Hearing Testimony

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On Behalf Of
The Medical Device Manufacturers Association (MDMA)

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Committee on Small Business

"Small Business Competition Policy: Are Markets Open for Entrepreneurs?"

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Introduction

As the Chief Executive Officer of Applied Medical Resources Corporation ("Applied") of Orange County, California and a member of the Medical Device Manufacturers Association ("MDMA"), I appreciate the opportunity to discuss the predatory and anti-competitive practices that exist in the healthcare system today.

Applied Medical was established in 1987 to develop products that can improve both clinical outcomes and financial outcomes for hospitals and patients. We did. Today, we develop, manufacture and market specialized devices that enhance clinical outcomes of minimally invasive procedures while reducing costs.

MDMA is a national trade association representing nearly 200 innovative, entrepreneurial medical technology companies across the country. Our mission is to ensure that patients have timely access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

Today's hearing is entitled, "Are Markets Open for Entrepreneurs?" Unfortunately, the answer for many smaller companies in the medical device industry is no.

The U.S. medical technology market is controlled by large hospital group purchasing organizations ("GPOs") and dominant suppliers that exclude smaller companies with better products at a better price from the market. The result is that patients and caregivers are often denied access to innovative, cost-effective technologies that have the ability to improve care and reduce costs. As a result, substantial savings afforded by true competition are often completely missed. Further exacerbating these problems is that fact that the Department of Justice ("DOJ") and the Federal Trade Commission ("FTC") have done little to protect consumers or competition.

In order to open markets for all medical suppliers and improve competition, federal agencies must engage in more vigorous oversight and enforcement of antitrust laws. In addition, the perverse incentives that exist within the current supplier funded GPO model must be eliminated by Congress.

Taking these measures will restore competition, improve the quality of care, reduce costs and promote innovation.

The Need to Reform Hospital Group Purchasing Organizations (GPOs)

GPOs were initially established to help small hospitals aggregate their purchasing power to negotiate lower prices with suppliers. However, in many cases they have morphed into marketing arms for the dominant suppliers. This is due to the fact that in 1986, Congress created a "safe harbor" from the Medicare anti-kickback statute that permitted suppliers to fund the GPOs. Until that time, GPOs functioned like other cooperatives and were funded by their member hospitals. Being paid by the hospitals better ensured that they acted in the interest of hospitals. The purpose of the GPO safe harbor was to reduce costs

and assist rural hospitals in their purchasing needs. However, the current model perpetuates the opposite effects.

Once the GPOs relied on suppliers to fund their operations, they no longer had any reason to independently review products or the proper incentive to negotiate for the best products at the best price. Dominant suppliers started bundling unrelated products together and pay a higher "fee" (aka kickback) to the GPO in exchange for promoting the bundle, and the GPO's disincentives (financial penalties) to the hospitals for buying any product included in the bundle from a competitor.

In addition, given that the GPOs collect fees based on a percentage of the total contract price, there is no incentive to negotiate lower prices. For example, a GPO generates twice the amount of revenues collecting 5% on a $20M contract ($1,000,000) than it would collecting 5% on a $10M contract ($500,000). The current supplier-funded GPO model actually creates an incentive to increase costs and decrease the number of companies they interact with.

For the most part, only those companies who have had the ability to testify before Congress have seen any relief from these behaviors. Applied had the good fortune to testify before Congress and pressed the GPOs to reform, so these markets have been opened somewhat to us. However, there are countless other smaller companies without these resources and the market is foreclosed. In our case, we have had some success in pockets, but comprehensive and lasting reforms for GPOs and dominant suppliers must occur if the markets are to be truly opened to small companies in general.

Therefore, in order to restore competition in the hospital marketplace, it is imperative that Congress repeal the GPO "safe harbor" from the Medicare anti-kickback statute, reverting back to a hospital funded model that worked for decades before. As renowned Harvard competition expert Michael Porter states in his book, *Redefining Health Care: Creating Value-Based Competition on Results*, "There is no valid reason for buying groups to accept financing or any payments from suppliers: if a buying group adds value, the customers (hospitals) should voluntarily pay for it."

