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<TitreType>**REPORT**</TitreType>

<Titre>on the petitions declared admissible concerning silicone implants (Petitions Nos 470/98 and 771/98)</Titre>

(2001/2068((INI))

Committee on Petitions

Rapporteur: <Depute>Janelly Fourtou

</Depute>

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**PROCEDURAL PAGE**

<PgReglementaire>Petition No 470/98, by Mrs Vurgun-Kern, concerning silicon implants, was referred to the Committee on Petitions on 6 May 1998, and Petition No 771/98, by Mr Harvey, on a ban on silicone breast implants, was referred to the same committee on 6 August 1998 pursuant to Rule 174(5) of the Rules of Procedure.

The Committee on Petitions declared the petitions admissible at its meetings of {21.10.1998}21 October 1998 and 11 January 1999.

By letter of 15 March 1999, and the repeat letter of 22 May 2000, the Committee on Petitions requested the opinions of the Committee on the Environment, Public Health and Consumer Policy and Committee on Women's Rights and Equal Opportunities, pursuant to Rule 175(1).

The Committee on the Environment, Public Health and Consumer Policy adopted its opinion at its meeting of 10 October 2000; the Committee on Women's Rights and Equal Opportunities adopted its opinion at its meeting of 22 November 2000.

At its meeting of 21/22 March 2001 the Committee on Petitions decided to draw up a report pursuant to Rule 175(1).

At that meeting it decided to apply the procedure without debate pursuant to Rule 114(1).

It appointed Janelly Fourtou rapporteur at its meeting of {22.03.2001}22 March 2001.

It considered the draft report at its meetings of 10/11 April, 25/26 April and 29 May 2001.

At the last meeting it adopted the motion for a resolution unanimously and decided to request Parliament to adopt its report without debate, pursuant to Rule 114.

The following were present for the vote: Roy Perry, vice-chairman and acting chairman; Proinsias De Rossa, vice-chairman; Luciana Sbarbati, vice-chairman; Janelly Fourtou, rapporteur; Mary Elizabeth Banotti, Felipe Camisón Asensio, Laura González Álvarez, Margot Keßler, Guido Sacconi, Christian Ulrik von Boetticher and Eurig Wyn.

The opinions of the {N}Committee on the Environment, Public Health and Consumer Policy and the Committee on Women's Rights and Equal Opportunities are attached.

The report was tabled on 29 May 2001.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

<PgPartieA><SubPage>**MOTION FOR A RESOLUTION**

**European Parliament resolution on the petitions declared admissible concerning silicone implants (Petitions Nos 470/98 and 771/98)**

*The European Parliament,*

<Visa>

−having regard to Petitions Nos 470/98 and 771/98,

−having regard to Rule 175(1) and (4) of its Rules of Procedure, relating to the examination of petitions,

−having regard to Articles 21 and 194 of the EC Treaty, which lay down the right of petition,

−having regard to the May 2000 STOA (Scientific and Technological Options Assessment) report on Health risks posed by silicone implants in general with special attention to breast implants[[1]](#footnote-1),

−having regard to the report of the Committee on Petitions and the opinions of the {N}Committee on the Environment, Public Health and Consumer Policy and the Committee on Women's Rights and Equal Opportunities (A5-0186/2001),

<Considerant>

A. having regard to the serious problems raised by the petitioners,

B. whereas the Commission is drawing up a communication on silicone implants (programme number 2001/261 of the measures to be taken in 2001),

C. whereas at the request of the Committee on Petitions, the Committee on the Environment, Public Health and Consumer Policy and the Committee on Women's Rights and Equal Opportunities have delivered their opinions,

D. whereas those opinions favour option 3 in the STOA report, which stops short of a total ban on silicone implants but calls for specific measures to be adopted and implemented as regards patient information and closer monitoring as well as product quality and basic research,

E. <Text>whereas foreign implants are being practised on ever younger people and the number of cosmetic operations is steadily increasing,</Text>

F. whereas to date there has been insufficiently systematic analysis of implants,

1. Welcomes the fact that the Commission will be issuing a communication in 2001 setting out measures to ensure that implants meet the highest possible standard of safety and quality;

2. Points out that, as far as silicone implants are concerned, attention must focus primarily on the safety and quality of the products and one pre- and post-operative support;

3. Recommends in particular that the measures to be proposed should cover the following points:

(a) all patients should have access to complete information free of charge from independent experts,

(b) any advertising for breast implants for use in cosmetic surgery should carry health warnings and warnings of the risks***,*** residual risks and sequelae inherent in every surgical operation,

(c) every person in whom an implant has been inserted should be issued with a passport listing the specifications of the implant and the postoperative precautions to take; the passport should constitute the consent form and be signed by the surgeon and the patient,

(d) detailed information about breast implantations, necessary follow-up operations and other follow-up measures should be recorded in the EU, and, to that end, each Member State should keep a compulsory national breast implant register,

(e) the above-mentioned patient register should serve as a database for long-term research into silicone implants and must be compiled in such a way as to respect the principle of confidentiality and patients' privacy,

(f) in the case of an implantation, pre- and postoperative support should comprise: a preliminary meeting with the surgeon who will be performing the operation, clear information about the residual risks and possible side-effects of an implantation and the alternative solutions, a sufficient cooling-off period, an exhaustive inquiry into the patient's medical history, to be completed beforehand, and postoperative care, including an annual check-up;

(g) breast implants for cosmetic surgery should not be inserted into patients under 18 years of age;

4. Points to the need to draw up research programmes in order to bring about European legislation seeking to expand and perfect the measures affording better protection of the health of persons in whom implants have been inserted and to improve certification, marketing and testing of implants and the technical standards governing implants;

5. Recommends that further scientific and clinical research be carried out, specifically focusing on some of the shortcomings of research to date:

- long-term outcomes –illness and health, systemic health effects at sites distant from the implant (not just autoimmune disorders and cancer), and possible effects on the health of children of women with implants;

- reliable techniques for measuring silicone concentrations in body fluids and tissues, and tissue responses to the presence of silicone;

- local complications, including local effects at the site of the implant;

6. Recommends treatment and aftercare for victims of silicone implant damage in accordance with the latest research findings.

