## Opening Statement of Senator Herb Kohl Special Committee on Aging Hearing "Surgeons for Sale? Conflicts and Consultant Payments in the Medical Device Industry" February 27, 2008

We welcome everyone to today's hearing and we thank our witnesses for taking time out of their busy schedules to be with us.

Last June, I chaired a Special Committee on Aging hearing that examined the financial and gift-giving relationships that exist between the pharmaceutical industry and physicians. What we learned is that there is a need for more disclosure relating to doctors accepting gifts from drug companies. Following that hearing, Senator Chuck Grassley and I introduced the Physician Payment Sunshine Act, which would create a national database of payments and gifts to physicians from a variety of medical sources.

Today, we will focus on the tangled, murky, and sometimes conflicting financial relationships between the medical device industry, surgeons and physicians. It is important to note that these relationships can play an important role in product innovation, and in areas where these relationships are legitimate and productive, we do not wish to disturb them. However, over the past decade, it's become clear that interactions between medical device companies and surgeons often involve substantial payments, taking the form of consultant fees, educational grants, royalties, funding for clinical trials, travel and gifts. Some of these payments have been alleged to be grossly excessive, illegitimate, and often not properly documented. It's not hard to see that these financial relationships create conflicts of interest, and can exert inappropriate influence over medical decisions. In some documented cases, they break the law.

We will hear testimony today that these types of frequently unethical payments are not anecdotal, but rather have been pervasive and industry-wide for far too long. We will hear that both the medical device industry and the physicians who take their money are equal participants and equally culpable. One witness will relate that some physicians make it known to these companies that they will be loyal to the highest bidder. If these physicians are essentially putting their medical judgment up for sale, where does the patient's well-being fit into the equation?

Over the past several months, Committee staff has interviewed dozens of surgeons and medical device industry sales representatives to learn more about the conditions surrounding these payments. Disturbingly, some physicians related that they felt shunned when they declined to take part in financial relationships with the industry. One surgeon provided a written statement to the Committee concerning payment offers explicitly intended to induce her to use particular medical device products.

To speak to this, we have with us today a clinical professor of surgery and an industry executive to offer their perspectives on the problems raised by these types of payments. We will also hear from the HHS Office of the Inspector General. The Justice Department and the OIG have been examining in-depth these troubling and widespread conflicts for at least three years. In September of last year, the Justice Department reached settlement agreements with the top five orthopedic device makers which dominate their industry. According to Committee staff's calculations, the five orthopedic companies which settled agreements with the Justice Department last fall spent a combined total of at least \$230 million dollars on these consultant and other payments.

While these companies have admitted no wrongdoing, they collectively paid the government more than \$310 million in settlement fines relating to their handling of these types of payments. Officials from two of these companies, Stryker and Zimmer, are here today. I would like to thank their representatives for agreeing to testify before the Committee, and I want to emphasize that the

concerns we raise today pertain to the entire range of firms that dominate the industry, not just to these two manufacturers. A witness from AdvaMed will also speak on behalf of the medical device industry today.

In fairness, this investigation has also shown that surgeon-owned medical device companies also have potentially serious conflicts of interest, as we will hear from the Inspector General's Office. The Committee has sent detailed questions and document requests to a number of these firms, asking for the same type of information and disclosure that we required from the larger medical device companies. Most have responded, and we intend to continue this line of inquiry to ensure that the entire industry is accountable in these conflict of interest matters.

In closing, I'm well aware that medical device associations and physician groups have written voluntary ethical guidelines addressing these areas--but the issue before us today is whether they have been or are being followed. There will be ample evidence presented today indicating that they are not. I look forward to working with my cosponsors Senators Grassley, McCaskill, Klobuchar, Kennedy and Schumer, along with my colleagues in the Senate, to get our important disclosure legislation passed. Once again, I thank everyone for their participation and now turn to our Ranking Member, Senator Gordon Smith, for his opening statement.