency with regard to its financial data. Novation properly discloses financial information to its parent companies and the members served by all three organizations.

The assertion by the SEIU that Novation's private label program, NOVAPLUS, is designed to generate higher fees is false. The primary purpose of the NOVAPLUS program is to provide significant savings to member hospitals by giving them access to high quality commodity products identical to their more expensive, brand name equivalents. Suppliers are willing to offer lower prices on these items because they do not require the same level of sales and marketing expenses used to promote a name brand. Historically, the NOVAPLUS program has helped level the playing field for smaller manufacturers to compete with larger companies that have more sales and marketing resources.

Other Testimony

Other GPO industry critics backed up their claims that the GPO Code of Conduct and system of self-regulation are not working with reports that were based on outdated information, sometimes reflecting information that described the market environment as far back as 2002, or before. Because the findings of the recent DOJ/FTC joint healthcare report did not suit their purposes, critics ignored the information in that report, which determined that there is no need for additional regulation of the industry.

Furthermore, some of the "questionable GPO practices" highlighted during the hearing are common in government and other industries, such as sole-sourcing and efforts to drive standardization. These practices, when voluntarily accessed by small rural hospitals, allow them to obtain pricing they otherwise could not obtain, and allow not-for-profit community owned hospitals to achieve pricing which would otherwise be available only to for-profit hospital entities.

As many have acknowledged, the full impact of the industry Code of Conduct will be realized over time, so it is premature for further legislative action to be taken, and in reality, it is unnecessary.

Conclusion

In order for U.S. hospitals and their patients to continue to benefit from group purchasing organizations, it is important that Congress continue to affirm its support for the business model represented by GPOs. Efforts by special interests to undermine the business operations of Novation and other health care cooperatives will result in higher health care costs for all Americans, for non-profit hospitals that provide extensive full care in their communities and for Medicare and Medicaid.

Moving forward, Novation will continue to work with members of the subcommittee to listen to any concerns, maintain open discussion and to update them on the positive effects generated by adherence to our self-regulatory operating principles.

TESTIMONY OF
CONNECTICUT ATTORNEY GENERAL RICHARD BLUMENTHAL
BEFORE THE
ANTITRUST, COMPETITION POLICY AND CONSUMER RIGHTS SUBCOMMITTEE
OF THE SENATE JUDICIARY COMMITTEE
SEPTEMBER 14, 2004

I appreciate the opportunity to submit comments on the issue of hospital group purchasing organizations.

Hospital group purchasing organizations (GPOs) are powerful purveyors of hospital supplies, equipment and medical devices, whose abuses of that power have been documented by this Subcommittee's inquiry, my investigation and the media. We must refocus GPOs on their original mission -- making available high quality health care related supplies and safe medical devices and equipment at the lowest possible prices.

Hospital group purchasing organizations began as a laudable cost-saving initiative based on the common sense principle that pooling purchasing power for acquisition of hospital-related supplies and equipment would produce significant savings for hospitals and other health care providers. In many instances, GPOs have in fact achieved that goal. Unfortunately, certain GPOs, including some of the largest in the United States, have strayed from that mission and veered into highly suspect practices and incestuous relationships with vendors, raising serious consumer protection, antitrust and antikickback issues.

In March 2003, as a result of concerns raised by this Subcommittee's investigation, investigative reports in the New York Times and other sources, I began an investigation to determine whether GPOs were violating state antitrust laws through various business practices. Such practices include negotiation of long-term bundled product agreements and sole-source contracts with high commitment levels and exorbitant administrative fees and other questionable payments made to the GPOs by the vendors. I am constrained as to the detail I can provide here because my investigation is indeed active and ongoing in cooperation with other authorities.

In particular, I have focused on practices at Novation, one of the nation's largest GPOs. Potentially, certain of the contracting practices at this GPO, combined with its dominant market power, may encourage or involve anti-competitive practices. Certain business practices or

agreements with larger medical device manufacturers, for example, may have unfairly -- and illegally -- excluded smaller manufacturers, thereby pressuring hospitals and other health care providers who are members of these GPOs to purchase less effective products. One serious question is whether certain agreements may have actually raised prices for member hospitals, and possibly exposed patients and health care workers to lower quality, less safe and effective medical supplies or equipment.

Seeking to discourage governmental regulation and scrutiny, the Health Industry Group Purchasing Association ("HIGPA") and the seven GPOs established self-regulating Codes of Ethics in August, 2002. I am highly skeptical about self-serving efforts at self regulation by companies engaged in apparent conflicts of interest and self-dealing. The conduct revealed over the last two years calls into question whether some GPOs have at heart the best interests of the constituents they were formed to serve. A voluntary code of ethics is simply insufficient to ensure an end to anti-competitive abuses and possibly fraudulent practices.

My antitrust investigation has broadened to determine whether vendor and GPO contracting practices have defrauded the Medicaid program. Specifically, I am scrutinizing the propriety of fees and other incentives provided to GPOs to determine whether they illegally induce GPOs to enter into contracts with certain vendors. I am also concerned that these fees and incentives may not be reported by hospitals or other healthcare providers in the cost reports or claims for reimbursement submitted to the Medicaid program, resulting in their receiving higher reimbursements then are legally warranted.

Finally, my investigation is also focusing on undisclosed relationships between hospital executives and the GPOs. I am concerned by a lack of transparency about the business relationships between these hospital executives and the GPOs and I question whether these individuals can fairly and fully represent and advocate the disparate interests of their hospital, their hospital association and the GPO.

Although my investigation is ongoing, based on the information that I have obtained so far, there is a clear, compelling need for federal regulation of GPOs. I urge the committee to support legislation that will:

- Eliminate conflicts of interest in this industry by prohibiting GPOs and health care related supplies and medical devices and equipment companies from having any ownership interest in each other. In addition, no member of a board of directors, officer, individual with contracting authority or owner of more than 5% of a GPO should have any ownership interest in health care related supplies and medical devices and equipment companies.

- Strictly and vigorously prohibit any GPO from accepting any fees from vendors in excess of three percent of the purchase price of goods or services sold to members by these vendors. Excessive fees, and other reimbursements such as stock options may rise to the level of an improper inducement to influence a GPO's selections of a vendor for its supply contracts, which poses potential conflicts of interest for the GPO, unfairly exclude

smaller vendors from the contracting process and possibly taint the vendor selection process, which ultimately may lead to higher prices or substandard products.

- Require GPOs to report to the Department of Health and Human Services all fees or other remuneration from vendors. This information should arguably be kept confidential only if it clearly constitutes a trade secret. Such reporting will assist the Department in monitoring compliance with the fee limits.

- Require that a GPO disclose to its hospital members any and all information concerning the quality, safety and efficacy of the products purchased from a health care related supplies and medical devices and equipment company.

- Prohibit any GPO contract provision that prohibits or penalizes a member from testing or gaining information about a clinical preference item that is offered by a vendor that does not currently have a contract with the GPO.

- Prohibit sole source contracts by GPOs for clinical preference items unless there is no other means of obtaining such products. Health care providers should be able to access the most effective medical devices and products where there are valid, documented clinical preferences for more than one type of such medical device or product.

- Prohibit GPOs from tying or bundling products in a manner that unreasonably restricts competition or clinical preferences for medical equipment or devices.

- Limit GPO contracts with health care related supplies and medical devices and equipment companies to no more than 3 years in order to encourage competition in the medical supply and product industries. Long term contracts, especially by larger GPOs, can restrict competition by limiting the available market for competing products.

- Require the Federal Trade Commission to promulgate regulations within two years of the effective date of the legislation to ensure robust competition in the GPO, hospital purchasing and medical supply industries.

- Require each GPO to designate a compliance officer to monitor the GPO's compliance with federal regulations and laws governing GPO practices.

In addition to legislative changes, the subcommittee should urge more aggressive federal action to investigate and prosecute antitrust violations by GPOs, particularly in light of *LePage v. 3M Corp.*, 324 F.3d 141 (3rd Cir. 2003) which supports and encourages such antitrust enforcement against health care product bundling and other anticompetitive abuses. The effectiveness of any law depends on tough, sustained enforcement.

I urge this subcommittee to take expedited action this year to approve such legislation to benefit consumers through lower health care costs and improve the delivery of quality medical supplies and equipment to hospitals at the lowest prices.

Statement of Senator Saxby Chambliss

Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights

September 14, 2004

Mr. Chairman, I would like to make a few comments today about the subject of this hearing. First, I think the subcommittee's past work in looking into questions about how hospital Group Purchasing Organizations (GPOs) operate has had many very good results. The GPO industry has adopted a voluntary Code of Conduct establishing ethical guidelines for its members that are among the strictest in the entire health care industry.

Second, I think we need to recognize how important hospital GPOs are in keeping the lid on health care costs; I certainly have heard from several hospital executives in Georgia about how important their GPO is for them in reducing the costs of all kinds of supplies bought through their GPO. I am aware of studies from the subcommittee's hearing record last year that found that GPOs save hospitals on average 10% to 15%.

Third, many of these hospitals have brought to my attention that there may be an effort to pass new, highly regulatory legislation covering how GPOs operate and even impacting the activities of individual employees responsible for hospital purchasing.

The voluntary Code of Conduct seems to be working very well – I have not received any complaints about it. In fact, the Federal Trade Commission's (FTC) recent study of the health care industry concluded that no new regulatory tools were needed for either the FTC or the Justice Department to make sure the GPO industry remains competitive. Any new regulation by Health and Human Services, the FTC, or the Department of Justice would likely just add more administrative and financial burdens to already struggling hospitals and detract from competition rather than add to it.

We should let the new voluntary Code of Conduct process continue to work and see how it plays out, rather than risk adding more unnecessary costs to hospitals and other health care providers. Thank you Mr. Chairman

Statement
United States Senate Committee on the Judiciary
Hospital Group Purchasing: How to Maintain Innovation and Cost Savings
September 14, 2004

The Honorable Mike DeWine
United States Senator , Ohio

OPENING STATEMENT
ANTITRUST SUBCOMMITTEE HEARING
"Hospital Group Purchasing:
How to Maintain Innovation and Cost Savings"
U.S. SENATOR MIKE DEWINE
SEPTEMBER 14, 2004

Good afternoon and welcome to the Antitrust Subcommittee hearing on hospital group purchasing organizations. Senator Kohl and I have devoted substantial energy and time to exploring allegations of questionable ethics and business practices in this industry. We have commissioned two General Accounting Office studies on this issue, and this is our third hearing on the hospital group purchasing organizations, often referred to as "G-P-Os".

The purpose of this hearing is to look toward the future. Since our first hearing in April of 2002, I am pleased to say that many of the questionable practices in the industry have been voluntarily eradicated by the GPOs, themselves. In particular, business practices, such as GPOs owning stakes in their vendors or GPOs accepting an ownership interest in a vendor in place of an administrative fee, appear to have ended.

The GPOs took these steps in response to the Subcommittee requests for them to implement voluntary codes of conduct, and they deserve our applause for so doing.

GPOs also have taken important voluntary steps to address certain controversial contracting practices that are of concern to both Senator Kohl and to me. For example, GPO practices, like the bundling of clinical preference products with commodity products, extremely high commitment levels, or sole source contracting are often the focal point of debate within the medical community. Small manufacturers complain that these practices prevent fair market access to new, potentially innovative products, and as a result, prevent improved patient care. Larger incumbent manufacturers and GPOs often argue in response that these practices generate significant cost savings for high quality products without harming patient care at all. One GPO, for example, recently has pointed to an instance where it entered into a long-term sole-source contract for surgical sutures and was able to save $55 million for its hospitals.

My sense is that both sides make good points -- in fact, these are business practices with the potential to save significant money in certain circumstances but, unfortunately, they sometimes make it harder for legitimately innovative products to reach the market. Under these circumstances, it seems that the best result is one that maintains maximum flexibility in the market, and in some ways, we may already have achieved that; all of the major GPOs have adopted codes that address these issues, but they vary in their details and how they are applied. As a result, it appears that we are seeing fewer long-term contracts, less bundling of clinical preference items, and less sole-sourcing, but that those contracting practices are still available in certain circumstances.

Unfortunately, however, the Subcommittee still hears complaints -- principally from small medical device manufacturers with arguably cutting edge products -- that they are unable to negotiate a contract with GPOs. I'll be honest: It is often difficult to assess the credibility of certain complaints from medical device manufacturers and the GPOs' responses to such complaints.

On one hand, I certainly don't believe that every small medical device manufacturer that fails to win a contract with a GPO has a legitimate complaint. We all know that competition for contracts produces winners and losers and sore losers ought not hamper free competition. On the other hand, these complaints have been continuous and steady and appear to have at least a degree of credibility. This makes me wonder if the GPOs, indeed, are all living up to their pledge to decrease or stop some of these controversial business practices.

So, that brings us here today -- to explore where we should go from here. I know Senator Kohl and I share a concern that if the Antitrust Subcommittee turns its "oversight spotlight" away from the GPO industry, there is a risk that there may be backsliding. That means we need to decide if we can trust that the current reforms are sufficient or, if not, what pathway we can take to ensure that the current reforms are actively implemented and long-lasting.

I think it is fair to say that we are at the crossroads and sitting here today, I see at least three paths we could choose. I have made no decision which path is best, nor do I think we are necessarily limited to these three paths. But, sitting here today, I think these three paths are evident.

One path is to do no more, at least for now. We have studied the issue, held numerous meetings within the industry, commissioned studies, and held three hearings. The GPOs, hospitals, and manufacturers know all of our concerns and have acted on them, to one degree or another. Some would argue that we have done our job and, perhaps more importantly, the GPOs have done their job, by adopting the voluntary codes. Under that view, no more action is needed.

Another path is to formally transfer our oversight of the industry somewhere else. The primary example thus far of this approach is embodied in the staff Discussion Draft that has been circulated within the industry and provided to today's witnesses.

It would move the oversight role to the Department of Health and Human Services, which as an executive agency, is arguably better equipped to oversee the activities in the GPO industry. The Department of Health and Human Services already has a degree of expertise in this area, and it currently oversees the "anti-kickback" exemption upon which the entire GPO industry is built.

