

104<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. RES. 527

Relating to breast implants, the Food and Drug Administration, and public health.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 19, 1996

Mr. MCINTOSH submitted the following resolution; which was referred to the Committee on Commerce

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## RESOLUTION

Relating to breast implants, the Food and Drug Administration, and public health.

Whereas breast implant safety is a public health issue of fundamental importance, particularly for those women who are diagnosed with breast cancer and who face urgent decisions about reconstruction and women who already have implants;

Whereas conflicting information has been provided to the public about the safety of silicone gel breast implants;

Whereas the Food and Drug Administration imposed restrictions on the availability and use of breast implants, based primarily on concerns of a possible relationship between silicone gel breast implants and connective tissue disease;

Whereas breast cancer patients seeking reconstruction may only gain access to silicone gel breast implants through participation in a clinical trial under an approved protocol;

Whereas only a small fraction of the postmastectomy patients in the United States who seek reconstruction have access to silicone gel breast implants through clinical trials;

Whereas research has been undertaken by many prestigious medical centers and universities on the issue of silicone gel breast implants and connective tissue disease;

Whereas controlled scientific studies conducted by these prestigious universities to date show no clinically relevant risk of connective tissue disease for women with silicone breast implants nor any connection between the devices and systemic connective tissue diseases or classic autoimmune symptoms;

Whereas the Food and Drug Administration has not issued a definitive statement on the relationship between silicone gel breast implants and connective tissue disease;

Whereas the Food and Drug Administration has not provided substantial information on breast care for women with implants;

Whereas the National Cancer Institute has not provided substantial information on breast care for women with implants, waiting for the Food and Drug Administration's lead in this matter; and

Whereas the controversy over silicone breast implants has a broader impact on the public health by adversely affecting the supply of raw materials used in other products, such as pacemakers, heart valves, hip and knee joints, and artificial blood vessels: Now, therefore, be it

1       *Resolved*, That it is the sense of the House of Rep-  
2       resentatives that the Food and Drug Administration  
3       should take immediate steps to—

4               (1) ensure that women with breast cancer and  
5       other women seeking breast reconstruction have en-  
6       hanced access to silicone gel breast implants; and

7               (2) eliminate requirements that these women  
8       participate in clinical studies in order to obtain the  
9       silicone implants.

10       In addition, the Food and Drug Administration should  
11       take immediate steps to resolve the fears and concerns of  
12       women with breast cancer and women who have breast im-  
13       plants by issuing a definitive statement on the relationship  
14       or lack thereof between silicone gel breast implants and  
15       connective tissue disease, classic auto-immune symptoms,  
16       and other serious diseases.

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