Testimony of

Mr. Mark Leahey

Executive Director
Medical Device Manufacturers Association
March 15, 2006

Testimony 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

"Hospital Group Purchasing: Are the Industry's Reforms Sufficient to Ensure Competition?"

March 15, 2006

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 Group Purchasing Organizations' (GPOs) attempts to reform their anticompetitive practices. This is the fourth time that MDMA has submitted testimony for the record and I would encourage those interested to refer to our previous statements for more background on the issue.

MDMA is a national trade association representing the innovative and entrepreneurial sector of the medical device industry. We represent hundreds of 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.

Overview

The efforts of this Subcommittee, especially of Chairman DeWine and Senator Kohl, during the past four years have been important in highlighting ethical and contracting practices by the GPO industry that have negatively impacted the quality and cost of health care in this country. These practices have included multimillion dollar stock payments to GPO senior executives from companies they did business with, the receipt of stock options from companies seeking GPO contracts, and the charging of million dollar up-front payments from suppliers seeking preferential treatment. Additional contractual problems have included long-term and sole-source contracts, the bundling of unrelated products and from multiple favored companies, charging excessive fees, requiring participation in for-profit GPO business ventures and preventing physicians and caregivers from freely selecting the products they deem best for their patients. .

MDMA is grateful for the efforts of this Subcommittee and its dedicated staff in addressing these problems. However, the lack of resolve and commitment by the GPO industry has prevented widespread meaningful reforms from being enacted. While there has been success in eliminating the most egregious practices such as GPOs receiving stock options from contract seekers and personal investments by GPO leaders in supplier companies many serious problems still persist. It is readily apparent that after nearly four years of congressional oversight, the development of individual GPO codes of conduct, a GPO association code of conduct, and most recently the Healthcare Group

Purchasing Industry Initiative ("GPO Initiative"), significant problems remain that are negatively impacting patients, caregivers, taxpayers, and innovation.

Since this process began in 2002, GPOs have not seemed to take the Subcommittee's requests for reform seriously. While GPOs publish codes and develop new "initiatives" that claim to have reformed the industry, their actions indicate otherwise. They continue to contract in exclusionary and anticompetitive ways, including bundling across companies and products, executing long-term contracts, engaging in sole-source contracts, awarding no-bid contracts, collecting excessive fees, and preventing caregivers and hospitals from access to a free and open marketplace of competitive products.

While MDMA would like nothing more than for the GPO industry to reform itself, that doesn't appear likely. Since the last hearing in October of 2004, additional press reports, private litigation and government investigations and reports continue to uncover anticompetitive and exclusionary practices, including the collection of excessive fees. For example, a recent antitrust case found that one supplier paid a single GPO $31 million in fees on a total of $345 million in business. This certainly exceeds the 3% fee that GPOs would have you believe they receive. If these payments exist between one vendor and one GPO, the broader impact of these fees is significant across the health care sector.

In 2005, the U.S. Department of Health and Human Services' Office of Inspector General published two audits examining the fees collected by 6 GPOs. The audits found that the 6 GPOs collected $2.3 billion in fees from vendors. Of that $2.3 billion, $1.6 billion exceeded their operating. Of the $1.6 billion, the GPOs withheld nearly $500 million from their member hospitals. Of the remaining funds the GPOs returned to their members, the majority of hospitals did not accurately reflect the fee receipts in their cost reports to Medicare.

Fortunately, a solution does exist that would restore competition in the health care marketplace, resulting in higher quality care at a lower cost. The answer is repealing the GPO "safe harbor" from the Medicare anti-kickback statute. This would end the financial dependence that GPOs have on a select group of dominant suppliers. This fee dependence is at the core of the anticompetitive and exclusionary practices of GPOs. So long as GPOs depend on fees from suppliers whose products they are charged with evaluating, patients will continue to be denied access to innovative, cost-effective technologies.

MDMA and our members understand and appreciate the rationale behind creating the GPO safe harbor in 1986. However, that exemption was established when there were hundreds of small, active GPOs and has never been modified despite the consolidation of GPOs to only seven having 85 %of the market with the two leading GPOs controlling over 60 percent of the business. Clearly, the experiment has not worked as Congress had envisioned. As a result, MDMA urges this Subcommittee to introduce legislation that would still permit GPOs to continue to aggregate volume on behalf of their member hospitals, but would terminate the financial dependence that GPOs have on the vendor fees. Such legislation will help ensure that GPOs are promoting competition and innovation, while truly serving the best interests of their member hospitals, patients, and U.S. taxpayers.

