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Urging Japan to honor its commitments under the 1986 Market-Oriented Sector-Selective (MOSS) Agreement on Medical Equipment and Pharmaceuticals, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 18, 2005

Mr. COLEMAN submitted the following concurrent resolution; which was referred to the Committee on Foreign Relations

CONCURRENT RESOLUTION

Urging Japan to honor its commitments under the 1986 Market-Oriented Sector-Selective (MOSS) Agreement on Medical Equipment and Pharmaceuticals, and for other purposes.

Whereas the revolution in medical technology has improved our ability to respond to emerging threats and prevent, identify, treat, and cure a broad range of diseases and disabilities, and has the proven potential to bring even more valuable advances in the future;

Whereas medical technology has driven dramatic productivity gains for the benefit of patients, providers, employers, and our economy;

Whereas investment from the United States medical technology industry produces the majority of the

\$220,000,000,000 global business in development of medical devices, diagnostic products, and medical information systems, allowing patients to lead longer, healthier, and more productive lives;

Whereas the United States medical technology industry supports almost 350,000 Americans in high-value jobs located in every State, and was historically a key industry, as it was a net contributor to the United States balance of trade with Japan, which was a trade surplus of over \$7,000,000,000 in 2001, and continued to be a surplus until 2005, when the trade balance became a trade deficit of \$1,300,000,000, due in part to changes in the policies of Japan that impact medical devices;

Whereas Japan is one of the most important trading partners of the United States;

Whereas United States products account for roughly $\frac{1}{2}$ of the global market, but garner only a $\frac{1}{4}$ share of Japan's market;

Whereas Japan has made little progress in implementing its commitments to cut product review times and improve their reimbursement system in bilateral consultations on policy changes under the Market-Oriented Sector-Selective (MOSS) Agreement on Medical Equipment and Pharmaceuticals, signed on January 9, 1986, between the United States and Japan;

Whereas, although regulatory reviews in Japan remain among the lengthiest in the world and Japan needs to accelerate patient access to safe and beneficial medical technologies, recently adopted measures actually increase regulatory burdens on manufacturers and delay access without enhancing patient safety;

Whereas the general cost of doing business in Japan is the highest in the world and is driven significantly higher by certain factors in the medical technology sector, and inefficiencies in Japanese distribution networks and hospital payment systems and unique regulatory burdens drive up the cost of bringing innovations to Japanese consumers and impede patient access to life-saving and life-enhancing medical technologies;

Whereas artificial government price caps such as the foreign average price policy adopted by the Government of Japan in 2002 restrict patient access and fail to recognize the value of innovation;

Whereas less than $\frac{1}{10}$ of 1 percent of the tens of thousands of medical technologies introduced in Japan in the last 10 years received new product pricing;

Whereas the Government of Japan has adopted artificial price caps that are targeted toward technologies predominately marketed by companies from the United States and is considering further cuts to these products; and

Whereas these discriminatory pricing policies will allow the Japanese Government to take advantage of research and development from the United States: Now, therefore, be it

1 *Resolved by the Senate (the House of Representatives*
2 *concurring)*, That Congress—

3 (1) urges Japan to honor its commitments
4 under the Market-Oriented Sector-Selective (MOSS)
5 Agreement on Medical Equipment and Pharma-
6 ceuticals, signed on January 9, 1986, between the

1 United States and Japan (in this resolution referred
2 to as the “MOSS Agreement”), by—

3 (A) reducing regulatory barriers to the ap-
4 proval and adoption of new medical tech-
5 nologies; and

6 (B) meeting or exceeding agency perform-
7 ance goals for premarket approvals and adopt-
8 ing an appropriate, risk-based postmarket sys-
9 tem consistent with globally accepted practices;

10 (2) urges Japan to honor its commitments
11 under the MOSS Agreement to improve the reim-
12 bursement environment for medical technologies by
13 actively promoting pricing policies that encourage in-
14 novation for the benefit of Japanese patients and the
15 Japanese economy and eliminating reimbursement
16 policies based on inappropriate comparisons to mar-
17 kets outside Japan; and

18 (3) urges Japan to honor its commitments
19 under the MOSS Agreement by—

20 (A) implementing fair and open processes
21 and rules that do not disproportionately harm
22 medical technology products from the United
23 States; and

- 1 (B) providing opportunities for consulta-
- 2 tion with trading partners.

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