Another path is for the GPO industry to build upon their work of setting up individual codes of conduct to create what I call a "voluntary plus" approach. Currently, existing voluntary codes are enforced by each company on its own, an approach which has both strengths and weaknesses. On the one hand, because it is voluntary and self-enforced, it provides maximum flexibility and does not hamstring the industry. On the other hand, for those very same reasons, there is no assurance that it will continue to be implemented in the future or that it always will be implemented actively. Most troubling is the fact that there is really no mechanism to discipline GPOs that don't follow their own code.

I welcome any proposals from the GPOs that would create this sort of "voluntary plus" approach -- proposals that build upon the current voluntary codes, but add some "teeth" so that the Subcommittee

can be assured that the reforms are made permanent and that if a GPO chooses to disregard its own code of conduct, that it is disciplined in a way that has real consequences.

I have set out these three paths as what I see now, but I am not wedded to just these three paths. If there is a fourth pathway or a fifth out there that are products of this hearing, I look forward to considering them too. We hope today to hear our witnesses comment not only on the strengths and weaknesses of the discussion draft, but on all of these ideas and any others that may arise.

Before I turn to our ranking member, Senator Kohl, I would like to add that throughout our oversight of the GPO industry, I have tried to stay in close contact with the hospitals in Ohio to find out how they view GPOs. Of course, GPOs work as purchasing agents on behalf of these hospitals, so it is really the hospitals that get the benefits of GPO activities.
I think it is fair to say that nearly all the hospitals I have spoken to are confident that their GPOs are saving them significant amounts of money. In this age of escalating health care costs, that is a very important outcome, and one that we must maintain. So, I certainly believe that GPOs can provide significant benefits for hospitals. Ensuring that in the future GPOs both save money and allow for new technology and vigorous competition in healthcare products is the goal of this hearing today.

One final point -- the Subcommittee first started investigating this issue in the fall of 2001, under the Chairmanship of Senator Kohl. He has continued to work tirelessly on this important issue. I think it is fair to say that without his work, the Subcommittee would not be holding this hearing today and the industry would not have progressed to where we are now without his efforts, so I thank him for that.

Foundation for Healthcare Integrity:
Restoring Trust in the Healthcare Delivery Chain

Independent, Non-profit, Non-partisan

September 21, 2004

The Honorable Mike DeWine
United States Senator
140 Russell Senate Office Building
Washington DC 20510

Dear Senator DeWine:

We would like to commend you for your commitment to the health care GPO issue and thank you for holding the hearing last week. Your statements during the hearing made it clear you were open to options for resolution beyond the three options presented. We would like to offer another option.

We fully support legislation designed to create rules and regulations to govern GPO behavior. Clearly, the current GPO Code of Conduct is not enough to prevent GPOs and their dominant suppliers from engaging in anti-competitive behavior. We also support establishing enforcement of those rules and regulations through the Office of the Inspector General in the Department of Health and Human Services. However, GPO contracting and business practices are extremely complex and may present enormous challenges to the Senate and other government agencies that will be tasked with oversight responsibilities. So while we support enforcement through the HHS/OIG, we believe that effective oversight leading to enforcement actions may be problematic due to the steep learning curve required. We believe effective oversight should be provided by a trusted third party organization that has both the awareness of current GPO practices at a granular level and the knowledge of best practices in supply chain procurement.

We would like to suggest that the Foundation for Healthcare Integrity, under a contract from the federal government, be charged with providing the necessary oversight of the practices of health care Group Purchasing Organizations. We are open to a variety of options for structuring the arrangement. As a first step, we offer the following model as a starting point in the discussion.

The Foundation for Healthcare Integrity would create a GPO Oversight Organization that would do the following:

1. Work with the Senate and the HHS/OIG to establish GPO practice baselines. This would be accomplished by creating and implementing an initial audit of each GPO that desires to avail itself of the benefits of the Safe Harbor.
2. Work with the Senate and the HHS/OIG to create GPO business practice standards and establish a "Medicare-Certified GPO" designation. This designation would be awarded to GPOs who meet the approved business standards. Business and contracting practice standards would be developed and implemented for manufacturers as well.
3. Create a GPO business practice complaint registry; establish a complaint reporting mechanism to be utilized by any patient, caregiver, physician or manufacturer who believes that a GPO has acted outside the bounds of the regulations.
4. Investigate each complaint; make a determination if the seriousness of the complaint and the volume of complaints against all GPOs; report findings that warrant a referral to the HHS/OIG for further investigation and potential enforcement action.
5. Establish an annual audit function for each GPO, which could be supplemented predicated on types and volume of complaints. The audit function would be carried out by audit teams that include expertise in legal, forensic accounting, sales management and procurement practice management.

The Foundation for Healthcare Integrity would have both an oversight dimension carrying out the tasks outlined as well as an educational dimension. The educational dimension would promote industry-wide understanding of regulations, acceptable GPO business practices, complaint reporting mechanisms and audit and enforcement actions. The Foundation is already established as a 501 (c) 3 tax exempt organization.

We believe that a combination of government enforcement and trusted third party oversight would provide the most effective solution to the challenges posed. Of utmost importance in our mission is to protect patients, taxpayers and medical innovation from GPO business practices that malign the world's preeminent health care system.

Sincerely,

Patti King

Lynn James Everard, C.P.M., CBM

Founders of the Foundation for Healthcare Integrity

Examining the GPO Code of Conduct

Prepared by

The Foundation for Healthcare Integrity

www.healthcareintegrity.org

Introduction

For many years, small medical device manufacturers have complained that the business practices of health care Group Purchasing Organizations (GPOs) preclude their ability to sell products to the majority of hospitals with which they seek to do business. These small medical device manufacturers have alleged, among other things, that the practices of GPOs were anticompetitive and were limiting physicians, caregivers and patients access to safer, more innovative, and effective products. This means innovations that would benefit doctors, patients, and health care workers—and grow the economy—do not reach those who need them. In 2002, a rising crescendo of complaints persuaded the U. S. Senate Antitrust Subcommittee to hold a hearing on the matter. To their credit, Senators Mike DeWine and Herb Kohl have taken a serious interest in the effects of GPO practices and have led efforts of the U. S. Senate Subcommittee on Antitrust in examining the issues.

Genesis of the Code of Conduct

On April 30, 2002, the U.S. Senate Subcommittee on Antitrust, Competition, Business and Consumer Rights held a hearing on hospital group purchasing asking the question: "Do Healthcare GPOs lower costs at the expense of patient health and medical innovation?" In their opening remarks, Senators Kohl and DeWine expressed a clear preference for the industry to "clean up its own act" and called upon GPOs to develop a Code of Conduct that would "address ethical problems and contracting issues."[1]

Three months later, the Health Industry Group Purchasing Association (HIGPA) delivered its Code of Conduct Principles to the U.S. Senate. Since that time, HIGPA and its member GPOs have attempted to convince both the U.S. Senate and the health care industry-at-large that the Code of Conduct will effectively address all concerns regarding the business practices of GPOs. The Foundation for Healthcare Integrity has examined whether the Code of Conduct has been effective in eliminating ethical and contracting issues since its execution.

Applying the Code of Conduct to the Complaints of Small Manufacturers

Small manufacturers have expressed serious concerns over a number of GPO business and contracting practices; the U.S. Senate has echoed many of those same concerns in Antitrust Subcommittee hearings in 2002 and 2003. Among those concerns are market access, bundling, sole-source agreements, long-term committed contracts, high

[1] April 30, 2002 U.S. Senate Antitrust Subcommittee hearing transcript

commitment levels, administrative fees, outside business relationships such as Novation's relationship with Neoforma, the Innovation Institute, and the serious absence of third-party oversight of GPO business practices.

Since its creation in 2002, the HIGPA Code of Conduct has been positioned as a suitable response to the complaints of small manufacturers and the Medical Device Manufacturers Association (MDMA), a trade group representing the interests of small manufacturers, and the Service Employees International Union (SEIU). A number of individual GPOs have produced their own Code of Conduct variations and the U.S. Senate Antitrust Subcommittee appears to be somewhat satisfied with the progress made to date. Yet, for all of the good will surrounding the Code of Conduct, the fact remains that it has not been tested against specific and troublesome market place situations. Testing the Code against actual market place experiences is critical in determining what impact the Code might produce. Not only must the Code protect competition and medical innovation, but the Code must also be effective in protecting the interests of patients, physicians, caregivers, and the general public.

Scenario One: Market Access

Without market access, a GPO contract may be of no value. Many small manufacturers claim that even when awarded a GPO multi-source contract, some GPOs seem to work in unison with their largest suppliers. When this occurs, the smaller manufacturers are prevented from gaining access to hospital customers; therefore they are unable to demonstrate the effectiveness and value of their products. The following example illustrates this point and occurred in 2004.

A small, single product manufacturer (Manufacturer B) was awarded a multi-source contract with a GPO. After the contracts had been executed, the GPO distributed "recommitment" arrangement documents to its membership on behalf of a large dominant manufacturer (Manufacturer A) that competes against Manufacturer B. Members who execute the recommitment arrangement receive 15 – 40% discounts from Manufacturer A's list prices in exchange for a commitment to purchase 75 – 95% of Manufacturer A's products. In order to receive the best pricing (40% off list prices) for Manufacturer A's products, a member must purchase at least 95% of Manufacturer A's products. Additionally, the member must have been a former private label purchaser through the GPO.

The effects of the executed recommitment arrangement cannot be underestimated, as it is another market access bottleneck. The sales representative for Manufacturer B attempting to market its products to the GPO member cannot access the clinical decision makers at the individual hospital. The reason for this is upon execution of the recommitment arrangement, the member effectively agrees to purchase exclusively from Manufacturer A (in some cases, within and outside the relevant product market). Consequently, the caregivers of this GPO member would be restricted in choosing

products it will purchase.[2] This example illustrates the market effects of a GPO conducting business in concerted effort with their "preferred" vendors. Even with a contract with the GPO, market access is hindered, potentially foreclosing sales for Manufacturer B while further entrenching Manufacturer A's market dominance.[3]

Clearly, establishing a multi-source contract without end-user access would nullify the intent of the Code of Conduct. How does the Code of Conduct prevent the above scenario from occurring? What specific aspects of the code would apply? Code of Conduct Section C.1.a. seems to address this issue by appearing to stipulate that "each GPO shall implement its policies and contracts in a manner that permits its Members to...assess Products or Services provided by a Vendor that does not have a contract with the GPO." This section appears to, at a minimum, promote the concept of vendor access to members/customers. Obviously, it would be extremely difficult to assess or evaluate a new product if a vendor could not access the hospital end-user. The Code ostensibly allows an open door to the hospital; however, the Code does not ensure that the member hospital has unencumbered purchasing options.

The health care supply chain is rarely as simple as the Code of Conduct would suggest. If a GPO permits a large dominant supplier that produces significant fee revenue for the GPO to utilize compliance tactics, commonly referred to as "contract compliance policing," a given hospital member may be threatened with financial penalties if it purchases rival products. As a result, even though the Code allows for product evaluations, the Code does not ensure the hospital member could actually purchase a competitive product without penalties. The GPO could then claim compliance to the Code while looking the other way and providing tacit approval to a large, contracted supplier with intentions of hindering competitors. Choice of product purchases is illusory if exercising those choices results in financial penalties to the hospital member.

One of the potential and problematic loopholes in the section on access is the manner in which the term "member" is defined. In the Code of Conduct, a member is defined as "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." The term "member" is still ambiguous as it seems to refer only to the provider as an entity and not to individuals within the provider's organization who may have certain and specific expertise, including clinical judgment. This is important because the Director of Materials Management, or even the CEO of the hospital may not possess the necessary expertise to effectively make a clinical determination of the fitness of any product for use in the hospital. Consequently, if that person officially represents the hospital in the GPO relationship, access to end-users may be predicated on the policies of

[2] The recommitment document utilized by this GPO required only one representative of the member to sign and execute the agreement.

[3] According to interviews with GPO members, some contract commitment forms are actually binding bilateral agreements. These bilateral agreements can be enforced by the manufacturer(s) even if the member leaves one GPO to join another. In preparing to leave its GPO, one member interviewed spent over 6 months negotiating out of its bilateral agreements in order to avoid termination penalties.

purchasing departments and executive suites. Therefore, to protect the interests of patients and caregivers, the definition of a GPO member should be expanded to include clinicians of the hospital who may be the only staff members capable of determining if a product is fit for use.[4]

The other aspect of access that is problematic is the use of the term "innovative." Section C.2 of the Code of Conduct seems to commit GPOs, "to engaging in programs that routinely evaluate and provide opportunities to contract for innovative Clinical Products or Services." Yet, the term "innovative" is not defined,[5] thus freeing each GPO to determine the criteria defining medical innovation, which in turn yields tremendous impact on market acceptance of any new medical technology or device in the United States. The critical decision as to what constitutes medical innovation should rest with physicians and clinicians, not with GPOs. For a GPO to act as an arbiter of medical innovation is improper due to the potential impact on patient care. Physicians and clinicians are trained and licensed to practice medicine; GPOs do not hold a license to practice medicine and should not be authorized to accept or reject medical innovation. For that reason, the Code of Conduct fails to effectively protect the right of hospital physicians and caregivers to determine which products and devices will be used in the delivery of patient care.

The reality is that while the HIGPA Code of Conduct attempts, albeit weakly, to address market access, it does nothing to actively support, ensure, and foster such access. For that reason, it is clear that the Code does not effectively remedy market-access complaints raised by small manufacturers. Furthermore, a review of the various Codes of Conduct adopted by AmeriNet, Consorta, MedAssets, Novation, and Premier produced the same disappointing results. In fact, none of the Codes of Conduct protect the essential right of unfettered hospital access by small manufacturers that are engaged in contracts with the GPO on a multi-source basis. Unfortunately, the ability of caregiver members to meet ethical responsibilities to patients and the community in identifying and utilizing the best and most cost-effective products may be severely compromised by the business practices of large manufacturers with market power that are condoned or permitted by GPOs.

Scenario Two: Equivalent Product, Better Price

Small manufacturers have another complaint: When offering a product that is equivalent or even superior to that of a larger competitor and at a lower price, smaller manufacturers are often unsuccessful in securing a GPO contract. Clearly, one practice that can have an effect on contract-award decisions is bundling, which can occur on two different levels.

[4] Moreover, as long as the Code continues to allow contracted vendors to thwart competition by offering coercive financial incentives in exchange for exclusive purchasing commitments, offering clarity on the definition of a member will not remedy market access issues.

