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HOUSE WAYS AND MEANS COMMITTEE
HEARING ON
PENDING FREE TRADE AGREEMENTS (FTAs)
AND JOB CREATION

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STATEMENT BY

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We thank the Committee for holding this important hearing today on the pending free trade agreements (FTAs) between the United States and some of our trading partners and the impact of FTAs on U.S. job creation. We strongly support the efforts to expand market access for U.S. products abroad through new FTAs as one means of increasing U.S. competitiveness in a global economy.

AdvaMed is the world's largest medical technology association. AdvaMed represents the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. AdvaMed is proud to represent an industry that brings new hope to patients around the world. U.S. companies are still benchmark manufacturing leaders in terms of total production, innovation and highest quality products. Our member companies manufacture nearly 90% of the \$94 billion U.S. health care technology market, and nearly 50% of the \$240 billion of medical technology products that are purchased globally each year. In 2009, U.S. exports in medical devices and diagnostics totaled over \$33.2 billion.

The size of AdvaMed member companies spans the full spectrum from large multinationals to very small start-ups. About two-thirds of AdvaMed members are small in size but are among the most dynamic in terms of innovation. Indeed, the medical technology industry is fueled by intense competition and the innovative energy of small companies – firms that drive very rapid innovation cycles among products, in many cases creating new product iterations every 18 months. Accordingly, our US industry succeeds most in fair, transparent global markets where products can be adopted on their merits without excessive regulatory hurdles or inappropriate reimbursement policies.

Medical technology products improve people's lives and contribute to economic progress. In a world of shrinking healthcare resources, medical technology products are an investment in our most valuable resource – the health of our people. The returns on that investment are the long-term benefits that can be achieved when we provide the resources needed for the best medical care. These benefits include greater quality of life, productivity and economic competitiveness.

Impact of Free Trade Agreements on Medical Technology Exports

Because of the relative size of the Korean market for medical technology, compared to the markets in Colombia and Panama, we have devoted limited staff time to focus on the Korea-U.S. Free Trade Agreement (KORUS). Also, the KORUS has specific provisions addressing the concerns of the medical technology industry. Provisions in the FTAs with Colombia and Panama, such as the elimination of tariffs on medical devices and diagnostics, would lower costs for our members' products entering those markets.

The KORUS illustrates the benefits that FTAs can bring to the medical technology sector and to job creation in the U.S. Korea is an extremely important market for United States medical technology exporters. According to the U.S. Department of Commerce, Korea is the fifth largest export market for U.S. medical device manufacturers. U.S.



manufacturers exported over \$700 million worth of medical technology products to Korea in 2009, while Korea exported \$253 million in medical technology products to the United States. The U.S. International Trade Commission estimates that the Korean medical device market will grow 10-15 percent in the next several years. With a growing economy, the Korean people will come to demand an even higher level of health care and, with it, will come increased U.S. export opportunities. AdvaMed views the implementation of the Korea-U.S. Free Trade Agreement as an opportunity to increase exports of medical technology products to this expanding market.

However, access to the Korean market is currently limited by excessive tariffs; pricing and reimbursement policies that discriminate against foreign manufacturers; burdensome product-testing requirements; and inappropriate requirements to register products in their country of origin and re-register following a change in manufacturing location. Korea was not a party to the Uruguay Round “zero-for-zero” tariff elimination initiative for medical devices, and maintains import tariffs on a range of medical technology products, including most of our top export categories.

AdvaMed strongly supports adoption and implementation of the U.S.-Korea FTA as quickly as possible as it will serve to assist in eliminating tariffs and non-tariff measures applied to medical technology products by Korea. We anticipate that implementation will provide greater access and a more equal competitive arena for U.S. medical technology in the Korean market. The effect of implementation of the U.S.-Korea FTA will be to increase the availability of medical technology in the Korean market, thereby allowing increased access by Korean patients to the most innovative technologies and treatment options.

The U.S.-Korea FTA is the first U.S. free trade agreement with specific provisions for the medical technology industry. Chapter 5 of the FTA contains a number of protections for the medical technology industry, and also attempts to address many of the concerns that have been experienced by our industry and that remain pervasive. Some of the provisions most beneficial to the medical technology industry include the following:

- The agreement 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 prices that are mainly derived from market competition;
- In instances where non-competitive practices define reimbursement rates, the manufacturer is permitted to apply for increased level of reimbursement based on the product’s safety or efficacy;



- Transparency of regulations and rules affecting medical technology is provided, including advance publication of rules prior to implementation with a reasonable opportunity (at least 60 days) to provide comment;
- Requests for approval or reimbursement for medical technology products will be processed within a reasonable timeframe;
- Applicants will be provided within a reasonable and specified time all procedural rules, methodologies, principles, and criteria, used to determine pricing and reimbursement for medical technology, including detailed written information regarding the basis for the decision or recommendation;
- Applicants will be provided timely and meaningful opportunities to provide comments at relevant points in the pricing and reimbursement decision-making processes;
- An independent review process will be provided that may be invoked at the request of an applicant directly affected by a recommendation or determination;
- Reimbursement decision-making bodies will be open to all stakeholders, including innovative and generic companies; and
- A membership list of all committees related to the reimbursement and pricing of pharmaceutical products and medical devices will be made publicly available.