Anti-competitive Activity of Dominant Suppliers

While ending the supplier kickbacks to GPOs would provide a more competitive landscape for smaller companies, additional action is needed to address the anticompetitive practices of dominant suppliers. In today's healthcare system, small companies face markets as closed as a fortified castle, with some GPOs looming as the most treacherous of moats. And, similar to how castles have concentric lines of defense, dominant suppliers have these GPOs as the outermost line closing the way to the market. However, they also engage directly in anticompetitive activities, including predatory practices and bundling. These practices have increased dramatically as the GPOs received some small amount of added scrutiny.

Applied has firsthand experience in being locked out of markets by large conglomerates using predatory practices, even while we offered higher quality and less expensive products. For years, we experienced what it is like to compete against a maintained monopoly that is leveraged to prevent competitive products, related and unrelated, from reaching the customer. We have repeatedly experienced the predatory market powers of giant companies, regardless of their respective market share in the targeted area. Applied and hundreds of other companies have suffered the most from the total absence of oversight and enforcement, while we have been denied access and faced exclusive-dealing arrangements disguised as price discounts.

In the medical device arena, the large players are creating buckets of products that effectively exclude any competitor that doesn't offer exactly the same mix of products, even though these competitors have higher quality and substantially less expensive products competing with individual products in the bundle. And, while it may be true the shoes without shoelaces may be at a competitive disadvantage, shoes without a laptop computer would not be. Let me briefly recount an actual example from the medical device market.

> The eventual monopolist first grouped together all types of surgical sutures – from ophthalmic to cardiovascular and skin sutures, and positioned them into a monolithic "sutures" offering. Initially, this seemed to the customer to reduce prices on sutures. As the monopoly took hold, one entity grew to control in excess of eighty-five percent of all sutures used in U.S. hospitals. I am not contending that creating a monopoly is illegal, but the follow-up predatory practices immediately followed. The creation and maintenance of this particular monopoly was but the starting point.
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> With sutures secure as a monopoly, the list prices of sutures rose to two and three times the average selling price. Following that, the company offered "better prices" (similar to those in effect previously) on the sutures if the customer also agreed to a bundled deal, where unrelated and loosely related products are bundled together. No volume discount is involved, simply a deal where as long as the customer buys virtually all of its requirements for the bundled products, the customer gets the "better prices."
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> The company argues that the customers can buy laparoscopic instruments, trocars or stapling products anywhere else they choose – but a customer choosing to do so, can see the cost of sutures climb up to twice that of the average selling price, or even three times.
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> And, here the statistics can be deceiving. By examining the company-wide average selling price, punitive pricing can hardly ever be detected. On the financial statements, the company is certainly making a profit on the whole bundle. Thus, to suggest that one must actually conduct predatory pricing to have an anticompetitive effect is simply nonsense.

> The one behemoth with this monopoly position in sutures was able to propel its position in the non-suture market of trocars from a few percentage points to their monopoly position of 75 percent of trocars, by leveraging its suture business and punishing anyone daring to buy trocars elsewhere with higher prices on sutures.

Interestingly, academicians and regulators, courts and jury, seem to expect the monopolist to be dropping prices to drive competition out. Instead, the monopolist raises the prices of the monopoly product, to effectively punish the customer into submission. Notably, the majority of customers don't feel punished. The nature of the bundle is deceiving, and the customers often think they are getting a great discount.

From the standpoint of the academicians, this monopolist did nothing wrong. After all, the monopolist did not sell sutures at below cost. And, with a cursory look, it appeared they had not sold the bundled products, trocars, below cost. If anything, the monopolist charged more. The shear fact that academicians can look at the situation of "shoes and laptops", where laptops are sold by causing the customer heavy pain with shoe costs, and see no predatory nature, or damage to free markets demonstrates how failure-prone the interpretation of the antitrust laws have become.

If the economists have so dismally failed to see the larger picture, can one expect a lay jury to understand? Can one sincerely expect a younger and smaller competitor to articulate what caused its effort to penetrate the market against the giant to fall flat?

