

108TH CONGRESS  
1ST SESSION

# H. CON. RES. 324

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

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 12, 2003

Mr. RAMSTAD (for himself and Ms. ESHOO) submitted the following concurrent resolution; which was referred to the Committee on Ways and Means

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## 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

\$175,000,000,000 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 1,000,000 Americans in high-value jobs located in every State, and the industry is a net contributor to the United States balance of trade, with a trade surplus of \$3,300,000,000;

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  $\frac{1}{3}$  share of Japan's market;

Whereas Japan has made little progress in implementing its commitments to cut product review times, improve their reimbursement system, and consult bilaterally 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, proposals currently under consideration in Japan would, in many cases, actually increase regulatory burdens on manufacturers and delay access without enhancing patient safety;

Whereas the general cost of doing business in Japan is among 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 at technologies predominately marketed by United States companies and is considering altering pricing rules to enable further cuts to these products; and

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

1        *Resolved by the House of Representatives (the Senate*  
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  
7        United States and Japan (hereafter in this resolu-  
8        tion referred to as the “MOSS Agreement”), by—

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

4 (B) establishing reasonable agency per-  
5 formance goals for premarket approvals and an  
6 appropriate, risk-based postmarket system con-  
7 sistent with globally accepted practices;

8 (2) urges Japan to honor its commitments  
9 under the MOSS Agreement to improve the reim-  
10 bursement environment for medical technologies by  
11 actively promoting pricing policies that encourage in-  
12 novation for the benefit of Japanese patients and the  
13 Japanese economy; and

14 (3) urges Japan to honor its commitments  
15 under the MOSS Agreement by—

16 (A) implementing fair and open processes  
17 and rules that do not disproportionately harm  
18 United States medical technology products; and

19 (B) providing opportunities for consulta-  
20 tion with trading partners.

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