Deficiencies with the Current GPO Initiative

In the spring of 2005, three years after GPOs created their own individual codes and two years after the HIGPA code was established, the GPOs created the Healthcare Group Purchasing Industry Initiative. The stated purpose of the Initiative was to monitor and promote best ethical and business practices. However, the Initiative permits each GPO to operate under their existing codes and it has no authority to prohibit anticompetitive practices. As a result, what real impact can the Initiative possibly have?

The GPO Initiative only has two requirements for their members. The first is that each member completes an annual questionnaire acknowledging that the GPO has created policies and procedures addressing certain issues. However, whether the underlying policies and procedures are meaningful or enforceable is irrelevant. Second, the GPO members must participate at an annual meeting with other GPOs. Nothing else is required. In addition, there is no real enforcement mechanism - the only penalty is being suspended from the Initiative itself.

This Initiative clearly is insufficient to address the ongoing exclusionary and anticompetitive practices of the GPO industry. As a result, action by this Subcommittee is necessary to ensure that patients, caregivers, and taxpayers are no longer harmed by GPO practices.

Repeal of the GPO "safe harbor" from the Medicare Anti-kickback Statute

So, what can be done? I strongly urge this Subcommittee, and Congress, to pursue the solution embodied in the "Ensuring Competition in Hospital Purchasing Act" draft bill circulated last fall. This proposal is the most efficient, effective option to reforming the GPOs' current anticompetitive practices. This repeal of the Medicare anti-kickback safe harbor would still permit the GPOs to aggregate volume on behalf of their member hospitals and thereby negotiate favorable prices for products and medical devices. All other efficiencies currently enjoyed by providers and suppliers would continue to exist. The only modification would be the GPOs' revenue source. Instead of continuing to be paid and influenced by their vendors, they once again would be compensated by their member hospitals. As a result, they clearly would need to show cost savings and value to justify their continued role as intermediaries negotiating with vendors.

Repealing the GPO safe harbor will undue a 20-year experiment that has obviously failed. The intention of the safe harbor was to create efficiencies and ensure that hospitals and patients have access to better products at a better price. However, based on various government reports and evidence presented during recent antitrust cases, this is not occurring. Unfortunately, under the current model, the GPOs seem more concerned about their fee revenues than with negotiating competitive contracts for their member hospitals.

Less Effective Alternatives

Other draft legislation has been proposed in an effort to help reform the anticompetitive practices of GPOs. While well-intended, these efforts create additional levels of bureaucracy and don't go far enough to truly reform the current system.

"The Medical Device Competition Act" is a draft proposal that would create additional contracting regulations, modify the existing safe harbor, create an independent certification process and establish penalties for non-compliance. However, there are concerns that this proposal may create another bureaucratic layer with unintended consequences. In addition, it creates additional demands on the Senate, the Federal Trade Commission and the Department of Health and Human Services to oversee the implementation of this process for years to come.

Another option, called "The Hospital Group Purchasing Organization Reform Act," may actually create a false sense of security. It also requires ongoing congressional oversight to ensure that the codes don't change and that no backsliding occurs. As the underlying codes have qualifying language limiting their effectiveness, it is very easy to certify compliance, yet no real reforms are likely.

Conclusion

In 2002, Senator Kohl said, "Without quick and effective self-regulation, we will have to consider congressional action." At that time, MDMA agreed with the Subcommittee's decision to allow time for a self-imposed code. The following year, Chairman DeWine stated, "our work in this area is not complete." It has been nearly four years since GPOs engaged in efforts to self reform and they have not achieved the results envisioned. As a result, legislative action is required to ensure that patients, caregivers, innovation and the American taxpayer have access to the best and safest products at the best prices.

I urge this Subcommittee to introduce legislation repealing the GPO safe harbor from the Medicare anti-kickback statute. It is vital to patient safety and to restoring competitive principles to the marketplace. Without a repeal of this safe harbor protection, patients and hospitals will continue to pay too much for medical devices and products - and will be denied access to the best and safest medical technology available today.

Thank you.

Mark Leahey
Executive Director
Medical Device Manufacturers Association

APPENDIX

The Current GPO Industry Initiative and Industry Code of Conduct Are Not Mandatory

In a letter dated September 2, 2004, to Chairman DeWine and Senator Kohl, former HIGPA President and CEO Robert Betz wrote that the HIGPA 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.

Furthermore, the current Healthcare Group Purchasing Industry Initiative does not include all GPOs and is not mandatory across the entire GPO industry.

The Current GPO Initiative and Industry Code 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 said, "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 said, "most troubling is the fact that there is really no mechanism to discipline GPOs that don't follow their own code." MDMA agrees with this concern and it is valid with the GPO Initiative as well.