[5] The term "clinical" is also not clearly defined; each GPO can determine its classification for clinical, clinical preference, or physician preference products.

The first level is the corporate bundle also known as a corporate compliance program. A GPO, such as Novation, will bundle unlike products from multiple vendors, offering hospitals reaching a high level of program compliance the opportunity to earn additional discounts, additional rebates, and other incentives.[6] While the corporate bundle ostensibly offers the potential to lower total costs for the hospital, it stipulates that if the hospital is presented with a comparable product by a competitor at a lower price, it will forego special program discounts and other incentives offered through the corporate bundle.[7]

Small manufacturers are less likely to be included in the corporate bundle because their product lines are narrower in breadth than those of the larger multi-line suppliers who are often able to secure two or more of the corporate bundle product lines. Novation's Opportunity/Spectrum Program is the most well known of the GPO corporate bundles. This corporate bundle closes the door to smaller manufacturers, which by virtue of their more limited product diversity, can be summarily dismissed from contention for the GPO contract. In effect, a conflict of interest is created between seeking the best price on any given product versus seeking the lowest total cost across a spectrum of product lines and suppliers. Moreover, this type of bundling practice severely alters the competitive landscape. No longer are rivals competing head-to-head on product merits and competitive pricing. Instead, rivals are competing in disparate product markets and, therefore, operate with insufficient market information. Even if a potential rival could afford to offer equivalent discounts derived from participating in a corporate bundle, it could only do so on a retrospective basis. It would not be possible for the GPO to give a potential vendor accurate future member purchases in a given product market.

Large manufacturers engage in a second type of bundling, both directly with the GPO and with individual hospital members. Unlike Novation's corporate bundle that includes multiple vendors with unlike products, single-vendor bundling offers additional discounts and financial remuneration in exchange for the hospital's commitment to purchase 90% or more of all products included in the bundle, even unrelated products. This bundling can occur either with or without the knowledge and tacit approval of the GPO. Tacit approval of the GPO could be as simple as a clause in a GPO contract that places artificial limitations on the circumstances in which a hospital could direct some of its purchases to a small supplier that is not on contract with the GPO.

An effective Code of Conduct would indisputably ensure that smaller manufacturers would have an equal opportunity to have their lower prices given fair consideration, which would also promote vigorous competition. The Code of Conduct fails to address an issue that clearly remains: As part of the contract negotiation process, large suppliers may still offer the GPO more in fees than smaller suppliers competing for a contract or

[6] It is important to note that these financial incentives are paid by the Opportunity/Spectrum contracted vendors, not Novation.

[7] Past versions of Novation's Opportunity Program Participation agreement prohibited participating member hospitals from engaging in efforts to evaluate products offered by non-contracted suppliers in an effort to ensure contracted vendors did not incur "negative selling costs."

for market share in a dual or multi-source contract. In this case, the GPO's conflict lies in its decision to accept special financial incentives of one supplier as a quid pro quo designed to thwart competition. Revenue generated from supplier fees directly supports the GPO's self interests.

While ethics is an important component of any Code of Conduct, the GPO Code of Conduct fails to account for the conflicts of interest that exist as a direct result of the GPO's ability to collect fees from suppliers. When small manufacturers offer the same products as large suppliers, but at a lower price, GPOs defend their exclusion of the small suppliers by relying on complex, but unproven, total cost savings arguments.[8] Yet, GPOs cannot escape the obvious conclusion that lower prices will result in lower fee revenue (for the GPO).[9] By choosing to exclude smaller manufacturers and their lower prices, GPOs protect a substantial portion of their annual revenue stream from erosion. Such decisions clearly demonstrate that GPOs will place their own needs above their members' needs whom they purport to represent. The Code of Conduct allows for tacit approval of this obvious conflict of interest.

Scenario Three: Superior Product

To someone unfamiliar with the complexities of the health care supply chain, it might seem superfluous to even discuss scenarios in which superior products are not always selected. Given a choice, most caregivers and patients would almost always choose the superior product; however, GPOs often do not seem to follow that logic. An open and competitive market creates the promise that any entrepreneur with a superior product will be able to get his product into the hands of those who need it most: the caregivers and patients. This is not the case where GPO product committees, comprised of a few dozen hand-picked people, are believed to effectively represent the clinical judgment and professional expertise of thousands of hospitals, tens of thousands of physicians and hundreds of thousands of nurses and other caregivers. These product committees often operate under the watchful eye of GPO executives, who have enormous power to determine the products and services their hospital members will be able to access.[10]

Little is known about the inner workings of these committees, how they make their decisions, the influence GPO management has with contracting opportunities, or information the committees' members are given that lead to contracting recommendations. These GPO product committees represent a powerful yet dangerous way to exclude small manufacturers who offer superior products. Unfortunately, product committee decision criteria, actions, and conflicts of interest are not addressed by the Code of Conduct. Contract recommendations of the product review committees are often

[8] For example, Novation uses a convoluted "Lowest Best Bid" measurement process.
[9] Even in situations where a GPO secures lower pricing through a bundled arrangement with a vendor in exchange for a sole source agreement, when those bundled arrangements are designed to lessen competition, consumer harm can potentially occur.
[10] *KCI v Hillenbrand Industries* 2002 trial testimony of Mr. Lynn Detlor, a former Premier executive

subject to the GPO oversight committee. In the case of Premier Purchasing Partners in 1996, the oversight committee comprised of executive employees had the power to ultimately approve or override the contracting recommendations made by the committee of representatives of Premier's members.

Executives who make up the oversight committee are often management generalists lacking clinical knowledge or training in specific medical practice areas. They often do not possess a detailed understanding of the products involved; moreover, these executives also may lack an understanding of sound purchasing practices and the economic and practical nuances as well as the legal ramifications of contracting practices such as bundling. The ability to overturn product evaluations and contracting recommendations of product review committees still exists. GPO senior managers can, and have, made contract awards that were not recommended by representatives of the GPO membership.[11]

The "superior product" scenario is very similar to the "equivalent product, better price" scenario: these tactics prevent small manufacturers from gaining acceptance for superior products in their respective relevant product markets.

Scenario Four: Superior Product, but Only a Clinician would Know

GPO contracting practices, coupled with certain business practices of dominant manufacturers with market power, has resulted in limiting physicians' and caregivers' choices in selecting products and technology that impact clinical outcomes and safety for patients and themselves.[12] Physicians must ultimately decide which products they believe work best for their patients and are fully accountable to their patients for the decisions they make, including the selection of appropriate medical devices. Physicians are routinely litigated against for their actions. One of the largest costs for a practicing physician is medical malpractice insurance. When GPO contracting practices and business practices of dominant manufacturers are designed to lessen competition and result in preventing a physician from choosing products that provide the best clinical outcomes, patient care suffers while physician liabilities increase.

GPOs acting in a concerted effort with contracted manufacturers possessing market power can also negatively impact nurses and other clinical caregivers. A single needle stick with an HIV-infected needle can end a caregiver's livelihood and their very life, as well as create hundreds of thousands of dollars in costs and additional expenses to a

[11] *KCI v Hillenbrand Industries*—2002 trial testimony of Mr. Lynn Detlor, a former Premier executive

[12] Moreover, caregivers do not have unfettered access to safety devices that protect themselves from injury and infectious diseases. For example, reference Occupational Safety and Health Administration (OSHA) complaints filed against Montefiore Medical Center and Yale-New Haven Medical Center. In September of 2004, Montefiore Medical Center in New York City became the first facility cited by the U.S. Occupational Safety and Health Administration (OSHA) for violations of the 2001 Needlestick Safety and Prevention Act, for purchasing the "safety" needles approved by its GPO contracts. http://www.nappsi.org/news.php?type=RL.

hospital and insurance company. Hospitals should have an unfettered choice of product purchases without the unnecessary bottlenecks created through GPO product review processes, innovative technology assessment processes, or the unwanted, and often unwarranted, bundling schemes of dominant manufacturers. More than likely, they would purchase the safest products on the market in order to protect caregivers and patients, as well as the hospital's financial interests. Would the currently adopted Code of Conduct prevent undue influences that may coerce hospital executives or purchasing managers to choose cost savings over the safety of the hospital's caregivers and patients? Does the currently adopted Code protect the professional clinical interests of physicians in their efforts to make the best possible decisions for their patients?

The Code of Conduct does not address the various types of bundling schemes prevalent in GPO purchasing, a finding that is problematic on its own. Additionally, the Code does not address issues surrounding the processes of Product Review Committees (PRC). The Code should ensure a true separation of powers within the GPO structure that would ensure that PRCs are acting in the best interests of patients and caregivers and are not simply serving as a rubber stamp for contracting decisions desired by the GPO. The role of the PRC should be to identify products that are clinically unacceptable so as to exclude them from the bid process. Ideally, the work of the PRC will result in substantially far more acceptable products than unacceptable ones. This outcome would stimulate competition by providing legitimate bid opportunities to a larger number of suppliers. PRCs should not be involved in contract recommendations; the objective of the committee should be simply to protect the membership from being forced to use unsafe or ineffective products. This would ensure fair facilitation of the bidding and contracting process, while stimulating competition and driving down pricing. No GPO should be permitted to contract for products that are not safe or have been determined inferior by physicians and caregivers.

Scenario Five: Potential Anti-competitive Actions of Dominant Suppliers

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Numerous aspects of GPOs' operations are regulated by federal statute and regulations. Whereas anti-kickback provisions exist under the Social Security Act, the Act also contains an exception for fees paid by contracted vendors of goods and services to a GPO acting as a purchasing agent for its members. In 1991, the Department of Health and Human Services established a series of regulations setting forth various proposed business and payment practices, or "safe harbors" that would not be treated as criminal offenses under the Act.

One of the concerns of small manufacturers is the potential for anti-competitive actions on the part of dominant suppliers. Over the past fifteen years since the Safe Harbor was enacted, fees paid to GPOs by contracted suppliers have become increasingly important to the financial well being of GPOs. Suppliers with broader product lines have more ability to create complicated sales offerings through the use of bundling and other tactics. Each new tier of savings and/or fee opportunity presented to the GPO increases the

likelihood that the GPO will take the easy money and slowly squeeze out the smaller manufacturers that cannot offer the same financial incentives. Moreover, some manufacturers have refused to engage in certain GPO business transactions they believe to be unethical or illegal. As each successive contract award further weakens the smaller manufacturers, the large, multi-line manufacturers increase their dominance and market power. Even if there are two or three dominant suppliers in each broad product category, robust competition is not guaranteed. One of the significant advantages in having a strong supply of small manufacturers is the role they play in applying constant pressure to dominant suppliers, forcing them to compete and innovate. The coercive effect of financial remuneration from large manufacturers greatly compromises the agency role of GPOs in maintaining a fair and highly competitive market place.

For better or worse, the actions of Congress, the Federal Trade Commission, and the Department of Justice, and the trust placed in them by their own members, have "anointed" GPOs as the primary gatekeepers of the health care supply chain and of the financial integrity of an economy that dwarfs that of many Third World nations. At the same time, dominant manufacturers in this industry are, by and large, publicly traded companies whose stock performance could greatly benefit from legal business transactions designed to weaken competition and boost market power. Does the currently adopted GPO Code of Conduct provide any protections that would prevent dominant suppliers from using GPOs, with or without the GPO's consent or active participation, to further their own anti-competitive agendas?

Interestingly, in I.B.3.a, the Code of Conduct prohibits GPOs from having 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." Generally, an equity holder or shareholder of a company is entitled to dividends paid out when the company's profits increase and a dividend is declared. Ironically, the structure of supplier fees paid to GPOs presents a similar scenario. When GPOs successfully drive contract compliance, manufacturer profits increase and GPOs essentially receive dividends through member purchases, effectively becoming business partners with the manufacturers. When a contracted supplier increases pricing to the membership, either through a built-in escalator clause or through an increase in a list price that drives percentage discount pricing, revenue generation to the GPO also increases. Consequently, while the members will be forced to cope with higher prices, the GPOs are rewarded for allowing the net prices to increase. The Code of Conduct fails to address conflicts of interest that improve the financial position of GPOs while harming downstream buyers: hospital members.

Other than the aforementioned section on Corporate Equity Interests, the GPO Code of Conduct provides no protections that might prevent anti-competitive activities of dominant manufacturers. Furthermore, the Code does not even suggest that such activity be reported to any investigative or enforcement entity inside or outside the federal government. The Code does not protect the interests of all parties: hospitals and other

care sites, physicians, caregivers, patients, payors of care, medical technology innovation, and competition.

The Code of Conduct and "The Money Trail"

Most business deals hinge on money: where it comes from, where it goes, and who gets more. One cannot discuss Group Purchasing in health care without taking this into account. The Safe Harbor was granted in the belief that GPOs would provide a service that would directly impact a hospital's bottom line. Placing large sums of money under the control of a few powerful entities with no formal oversight invites greed and leads to harm.

The Safe Harbor was allegedly created to help hospitals create purchasing efficiencies and to lower costs of health care products and services by aggregating purchasing volume. Fifteen years after the Safe Harbor was granted, hospitals are still struggling to remain financially sound. If valid GPO accounting audits are not completed and disclosed on a regular basis, it will remain unclear what percentage of fees and other financial remuneration paid to GPOs by contracted suppliers is dispersed to member hospitals. If GPOs continue to negotiate pricing based on discounts from list price instead of true manufacturing and distributing costs, prices of health care products and services will continue to climb because the GPO system will allow it.

The Safe Harbor can only achieve its goal when the Code of Conduct is amended to address not only the business transactions of GPOs, but also the business transactions of contracted vendors. A Code of Conduct for Health Care Manufacturers should also be created and enforced. The following recommendations addresses changes to the current GPO Code of Conduct and are offered for consideration:

1. Limit all financial payments from contracted suppliers to the GPO (including parent corporations, holding companies, and its members) to a total of three percent of supplier contract purchases. Any additional side payments would be considered an illegal kickback.
2. Limit the use of supplier fees to only those activities that are directly related to supply contracting within the confines of a strict budget. All monies collected above and beyond that required to meet budgetary needs should be returned to the hospital members regardless of their membership status (member or shareholder) and irrespective of contract compliance that produced the fees. It makes no sense for a GPO to be using financial resources derived from supplier payments for non-contracting services while its member hospitals are struggling to survive.
3. GPO shareholders should only be able to receive financial payments from contracted vendors or the GPO that can be directly correlated to the shareholders purchasing activity.

