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# Congress of the United States

## U.S. House of Representatives

COMMITTEE ON WAYS AND MEANS

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March 7, 2006

→ 110  
Sec 332 - med. devices

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*received @ ER on 3/9/06  
#023*

The Honorable Stephen Koplan  
Chairman  
United States International Trade Commission  
500 E Street, S.W  
Washington, D.C. 20436

Dear Chairman Koplan:

On behalf of the Committee on Ways and Means, and under authority of section 332(g) of the Tariff Act of 1930, 19 U.S.C. § 1332(g), I am requesting that the U.S. International Trade Commission institute a fact-finding investigation on competitive conditions affecting U.S. trade of medical devices and equipment in principal foreign markets. A number of important trade issues were raised at the September 28, 2005, hearing held by our Committee on United States-Japan Economic and Trade Relations, including regulatory and reimbursement policies affecting the U.S. medical device and equipment industry in Japan. Members of the Committee have a long-standing interest in this matter as they expressed at the hearing.

In order to gain a greater understanding of these issues, we ask that, in its investigation, the Commission closely examine the regulatory conditions of competition affecting U.S. sales and trade of medical devices and equipment in Japan, and other principal foreign markets, for the most recent five-year period. The investigation should focus on the main U.S. exports of medical devices and equipment to these markets during this period, and compare Japan's regulatory conditions to those of the other major foreign markets for U.S.-made medical devices and equipment. To the extent possible, we ask that the report also include for the most recent five-year period:

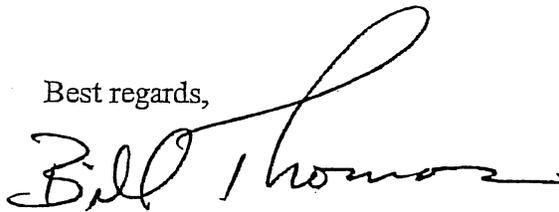
- an overview of the global market for medical devices and equipment, including production, consumption, and trade;
- profiles of the medical device and equipment industries in the United States and principal foreign producer countries;
- an analysis of U.S. trade in medical devices and equipment with major competitor

countries, including a description of trade practices, regulatory measures such as product approvals, and government and private expenditures on medical research; and

- an examination of bilateral and multilateral trade agreements that have addressed regulatory issues in major foreign markets, including Japan's, and the implications for the U.S. medical device and equipment industry.

The Committee requests that the Commission transmit its report no later than 12 months following receipt of this request. It is the Committee's intent to make the Commission's report available to the public in its entirety. Therefore, the report should not contain any confidential business or national security confidential information. Thank you for your consideration in this matter.

Best regards,

A handwritten signature in black ink, appearing to read "Bill Thomas". The signature is written in a cursive style with a large, looping initial "B".

Bill Thomas  
Chairman