Opening Statement of Senator Herb Kohl
Special Committee on Aging Hearing
Marketing or Medicine: Are Direct-to-Consumer
Medical Device Ads Playing Doctor?
September 17, 2008

Good morning. Thanks to all our witnesses for being here. Today we are examining issues related to direct-to-consumer, or DTC, advertising for restricted medical devices that are regulated by the Food and Drug Administration. This is part of an ongoing, fifteen-month series of oversight hearings we have held on medical device and pharmaceutical marketing.

Unlike direct-to-consumer advertising of drugs, DTC advertising of medical devices has not yet been highly scrutinized. Since the mid-1990's, when the federal government changed the rules regulating such advertising, the drug industry has spent billions of dollars advertising their products directly to consumers. The FDA has devoted considerable resources to the oversight of DTC pharmaceutical advertising, and there have been several congressional hearings held on the controversial practice.

However, the medical device industry is just beginning to get into the game. Over the past four or five years, their use of DTC ads is growing on television, in print, and on the Internet. Hundreds of millions of dollars have been spent on them, according to the Congressional Research Service, or CRS. While their spending on DTC ads is still only a fraction of drug industry spending, the medical device industry's stake in this marketing practice is growing.

In recent years, a number of DTC ad campaigns have been launched in an effort to market specific and often complex medical device products, some of which require surgery to obtain. As with DTC drug ads, the FDA has raised concerns about advertising restricted medical devices; specifically, about whether appropriate risk and safety information is provided to consumers, including seniors and the elderly.

This morning we'll hear from a variety of medical, advertising, and consumer experts. They will detail for the committee perceived shortcomings in DTC advertisements for medical devices, and how these ads can subtly influence consumers and patients. Our witnesses also will outline recommendations on how we might improve the review and oversight of these ads. We'll hear from the head of the FDA's medical device center about how the agency oversees these DTC medical device ads, as well as how those methods differ from the more extensive FDA efforts to track and analyze DTC drug ads.

We've also invited AdvaMed to testify this morning. AdvaMed is the largest medical device industry organization and will weigh in on the question of regulating DTC medical device ads. I should note that in 2006, the American Medical Association announced its support for enhanced regulation of DTC ads by the FDA, and went so far as to call for a moratorium on all new DTC ads until physicians have been appropriately educated about the drug or medical device. Based on what we learn here today, I am prepared to work with Chairman Dingell in the House to consider similar legislative measures.

I want to acknowledge that DTC advertising may have benefits. Responsible DTC advertising can encourage consumers and patients to become proactive in their own treatment plan, and encourage a wide audience to consider preventative medicine. These are positive and potentially valuable aspects of DTC advertising.

Again, I thank our witnesses and welcome them here today.