

**THE FDA'S REGULATION OF
SILICONE BREAST IMPLANTS**

A STAFF REPORT PREPARED BY THE
**HUMAN RESOURCES AND
INTERGOVERNMENTAL
RELATIONS SUBCOMMITTEE**
OF THE
**COMMITTEE ON
GOVERNMENT OPERATIONS**

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FOREWORD

House of Representatives,
Committee on Government Operations,
Washington, DC, December 31, 1992.

There has been increasing public concern about the safety of silicone breast implants since the Subcommittee on Human Resources and Intergovernmental Relations held a hearing on this topic in December 1990. During the past 2 years, there has also been new research and medical evidence of the potential risks of breast implants, as well as disclosures of evidence dating back to the 1970's. This report, which has been prepared for use by the Committee on Government Operations by members of a staff research team, provides a summary of FDA's role in the regulation of silicone breast implants.

The findings and conclusions contained in this report are those of the staff, and do not necessarily reflect the views of the members of the Committee on Government Operations.

John Conyers, Jr., *Chairman*

LETTER OF TRANSMITTAL

House of Representatives,
Committee on Government Operations,
Washington, DC, December 31, 1992.

Hon. John Conyers Jr.
*Chairman, Committee on Government Operations,
House of Representatives, Washington, DC.*

Dear Mr. Chairman: I have enclosed a copy of the staff report entitled "The FDA's Regulation of Silicone Breast Implants."

The report is based on the subcommittee's 3-year investigation of the FDA's regulation of silicone breast implants, which was initiated by Chairman Ted Weiss. Because of his tragic death in September of this year, it was not possible to complete the report in time to release it as a committee report. Unfortunately, our investigation indicates that FDA continues to fail to safeguard implant patients, making it very important that this report be released in a timely manner. For that reason, it is being released as a staff report of the 102d Congress.

Thank you for your assistance.

Sincerely
Donald M. Payne
*Chairman, Human Resources and
Intergovernmental Relations Subcommittee.*

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