STATEMENT OF SENATOR KOHL IN SUPPORT OF THE MEDICAL DEVICE COMPETITION ACT OF 2004 OCTOBER 1, 2004

MR. KOHL: Mr. President, I rise today with Senator DeWine to introduce the Medical Device Competition Act of 2004. The legislation that we are introducing today is the product of 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.

For nearly three years, the Antitrust Subcommittee has undertaken a thorough investigation of the hospital purchasing industry. This industry – accounting for more than an estimated $ 50 billion in commerce – is responsible for purchasing nearly everything that a hospital buys to treat sick or injured patients, everything from simple band-aids to high tech x-ray machines, from pacemakers to surgical devices. Much of this purchasing is done under contracts negotiated by what are known as "group purchasing organizations" ("GPOs"), large organizations that aggregate the buying power of hundreds, and sometimes thousands, of hospitals in order to gain bargaining power and volume discounts from hospital suppliers.

Without question, the goal of gaining volume discounts through aggregating buying power that led to the creation of GPOs is laudable. Unfortunately, our inquiry revealed that a system created to aggregate demand and hold down cost had sometimes mutated into a tool for entrenching market power of dominant suppliers, locking out competitors, and suppressing innovation. All too often conflicts of interest and questionable GPO business practices denied physicians and their patients choice of needed medical devices and robbed hospitals of the benefit of competition.

Moreover, the power and importance of GPOs to our health care system increased as the GPO industry has undergone enormous consolidation in the last decade. As originally envisioned, GPOs were generally local or regional buying cooperatives each of whom accounting for a very small proportion of the market. Today, this situation is transformed. The two largest GPOs negotiate purchasing contracts for more than an estimated 60% of the nation's not for profit hospital beds. The size and national scope of these large GPOs have turned them into the gatekeepers who can decide which medical devices doctors will use and which medical device companies will be able to sell their lifesaving goods..

Our investigation uncovered abuses and questionable practices that interfered with the GPOs' mission of buying the best products at the best prices. At the time our investigation began in 2001, it was all too common a practice for GPOs to contract with only one supplier of a medical device for lengthy terms. Industry observers also raised concerns over contracts which bundled commodities like hospital gowns with medical devices like pacemakers and surgical equipment, creating nearly insurmountable barriers for smaller manufacturers with specialized product lines to compete, regardless of the quality or effectiveness of their product. Some GPOs accepted high payments – so-called "administrative fees" – well in excess of 3% from manufacturers. Worst of all, supposedly neutral contracting decisions were at times infected by equity interests held by GPOs or their executives in medical device companies.

We can be proud of the work of our subcommittee – and, indeed, many in the GPO industry -- in responding to this situation. At our behest, six of the largest hospital buying groups 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. The GPOs that agreed to these new codes should be commended for their willingness to engage in real reform. Thanks to these GPOs' good work and willingness to engage in reform, many of the most egregious practices began to disappear from the marketplace and barriers to patients getting access to the best medical devices more have begun to come down.

Yet these reforms – as real and important as they are – have inherent limitations. They are completely voluntary and can be modified or even withdrawn by the GPOs at will. They have no enforcement mechanism nor any manner to objectively verify that they are being adhered to. We have no assurance that the reforms will not be abridged or abrogated should our subcommittee's oversight come to an end. We must now, therefore, find a way to ensure that these gains cannot be reversed.

Despite their enormous influence, GPOs have until now operated with little, if any, governmental oversight. Quite the contrary, these GPOs have operated under special government protection – a Congressionally granted exemption from anti-kickback law. This exemption – commonly known as the "safe harbor" for GPOs – allows GPOs to accept payments from hospital suppliers even though these purchases are reimbursed by the Medicare program. Acceptance of

these payments from suppliers would be illegal absent this special exemption. The fact the hospital purchasing has this specially, Congressionally granted immunity from kickback mandates that government have the ability to oversee the manner GPOs are behaving under the protection of this exemption – oversight currently not required by law.

We are therefore today introducing legislation which will ensure that the Department of Health and Human Services will have the authority to oversee the functioning of the safe harbor and prevent anti-competitive or unethical GPO business practices. This is moderate and measured legislation which is not prescriptive in almost all respects. With only one exception, it does not outlaw any GPO practices or business arrangements. Instead, the bill grants oversight authority over hospital purchasing to HHS, and directs the HHS to draft regulations to prevent improper GPO conduct -- that is, unethical conduct, anti-competitive practices, or practices which preclude products necessary for patient care or worker safety from reaching physicians and patients. HHS is further directed to consult with the Federal Trade Commission and the Attorney General in developing these guidelines. Rather than micro-managing specific business practices, the discretion is left to the health policy experts at HHS, after consulting with the antitrust agencies – and only with the input of industry representatives through the notice and comment process – to develop the appropriate standards.

We recognize that different GPOs have different business models, and the goal of this approach is to permit GPOs to maintain these models as long as they do not violate basic precepts of good business conduct. As long as a GPO does not violate these standards, it continues to receive the immunity from anti-kickback law granted by the safe harbor. However, the penalty for GPOs that violate these standards is to be ineligible to participate in the safe harbor -- that is, being unable to accept payments from hospital suppliers. This sanction should prevent GPOs from reverting to unethical or anti-competitive conduct, and give HHS the regulatory tools to supervise the industry so that it serves the interests of hospitals and patients.

The one area in which our legislation is prescriptive addresses a principle to which most parties on all sides of the GPO debate – hospitals, manufacturers, and most GPOs themselves – have already agreed. This is the provision that bans GPOs from accepting payments from vendors which exceed three percent of price of the good or service sold. The intent of this provision is to forbid excessive vendor fees which can bias a GPO contracting decision. The decision on which

product is placed on a GPO contract should never turn on the amount of money paid by the manufacturer to the GPO; rather, a GPO's only goal should be to contract for the highest quality product at the lowest possible price. Most GPO's codes of conduct already ban vendor fees higher than 3%; however, during our investigation we learned that one of the nation's two largest GPOs had accepted fees above 20%. Indeed, data submitted to the Subcommittee showed that during 2002 over 20% of that GPO's revenues was derived from contracts with vendor fees higher than 3%, a proportion that had increased from the previous year. The safe harbor should not shield such practices, conduct which has the strong potential to bias the whole system.

In sum, we believe that our bill is a modest yet effective legislative approach to ensuring that the gains we have achieved over the past two years are not reversed, and that the safe harbor is administered in a way to promote innovation, competition, and cost savings. This legislation will give the authority that HHS needs to be an effective watchdog over hospital purchasing practices. Once this legislation is passed we can be confident that the reforms to the hospital purchasing industry that we have achieved over the last two years will remain in place, and that there will never be a return to practices that imperiled patient health and health worker safety, and blocked competition and innovation in this vital industry.

The bottom line is that our bill will encourage medical innovation, ensure doctors get the broadest choice of medical devices, and ensure that patients will receive the best possible devices available. These are goals we should all support. I urge my colleagues to join me in supporting this legislation.