4. All supplier payments not addressed by budgetary considerations should be returned to hospitals as a cash payment or in the form of financial credits clearly reflected on invoices from manufacturers and directly corresponding to product purchases, not compliance payments or incentives for exclusive purchasing arrangements.
5. Each GPO should return a minimum of seventy percent of its total revenue generated from contracted suppliers back to its hospital members.[13]
6. Commitment/compliance programs and bundling should be prohibited. Best pricing would be derived from volume purchasing.
7. All GPOs would undergo mandatory annual antitrust audits of business and contracting practices.[14]

The changes recommended above would provide meaningful business conduct guidelines for the Office of the Inspector General to enforce. Combining enforcement with severe penalties would ensure/protect competition and the interests of patients and taxpayers.

Conclusion

If the goal of the Code of Conduct is to ensure competition in the health care supply chain, the scenarios presented in this paper offer compelling arguments that the current Code falls seriously short of its goal. The GPO Code of Conduct as it now stands is merely a mission statement that cannot be defined, measured, or enforced. Most importantly, the Code fails to protect patients, caregivers, competition and medical innovation and fails to do justice to the tireless efforts of Senators DeWine and Kohl.

[13] Consorta returned 73 cents of every revenue dollar to its members in 2003. See Consorta Press Release dated 12/08/03, "Consorta Distributes 73 Cents of Every Revenue Dollar to Shareholders – Cash Returns Grow 258% in Five Years

[14] August 18, 2004 ABA Sherman Act Section One Committee Questionnaire for FTC Commissioner Pamela Jones Harbour: Question – With respect to violations of Sherman Section One, what do you believe to be the most important way businesses can minimize their risk? Answer – "In my experience, both as a prosecutor and as a counselor, most businesses encounter Section One problems when they fail to draw the appropriate lines between the legitimate needs of their businesses and their aspirations for business success. Not surprisingly, a lack of clear business planning is often accompanied by – if not the product of – an ineffective or nonexistent antitrust compliance program."
Sherman Section One – Trusts, etc., in restraint of trade: Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.

Testimony of Joe E. Kiani
Founder & CEO of Masimo Corp.

Before the Antitrust, Business Rights and Competition
Subcommittee of the US Senate Judiciary Committee

September 14, 2004

Chairman DeWine, Ranking Member Kohl and Committee Members, thank you for inviting me to speak here today as the CEO of a medical technology company, Masimo and as a Board Member of the Medical Device Manufacturers Association. As a Board Member, I have also been asked to speak on behalf of the hundreds of medical technology companies who continue to face barriers in accessing the hospital marketplace.

Two years ago, I testified before this Committee about the anticompetitive practices of certain GPOs and their collusion with the incumbent dominant suppliers. These practices included the bundling of unrelated products, the enforcement of long -term sole-source contracts, the payment of excessive fees from the dominant suppliers and other clear conflicts of interest.

After the hearing, I had the opportunity to meet with Senator Kohl, and during that discussion, Senator Kohl asked me, "what do you think, do we need legislation? I replied, "Hopefully not. Let's see how the code of conduct works." Well it's been over two years since then, and I can tell you that for the most part, it hasn't worked and in the absence of oversight, it will get worse. As a result, I believe that oversight is required if patients and caregivers are to have access to the innovative medical technologies they deserve.

Although progress has been made in some areas--due largely to the persistent efforts of this Committee--both the industry code of conduct and the individual GPO codes do not adequately address many of the anticompetitive contracting practices that have denied patients and caregivers access to innovative technology and have increased the cost of health care. In addition, some of the codes have not been implemented in a timely, honest and effective manner. Finally, hospitals, and the federal government in its role as a primary funder of health care services, are continuing to pay more than they should for effective health care products and medical devices, because of these types of anticompetitive practices.

Without passage of the legislation, which would provide the authority and oversight for permanent, comprehensive and verifiable reforms to ensure competition and access to most effective health care, not only will the situation not improve, but the GPOs will likely revert back to their old ways once the Senate spotlight has faded. Unfortunately, patients, medical innovations and providers of health care will then be the victims.

As you may recall, my company, Masimo Corporation, has developed the first read-through motion and low perfusion pulse oximetry, often described in the industry as Next Generation pulse oximetry. A pulse oximeter is the non-invasive monitor used to measure oxygen in the blood. This is important because if your blood oxygen level drops below normal, within three minutes brain damage can occur and within five minutes you can die. With babies there is the additional problem of too much oxygen in the blood. If this occurs, the baby can get serious eye damage, and go blind. Approximately 12% of the babies in the Neonatal Intensive Care Units are affected by this each year. Before the advent of our technology, pulse oximeters gave false alarms nine out of ten times and did not work in the most critical times.

Our technology has been clinically proven to be much more accurate and reliable than the previous generation, which many clinicians have concluded should lead to improved patient care. In fact, since I last testified, a landmark study was published on data collected over five years at Cedars Sinai Hospital in Los Angeles. That study concluded that a neonatal eye disease, called ROP, could be virtually eliminated through the use of a new oxygen management protocol utilizing our technology. (Exhibit 1) So, at the very least, you should know that your efforts and the past hearings you have held, probably saved the eyesight of countless premature babies.

Another important study was published by researchers from the University of Virginia that examined the impact of our improved performance on caregiver effectiveness. That study concluded that the use of Masimo SET improved caregiver effectiveness, resulting in positive impacts on caregivers and patient outcomes. The researchers suggested that these improvements could lead to reduced medical errors. (Exhibit 1)

You may remember that at the time of the first hearing, Masimo had been denied contracts from most of the nation's GPOs, including the two largest, Novation and Premier. This was in spite of the fact that there had been over 50 clinical studies by independent researchers around the world that proved that Masimo's technology was indeed superior -- by improving care and reducing costs. It was determined, by Premier's technology assessment group, that Masimo Set could be considered a "Breakthrough" and put on contract. Yet, we were not awarded a contract at that time.

Thanks to this Committee and its efforts, Premier reviewed our technology a second time and ultimately changed the contract from a sole-source to a multi source contract and eliminated their bundling contract with Tyco; thereby including Masimo. Since then, we have been making progress in selling to Premier hospitals, offering their members better technology at a lower cost than the incumbent supplier, Tyco-Nellcor. We have seen our annual sales to Premier members increase more than tenfold, with 39 Premier hospitals converting hospital wide to our pulse oximeters. As you may recall, prior to your intervention, I testified at the 2002 Senate Hearing, that not even one Premier hospital had converted to Masimo SET hospital-wide, despite the fact that many Premier member hospitals had shown great interest in acquiring our pulse oximetry technology and had purchased up to their 10% limit, decreed by the GPOs and Tyco. Although Premier has

made some changes for the better, we have heard that Premier is considering reverting back to sole source contracting practices.

With Novation, the market leader, things have not been as positive since your hearings and the voluntary codes of conduct. Although Novation claimed to be nothing more than agents for the hospitals, their actions indicate they are generally agents for the dominant suppliers. First, it was not until the eve of this Committee's second hearing that Novation opened up it's sole-source contract and awarded us a contract for pulse oximeters. Novation even argued that pulse oximetry was not a "clinical preference" item, contrary to all of the literature, and the fact that pulse oximeters have to be prescribed by doctors. But thanks to your second hearing, Novation changed its mind and put us on contract. And although Novation claimed at that time that they were going to be a "neutral middleman" and their members were free to choose either product, Novation continued to actively promote the dominant supplier's product over ours and attempted to lock in their member hospitals to Tyco pulse oximetry immediately before Tyco's key pulse oximetry sensor patents were to expire.

I would like to show you an excerpt from a letter that was sent out by Novation in the third quarter of 2003, right around the same time that Masimo was awarded a contract and we were told that we would be competing on a level playing field. As you can see, it asks their member hospitals to re-commit to buying Tyco's pulse oximeters and participate in the bundle. (Figure 1)

I was shocked when I saw this. It clearly contradicts what Novation has said about being neutral and being agents for hospitals. You may be interested to know that Novation refused to discontinue their bundling program, as Premier did. Instead, Novation agreed, at our insistence, to let hospitals opt out of the pulse oximetry piece, if hospitals wanted to buy Masimo instead of Tyco's pulse oximeters. We thought this meant that the hospital would be allowed to buy Masimo pulse oximetry without losing their bundling rebates on the other 11 products in the Novation bundle program. So when we saw this notice to the hospitals from Novation, we realized how disingenuous Novation was to us, to their member hospitals and their own code of conduct. At the same time that Novation was insisting on its neutrality, they sent a letter asking for their members to recommit to include Tyco pulse oximetry in the bundle. This behavior is duplicitous and not in the best interest of hospitals or, health care and is a clear example why the codes of conduct are not sufficient to reform the GPO industry.

What is even more troubling about Novation's actions was that they were pushing a product that would cost their member hospitals more than they would otherwise have to pay. As I explained earlier, a key patent was set to expire on Tyco's sensors soon after Novation sent out this re-commitment letter. In fact, the deadline imposed by Novation in the letter to recommit, October 31, 2003, was only a couple of weeks before Tyco's patent expiration in November of 2003. (Figure 2) I am sure everyone, let alone this committee, can appreciate what generic products can do to reduce costs for patients and hospitals. Many companies were waiting in the wings ready to provide a generic sensor

at a great savings, but this letter thwarted generic sensor sales in Novation hospitals. I hope this letter can be made a part of the record here today. (Exhibit 2)

As this example indicates, GPOs have often acted as an agent to the suppliers, rather than their member hospitals. Otherwise, why would they favor a more costly product for their member hospitals? The only logical conclusion is because it generates more revenues for the GPOs, since their earnings are largely based on a percentage of a product's total contract price. This type of conduct by Novation, the nation's largest GPO, is very troubling – especially in this era of rising health care costs.

The GPOs have stated that forcing them to abandon their sole source contracts and bundling programs would end up in higher prices being charged to their members. Our experience has proven the opposite. We have converted over 100 hospitals, both large urban hospitals and small rural hospitals, from Tyco to Masimo and have provided those hospitals substantial savings over what they were previously paying under the sole source contract pricing. We would be happy to provide to the Committee a confidential list of those hospitals.

While Premier and Novation have been the primary focus of this Committee's attention, it is important that reforms are applied uniformly. Several of the GPOs have submitted codes of conduct to this Committee, but some of them have taken advantage of the fact that they are lower profile. One example of that is MedAssets, now the third largest GPO. In fact, MedAssets CEO often cites that his company had been the biggest beneficiary of the NY Times articles and the Senate Investigations since many of the members of Premier and Novation who did not want to be associated with Premier and Novation any longer had moved their business to MedAssets. MedAssets claims to now represent $10 Billion of US hospital products purchases. In contrast, prior to the first Senate Hearing, NY Times published that Novation and Premier represented $19 Billion and $14 Billion of the hospital purchases, respectively. MedAssets is no longer a small GPO.

MedAssets awarded Masimo a multi source contract just before last year's hearing and we were told that we had an equal opportunity to compete. Earlier this year, we started getting reports from our sales people that certain MedAssets accounts couldn't afford to purchase and wouldn't even evaluate our products due to rebates that they would lose in the Select Program. Select is a program structured very similarly to Novation's Opportunity Program in that it ties rebates based on the purchase of a bundle of unrelated products from different suppliers—and to receive the rebates, a hospital must purchase at least 90% of the products in every product category of the program. (Exhibit 3)

Currently Tyco has multiple products in the "Select Program", including pulse oximetry. Therefore, if a member hospital were to purchase only 89% of their pulse oximetry products from Tyco and 11% from Masimo, the member would lose all of their rebates, not only on pulse oximetry products, but on all other Tyco products and on all products from all other manufacturers they purchase through the "Select Program". This lost

rebate can easily be worth more than the member's entire purchases of pulse oximetry products.

MedAssets' code of conduct, which was introduced in February of last year specifically stated that they would not bundle clinical preference products with any other unrelated products. The Select bundling program is a direct violation of that code of conduct.

When I confronted the CEO of MedAssets with the Select program, instead of him saying he planned to discontinue it, we were invited to take part in it. After reviewing the program and seeing that it indeed was what we thought it was; it bundled clinical preference products even more onerously than the Novation Bundle program, we refused to bid. We sent a no-bid with an explanation to why we refused to bid. MedAssets response was the usual "our members want it, it's voluntary, …", and something new: that the staff of this Committee had blessed it, which I seriously doubt.

On their web site, we noticed that MedAssets had modified its code of conduct in October 2003 and no longer stated that they would not bundle. In fact, their current code is silent on most practices questioned by this Committee. What is happening at MedAssets is a great example of why there needs to be lasting reforms which are equally applied. MedAssets could become the biggest GPO in less than 3 years from the date that Premier & Novation were asked to come up with codes of conduct that would eliminate their anti-competitive practices, such as bundling and sole source contracting. Yet, MedAssets, not being under the microscope never stopped their bundling program which they promised they would do in February 2003 and now over a year later feel that they can unilaterally modify their code of conduct. (Exhibit 3A)

Absent the establishment of ongoing oversight, we are very concerned about what will happen when this Committee focuses on other pressing issues. Unfortunately, the problems that Masimo has been experiencing are not very different from what hundreds of other companies are going through. I understand that the Medical Device Manufacturers Association (MDMA) provided the Committee with nearly 20 key examples, affecting thousands of contracts, of the sorts of problems that, unfortunately, have not been corrected by the codes of conduct. These still include examples of the bundling of products from unrelated companies, the bundling of unrelated products, sole-source agreements, the charging of excessive fees, high commitment level contracts and requiring vendors to participate in outside business ventures. Unfortunately, companies like Applied Medical, Retractable Technologies, Nova Biomedical, Rochester Medical, Adroit Medical, Pevco and many others are still facing serious barriers to the marketplace. Like Masimo, some of these companies have been granted "token" contracts by some of the GPOs or no contract at all. These are situations similar to what I have described above with Novation and MedAssets where we were put on contract while at the same time the GPO favors and promotes the incumbent dominant vendor's products through promotions and active bundling programs. I would characterize the majority of our GPO contracts in this way.

