



**HOUSE WAYS AND MEANS COMMITTEE
SUBCOMMITTEE ON TRADE**

**HEARING ON
U.S. – Korea Free Trade Agreement (FTA)
April 7, 2011**

**STATEMENT BY
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Accuray Incorporated, manufacturer of the CyberKnife® Robotic Radiosurgery System, would like to thank the Committee for holding this important hearing on the U.S. -Korea Free Trade Agreement (FTA). Not only will this FTA expand market access for our product and those of other U.S. companies operating in Korea, it will allow Accuray to improve access for patients in Korea to the life-saving technology that our company designs and manufactures.

Founded in 1990, Accuray manufactures the CyberKnife® Robotic Radiosurgery System, a non-invasive alternative to surgery for the treatment of both cancerous and non-cancerous tumors anywhere in the body. The treatment – which delivers precision beams of high dose radiation to tumors with extreme accuracy – allows physicians to treat highly complex or hard to reach tumors safely (for example, tumors inside the spine or those wrapped around critical structures) while sparing surrounding healthy tissue. For many patients, treatment with the CyberKnife System, is life-saving. For others, it is a clinically effective and patient-friendly alternative to invasive surgery or long courses of less precise radiation treatment. CyberKnife treatments are typically offered in five or fewer short daily sessions. They are pain-free with minimal to no side effects, and allow patients to return immediately following treatment to normal activities, minimizing time away from family and work. The CyberKnife System exemplifies American ingenuity in the service of the public's health.

To date, over 200 CyberKnife Systems have been installed worldwide, and over 100,000 patients have been treated, including over 6,000 in Korea. Accuray's business is strong, but we cannot underestimate the importance of sales outside the U.S. to the continued health of our organization. In FY 2010, 57 percent of new orders for the CyberKnife System were generated



outside of the U.S. Company exports, therefore, play a key role in supporting our U.S. workforce of over 400 employees. Accuray employs a highly skilled and highly paid work force, including jobs in engineering, clinical development, manufacturing, management, marketing, service, and sales.

The U.S. Department of Commerce notes that Korea is one of the largest and fastest growing export markets for medical technology, with growth between 10 and 15 percent expected over the next several years¹. To date, Accuray has had good success making its cutting edge technology available to Korean patients, with export sales of roughly \$30 million and an installed base in Korea of 9 Systems. By expanding market access, free trade agreements like the U.S.-Korea FTA will support the commercial success of companies like Accuray, increasing US competitiveness in a global economy. At the same time, they will allow our trading partners to benefit from American leadership in medical technology through adoption of products like the CyberKnife System that benefit the health and welfare of their citizens.

The U.S.-Korea FTA comes at a timely moment. With Korea's evolving national health insurance system expanding to cover more and more procedures, the Korean people are becoming accustomed to a higher level of health care. This could create significant U.S. export opportunities for companies like ours. However, expansion of the health insurance system has not been without growing pains. As government officials seek, understandably, to control cost while expanding access, a need arises to ensure that well-intentioned payment policies do not

¹ International Trade Administration, US-Korea Trade Agreement, Opportunities for the US Medical Equipment Sector, April 2011 Report



have the unintended consequence of reducing patient access to Accuray's and other U.S. companies' effective, patient-friendly and efficient technologies. Without the FTA, American manufacturers have no voice in the Korean reimbursement setting process, or ability to provide crucial product information to support informed decision-making by the Korean agencies. With the FTA, both U.S. manufacturers and Korean patient interests are better served.

The U.S.-Korea FTA is the first U.S. free trade agreement with specific provisions for the medical technology industry. Included in Chapter 5 on Pharmaceutical Products and Medical Devices, these provisions, among other things, affirm the importance of sound economic incentives in assuring patient access to medical technology and provide a needed voice for the manufacturer in the determination of product reimbursement. Specific provisions of the U.S. – Korea FTA addressing the concerns of U.S. medical technology companies, like Accuray, include the following:

- The FTA acknowledges the importance of access to medical technology to the provision of high quality health care and the importance of patented products in reducing other more costly expenditures;
- It provides for the promotion of innovation and timely and affordable access to safe and effective medical devices through transparent and accountable procedures;
- It calls for fair, reasonable and non-discriminatory procedures for the setting of reimbursement rates that are mainly derived from market competition;



- In instances where non-competitive practices define reimbursement rates, the agreement permits manufacturers to apply for increased level of reimbursement based on the product's safety or efficacy;
- The FTA contains a requirement for transparency of regulations and rules affecting medical technology, including advance publication of rules prior to implementation with a reasonable opportunity (at least 60 days) to provide comment;
- It calls for timely approval of reimbursement requests for medical technology products;
- It enhances transparency via a commitment to make available in a timely manner to applicants all procedural rules, methodologies, principles, and criteria, used to determine pricing and reimbursement for medical technology, including detailed written information regarding the basis for a decision or recommendation;
- It provides manufacturers timely and meaningful opportunities to provide comments at relevant points in the pricing and reimbursement decision-making processes;
- It establishes an independent review process that may be invoked at the request of a manufacturer directly affected by a recommendation or determination; and
- It establishes an important commitment to openness of reimbursement decision-making bodies to all stakeholders, including innovative and generic companies.



These commitments are especially important to Accuray at this moment in time. The Korean Government health insurance authority is in the midst of setting a new price for CyberKnife treatments in Korea. Without the important safeguards provided in the U.S.-Korea FTA, we find ourselves, as a manufacturer, without a place in the decision-making process and concerned that a new pricing policy may be implemented based on incomplete assumptions about our product, its clinical applications, and its cost. Without the kind of transparency safeguards, and commitments to pricing policies that are based on sound economics that exist in the US-Korea FTA, our ability to continue to do business in Korea may be compromised, to the detriment of both US economic and Korean patient interests. Accordingly, the value of Chapter 5 has become increasingly apparent to Accuray. It is for this reason that we are reaching out to support approval of the FTA by the Congress as quickly as possible.

We join our trade association, AdvaMed, in recognizing the strong effort by USTR in negotiating these provisions on behalf of our industry. We agree that the U.S.-Korea FTA will establish essential protections that will better ensure a more competitive, transparent and predictable market in Korea. Importantly, it will also better enable Accuray and other U.S. medical technology companies to bring life saving treatments to Korean patients who need them.

Thank you for the opportunity to comment on this important trade agreement.