

Testimony of Hans Beinke
Vice President, Healthcare
USA Country Head for Quality and Technology for Siemens Medical Solutions
United States International Trade commission
February 9th 2012

Good morning Chairman Okun and members of the commission. I am Hans Beinke, the Vice President, Healthcare USA Country Head for Quality and Technology for Siemens Medical Solutions. I have been in the medical device industry for over 30 years. Siemens Medical Solutions is a manufacturer of medical imaging devices such as X-ray, computed tomography (CT), radiation therapy, diagnostic ultrasound, molecular imaging, magnetic resonance (MR, and remanufactured imaging medical devices. Siemens is also a publicly traded company in the US and a proud employer of roughly 17,000 US healthcare workers. Perhaps you saw President Obama's State of Union Address January 24 in which he highlighted the job creation efforts of Siemens related to innovative technologies.

I would like to thank the commission for the invitation to testify before you today. It is an honor to be here to provide some insights on the state of remanufactured goods from a medical imaging device perspective. I would also like to thank you for the commitment of the United States International Trade Commission (USITC) to the growth of industry and the US economy.

During this testimony, I will provide you information on the state of the remanufacturing business available to me. What follows is a detailed response to questions raised in your invitation on January 9th 2012. I will qualify my responses with the fact that my expertise is in the area of FDA medical devices regulations and not as a marketing expert.

The size and scope of remanufacturing in the United States, including principal producers, levels of employment, investments, and sales, (including in the domestic and exports)

The current world market for remanufactured medical imaging equipment is estimated at 1.5 billion dollars per annum. The U.S. market accounts for about 560 million dollars a year. The U.S. medical imaging device remanufacturing business is

split between 3rd party remanufacturers and original manufacturers such as GE, Siemens, Philips and Toshiba.

The U.S. market for remanufactured goods, including the goods supplied by domestic producers;

The market size for the U.S is approximately 560 Million dollars, which accounts for more than 35 percent of the global market. Approximately 90 percent of the 560 Million dollars is domestically produced by U.S. based companies.

U.S. exports of remanufactured goods, including by primary sector and leading exports destinations. The report should also compare U.S. exports of remanufactured goods to free trade agreements partners with exports to non free trade partners. To the extent possible, information on the level of U.S. imports of remanufactured goods as well as the level of imports of “cores” (used goods acting as the primary component input(s)) and the primary source for these products;

Different countries have very different laws regarding importing used or remanufactured system, e.g. Presently, China and a few other countries do not allow any import of remanufactured medical imaging equipment; while countries like Japan, India, Mexico allow imports. Most countries also have different purchasing rules for their government, public and privately owned providers when buying new vs. remanufactured equipment.

With regard to importing used, remanufactured goods into the U.S., 3rd party providers import used equipment into the U.S. from Asia, and Europe to resell to other 3rd parties or end customers. From an OEM perspective, some OEMs manufacture outside the U.S. and then their U.S. sales force sell the equipment to end customers.

The factors affecting sales, trade, and investment in US remanufactured goods including a discussion of recent trends.

Recession and reimbursement cuts require providers to look for state-of-the art as well as economical imaging solutions. Institutions buy based on clinical needs as well as budgetary constraints. Remanufactured imaging equipment can be a solution for

these institutions. Thus, the market is estimated to continue to grow 3 to 4% annually and continue to be a stable part of the imaging product offerings. The primary customers for remanufactured systems are smaller, rural hospitals and diagnostic imaging centers. The availability of remanufactured medical imaging devices is limited by the willingness of providers to replace their systems and make these replaced systems available for remanufacturing.

It can be assumed that if larger health facilities buy newer devices, their used medical imaging devices can be sourced, remanufactured and sold to medium to small health facilities that may not have the capital resources for the newest devices available on the market.

Regarding trends, there are ongoing discussions to harmonize terminologies and practices used in the medical device remanufacturing industry. To this end, a Good Refurbishment Practices (GRP) document has been developed by a collective of international organizations (JIRA, MITA and COCIR). Additionally, this group is considering the appropriate term to refer to these activities (remanufactured, refurbished, remarketed. Note: the FDA defines “remanufactured” as changing the initial intended use of the device). Industry hopes these efforts will facilitate the exchange of information globally and create a common understanding of best practices within the industry.

An assessment of foreign direct investments (FDI) in U.S remanufacturing, including associated employment and the extent to which foreign firms have invested in U.S. enterprises producing remanufactured goods;

It is estimated that approximately 180 million dollars is invested in the medical imaging device remanufacturing industry yearly by multinational entities. This figure includes the costs for remanufacturing plant improvement, capital equipment, and labor.

An overview of outward FDI in remanufacturing by leading US based firms, including their major markets;

OEM manufacturers also invest in additional remanufacturing plants outside the U.S. such as India. Because, some countries only allow the sale of remanufactured

equipment in their country if it was produced in their country, we might see remanufacturing plants being opened in these countries.

An analysis of trade by foreign remanufacturers invested in the United States, include trade in “core” and

Medical imaging device “cores” are large and bulky; so many remanufactured medical imaging devices are remanufactured within the country where they are sourced. Approximately 80 percent of “cores” are locally sourced and about 20 percent are imported.

An overview of the global markets for remanufactured goods and enterprises engaged in remanufacturing.

As I stated earlier, it is approximated that the US accounts for 35 percent of the global medical imaging device manufacturing. Within the medical imaging device industry, most remanufacturing activities are carried out by 3rd party vendors and original manufacturers such as Siemens, Toshiba, Philips and GE

In conclusion, I would like to once again thank the commission for your time and consideration of this important issue. I hope you find my answers helpful to your work. I look forward to continuing the dialogue with the commission. I will take any question you may have. Thank you