Additional manufacturers and healthcare workers are extremely concerned about the anticompetitive practices of certain GPOs and are calling for reform, but need to do so anonymously because of a real fear of retribution. If there is any doubt, let me quote from an email sent to me by Jim Fitzgerald, the CEO of HealthTrust, one of the leading GPOs. HealthTrust had put us on contract prior to this Committee's initial hearing, but Mr. Fitzgerald was not happy that we chose to speak out and push for GPO reforms, and specifically legislation proposed in California to deal with these same issues. In his email he said, "As our President says, you are either with us or against us in our fight against terrorism. You decide what side of the fight you are on. I will know by your support of this legislation." (Figure 3/ Exhibit 4)

After our testimony, the HealthTrust management along with Tyco were reportedly active in derailing any hospital negotiations Masimo was involved in with their members. And, shortly after this email, we were informed that our contract, which had been a "token" contract, would not be renewed. HealthTrust now has a sole source contract with Tyco for pulse oximeters. In addition to this example, we have heard numerous comments through friends in the industry that GPO representatives are saying that Masimo "upset a lot of people" and that Masimo, along with other smaller vendors, were added to their contracts only because of the oversight activities of this Committee. They are also pledging to move back towards sole-source contracts once the Senate light is off of them.

I am not one to trumpet more legislation over less, but the situation here is different. The problems that we are talking about today were caused by the legislation that gave GPOs safe harbors from the anti-kickback statutes. The dominant vendors found that exclusionary GPO contracts could be a very powerful arsenal in their monopolistic quests. The dominant vendors could control the GPOs by offering large payments in exchange for exclusivity. Not only do the GPOs help the largest vendors keep competition out, by not awarding contracts to competitors and building multi-level bundling roadblocks, but the GPOs even waste millions of dollars of what might be taxpayer's money each year actively promoting those dominant vendors' products through GPO salesmen. There really is a fatal flaw in the current system that can only be fixed with legislation and permanent oversight.

Medical technology and biotechnology companies are regulated by the FDA to help ensure that the quality and efficacy of medical products meet established standards. Because of their unique advantage granted through their exemptions to the anti-kickback statutes, GPOs have become the gatekeepers of which products get purchased and which companies ultimately survive. It seems entirely inconsistent to grant any group this kind of power and potential impact on public health without any persistent oversight to ensure that the public is being served and not harmed by the power granted to them.

Despite what you may hear from others in the industry, the only parties worse off from this legislation will be the large vendors who have been benefiting from their purchased exclusivity and the GPO executives, some who have personally benefited millions from their powerful positions as gatekeepers. Certainly, hospitals and their patients will be better off because real competition will be restored to the marketplace, which will result

in lower prices and better products. The GPOs as a whole will be better off because they will no longer be subject to the pressure exerted by the largest vendors who threaten to take their fees away if they don't get the exclusionary contracts they want. At last year's hearing, Premier's CEO, Richard Norling, stated that many of the controversial practices were at the insistence of the vendors. He seemed to be asking for your help. This legislation would give the GPOs more leverage with the vendors because they would be prohibited from granting such contracts.

For the wellbeing of patients, clinicians, and innovation, please do not take your oversight away from this issue without enacting this legislation. Without your leadership and oversight, I am certain no progress would have been made over the past few years, even for Masimo. However, I hope that you will agree that the examples I have provided indicate that problems still exist in the health care field regarding the GPOs, and therefore, further action is needed. The draft legislation is needed to allow the hundreds of innovative companies -- that have not had the opportunity to testify before the US Senate – to compete fairly in the health care arena. I firmly believe, that, but for the oversight by this committee together with my company's vigorous efforts to provide a better product at a better price, many patients would still not have access to Masimo's breakthrough, cost-effective pulse oximeters.

This legislation would provide the opportunity for additional oversight to ensure that clinicians have access to the best technology and that EVERY company making effective products, competitively priced, is given a chance to compete and sell to hospitals through a GPO, not just the dominant suppliers or those who testify before a Senate Committee.

I urge you to enact this discussion legislation, which will provide the necessary framework for steady oversight of the GPO marketplace. This legislation will benefit people across America. Again, I want to thank everyone on this Committee for all your efforts to infuse competition back into the hospital marketplace.

Statement
United States Senate Committee on the Judiciary
Hospital Group Purchasing: How to Maintain Innovation and Cost Savings
September 14, 2004

The Honorable Herb Kohl
United States Senator , Wisconsin

Mr. Chairman, thank you for your continued efforts on this important issue and for holding this hearing today. The subject matter of this hearing centers on perhaps the most important work of our Subcommittee in the last few years -- ensuring that physicians, patients, and health care workers have access the best and safest medical devices, devices that can literally make the difference between life and death. With the cooperation of the industry, we have accomplished much over the past two years to reform the hospital purchasing system to make it better serve the interests of competition, of innovation, and patients. The changes we have seen are real. We should all be proud that more patients are getting access to the best medical devices more often. We must now find a way to ensure that these gains are maintained.

A review of the reforms shows how far we have come. Most significantly, six of the largest hospital buying groups, known as GPOs, agreed to fundamental reform by adopting codes of conduct governing their business activities and ethical responsibilities. These codes forbid anti-competitive business practices, and ban conflicts of interest that interfere with the GPOs' mission of buying the best products at the lowest prices.

We commend the GPOs that worked cooperatively with us in this process. The actions of Premier and the other GPOs that followed its lead especially deserve praise. Premier acted first to clearly and unequivocally ban each of the most troublesome practices. Many of its competitors followed suit, and the marketplace began to open.

We are pleased that we have made a real difference, but we also realize that two primary tasks remain. First, how can we be certain that these considerable gains will remain when the spotlight of a Senate hearing room fades away? The GPO codes of conduct are entirely voluntary and, at present, not backed with any sanctions or enforcement mechanisms. We

need to be sure that these reforms will not be reversed. Second, how can the industry continue to improve in those areas that still need work?

To answer these questions, we have drafted a legislative proposal which will assure that our reforms are truly permanent. This draft was only prepared after extensive discussions with the GPO industry over the last eight weeks, discussions at which we repeatedly solicited their suggestions. Our draft legislation gives the Department of Health and Human Services the authority to forbid GPO business practices which are anticompetitive or are unethical. The purpose of this legislation is simply to create a regulatory framework so that improper business practices never return to this important industry. However, our proposal remains just that, a proposal – we are anxious to hear the suggestions and views of today's panel regarding our ideas.

We are also happy to consider any non-legislative proposal that the GPO industry or others may suggest with an open mind. However, it is essential that any such measure have teeth. In other words, any industry plan must include real and meaningful sanctions if any GPO violates ethical principles or the rules of free competition. In an industry as important to health and safety as the purchasing of medical equipment for critically ill patients, half-measures which do not assure that the best medical devices are available for patients are simply not acceptable.

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

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

September 14, 2004

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 and cost savings in the hospital marketplace.

MDMA is a national trade association representing the innovative and entrepreneurial sector of the medical device industry. Over 200 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

This is the third time that MDMA has submitted testimony for the record and we continue to emphasize the importance of greater oversight for the GPO industry. Without consistent, permanent and enforceable reforms in place, patients, care givers and innovation will all continue to suffer.

The efforts of this Subcommittee over the past three years have been critical in highlighting problems that impact the quality and cost of health care in this country. MDMA is grateful for your efforts, but remains concerned that unless uniform, comprehensive and enforceable reforms are established, the progress that has been made to date will be short lived. In addition, while some GPOs have taken steps to reform their practices, others have continued acting in an anticompetitive manner that harms patients, care givers and innovation. MDMA urges this Subcommittee to introduce legislation that will provide the proper oversight for the entire GPO industry. This legislation will help ensure that GPOs are promoting competition and innovation, while serving the best interest of their member hospitals, not the incumbent manufactures who provide their revenues.

Since the Codes of Conduct were established in the summer of 2002, GPOs have had ample opportunity to reform their practices. While some GPOs have reformed, the market leading GPO and other billion dollar GPOs continue to act in an anticompetitive manner.

These GPOs continue to bundle unrelated companies and products, charge excessive fees, require high commitment levels and prevent hospitals from buying technologies they deem necessary without the permission of the incumbent vendor. These continued anticompetitive actions by certain GPOs are clear examples why further reforms and oversight are necessary.

As David Balto, former FTC Policy Director, discussed in his testimony, the current codes do not adequately address the anticompetitive issues. Mr. Balto gave three main reasons why the Codes have not worked: 1) they are inconsistent and ambiguous; 2) no enforcement mechanisms for noncompliance; and, 3) there is no enforcement entity. The draft legislation would address these issues and provide the necessary oversight from HHS. MDMA agrees with Mr. Balto's independent assessment and urges this Subcommittee to move forward and support legislation providing greater oversight of the GPO industry.

Problems with the Existing Codes

The Current Codes are Not Mandatory

In a letter dated September 2, 2004 to Chairman DeWine and Senator Kohl, HIGPA President and CEO, Robert Betz stated that the Code was "the only mandatory one in the health care supply chain." However, after a closer examination of the facts, one finds that this statement is incorrect. Multibillion dollar GPOs such as Broadlane, HealthTrust and others have not certified that they are in compliance with the HIGPA Code. In fact, they are not even members of HIGPA. As a result, the current Code is not mandatory within the industry. The draft legislation would provide the proper framework to hold all GPOs accountable, not simply those belonging to a trade association.

The Current Codes Have no "Teeth"

During the September 14, 2004 hearing, Chairman DeWine expressed concern that the self-policing codes did not have adequate penalties. In HIGPA's testimony to this Subcommittee submitted on July 16, 2003, Robert Betz stated, "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." MDMA agrees with Chairman DeWine that the current penalties are not adequate. Losing your membership to a trade association is not an appropriate deterrent.

In addition to the industry code not having "teeth", Senator DeWine stated, "most troubling is the fact that there is really no mechanism to discipline GPOs that don't follow their own code." Unless and until real penalties, such as losing the government "safe harbor" status are established, certain GPOs will continue to ignore the Senate's calls for reform.

Concerns of Backsliding

During the hearing, both Senators DeWine and Kohl expressed concern about backsliding. MDMA shares this concern as well. In fact, MDMA has already witnessed backsliding from the third largest GPO. This GPO amended their code less than seven months after enactment. The amended code eliminated language from the original code which prohibiting certain types of bundling and other anticompetitive contracting practices. **(Exhibit A)**

In HIGPA's July 16, 2003 testimony before this Subcommittee, Betz stated that the Code was a "living" document. MDMA is concerned that this "living" document will backslide without proper and continued oversight. This would be easily addressed under the draft legislation providing HHS with greater oversight and authority of the GPO industry.

Concerns of Retribution

Without permanent oversight established through this enabling legislation, manufactures, health care workers and others, face severe retribution. During the recent hearing, Joe Kiani, CEO of Masimo, testified that he was the target of retribution from a multi billion dollar GPO because of his efforts to reform the GPO marketplace. The email Mr. Kiani cited at the hearing stated that he (Kiani) was "either with us or against us. I will know by your support of this legislation." (referring to a CA state bill last summer) Kiani continued to push for reforms. Shortly thereafter, Masimo's contract with HealthTrust was terminated and the GPO entered into a sole source agreement with Tyco for pulse oximeters. It is worth noting that HealthTrust put Masimo on contract before any of the GPO investigations began.

This type of retribution will be commonplace without comprehensive, lasting and enforceable oversight through the enactment of the draft legislation.

Inconsistent and Ambiguous Codes

On July 16, 2003, the GAO published their second report on GPOs. This report stated, "the conduct codes are not uniform in how they address business practices. In addition, some GPOs' conduct codes include exceptions and qualified language that could limit their potential to effect change." Recent specific examples in the GPO industry support GAO's belief that the codes impact may be limited because they lacked uniformity and clarity.

Below please find examples of GPO practices that are currently ongoing in the GPO industry. The majority of these examples are from contracts within the last 6 months and many are from contracts within the last 3 months.

Specific Examples of Continued Anticompetitive Behavior from Certain GPOs

- Hospitals and Clinicians Lack Choice
  GPOs and incumbent vendors still may prevent a hospital or clinicians from selecting alternative products they deem necessary. Certain GPOs still require their approval as well as the incumbent vendor's approval before a hospital can purchase a competitor's product off contract. **(Exhibit B)** This allows the dominant supplier incredible leverage over their competitors.

- Bundling of Companies
  Two of the three market leading GPOs continue to promote programs that bundle companies. These programs artificially tie the success or failure of one company with that of another. This practice excludes other manufacturers from gaining access to the marketplace who are not part of the exclusive bundle. **(Exhibits C & D)** No one knows what suppliers pay to be part of the bundle. This highlights the need for greater transparency regarding the financial incentives.

- Bundling of Unrelated Products

GPOs continue to solicit bids which bundle unrelated, clinical preference products. **(Exhibits C & D)** In many cases, the GPOs have posted or solicited bids which bundle unrelated products that only one or two vendors could supply. This excludes smaller, more efficient competitors from participating in the bid process simply because they lack product breadth.

- Inviting Bundled Bids
  Although GPOs have said that they will break up product "bundles" and bid contracts based on individual product categories, they are still asking vendors to submit two different pricing schemes: one price for a "bundled" contract, the other for individual products. **(Exhibit E & F)** The end result is often a bundled contract.

- High Commitment Levels
  Two of the three largest GPOs continue to promote programs that require their hospitals to purchase between 90-95% of a particular product from one supplier. **(Exhibits C & D)**. In addition, in order to receive the rebates, compliance must exceed 90-95% across multiple product categories. These types of programs prevent hospitals from being able to choose alternative products that are clinically preferred or more cost-effective because they will forfeit their rebates unless they meet the high thresholds.

- Requiring Participation in Other Business Ventures
  While the days of million dollar payoffs for "Innovation Councils" may be behind us (or postponed), the market leading GPO continues to require manufacturers to sign up for Neoforma, a separate e-commerce company, as a prerequisite to being awarded a contract. **(Exhibit G)** This is required even if a supplier has no intention or the capabilities of selling their product through an e-commerce platform. In addition, Novation requires the supplier to negotiate in good faith with Neoforma, for the purchase of additional supply chain solutions. One must remember that this GPO is the majority shareholder of Neoforma.

