Testimony
United States Senate Committee on the Judiciary
Hospital Group Purchasing: Has the Market Become More Open to Competition?
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A ONE YEAR RETROSPECTIVE ANALYSIS OF GROUP PURCHASING ORGANIZATIONS AND THEIR IMPACT ON SMALL-TO-MEDIUM SIZED COMPANIES IN THE UNITED STATES HEALTH CARE DELIVERY SYSTEM

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

BIOTRONIK, Inc. is a privately owned US company that became incorporated in the state of Oregon in 1988. During 2002, BIOTRONIK achieved approximately $80,000,000 in annual US sales. BIOTRONIK, Inc. employs approximately 160 people throughout the US and has another 100 people representing the company as independent sales agents. Our sister company, known as Micro Systems Engineering, Inc., also located in Lake Oswego, employs another 300 employees who are principally engaged in the design, development, and manufacture of cardiac pacemakers and implantable cardiac defibrillators.

The industry, known as the Cardiac Rhythm Management business, has been in existence since the early 1960s. Cardiac pacemakers and implantable cardiac defibrillators are used to treat cardiac rhythm disturbances and are “life saving” products. Cardiac pacemaker (pacemaker) or implantable cardiac defibrillator (ICD) therapy is generally managed by a Cardiologist or Electrophysiologist (EP).

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

The medical condition requiring pacemaker or ICD therapy is primarily associated with patients over the age of 60 years and, as such, most of the products are purchased through the United States Medicare System. The individual hospital purchasing the product is reimbursed by Medicare through what is known as the Diagnostic Related Group reimbursement codes, which pay a “set” amount of reimbursement to the hospital for the entire procedure. Physicians are reimbursed separately for their professional services.

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

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

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

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

GPOs began as organizations that were primarily interested in taking the collective buying power of the membership and entering into contracts that conceptually save the individual members money in their purchases of medical equipment and supplies. Today, GPOs have become much broader in the scope, service and value they attempt to deliver to their membership. Presently, the contracting element remains a primary piece of their business and continues to be the “principal” form of revenue generation for GPOs. Via the contracting service, GPOs negotiate and administer contracts at a national level for goods and services that their member hospitals are then expected to adhere to. GPOs typically do not purchase anything; they negotiate and administer contracts and administer the collection and distribution of the administration fees. The concept of GPOs remains valid in regard to their attempt to secure better pricing on products purchased by their members through the power of the total organization, as opposed to the power of an individual hospital. GPOs provide value-added services to their members and, certainly, in all cases, provide revenue-generating opportunities which hospitals may not have on their own merit because they do not participate in the same “safe harbors” that the GPOs have been granted in relation to the Medicare Anti-Kickback and Fraud statutes.

As a direct result of the pressures brought to the GPOs by the New York Times, and by the investigation of the United States Senate Committee on Antitrust, Competition Policy and Consumer Rights, GPOs have been requested to begin policing themselves and to establish “Codes of Conduct”. These so-called “Codes of Conduct” were to be established to (1) insure conflicts of interest do not exist, (2) insure contracting practices do not reduce or stymie competition or innovation in health care or narrow the ability of the physician to choose the best treatment for their patients, and (3) insure health care cost is being reduced by securing the best prices through volume purchases. In other words, to quote the April 30, 2002 report from the United States Senate Committee on the Judiciary, “The industry should clean up its own house.”.

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

As one would hope, BIOTRONIK has experienced improvements as a result of the efforts of the US Senate Subcommittee investigation. However, there remains “significant” work to be done to insure

that all companies, with an emphasis on smaller or newer companies in the Health Care industry, have equal and fair access to sell within the GPO system.

Areas of Improvement:

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

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

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

3. Over the past year, BIOTRONIK is pleased to report that GPOs, in general, have moved away from "sole source contracting" and are implementing dual source or multi-source contracts. A great example of this is HealthTrust who recently implemented a multi-source contract with all manufacturers within our industry.

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

Unfortunately, there are many areas that still need attention and improvement. The following points

will highlight some of the areas of concern that remain for BIOTRONIK and other small companies attempting to compete within the GPO environment.