And, in case one may think duopolies are slightly or considerably better than monopolies, it is important to point out that, where duopolies covertly lock steps, the situation is considerably worse than monopolies, mainly because the laws and casual academic observers view the situation as one of fully open competition and free choices. But it is not. Lockstep Duopolies are as insidious as monopolies, and untenable when tied into *quid pro quo* and the lack of enforcement. (For an illustration see Appendix II)

Lack of Oversight and Enforcement

The point here should be clear: our antitrust laws do not anticipate many of these situations, let alone address them. It seems that the economists, often with studies well funded by the dominant firms, and the DOJ do not comprehend this or have been persuaded by the dominant companies. It is true that maintaining or leveraging a monopoly is against the law. But regardless of whether or not we have laws that address these situations, without sophisticated, well financed enforcement, free competition is at risk. The likelihood of successfully explaining such convoluted practices to juries in a court of law is low. Even without the DOJ's accommodating declarations and safe harbors, small businesses have had an impossible time fighting back predatory approaches by monopolies and lockstep duopolies. The new declarations by the DOJ only raise the bar further. A smaller company attempting to expose predatory and anticompetitive practices by a much larger predator finds itself, its record, strategies, financing and product offering under attack. Too often, the victim becomes the accused,

receiving the blame for being smaller and, therefore, presumably less capable and less useful to the consumer. University economists make millions of dollars "studying" the presumed damages or supplying rebuttals to the hypothetical situations.

The current interpretation of antitrust laws indicates that more oversight and enforcement is necessary to achieve a fair, competitive marketplace for hospital purchasing. There are clear-cut situations where the DOJ could have identified and prosecuted violators. Instead, it stood by passively. The *qui tam* cases that have been brushed aside are amazing by themselves. The outing of *qui tam* reporters, as part of the rejection process, is exceptionally alarming. The handling of *quid pro quo* cases through purely financial settlements and deferred prosecution is analogous to a license to steal – pay only a fraction of the take, but only if caught in the act.

Yes, the country, economy, open competitiveness and, most importantly, consumers and patients can benefit from updated laws to deal with antitrust and predatory practices. But that should not mean a continuation of the hiatus on enforcement. To the contrary, enforcement needs to go into overdrive.

Our antitrust laws have been watered down or ignored as present-day approaches instigated by large monopolies and duopolies took hold. The DOJ and FTC must take a more proactive oversight role to protect consumer and promote competition. Unfortunately, the recent DOJ report, *Competition and Monopoly: Single-Firm Conduct Under Section Two of the Sherman Act*, attempts to create additional "safe harbors" for monopolists at the expense of competition, consumers and innovation. This is not the direction the government should be moving. MDMA agrees with the FTC's dissent that the DOJ's position "prescribes a legal regime that places these firms' interests ahead of the interests of consumers." Progressive European and Australian agencies are well ahead of us on these issues, and are often dealing with violators promptly and firmly. Indeed, many MDMA member companies now find Europe to be, in many respects, a much more open and competitive market than in the U.S. We can and must do better moving forward.

Conclusion

The practices outlined above by GPOs and dominant suppliers, individually and in the aggregate, favor and promote the dominant vendors and deprive patients and caregivers access to innovative and lower cost medical technologies, increasing costs of health care. As a direct result, hospitals and the federal government (as a primary funder of health care services) continue to pay more than necessary for often inferior healthcare products and medical services.

By repealing the GPO safe harbor and providing proper oversight and enforcement of dominant firm conduct with consumers interest in mind and not the dominant vendors' interest in mind, we can make great strides in promoting competition, protecting consumers and fixing our healthcare system.

Appendix I

APPLIED IS AN INNOVATOR IN SEVERAL SURGICAL FIELDS

Founded in 1987 and headquartered in Orange County, California, Applied designs, develops, manufactures, licenses, markets, and sells seventeen lines of specialized devices for general, colorectal, obstetrics, urology, laparoscopy, cardiovascular and vascular surgery. Our products are 99 percent manufactured in the United States.