- Private Label Programs
  Two GPOs, including the market leader, continue to engage in the practice of private labeling and receive excessive fees for this practice. Private labeling is a tactic used by some GPOs to collect money outside the "administrative fee" structure since is not regulated. These fees far exceed the recommended 3% administrative fee and are collected on top of the administrative fee. **(Exhibit H)**

- Excessive Fees
  As the GAO reported in 2003 and as recent GPO contracts illustrate, the nation's largest GPO will not cap fees on non-clinical preference items at 3%. **(Exhibit I)** This provides the opportunity for a supplier to pay the 3% maximum for clinical preference products, but pay as much as the GPO wants to charge for the non-clinical products. A supplier who is only willing to pay 3% for both product categories will likely lose out on the contract, regardless of the quality or the price of the product.

  In 1991 the OIG noted that the legislative history of the 1987 law "shows Congress's concern for excessive GPO fees, particularly those exceeding 3 percent," and thereby revised the rule to require a GPO to specify the administrative fee "only if any fee will be above 3 percent." The OIG believed that this would "retain the focus on excessive fees about which Congress was concerned." [56 Federal Register 35952, 35982]

Today, GPOs are no longer using the safe harbor simply as a means to cover the costs of contracting as Congress intended. In fact, contracts that had previously charged 2% admin fees are now charging 3% for renewals. These new contracts do not even require additional product evaluations. They are simply extensions of existing contracts, yet they charge a higher fee. This type of behavior only adds baseless costs to the overall healthcare marketplace.

- GPOs Not Acting in the Best Interest of Their Members
  Recently, the market leading GPO actively sought to recommit their hospital members to the incumbent vendor over a smaller vendor. However, both suppliers had a GPO contract. This contradicts what GPOs say about being a "neutral middleman". In addition, the solicitation to recommit needed to be executed by October 31, 2003. **(Exhibit J)** What the GPO failed to disclose to their member hospitals was the fact that two weeks later, a cheaper generic version would be available at a minimum of 30% savings.

  The current system rewards the GPO for contracting for the higher priced product, because their fees are based on a percentage of the total contract price. If the member hospital contracted for the less expensive product, the GPOs revenues would have decreases 30 percent. This example illustrates the fact that often the member hospitals of a GPO do not have all the information they need to make an informed decision. The draft legislation would ensure that hospitals were making the best decisions for their members, not themselves.

- Back to Sole Sourcing (Second Event Program)
  On December 16, 2003 at a GPO's supplier meeting in Chicago, IL, GPO executives discussed a "second event" program. This entails the GPO contracting with multiple vendors for clinical preference items on a national level so they would comply with their code of conduct and the Senate's request for multi-sourcing. However, the GPO would then permit a "second event" which would be a sole source contract at the regional or IDN level. The GPO would collect the admin fee on this sole source second event as well. This is being done by MANY GPOs. **(Exhibit K)** While this may meet the letter of the codes, it certainly falls short of the spirit or intent.

Next Steps

The manufacturers who have testified before you over the past two years have discussed their experiences since the codes have taken effect. Although some progress by certain GPOs has been made, some of the largest GPOs in the nation continue to bundle unrelated companies and products, charge excessive fees, require high commitment levels, require participation in for-profit ventures, require hospital's to receive the incumbent vendor's permission to buy off contract, promote private label programs and subject outspoken manufacturers to retaliation for their efforts to reform the GPO marketplace. These practices cannot be allowed to continue. It is not fair to patients, caregivers and innovation. It also disadvantages the GPOs who took the necessary steps to reform their practices or who were never acting in an anticompetitive manner.

In 2002, 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 2003, Senator Kohl asked Elizabeth Weatherman, representing the National Venture Capital Association, "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?" She answered, "it seems to me either the exemption to the antitrust (safe harbor) 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." She went on to say, "I think that an even playing field would be far better. Having the intermediary aspect of deciding what innovative technology and what is not would be extremely positive, for that not be the purview of the GPOs or, for that matter, the large manufacturers. Let the customer decide which products they want to purchase and have the full basket available to them."

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. The draft legislation being considered by this Subcommittee will enable HHS to 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.

Please support the draft legislation which would provide greater oversight of the GPO industry. It is necessary to ensure the continued health and safety of our people and restore competitive principles to this marketplace. 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.

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 over 60 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.

- ***GPOs* 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

Statement of Senator Patrick Leahy
Ranking Democratic Member, Senate Judiciary Committee
"Hospital Group Purchasing: How to Maintain Innovation and Cost Savings"
September 14, 2004

Today we face the reality that the dramatic rise in health care costs in recent years is not slowing. In fact, we learned just recently that seniors will experience the largest increase in Medicare premiums in the program's 40-year history. The Bush Administration, presiding over this record increase, has obstructed many of the common sense proposals to bring down health care costs and protect the buying power of seniors' Social Security benefits. Instead of allowing Medicare to directly negotiate lower drug prices for seniors, or allowing Americans to buy affordable prescriptions from Canada, this Administration has decided that they would rather hand out billions of dollars to entice HMOs into the Medicare program at the expense of American seniors and taxpayers.

Fighting to keep health care costs down while simultaneously ensuring high quality of care is an enormous and challenging task but nonetheless one that can be addressed through responsible leadership. In addition to the proposals I just mentioned, Group Purchasing Organizations, or "GPOs," were developed as one possible solution to this clear and pressing concern.

This hearing examines the effectiveness of GPOs in bringing us closer to what should be our bottom line: We need a health care system that can keep costs in check while continuing to provide high-quality service, and that ensures that new, effective technologies reach the marketplace. These goals are intimately related -- ensuring that new companies and technologies have access to the marketplace will fuel competition, which will help guarantee that patients have the best possible health care at the lowest possible price.

Recently, questions have been raised about whether GPOs are serving their intended purpose. A GAO study requested by Senators Kohl and DeWine suggested that, in many cases, hospitals did not save money at all as a result of their participation in GPOs. At our last hearing, the Committee heard concerns that GPOs have expanded their original role beyond providing aggregate discounts and into something more like agents for large, multi-product suppliers. This phenomenon – if it is true – could threaten to lock out smaller companies and new technologies, resulting in less competition and less effective medical products and, at the very worst, harm patients.

To their credit, GPOs have not been sitting on the sidelines while the Subcommittee has led our consideration of these issues. The largest GPOs have already adopted "codes of conduct" in an attempt to address some of the claims raised by this subcommittee. This is a significant step in a good direction, and one that deserves commendation. The last hearing began the difficult task of reviewing the effectiveness of these "codes of conduct" and discussing what other measures GPOs should be encouraged, or required, to take.

I look forward to continuing to explore these issues at today's hearing, and I want to thank Senators Kohl and DeWine for their laudable and bipartisan efforts to ensure that these and other important antitrust issues are considered in this forum. Their cooperative and productive working relationship shows us that working across party lines should be the rule and not the exception in this Senate. Additionally, I would like to thank the witnesses for taking their time to have this conversation with us today, and I look forward to their testimony.

This afternoon's hearing marks a technological milestone for the Senate. For the first time, a hearing will be officially broadcast live on the Senate television system with closed captioning that uses the advanced technology of voice-recognition software.

Working with Secretary of the Senate Emily J. Reynolds and with the Committee on Rules, the Judiciary Committee has developed a pilot project that will allow us to study the captioning of committee hearings, offering realtime captioning as a demonstration for the use of Senators and their staff. We are very proud of the Judiciary Committee's groundbreaking role in testing this new technology.

After the completion of the pilot, we will evaluate the results to help the Senate determine the cost and feasibility of providing real-time captioning for all Senate committee hearings. Our hope is to bring closer the day when hearing-impaired Americans will have access to the legislative process. And at a time when we see barriers being erected all around Washington in the interest of security, we are glad for this opportunity to actually bring down a barrier between the American people and their government.

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Comments by the Service Employees International Union on Hospital Group Purchasing Organizations before The United States Senate Judiciary Committee, Subcommittee on Antitrust, Business Rights, and Competition

September 14, 2004

The 1.6 million members of the Service Employees International Union (SEIU) are pleased to submit testimony to the United States Judiciary Committee, Subcommittee on Antitrust, Business Rights, and Competition on the impact of hospital group purchasing organizations (GPOs).

We applaud the efforts of the subcommittee in investigating GPOs and are grateful for the leadership of Senators DeWine and Kohl. The Senate has made significant progress in bringing to light many of the anti-competitive practices of GPOs and encouraging the creation of voluntary codes of conduct. However, there is more work to be done to ensure that the entire GPO industry follow the lead of GPOs who have successfully reformed their practices.

This is not to suggest that all GPOs are problematic. In fact, SEIU believes that GPOs can be a positive force in reducing health care costs and SEIU stands behind the concept of group purchasing. We believe that many GPOs, including Premier, Broadlane, Consorta, and MedAssets, have greatly improved their practices. But no matter how hard some GPOs work for reform, those efforts will have little impact if Novation, the market leader, continues practices that do not result in the best product at the best price for health care consumers. Enhanced transparency and oversight could help control the cost of medical supplies by insuring that GPOs are truly controlling costs for health care consumers.

As a union whose members are both health care workers and health care consumers, SEIU is pleased to contribute our voice to this important matter of health policy. We look forward to working together with those who seek to control health care costs by creating openness, accountability, and true competition in the health care supply chain.

SEIU is concerned that questionable practices by the nation's largest GPO, Novation, lead to rising costs in the health care supply chain, while at the same time limiting provider choices in a way that risks the safety of both health care workers and their patients. These rising costs

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lead to short staffing in hospitals, loss of insurance for working families, increased cost pressure on small businesses, over-crowded emergency rooms, and growing burdens on public and private health care purchasers.

As committee members may be aware, nearly every time SEIU members reach the bargaining table, employers inform us that they are unable to maintain current levels of health coverage. We are then presented with the choice of either cutting back on coverage or paying more ourselves, either in wage freezes, salary givebacks or increased premiums. This is a choice no worker should have to make. While questionable GPO practices are one factor among many in rising health care costs, they are a factor that should not be ignored.

We believe that Novation continues to favor dominant manufacturers while excluding emerging technologies and smaller device manufacturers. While other GPOs claim to stay within the maximum 3% fee levels required by congress, a level that appears to be appropriate, Novation has continually sought new ways to collect additional fees from manufacturers, which drives up the cost of care.

Though we support the voluntary codes of conduct, we believe that health care consumers would benefit from greater transparency of GPO operations. For GPOs who have reformed their practices, greater transparency will serve to demonstrate the positive role they play in the health care marketplace. Disclosure is an unattractive option only for GPOs who abuse the safe harbor at the expense of hospitals and health care consumers. Increased transparency is necessary not because group purchasing as a concept is bankrupt, but rather because Novation does not appear to successfully self-regulate.

The flawed business practices of Novation call into question its commitment to its code of conduct, which it announced in August 2002. For example:

- In its code of conduct Novation states, "Participation in Novation contracts is not a prerequisite for membership or continued membership in VHA or UHC."[1] Yet, in at least one instance, a health system that recently chose to leave Novation was also forced to leave VHA, according to that health system's purchasing director.

- In October 2003, Novation sent a letter to its 2,400 hospital members recommending that they "recommit" to purchase pulse oximeters from Tyco/Nellcor. Novation apparently sent the letter, in spite of the fact that Tyco's patents were due to expire within months, which would have resulted in reduced pricing of certain products and created market opportunities for competitors. However, perhaps due to the incentive structure by which Novation generates revenue, it supported the higher priced incumbent's product. Regardless of the obvious cost issues, Novation should not have

[1] "Novation Commits to New Operating Principles to Enhance Value and Opportunities for Hospitals and Suppliers" August 8, 2002.

favored the incumbent vendor. Novation acted to protect the interests of Tyco while neglecting the interests of the hospitals and patients it purports to serve.

The following examples illustrate that while we face skyrocketing health care inflation and short staffing in our nation's hospitals, Novation is finding new ways to exploit its position as dominant GPO by receiving fees above and beyond the 3% ceiling mandated in the safe harbor.

- Novation's private label brand, NovaPlus, appears to serve little purpose other then to collect additional fees beyond those permitted by the safe harbor.

- Novation charges manufacturers for the required use of Neoforma, an e-commerce company whose largest shareholders are Novation's parent companies, VHA and UHC. Neoforma has lost hundreds of millions of dollars since its inception while adding unclear value, and represents yet another layer of administrative costs.

- According to our research, the VHA Health Foundation, a wholly owned not-for-profit subsidiary of Novation's parent, VHA, receives nearly all of its support from the same manufacturers who have benefited from sole-source or bundled Novation contracts. These manufactures include: Abbott Laboratories, Baxter Health, Cardinal Health, Eastman Kodak, Johnson & Johnson, and Standard Textile. Furthermore, the VHA Health Foundation received two questionable million-dollar donations from unnamed companies in the last two years.[2]

In order to insure that all GPOs work towards a more efficient health care supply chain, state regulators have begun to join with the federal authorities already examining GPOs. We are pleased that Connecticut Attorney General Richard Blumenthal has intensified his investigation of Novation in Connecticut. According to press reports, Attorney General Blumenthal is investigating whether Yale-New Haven Hospital and other nonprofit hospitals in Connecticut are overcharging Medicare and other government agencies for medical supplies. Attorney General Blumenthal's investigation is all the more important given that Novation is the dominant GPO in the state. Moreover, Connecticut's largest health system, Yale-New Haven Health System, plays a leading role in Novation's parent company, VHA.

Yale-New Haven's current CEO, Joseph Zaccagnino, is a long time board member of VHA, In April 2004, Zaccagnino was appointed Chairman of VHA and, according to his resume, sits on VHA's Executive Committee, Executive Compensation Committee, CEO Search Committee, and Finance and Audit Committee. C. Thomas Smith, President of Yale-New Haven Hospital from 1977 to 1991 (during which time Zaccagnino worked under him as COO), served as President and Chief Executive Officer of VHA from 1991 to 2003. Smith currently serves on the boards of companies who do business with VHA or Novation, including: Neoforma, Kinetic Concepts and IPC. Yale-New Haven's current

[2] VHA Health Foundation IRS Form 990, 2002, 2001.

Executive VP and COO, Marna Borgstrom, was a founding board member of Novation and sits on the board of the University HealthSystem Consortium. Yale's VP for Materials Management, Patrick Luddy, is a member of the Novation Materials Leadership Council and the Novation Information Leadership Council.