The GPO Initiative also fails to have any real penalties for non-compliance. GPOs may be suspended from the GPO Initiative for failure to meet the basic requirements of responding to a questionnaire and attending an annual meeting. However, even if a GPO fails to meet these minimal standards, the impact of being suspended from an organization that was established less than a year ago and has no real purpose is questionable.

Concerns of Backsliding with the Current GPO Initiative and Industry Code

During the hearings, both Senators DeWine and Kohl expressed concern about backsliding. MDMA shares their concerns about this as well. In fact, MDMA has already witnessed backsliding from certain GPOs. The third largest GPO amended its code less than seven months after enactment. The amended code eliminated language prohibiting certain types of bundling and other anticompetitive contracting practices.

In HIGPA's July 16, 2003, testimony before this Subcommittee, Betz said the Code was a "living document." GPOs have made the same claims about their individual codes. MDMA is concerned that without repealing the GPO "safe harbor" from the Medicare anti-kickback statute, problems will persist and these so-called living documents will revert back to old practices, even in areas where GPOs have shown modest improvements.

Eliminating the GPO safe harbor from the Medicare anti-kickback statute would provide the most effective and efficient solution to the exclusionary and anti-competitive practices of the GPO industry. In addition, it would not require ongoing congressional oversight.

Fear of Retribution

Without eliminating the GPO safe harbor- which would result in free and open markets in health care - manufactures, health care workers and others, face severe retribution. During the September 2004 hearing, Joe Kiani, CEO of Masimo, testified that he was the target of retribution from a multibillion dollar GPO because of his efforts to reform the GPO marketplace. The email Mr. Kiani cited at the September 2004 hearing was from a GPO CEO and stated that he (Kiani) was "either with us or against us. I will know by your support of this legislation" (referring to a California bill seeking to provide greater oversight of the GPO industry). Mr. 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 awarded Masimo a contract before any of the GPO investigations began and only terminated the contract once Mr. Kiani came forward to address the exclusionary and anticompetitive practices of the GPO industry.

This type of retribution will be commonplace unless real and lasting reform occurs. This can be achieved by repealing the GPO safe harbor from the Medicare anti-kickback statute.

The GPO Initiative is Dependent on Inconsistent and Ambiguous Codes

The GPO Initiative is entirely dependent on GPO self certification that they are in compliance with their own code of conduct. However, on July 16, 2003, the GAO published a report on the GPOs' codes of conduct. The GAO found, "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." Therefore, certifying compliance to codes that have no teeth is not proof that the GPOs have reformed. In fact, it merely provides a false sense of security that things have changed.

The examples below indicate that little has changed related to the exclusionary and anticompetitive practices of GPOs.

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. 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 who are not part of the exclusive bundle from gaining access to the marketplace. Until recently, little was known about what suppliers paid to be part of the bundle. Recent evidence in an antitrust case showed that fees were 5%. This highlights the problem that a select group of vendors enjoy preferential treatment if they pay the GPO significant fees.

? Bundling of Unrelated Products
GPOs continue to solicit bids that bundle unrelated, clinical-preference products. In many cases, the GPOs have posted or solicited bids that 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. 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. 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), Novation, the market-leading GPO, continues to pressure manufacturers to sign up for Neoforma, a separate e-commerce company, as a prerequisite to being awarded a contract. 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 the owners of Novation also own 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 it is not closely monitored. These fees far exceed the recommended 3% administrative fee and are collected on top of the administrative fee.

? Excessive Fees
The nation's largest GPO will not cap administrative fees on non-clinical preference items at 3%. 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 health care marketplace.

? GPOs Not Acting in the Best Interest of Their Members
During the September 2004 hearing, evidence was presented showing that the market-leading GPO actively sought to recommit its hospital members to the incumbent vendor over a smaller vendor. However, both suppliers had a GPO contract. This contradicts what GPOs say about being "neutral middleman." In addition, the solicitation to recommit needed to be executed by October 31, 2003. What the GPO failed to disclose to its member hospitals was the fact that two weeks later, a cheaper generic version would be available at a minimum of 30% savings.

This is not surprising since the current system rewards the GPO for contracting for the higher priced product, because its 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 decreased 30%. This example illustrates the fact that the member hospitals of a GPO often do not have all the information they need to make an informed decision. Repealing the GPO safe harbor from the Medicare anti-kickback statute would ensure that the GPOs aggressively negotiated on behalf of their member companies and were responsible solely for their member hospitals.

? Back to Sole Sourcing (Second Event Program)
On December 16, 2003, at a GPOs' 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. While this may meet the letter of the codes, it certainly falls short of the spirit or intent.