Additionally, under the FTA's strong dispute settlement provisions, implementation of the FTA will mean that the medical technology industry will gain very important procedural safeguards against arbitrary and non-transparent reimbursement and regulatory decisions by Korea.

The implementation phase of the agreement is critical in ensuring the success of these provisions and will offer challenges to maintain their letter as well as spirit. The negotiation of these provisions and their inclusion in the FTA is a tribute to the effort by USTR, working with our industry.

We view these as essential protections that will better ensure a more competitive, less arbitrary market in Korea. Implementation of the FTA will ensure these hard won provisions are brought to life.

Impact on U.S. Jobs

The medical technology industry is a powerful economic driver in the United States. In the United States in 2008, the medical technology industry employed 422,778 workers; paid \$24.6 billion in salaries; and shipped \$135.9 billion worth of products.

Until 2003, the United States ran a significant trade surplus in medical technology products. The U.S. industry is witnessing a slow-down in the value of exports, largely as

a result of foreign government reimbursement and regulatory policies. The industry needs U.S. Government support to address these issues and to eliminate other market access restrictions.

Examining the industry on a state by state basis, according to recent data, the median figure for all states in the United States indicates the following:

- Each medical technology job generates an additional 1.5 jobs in that state.
- Each medical technology payroll dollar generates an additional \$0.90 in earnings in that state;
- Each dollar of medical technology sales generates an additional \$.90 in sales in that state.

Implementation of the FTA would help United States retain and expand jobs in the U.S. Decreasing tariff and non-tariff barriers will obviously lead to more sales of U.S. medical technology products in Korea. Implementation of the FTA would therefore benefit not just the medical technology sector, but also would create positive collateral benefits to the U.S. economy as a whole. These benefits are in addition to the benefit that will accrue to the Korean people, benefits derived from obtaining the most innovative products, increased patient choice and treatment options, and improved quality of life.

Non-implementation would put us at a disadvantage because, as other nations establish FTAs with Korea, the U.S. domestic industry would face increased competition. For example, some U.S. firms manufacture in the European Union (EU), which has negotiated an FTA with Korea. If, as a result, shipping manufactured medical technology products from the EU becomes more cost-effective than shipping it from U.S. manufacturing plants, valuable jobs could shift overseas.

Conclusion

The United States must negotiate and implement strong FTAs as one means of providing a level playing field for U.S. firms and improving U.S. competitiveness in the global market place. We cannot afford to cede U.S. leadership on international trade to other countries. The KORUS provides an illustration of the benefits that FTAs can bring to the U.S. medical technology industry. These benefits are the result of improvements in market access that the agreements provide. This improved market access will help U.S. medical technology firms increase their exports, with a direct and strong impact on employment in the United States. Adoption of FTAs will benefit U.S. workers, the U.S. economy, and patients overseas.



ANNEX I

Medical Devices – Harmonized Tariff Schedule (HTS) Codes

HTS Heading	HTS Description	Tariff Rate in Korea's 2005 Schedule
2844.40	Radioactive elements and isotopes	0
3005	Wadding, gauze, bandages and similar articles for medical, surgical, dental or veterinary purposes	0
3006.10	Sterile surgical catgut, similar sterile suture materials and sterile tissue adhesives for surgical wound closure and similar sterile material	0
3006.20	Blood-grouping reagents	0
3006.30	Opacifying preparations for X-ray examinations; diagnostic reagents designed to be administered to the patient	0
3006.40	Dental cements and other dental fillings; bone reconstruction cements	0
3006.50	First-aid boxes and kits	0
3407 <i>Excluding 3407.00.2000 (modeling clay)</i>	Preparations of dental wax or dental impression compounds; other dental preparations of plaster	6.5
3821	Prepared culture media for development of micro-organisms	6.5
3822	Diagnostic or laboratory reagents on a backing and prepared diagnostic or laboratory reagents	3822.00.10.00-3822.00.10.90: 0 3822.00.10.91: 6.5 3822.00.10.92: 8 3822.00.10.93: 0 3822.00.10.99: 8 3822.00.20.11-3822.00.20.90: 0 3822.00.20.91: 6.5 3822.00.20.92: 8 3822.00.20.93: 0 3822.00.20.99: 8
4015.11	Surgical gloves, of vulcanized rubber other than hard rubber	8
4015.19.0510	Medical gloves, of natural rubber	8
4015.19.0550	Medical gloves, other	8
4206.10.30	Articles of gut for use in the manufacture of sterile surgical sutures	8
6115.12.10	Surgical panty hose of synthetic fibers	13
6115.19.20	Surgical panty hose of other textile materials	13