Zaccagnino and Borgstrom's leadership roles in VHA and Novation, create a potential conflict of interest between their responsibility to further Yale-New Haven's mission and their responsibility to increase profits for VHA. These potential conflicts are exacerbated by VHA's unusual ownership and governance structure. VHA is a for-profit cooperative owned by 2,200 nonprofit community hospitals and health systems.[3] VHA shareholders also include hospital administrators at VHA member hospitals. At the time of VHA's private offering in 1985, press reports revealed that hospital administrators were allowed to purchase shares in VHA's financing arm, Voluntary Health Enterprises.[4] As executives of Yale-New Haven in 1985, Zaccagnino and Borgstrom were in a position to personally profit at the possible expense of Yale-New Haven and its patients. We hope that in the coming months regulators will establish whether or not executives of VHA member hospitals like Yale-New Haven are using their positions for personal gain.

As purchasers of medical care for over one million SEIU members and their families, we have a responsibility to ensure that our health funds are not being overcharged for medical supplies. If Novation truly does save money for its members and health care consumers, then it should be willing to open its books to public scrutiny. Nevertheless, Novation and its parent VHA have thus far been unwilling to disclose more then the most superficial financial data.

For example, in a recent article in *Modern Healthcare,* a VHA representative refused to disclose executive compensation at VHA. According to the article, a VHA representative asserted, "we looked at the issue very carefully and the consensus was that there was not a lot to be gained from disclosing salaries."[5] Yet, in 1999, the VHA Health Foundation was forced to disclose in an IRS 990 tax form that it paid Daniel P. Bourque, President of the Foundation and Senior Vice President of VHA, an annual salary and benefits package of $352,920 for 4 hours of work per week.[6] In other words, Bourque was being paid $1,696.73 per hour to lead a tax-exempt, non-profit organization. If this excessive figure is consistent with VHA or Novation's general compensation practices, then a Senior Vice President at VHA in 1999 would have had an annual compensation package of $3,088,050 for a standard 35-hour week. SEIU believes there is much for the public to gain from increased disclosure from Novation and VHA.

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[3] VHA Corporate Fact sheet available at https://www.vha.com/news/public/factsheet.asp

[4] Jenifer Fine, "Building a Health Care Giant: VHA's Unique Private Offering." Dallas Business Courier, August 19, 1985.

[5] Cinda Becker, "Going on the record; VHA offers financial information but withholds executive compensation" *Modern Healthcare,* June 28, 2004.

[6] VHA Health Foundation IRS Form 990, 1999.

If Novation and VHA drive up health care costs through high administrative overhead and anticompetitive practices, more and more Americans will join the ranks of the already 45 million without health insurance and the millions more who are underinsured. SEIU believes that all Americans will benefit when the medical device market is opened up to true competition. This can only happen if we hold GPOs accountable.

We are pleased that the Federal Trade Commission (FTC) addressed GPOs in its recent report on health care and competition. The FTC found that "Statement 7 governs Agency actions examining monopsony and oligopoly issues in connection with a GPO's formation. It does not preclude Agency action challenging anticompetitive conduct--such as anticompetitive contracting practices--that happens to occur in connection w/GPOs."[7] FTC scrutiny in addition to enhanced transparency and regulation of GPOs will demonstrate to the public that GPO's do serve a positive role in the medical supply chain.

We encourage the subcommittee to continue its important work on this matter. SEIU is committed to insuring that all GPOs operate in the best interest of hospitals, health care workers, and patients.

[7] "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and the Department of Justice, July 2004. http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf

September 14, 2004

Chairman Mike DeWine
Ranking Member Herb Kohl
Antitrust, Competition Policy and Consumer Rights Subcommittee
Senate Committee on the Judiciary
161 Dirksen Senate Office Building
Washington, DC 20510

Re: Comments on the Subcommittee Hearing "Hospital Group Purchasing: How To Maintain Innovation and Cost Savings"

Dear Chairman DeWine and Senator Kohl:

On behalf of the venture firms that have invested more than $52 billion in more than 7,000 companies during the last 20 years in the life science industry, I would like to thank you for your continued vigilance regarding anti-competitive practices at America's leading hospital group purchasing organizations. At your request, Elizabeth Weatherman of Warburg Pincus testified twice (April 30, 2002 and July 16, 2003) on behalf of the venture community to provide insight to the committee about assessing market potential for a venture-backed life science product and the 'red flags' that limit venture investment into certain markets.

To reiterate the overarching theme of our previous testimony, **the importance of an open and competitive market as an incentive to invest in high-risk, but also high-growth life science companies cannot be understated, and some common business practices of the hospital group purchasing industry are barriers within the medical products markets.**

The NVCA stands behind the previous testimony provided by Ms. Weatherman, and believes the GPO adoption of Codes of Conduct has been a step in the right direction to providing added transparency into the GPO contracting process. But, these voluntary non-uniform codes will not be enough and GPO adherence to them may wane once the oversight by this committee and the agency with jurisdiction are gone.

In 2002, the venture community encouraged the committee to consider legislation to correct abuses within the GPO purchasing and contracting system to again open the markets to fair and vigorous competition. We believe legislation to expand existing reforms the group purchasing organizations have already undertaken to break down these barriers to entry-- an effort brought about in large part because of your leadership on this issue---is not only appropriate, but continues to be necessary. Legislation is a reasonable

approach to correct the unintended problems that have arisen out of the anti-kickback safe harbor. Your discussion legislation will provide permanent oversight, ensure that anticompetitive activities, such as the bundling of unrelated products, and sole source contracting will be addressed through rulemaking, and hold the GPO industry accountable to the commitments that have been made to this Subcommittee.

As Ms Weatherman said last year, "by shining a spotlight on the GPO industry's business models, practices and ethics, the committee has initiated a process that could be vital to ensuring that anticompetitive practices will not artificially limit access to medical markets of young companies." The National Venture Capital Association remains committed to these reform efforts and renews its offer of assistance in any way the committee sees fit.

Sincerely,

Nancy L. G. Saucier
Director
Medical Industry Group

Statement of

Thomas J. Shaw, President & CEO

Retractable Technologies, Inc.

Before the

United States Senate

Committee on the Judiciary

Subcommittee on Antitrust, Competition Policy, and Consumer Rights

Hearing on

"Hospital Group Purchasing: How to Maintain Innovation and Cost Savings"

September 14, 2004

Once again, on behalf of my colleagues at Retractable Technologies and other small medical device makers, I'd like to thank you for the opportunity to offer my views on how to remove the barriers to free market competition in the medical device industry. I'd also like to commend Senators DeWine and Kohl and the other Members of this Subcommittee for their unflagging dedication to exposing and eliminating the obstacles to medical device innovation created by the big hospital group purchasing cartels and their big manufacturer partners.

Thanks to you, the federal government has finally awakened to the significance of the GPO scandal. Before you placed this matter on your agenda, it was impossible to get the attention of anyone in Washington. Now, in the wake of the news, which was reported in *The New York Times* of August 21, that the Justice Department has launched a massive criminal investigation into healthcare purchasing, it's not unreasonable to expect that future hearings will take place in a federal courtroom rather than in a Senate hearing room.

The purpose of this third hearing, as I understand it, is to focus on possible solutions to the problems identified in the earlier hearings held by this Subcommittee. You may recall that on April 30, 2002 I submitted written testimony detailing my company's wrenching experience with hospital group purchasing organizations, and on July 16, 2003 I submitted a statement indicating that nothing had changed since the first hearing. Regrettably, I have to report to you that despite the adoption by the GPOs of so-called voluntary codes of conduct, a smattering of contract awards, and the settlement of our federal anti-trust suit against the two big GPOs, Becton Dickinson and Tyco, we have

seen no meaningful change in our ability---or that of other small to mid-sized medical device manufacturers---to gain access to U. S. healthcare facilities controlled by group purchasing organizations. Meanwhile, we continue to make significant strides in marketing our lifesaving VanishPoint® syringes to public facilities. In our own backyard, for example, our satisfied customers include the Dallas City and County health departments, and even the Texas Health Department. We now even have contracts to supply them to Africa, under the Global HIV/AIDS initiative, and to Australia. Yet we continue to be stonewalled by Parkland and Baylor hospitals, which are members of Novation, and by Presbyterian hospital, a Premier facility.

Quite frankly, the only difference we can see is that our salespeople no longer are escorted to the hospital parking lot by security guards when they announce to the purchasing department receptionist that they represent Retractable Technologies. But the reality is that the GPOs and their big manufacturer partners---Becton Dickinson in our case---are just as brazen in their illegal, anti-competitive activities as they were on April 30, 2002, when you held your first hearing.

Our recent unpleasant experience at Yale New Haven hospital, a Novation flagship facility, says it all. In 2000, we succeeded in introducing our automated retraction syringes to Yale. By all accounts, we virtually eliminated accidental needlestick injuries in every application in which our products were used. Clinicians actually told us they "loved" our product. Then came the shocker. Last fall, a materials management official abruptly informed us that our relationship would be terminated. She cited several bogus "reasons," including our decision to sever our marketing relationship with Abbott Laboratories. We subsequently learned that our syringe would be replaced by a Becton

Dickinson so-called "safety" device that had received an inferior rating from ECRI, the leading independent healthcare devices agency. While several clinicians attempted to intercede on our behalf, they were told in no uncertain terms to "stay out of this." In April, the Service Employees International Union (SEIU), citing violations of the Needlestick Safety and Prevention Act, filed a complaint with OSHA. Perhaps as his unjust reward for terminating us, Joseph Zaccagnino, the president and CEO of Yale New Haven Health Systems, was recently elected chairman of the board of VHA Inc., the parent of Novation.

Our market sources also tell us that the big GPOs and manufacturers are now biding their time, erecting a façade of contrition and cooperation that they intend to dismantle as soon as this issue disappears from this Subcommittee's agenda. They will then return to business as usual. This is very worrisome.

This Subcommittee's insistence that the GPOs write and enforce voluntary codes of conduct was a useful and appropriate first step in addressing this problem. But in the last year or so, we've seen that such voluntary codes of conduct will not restore free market competition to the medical device marketplace. They do not and cannot fix the flaws of the current system. First and foremost, they do not go far enough. And over the long-term, we cannot depend on the purchasing cartels to police themselves.

In my view, there is one key reason why we have yet to see real and lasting change in this marketplace: the big GPOs are still inextricably bound and beholden to giant manufacturers through a vast array of administrative and marketing fees, rebates, prebates and other questionable payments. The big manufacturers, *not* the GPOs' member hospitals, are still the principal customers of the GPOs. The big manufacturers,

not the hospitals, fund the GPOs' operations, including executive salaries. Consequently, the big manufacturers, *not* the hospitals, are still the masters of the hospital marketplace. In the healthcare arena, they are the masters of the universe.

Premier's code of conduct, which is probably the toughest of all of them, still permits administrative fees of up to 3%. As long as big manufacturers pay fees *of any kind* to the GPOs, the GPOs will continue to treat the dominant manufacturers as their customers. In turn, the manufacturers happily pay these fees to the GPOs to ensure exclusive access to the hospitals. The big GPOs are the big manufacturers' marketing, promotion, and advertising departments all rolled into one. And as long as they pay fees to the GPOs, they will never have to spend money to develop innovative, lifesaving products.

If, as the GPOs claim, they save hospitals oodles of money, they ought be able to fund their operations out of these savings rather than from fees. But that, of course, would mean slashing their executives' outlandish salaries, moving out of their flashy skyscraper offices, and giving up their junkets to resorts in Hawaii and the Caribbean. The fact is, of course, that the GPOs do not save hospitals any money at all. Their anti-competitive activities, in collusion with the big manufacturers, actually drive up healthcare costs. The GPOs would have you believe that their activities shrink manufacturers' margins. If that were true, you can be sure that well-heeled lobbyists representing the dominant manufacturers would be storming your offices to press for the abolition of the GPOs.

The GPOs would also have you believe that they have nothing to do with their hospitals' buying decisions, that it's all up to the hospitals. Nonsense. We are all well aware that the big GPOs continually exhort their member facilities, formally and informally, orally and in writing, to boost their compliance levels with their large,

preferred vendors. Forgive me for repeating myself, but that's because their real customers are the big manufacturers, not the member hospitals, and their real mission is to generate fees for themselves, not to cut healthcare costs.

We are now into the fourth year of your investigation into these practices. During this period, you have accumulated a mountain of evidence from many participants in the healthcare supply chain---small manufacturers, clinicians, even venture capitalists---attesting to the role that the purchasing cartels and their dominant manufacturer partners play in crushing innovation in this critical industry sector. Wisely, you gave the GPOs a chance to demonstrate their intention and ability to halt these abuses voluntarily. In my opinion, the evidence shows that they have not. The good news is that the codes of conduct can now 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 restore free market competition into this industry. ***It is time to make compulsory what is now voluntary, and to make permanent what is now temporary.***

I believe that the place to start is by repealing the so-called "safe harbor" provisions of the federal anti-kickback statutes that created this mess in the first place. As I've said in my previous written statements to this Subcommittee, Congress may have passed the ill-conceived "safe harbor" statutes with the best of intentions, but they have instead morphed, if you will, into a "pirate's cove" for monopolist manufacturers with inferior products seeking to avoid the rigors of free and fair competition. They have become a safe harbor created by the government that allows these corporate pirates to rob the government and the American healthcare system. They have become a safe harbor from

having to spend money on research and development for new technology and on advertising and marketing. And they have become 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.

In addition, Congress should abolish the payment of fees, administrative and otherwise; reinstate criminal penalties for companies, GPOs and individuals who pay or receive kickbacks; and prohibit the kinds of abuses that this Subcommittee and *The New York Times*, in its prize-winning 2002 series, have uncovered, including, but not limited to tying and bundling and sole-source contracting.

Let me add that just because I'm from Little Elm, Texas, I'm not so naïve that I believe you can get everything you want in life, or in Washington. I also recognize that the complete elimination of the safe harbor may not be politically feasible. If that's the case, I would be willing to accept a compromise that maintains the safe harbor for GPOs that return at least 90% of their revenues, plus interest, to all of their member hospitals---not just their shareholder facilities. Under this arrangement, the GPOs would have to provide full financial disclosure that they have in fact done that.

In any case, companies like Retractable Technologies 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.

Our patience with the current system has run out. I appeal to you to introduce legislation that would correct these abuses before they wreak more havoc on patients, healthcare workers, innovation, and the American healthcare economy.

Once again, thank you all very much for all your hard work and attention.