At its inception, Applied recognized that the national trend of rapidly escalating healthcare costs would reach 20 percent of GDP within a decade. This presented a serious national problem and an opportunity for innovative companies that could affect improved clinical and financial outcomes concurrently. Accordingly, Applied's business strategy has been to develop products and practices that enhance performance while reducing the cost of products and procedures. Since 1988, Applied has evolved as a prolific developer of products and technologies that fulfill this dual requirement, resulting in over 650 pending and issued medical device patents worldwide.

Our products have been safely, successfully, and satisfactorily used in many hospitals throughout the globe and for many years. Millions of our devices have been sold and used as testament to their acceptance and performance. Our outstanding record with the FDA also attests to the quality and performance of our products.

Applied maintains one of the highest commitments to innovation and quality in its industry. Over the past decade, Applied has spent 20 percent of its revenues on R&D, resulting in impressive clinical results and financial savings. One example of the results of Applied's investment is our device named GelPort® System, used in advanced laparoscopic procedures to reduce the trauma of open surgery in colorectal procedures. The GelPort product is rapidly expanding the field of minimally invasive hand access surgery. We were awarded Innovation of the Year 2002 by The Society of Laparoendoscopic Surgeons. The Acucise® product is another proud innovation for dealing with ureteral strictures. Peer-reviewed clinical papers attest to the fact that the Acucise® product eliminated hospital stay, reduced costs by $14,000 per procedure and replaced a 210-minute surgery under anesthesia with a 42-minute minimally invasive procedure under sedative and achieved a hundred percent success rates in secondary procedures. Applied also has introduced new generations of atraumatic, minimally invasive surgical devices for occluding blood vessels and grasping tissue, and has eliminated sometimes life-threatening latex from its products.

Applied's trocar seal technologies set the standard for seals used in minimally invasive surgery and are utilized in the majority of trocars currently on the market. The Applied trocars were the first to accommodate instruments with a wide range of diameters to traverse the seal without adaptors, leakage or excessive friction. The patented seal technologies developed by Applied have resulted in real improvements in patient care in minimally invasive surgery by reducing time in the operating room and improving surgeon control during the procedure.

Applied introduced the Separator™ product, a new generation of access products that uniquely separates the abdominal wall layers along their natural lines without the use of traumatic plastic or metal blades.

Appendix II

One may believe duopolies are slightly or considerably better than monopolies. However, it is important to point out that, where duopolies covertly lock steps, the situation is considerably worse than monopolies because the laws and casual academic observers view the situation as one of fully open competition and free choices. This is, however, not the case. Lockstep Duopolies are as insidious as monopolies, and untenable when tied into *quid pro quo* and the lack of enforcement. Here's an illustration:

> Assume that Duopoly A will grant the customer 60 percent discounts off its exaggerated list price for buying 70 percent of volumes from Duopoly A. Suppose also that Duopoly B penalizes the same customer by charging its exaggerated list price for the customer's remaining 30 percent of volume. In such a situation, Duopoly A makes a good sale, capturing 70 percent of the units. So does Duopoly B, making perhaps 70 percent of the dollars spent by that customer, while providing only 30 percent of the volume. The customer is often in a terrible situation of being caught between the two duopoly providers.
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> Can the hospital switch from Duopoly A to Duopoly B? Of course, but now, 30% or more is purchased at the inflated list price from Duopoly A instead of Duopoly B. Can the hospital standardize on one supplier? Of course, except that, in some situations, *quid pro quo* and surgeons pounding the table to demand their product from their sponsoring buddies makes such unanimity next to impossible in most cases.
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> In some cases where Applied earned the trocar business, Covidien (previously Tyco Corporation, Bahamas) raised the prices on stapling products anywhere from 17 percent to 366 percent above the previous price. This is supposedly while facing severe competition from the other duopoly player who claims the balance of the market share in stapling products. Volumes and volume efficiencies in no way justify such fluctuations in pricing. The other half of the duopoly obviously did not present any relief to the beleaguered customer.