Testimony of

Mr. Said Hilal
President and Chief Executive Officer
Applied Medical Resources Corporation

United States Senate
Special Committee on Aging

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Thank you, Chairman Kohl and Ranking Member Senator Smith for holding this hearing. My name is Said Hilal, and I offer this statement on behalf of Applied Medical of Orange County, California. I appreciate the opportunity to outline the serious concerns I and my fellow Applied Medical officials have, about conflict of interest and ethics we have observed in America's health care system.

Applied has supplied improved clinical outcomes coupled with value since shortly after its inception in 1987. Our company offers sixteen surgical products lines, many of which represent significant advances in laparoscopy and minimally invasive surgery. We lead the market in hand access surgery for colorectal and abdominal procedures. Another one of our product lines protects incisions during abdominal procedures, especially C-Sections, and shows promise in reducing both infection rates and the need for follow-up pain medications. Yet another one of our product lines is "trocars." Trocars are access tubes equipped with advanced seals through which a surgeon inserts surgical instruments while maintaining pressure within the body cavity of a patient undergoing "minimally invasive" surgery. This type of surgery, using trocars, also is referred to as "keyhole" surgery, because the hole made by the trocar is about the size of an old-fashioned keyhole. Typically, the trocar provides a half-inch or smaller aperture for surgical instruments and a television camera to negate the need for large, open incisions and the lengthier recovery time typically associated with conventional open surgery.

In the interest of full disclosure, Applied has been in litigation related to antitrust and intellectual property against several other companies in the medical device industry. I have previously testified about issues relating to some of these matters before the Senate Judiciary Antitrust Subcommittee. While those issues are serious hurdles facing the smaller U.S. companies and start-ups, they do not compare to the challenges and damage of unethical practices and quid pro quo, given in return for sales. Manufacturers' rebates to hospitals, and fees and other payments, exaggerate the cost of individual procedures to Medicare accountants, and funnel funds through the backdoors of the institutions. Opaque pricing and bundling is gaming the American health care system every single day.

Because our products are used by surgeons, we sell to hospitals. We therefore, are very much affected by how business is conducted in hospitals. And because we pioneer new modalities and techniques, we support surgeon and resident training, as well as peer-reviewed scientific studies. Therefore, university hospitals are exceptionally important to us.

Ethical relationships between surgeons and device innovators are critical to the collective mission of improving clinical outcomes. New devices could not be developed without appropriate cooperation with clinicians. To us, medical device companies have an obligation to support research and education through unrestricted grants – but they must be unrestricted, with no strings attached.

Sadly, grants have deteriorated, often quite creatively, into quid pro quo instruments. We believe the correlation between grants and purchases is exceptionally and astoundingly high. We believe this clandestine correlation has a significant impact on market economics – and some surgeons have become inextricably beholden to suppliers. Such relations go past "corrupt" and become "corrupting". Clinicians become gatekeepers for suppliers, for the wrong reasons.

Corrupting influences are by no means reserved for teaching hospitals alone. While there are many appropriate consultant relationships that exist between medical technology companies and physicians during the development phase of a product, we hear of large suppliers approaching hundreds of surgeons with invitations to become "consultants". However, these physicians appear to be no more than an extension of the sales and marketing efforts of the large companies. Years may go by without any follow-up activity – until a new competitor is at the gates of the hospital. It is then that the so-called consultants are activated by the large supplier and paid to lecture, proctor and consult. As money starts flowing, the so-called consultants become ardent opponents of any change that threatens their sponsor's business, often adopting sponsor-designed lists of objections to challenge the new supplier.

With some hope, we watched as large companies adopted codes of conduct in an attempt to address their interactions with clinicians. But, since then, our hope has evaporated. My colleague, Gary Johnson, and I attended a meeting where large manufacturers put on a presentation to leading surgeons, allegedly to educate the clinicians on new AdvaMed guidelines for receiving "unrestricted" grants from suppliers.

The presentation was entitled "Is the Party Over?"

It turns out the party is far from over, if the presenters are right. At the presentation, surgeons were coached on how to act and communicate in a "safe" manner. The surgeons were actually reminded that grants are "…all about ROI, the return on investment." Although the words were often very carefully chosen, the message was clear – don't use the wrong words in your communications, don't e-mail, grab the phone

and call us, and you can still get the grants, and you just have to know what is expected in return, because that cannot be discussed.

To the credit of most surgeons, they deemed the effort inappropriate and distasteful. This is one reason U.S. clinicians and medical organizations remain the most respected around the world. They are believed to be mostly resistant to improper influences and pay-offs. Unfortunately, the reaction by many clinicians is not deterring manufacturers from searching for those who will "listen and cooperate." It is time to restrain the corrupting influence of big money and remedy this unhealthy situation.

Sadly, voluntary codes from industry, self-governance, and gentle slap-on-the-wrist settlements and "penalties" have been ineffective. Many manufacturers still feel comfortable skirting the edge and breaking promises of ethical conduct, while hiding behind superficial credos and codes. And as long as the penalty for making billions of unethical dollars for years is a few million dollars once every few years, these corrupting behaviors will not recede. Rather, these practices will continue to keep cost high, stifle competition and innovation and defer or prevent these cost-saving improvements from reaching our aging population.

In our opinion and experience, a multibillion-dollar medical supplier does not consider $40 million or $ 400 million in penalties, after years of violations, as painful or prohibitive or even painful. The reward far outweighed the consequence of the improper conduct. Settlements of this nature simply inform abusers how to better proceed with caution to obscure their tactics. This is what my colleague and I witnessed at the meeting I described – an invitation for participants to be more careful and covert.

We believe the country has unintentionally made available an affordable "Get out of Jail" card for these situations. Given the disproportional nature of profit to penalty, these monoliths do not even feel the slap.

Applied continues to enthusiastically support the efforts of this Committee. There is little that ethical companies can do alone. We hope and trust these unethical practices will continue to have your attention.

Given a level and honest playing field, we – and many American companies like us – can bring exceptional value to healthcare in the U.S. and around the globe. This great nation deserves the best healthcare, and it is our duty to aim for the best.

ADDITIONAL INFORMATION

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 645 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.

II. SOLUTIONS/CONCLUSION

We urge you to push forward with efforts to draft and enact legislation that permanently reforms behavior in this area and restores grants and research funds to their proper and constructive role in the process, for the sake of patients and hospitals, healthcare and improved clinical outcomes, and the continuing competitiveness of innovative U.S. manufacturers in world markets.

We also urge you to exercise your oversight responsibilities to encourage enforcement of the existing laws by the Federal Trade Commission and Department of Justice and at the same time as you act to strengthen those existing laws. Progressive European and Australian agencies are way ahead of us on these issues, and are often dealing with violators promptly and firmly.

We believe the U.S. has some catching up to do. Our nation has led the world in many fields where as capabilities increased, cost decreased, and, as volumes went up, so did availability, choice and competitive spirit.

At the risk of repeating the Applied mantra one more time, these favorable economic trends and accomplishments have not had the same opportunity to positively impact medical devices and healthcare. Clandestine practices and anti-competitive bundling of grants with products continue to take their toll.

On behalf of Applied Medical and its 1,200 team members, I urge you to restrain quid pro quo practices from the medical field.

Thank you.