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STANDARD TEXTILE

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September 13, 2004

VIA TELECOPY

The Honorable Mike DeWine
140 Russell Senate Building
Washington, D.C. 20510

Re: Standard Textile's Comments On The Draft Medical Device Competition Act

Dear Senator DeWine:

I want to express my appreciation that Peter Levitas, Majority Chief Counsel for the Senate Antitrust Subcommittee, recently forwarded a copy of the draft bill entitled the "Medical Device Competition Act of 2004" to Walter Spiegel, Standard Textile's General Counsel. Standard Textile appreciates the opportunity to provide the Subcommittee with our comments on this draft bill. Standard Textile has reviewed the draft bill and strongly and unequivocally opposes passage of this bill. For the reasons stated in this letter, we respectfully urge the Subcommittee not to move forward with this proposed legislation.

Standard Textile is a family-owned business headquartered in Cincinnati, Ohio that supplies reusable textiles and apparel to the health care industry. Standard Textile employs approximately 1,200 people in the United States, including 350 employees in Ohio and 600 in Georgia and Alabama. Standard Textile sells its products to many hospitals that are members of Group Purchasing Organizations (GPOs), as well as to other hospitals that are not GPO members.

In our view, GPOs bring many benefits to the health care industry that would be undermined by the proposed bill. Rather than promoting competition, the proposed bill would instead impose an unnecessary and burdensome regulatory regime on the industry, thereby driving up costs to the detriment of providers, patients and suppliers. The proposed legislation is also contrary to established government contracting policies and to the findings of the Federal Trade Commission and the Department of Justice. In addition, Standard Textile strongly disagrees with certain of the underlying premises of the proposed legislation.

Standard Textile believes that GPOs benefit the healthcare industry by bringing efficiencies to the supply chain process. Small and medium-sized companies like Standard Textile are able to take advantage of this more efficient contracting process to reduce costs that would otherwise serve to increase the prices of our products and services. In addition, because the GPO contract bidding and selection process focuses on selecting the best products for member hospitals at the

best price – irrespective of the size or resources of a supplier – companies like Standard Textile are able to compete on a level playing field against larger competitors.

Standard Textile recognizes that the Subcommittee has expressed concern that some GPOs have engaged in business practices that have served to reduce competition. In our view, the GPO industry has responded appropriately to the concerns of the Subcommittee by implementing voluntary codes of conduct to ensure ethical and appropriate business practices. We believe it would be a serious mistake for the Subcommittee, in an effort to "codify" these voluntary codes, to propose legislation that would in fact go well beyond the voluntary codes. Instead of promoting self-regulation, the proposed legislation would instead create a new regulatory regime and new oversight bodies that would impose substantial administrative burdens on the healthcare industry. As a result, rather than focusing scarce resources on innovation and development of new products and services that would directly benefit patients, GPOs, providers and suppliers would instead be forced to focus on responding to and implementing these new regulatory demands.

Moreover, Standard Textile strongly disagrees with certain of the underlying premises set forth in the proposed bill. For example, the proposed bill would characterize contracting practices such as bundling and sole source contracting as "anti-competitive." This type of broad, across-the-board characterization of a complex contracting process, without any effort to further define or limit the use of these terms, is exceptionally dangerous. In fact, there is substantial literature and case law that establishes that these contracting practices are often pro-competitive and must be analyzed based on the specific situation. The characterization of these contracting practices as anti-competitive is also contrary to established government contracting practices (the General Accounting Office recently recommended that the Department of Defense and the Department of Veterans Affairs increase their use of competitive contracting mechanisms such as sole source contracting in order to obtain lower prices) and to the findings of the Federal Trade Commission and the Department of Justice, which examined GPO contracting practices in detail but did not recommend any regulatory changes.

In sum, we believe that the passage of legislation that would impose burdensome regulations on GPOs is unnecessary and would only serve to drive up healthcare costs. Furthermore, we believe that the proposed bill is flawed and relies on erroneous assumptions and findings. Accordingly, we respectfully urge the Subcommittee not to move forward with the proposed "Medical Device Competition Act of 2004."

I request that this letter be made a part of the official Subcommittee record of proceedings at the Subcommittee hearing scheduled for Tuesday, September 14 at 2:00 p.m. in Washington, D.C.

Respectfully submitted,

STANDARD TEXTILE CO., INC.

Gary Heiman
President & CEO

cc: Peter Levitas
Laurel Pressler
Walter Spiegel

Statement

Of Mark H. Wallis, Chairman & CEO

Invatec

Before the

United States Senate

Committee on the Judiciary

Subcommittee on Antitrust, Competition, and Consumer Rights

Hearing on

"Hospital Group Purchasing: How to Maintain Innovation and Cost Savings"

September 14, 2004

Mr. Chairman and Members of the Subcommittee:

As a participant in the distribution link in the healthcare supply chain, I've followed with keen interest your efforts over the last three years to uncover and correct the anti-competitive practices and abuses of the giant hospital group purchasing organizations (GPOs) and their big manufacturer partners, and I commend you for your courage, perseverance, and hard work in tackling this critical and complex healthcare issue. By investigating these practices, including conflicts of interest, tying and bundling, long-term sole source contracts, and the role the largest GPOs play in stifling medical device innovation, you have performed a tremendous public service. I understand that the purpose of this third hearing is to consider possible legislation to end these abuses. You can be sure that I would support such legislation wholeheartedly.

Understandably, you have so far focused primarily on the role played by the largest GPOs and the giant manufacturers in blocking smaller manufacturers with better, life-saving devices from the hospital marketplace and in discouraging medical device innovation, practices that ultimately harm patients and caregivers and raise the cost of healthcare in the U. S. My goal in submitting this statement is to call to your attention the fact that the very same abuses that you have examined over the last few years also lead to waste, inefficiencies and losses of more than $6 billion in medical products in the healthcare supply chain. Incredible as it may sound, this means that every year more than $6 billion of perfectly usable medical supplies---everything from bandages to I. V.

catheters--- literally winds up in hospital incinerators or dumpsters. In our industry, we refer to this as overstock inventory, or simply overstock. At a time when an estimated 45 million Americans are uninsured, and physicians are leaving the profession in droves because their clinical decisions are all-too-frequently driven by insurance reimbursement schedules, waste on this scale is inexcusable. It need not happen. The good news is that there is a solution.

To be sure, the witnesses who have appeared before you so far have already made what is, in my opinion, an urgent, ironclad case for immediate reform of the GPO system. But for anyone who might remain on the fence I would like to offer additional evidence and support from my company's experience, and to join with my many industry colleagues in calling for corrective legislation. In all honesty, it would be a bit of a stretch for me to try to make the case---like the one made by the small manufacturers--- that lives of patients and healthcare workers are *lost* because of the impact these abuses have on the segment of the healthcare supply chain in which I operate. But I can assure you that billions of dollars' worth of healthcare supplies could be *saved* if it were not for the questionable financial activities and policies at the largest GPOs and the giant manufacturers. As you well know, one of the General Accounting Office studies on GPOs commissioned by this Subcommittee called into question GPO claims that they save hospitals money on medical supplies, which is supposedly their primary mission. If you need further evidence that the perverse incentives and questionable practices of the big GPOs and big manufacturers are actually costing rather than saving hospitals money, I urge you to take a close look at the distribution link in the healthcare supply chain.

As I see it, the basic problem is the GPOs are beholden not to the hospitals they are supposed to be serving, but to the big manufacturers because of the outrageous fees the manufacturers pay to the largest GPOs. As Senator Leahy told *The New York Times* in 2002, this is a case of "the tail wagging the dog." If the GPOs were forced to serve their hospital members, billions of dollars could be saved not only through increased competition in the medical device and supply sectors but also through efficiencies and reduced waste in the distribution of supplies.

Before elaborating, let me explain briefly who we are, what we do and how we became so deeply concerned about this issue.

My company, Invatec, is in the business of reducing healthcare costs by buying, selling, and recycling distributors' overstock inventory. Our database includes more than 600 manufacturers and 350,000 medical and surgical products, and we use sophisticated proprietary software that can review a distributor's inventory, identify overstock, and then match this information with the supply needs of other distributors that use our service. Our program--- a global, online medical products clearinghouse--- was designed in partnership with the Health Industry Distributors Association (HIDA). After the system finds a match, we are able to bring the distributors together to execute a sale, typically at a discount to the buyer. If there is no domestic buyer, we can arrange for a sale, through our warehouse in Miami, to other countries. I founded this business more than 20 years ago after leaving a job as an area manager for a national medical/surgical distribution company in San Francisco. My own branch office had overstock, and I was aware that other distributors had the same problem. So I started by executing inventory

swaps, a program I called FISH. FISH---which stands for "First In, Still Here"--- became the cornerstone of Invatec's computerized matching program.

Yet despite dramatic advances in computer technology and inventory management, waste and inefficiency due to overstock remain a huge drain on the healthcare system. As I indicated earlier, the healthcare supply chain generates more than $6 billion or more in overstock each year, or about 10% of U. S. annual expenditures on medical supplies, according to a 2002 Minnesota Medical Association report that was based on U. S. Department of Commerce data. Other studies support these findings. To make matters worse, healthcare facilities spend another $700 million annually to dispose of overstock. In other words, about one dollar out of every ten spent on healthcare supplies is wasted. Compare that with the supermarket industry---which has to deal with countless perishable items like milk, eggs and meat---in which waste is negligible.

So how could perfectly good, fresh, sterile bandages, syringes and the like---still in their original, undamaged packaging and still in use in a downtown Houston hospital---- have become unusable at another facility in downtown Dallas? The answer is fairly simple. Every day purchasing agents in thousands of hospitals, nursing homes, clinics and other healthcare facilities make changes in the companies, brands, specifications, or sizes of the various products that they order. A hospital merger or change in a group purchasing organization may result in different products becoming the system-wide standard. Or one manufacturer may make an offer to a hospital purchasing agent that he or she can't refuse to stop using another's products. Manufacturers may discontinue product lines, and Medicare may change reimbursement schedules for certain products. For example, last year J&J shut down a factory in Arlington, Texas that made gauze and

other commodity products for the hospital market, apparently because J&J's profit margins on these products had suffered as a result of intense offshore competition. Many hospitals and distributors throughout the U. S. were stuck with thousands of dollars worth of perfectly good but orphaned medical products. In another instance, when Medicare revised its reimbursement schedule for sterile dressing trays a while back, one of our dealer customers in Illinois was suddenly stuck with more than $70,000 in dressing trays that nobody wanted. These goods will either be discarded immediately or gather dust in distributor warehouses or hospital stockrooms until they reach their expiration dates, which in our industry is usually five years after the date of manufacture. To paraphrase the late Senator Everett Dirksen, pretty soon a case of bandages here and a pallet of surgical gloves there add up to real money.

Invatec's inventory recycling system is a relatively simple solution to this problem. Trouble is, the big GPOs and the big manufacturers like J&J and Tyco want no part of such a program. Why? The answer is greed, pure and simple. Not only do they thrive on waste and inefficiency in the supply chain, they actually *facilitate* it. For every case of syringes or gauze bandage that is wasted, one new case is sold. Conversely, every case recycled represents a lost sale. The vast majority of the big manufacturers either refuse to accept returned merchandise from their distributor or hospital customers or impose onerous penalties on returned goods. Moreover, they threaten to terminate sales agreements to distributors who try to purchase overstock inventory from other distributors in the supply chain. As a result, distributors find themselves caught between a rock and a hard place. While they're contractually obligated to accept returned merchandise from their hospital customers, they can't return it dollar for dollar to the

manufacturers. These policies are roughly akin to General Motors telling the buyer of a new Buick that he won't be allowed to resell it directly to his friend, neighbor, or ex-wife, and that the only way he will be permitted to resell it is through GM. The main reason big manufacturers like J&J and Tyco give for refusing to allow recycling of their products between distributors---that the integrity of the product may be compromised---is a red herring. When we receive recycled goods from a distributor, we inspect them thoroughly for everything from punctures to missing labels. Any package not in pristine condition is immediately rejected. In point of fact, virtually every other industry in America *except for medical supplies* recycles its surplus inventory. Even the pharmaceutical industry, which obviously has good reason to be concerned about product integrity, uses an independent clearinghouse to handle returns from distributors. That speaks volumes about the current state of the medical supply industry.

Likewise, the big GPOs have no incentive to promote inventory recycling, even though as intermediaries between manufacturers and hospitals they're in an ideal position to facilitate such programs. But they've already received their administrative and marketing fees from the manufacturer and have absolutely no interest in returning them.

In 2002, my company initiated discussions with a Georgia-based Novation affiliate to try to set up a pilot program with its member hospitals to recycle overstock that would otherwise find its way to hospital incinerators. Even though Novation officials demanded a 5% administrative fee to participate in the program, we were initially encouraged by what we naively thought was a good faith interest on their part. Unfortunately, our optimism was short-lived. For more than two years, in a futile attempt to get this project off the ground, we exchanged countless e-mails with Novation officials and attended

numerous meetings that went nowhere. Suffice it to say that after all this wheel-spinning, we concluded that Novation was giving lip service to efficiency and cost savings and had absolutely no intention of actually implementing this program. I was reminded of a line by Mark Twain: "There is no sadder sight than a young pessimist, except an old optimist."

On the other hand, our subsequent venture with Consorta, an innovative GPO, demonstrates beyond any doubt that inventory recycling could, if implemented on a large scale, achieve significant savings for the healthcare system. In one early transaction with Consorta, we were able to save $108,000 recycling J&J sutures among Consorta's member hospitals. And Consorta's fee for helping to perform this important service was a mere ½ of 1%.

In my opinion, the inescapable conclusion is that the big GPOs are in a symbiotic relationship with the big manufacturers that not only provides zero financial benefit to healthcare facilities, but is actually costing those facilities millions of dollars. The big GPOs serve the big manufacturers, and the big manufacturers serve the big GPOs, because at the end of the day the big manufacturers write the big checks.

At your last hearing, you urged the GPOs to adopt voluntary codes of conduct aimed at eliminating the conflicts of interest, anti-competitive practices and other abuses you had identified in your investigation. It is now clear that voluntary codes of conduct are not enough. I strongly urge you to enact legislation that will not only restore free market competition to the medical products manufacturing sector, but will also reduce waste and inefficiency in the medical products supply chain by allowing my company, and any other company for that matter, to do what we do best: recycle the more than $6 billion of overstocked medical supplies. America's patients, healthcare workers, and taxpayers can't wait any longer. Thank you for your kind attention.

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