6115.92.30	Surgical stockings of cotton	13
6115.93.30	Surgical stockings of synthetic fibers	13
6307.90.60	Surgical drapes of fabric formed on a base of paper or covered or lined with paper	10
6307.90.68	Surgical drapes of spunlaced or bonded fiber fabric; disposable surgical drapes of man-made fibers	10
6307.90.72	Other surgical drapes	10
6307.90.89	Surgical towels	10
8419.20	Medical, surgical or laboratory sterilizers	0
8419.90.5040, 8419.90.9040	Parts and accessories for medical, surgical or laboratory sterilizers	0
8543.89.85	Electrical machines and apparatus for electrical nerve stimulation	0
8713	Carriages for disabled persons, whether or not motorized or otherwise mechanically propelled	0
8714.20	Parts and accessories of carriages for disabled persons	0
9001.20	Sheets and plates of polarizing material	8
9001.30	Contact lenses	8
9001.40	Spectacle lenses of glass, unmounted	8
9001.50	Spectacle lenses of other materials	8
9003.11	Frames and mountings of plastic	8
9003.19	Frames and mountings of other materials	8
9003.90	Parts for frames and mountings, spectacles, goggles or the like	8
9004.10	Sunglasses	8
9004.90	Spectacles, goggles and the like, protective	8
9018	Instruments and appliances used in medical, surgical, dental or veterinary sciences, and electro-medical apparatus and sight-testing instruments; parts and accessories thereof	8
9019 <i>Excluding 9019.10.2020 and 9019.10.2030 (hand-held massagers and parts thereof)</i>	Mechano-therapy appliances; massage apparatus; psychological aptitude testing apparatus; ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus; parts and accessories thereof	0
9020.00.60	Breathing appliances and gas masks	8
9020.00.90	Parts and accessories for breathing appliances and gas masks	8
9021	Orthopedic appliances, including crutches, surgical belts and trusses;	0



	splints and other fracture appliances; artificial parts of the body; hearing aids and other appliances which are worn or carried, or implanted in the body, to compensate for a defect or disability; parts and accessories thereof	
9022 <i>Excluding 9022.19.0000, 9022.29.4000, 9022.29.8000, and 9022.29.0700 (non-medical equipment; smoke detectors and parts thereof)</i>	X-ray equipment	8
9025.11	Liquid filled clinical or veterinary thermometers	8
9025.19.00.40, 9025.19.80.40	Other clinical thermometers	8
9402	Medical, surgical dental or veterinary furniture and parts thereof	0
9608.20.0000*	Felt-tipped and other porous-tipped pens and markers.*	8

Source: U.S. Harmonized Tariff Schedule, Advanced Medical Technology Association, Korea 2005 Tariff Rate Schedule as reported on the APEC Tariff Database

*Note: Skin markers for surgery are included in this category; if the tariff cannot be removed from the entire category, AdvaMed recommends creating a more specific eight- or ten-digit code for the surgical markers and lift the tariff on that code.



ANNEX II

Top 10 U.S. Medical Technology Exports to Korea, 2005

HTS Heading	HTS Description	U.S. Dollars	Tariff Rate in Korea's 2005 Schedule	Est. Cost of Tariff in 2005
3822000002	Diagnostic or laboratory reagents on a backing and prepared diagnostic or laboratory reagents	\$60,375,932	0	-
9001200000	Sheets and plates of polarizing material	\$59,222,040	8	\$4,737,763
9018908000	Instruments and appliances used in medical, surgical, dental or veterinary sciences, and electro-medical apparatus and sight-testing instruments	\$54,706,123	8	\$4,376,490
9018390030	Bougies, catheters, drains and sondes and parts and accessories	\$30,466,031	8	\$2,437,282
9022140000	X-ray equipment	\$23,303,336	8	\$1,864,267
9018120000	Ultrasonic scanning apparatus	\$22,946,442	8	\$1,835,715
9018906000	Electro-surgical instruments and appliances and parts and accessories	\$21,185,957	8	\$1,694,877
9018199560	Parts and accessories for electro-diagnostic apparatus	\$19,734,740	8	\$1,578,779
8419200000	Medical , surgical or laboratory sterilizers	\$18,614,420	0	-
9018130000	Magnetic resonance imaging apparatus	\$18,614,420	8	\$1,489,154
Total (Top 10)		\$329,888,696		\$20,014,327
Total Export Value		\$623,185,405		

Source: U.S. Department of Commerce, U.S. International Trade Commission, Korea 2005 Tariff Rate Schedule as reported on the APEC Tariff Database