AREAS OF CONCERN:

1. Contracting decisions, in general, continue to be "greatly influenced" by the market share of the vendor and the amount of money the vendor contract will generate for the GPO. The administration fee averages 3% within the industry; and within the Cardiac Rhythm Management industry, we are talking about a domestic revenue stream estimated to be $4,884,000,000. This means that between most GPOs there is approximately $146,520,000 in "administrative fees" available for distribution. This is a tremendous influence on the decision-making process. Many of the larger vendors pressure the GPOs to limit the contract award to one or two vendors. When you are holding 35% to 50% market share, you may wonder why should one pay the GPO an administrative fee at all, unless you are getting something for it. The something most large vendors are seeking is "exclusivity". Contracts where administrative fees are involved should be open to all vendors. We should not allow the large companies to put pressure on the GPOs to limit access of smaller companies. A case can be made that there is simply too much money involved in this process for GPOs to really be objective about the process. Administrative fees generally prevent a level playing field for small-to-medium sized companies.
2. GPOs tend to utilize physician advisory panels to help make decisions regarding which company provides the best product or the best combination of products, service, price, etc. At first glance, this appears to be an excellent way to identify which vendors to use; however, the physician panel will always "generally" represent the US market share and usually the contracting decisions nearly always reflect this decision. You can always count on the large market share leaders being accepted because this will represent the consensus of most "expert panels". If the GPO is limiting their contract to two vendors, the small vendor will rarely have a chance, even if their price could save the buyer thousands of dollars per unit. To insure fair access by all vendors, contracts need to be structured in such a way that they do not automatically guarantee the contract award to large market shareholders. Additionally, an almost ideal scenario would be contracts structured in such a way that the GPO allows all vendors to participate if the vendor is willing to meet a certain price (known as capitated pricing).

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

4. The total "projected" GPO industry purchasing volume, based on a survey conducted by Hospital Purchasing News, is estimated to be approximately $54.5 billion dollars. Assuming that most of this

is covered by administrative fees on an average of 3%, the net income generated through the administrative fee process is $1,635,000,000. This is a tremendous amount of money and very difficult to be objective about. The administrative fee concept needs to be reevaluated and policies put in place which insure that contracting decisions are not made based on how much revenue is generated by the individual contracts. Decisions should be based on the quality of the product, the service level of the provider and the savings generated by negotiating excellent pricing. Administrative fees should not be allowed to prevent market entry of small companies whether they are new or whether they simply find that they cannot penetrate a system that has the ability to lock out viable competitors. Today, we are seeing improvement as mentioned earlier. However, the single largest issue remains that the administrative fee process principally funds GPOs. The "Code of Conduct" does nothing to address this issue or the influence on the contracting decisions the administrative fees have on the system. This must either be corrected to insure all companies have fair access, or GPOs should operate on membership fees, and possibly share in the net savings they bring to their membership for each contract negotiated. In this case, the hospital would pay the GPO for some portion of the net savings realized.

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

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

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

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

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

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

Some GPOs appear to be managing this change better than others. On the other hand, there is still much to be done to insure that an open market occurs and we see both small and large companies having equal access to the GPO market. Virtually all hospitals in America are members of a GPO, or multiple GPOs. This means that for competition to thrive, for cost to be driven down, for physicians to have access to all technologies that can save lives or improve patient care there is still work to be done. The establishment of specific "Codes of Conduct" by various GPOs is only a start. Talk is cheap; in this case, action clearly speaks louder than words. GPOs must further implement provisions allowing fair access to vendors of any size and demonstrate that they are not being unduly influenced by the revenue generated from the administration fees versus the savings realized for their membership. As a company, BIOTRONIK believes in the basic concept of GPOs and wants to work with them to assist in achieving their individual objectives. We simply ask for a fair chance to sell to their systems and for a level playing field in which to work. There are still hindrances to this goal, which I discussed in the section of this paper addressing the concerns we are still observing one year after the April 30, 2002 report issued by the United States Senate Committee on the Judiciary "Hospital Group Purchasing: Lowering Cost at the Expense of Patient Health and Medical Innovation? We have every hope that your intervention will continue to provide a positive impact on this situation.

Respectfully submitted,

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