7. considers that the Commission must do everything possible to be consistent with the philosophy underlying the criteria of the European precautionary principles;

8. Instructs its President to forward this resolution to the Commission, the Council, and the petitioners.

**EXPLANATORY STATEMENT**

By way of an explanatory statement, the rapporteur would draw attention to the conclusions set out in the opinions of the Committee on the Environment, Public Health and Consumer Policy and the Committee on Women's Rights and Equal Opportunities, attached to this report, and to the final study compiled by STOA (Scientific and Technological Options Assessment) (PE 168.396/Fin.St.).

Regarding the Commission communication on silicone implants, Mr Liikanen, the Member of the Commission responsible for enterprise and the information society, appeared before the Committee on Petitions on 21 March 2001. The main points of his statement were as follows:

* ‘As regards silicone breast implants, the role of European legislation is to ensure that the products available are of the highest possible quality and that innovation and progress is encouraged to improve quality constantly. This legislation is working relatively well.
* The utmost care should be shown to ensure that all measures are taken to avoid such complications related to implants, to reduce inherent or inevitable risks, and that patients are properly informed of residual risks or possible inconveniences.
* Over the recent months, the Commission and national authorities have therefore been working on a number of measures in order to clearly specify the requirements applicable to breast implants, and to reinforce the procedures on conformity assessment under which breast implants can be put on the market.
* I have the intention to present a communication for adoption by the Commission in the near future. This communication will increase clarity for the necessary requirements and provide [a] basis for … complete information in this field to the patients.
* We will highlight to Member States the importance to be attached to ensure informed patient consent, and to invite all Member States to take the necessary measures in this respect.’

Given that the petitions on which this report is based are seeking to amend or produce legislative provisions on implants, the Commission communication to be submitted in 2001 ought to contain measures of that type.

**ANNEX**

**NOTICE TO MEMBERS ON PETITIONS1**

Subject: Petition No 470/98, by Mrs Ingeborg VURGUN-KERN, (Belgian) on behalf of the Self‑help Group for Women damaged by Silicone bearing about 1000 signatures concerning silicon implants

Petition No. 771/98, by Mr Frank HARVEY, of British nationality, on a ban on silicone breast implants

I. Summary of petition No. 470/98 :

The petition is worded as follows: 'We of the German Self-help Group for Women damaged by Silicone call for a transparent information policy and quality guarantees concerning the short and long-term effects on the living organism of all breast implants currently available on the European market. Until conclusive proof has been provided that they have no harmful effects either on women or their children born after the implant operation, we call for an immediate ban on silicone breast implants.'

INFORMATION: - The petition was forwarded by Bill MILLER, MEP,

- To be treated in public

Summary of petition No. 771/98 :

Referring to a newspaper article attached to the petition, the petitioner expresses concern about the danger to women’s' health of silicone breast implants. He criticises the appointment of a male panel of experts set up in the UK to investigate the problems, which concluded that there was no evidence to show that implants are not safe. The petitioner points out that silicone implants have been banned in the United States, and the manufacturers have paid compensation to the victims. He calls for an immediate ban on silicone breast implants throughout the European Union.

II. Petition No. 470/98 was declared admissible on 21 October 1998; the Commission was asked to provide information pursuant to Rule 157(3) of the Rules of Procedure.

Petition No. 771/98 was declared admissible on 11 January 1999; the Commission was asked to provide information pursuant to Rule 157(3) of the Rules of Procedure.

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1 PE 230.105/rev. III

III. The reply from the Commission on petitions Nos 470/98 and 771/98, received on

5 February 1999 reads:

Silicone implants are considered as medical devices within the scope of Council Directive 93/42/EEC of June 1993 concerning medical devices (O.J. L 169, 12.7.1993). Implantation of silicone implants may imply certain risks which may be associated with the implants and the required surgery. In the context of the implementation of Directive 93/42/EEC the issues of safety and certification of silicone implants were discussed between the Commission and Member States.

Review of scientific evidence in 1994 and 1996 confirmed that the different studies on the incidence of connective tissue disease in women with silicone breast implants did not show any appreciable difference from that in the unimplanted population. It is, however, well established that all kinds of breast implants can present side effects such as capsular fibrosis.

Safety-related issues such as biocompatibility, mechanical properties, migration of the filling and shell material, compatibility between filling and shell material, ageing, stability and labelling have been examined by the European Committee for Standardisation (CEN) and by a special working party of certification bodies in charge of certification of these products on the basis of Directive 93/42/EEC. The relevant standards and guidance documents which have been accepted by this working party aim to ensure a high level of protection of patients being implanted.

Due to residual risks which, as in other implants, cannot be entirely excluded and in view of possible complications related to the implantation, it is important that patients are adequately informed about possible problems. EQUAM (European committee on quality assurance and medical devices in plastic surgery) has prepared a detailed protocol and consent form on which patient representatives have also been consulted. This document, accepted by the above-mentioned working party, will help to improve the information.

Apart from Directive 93/42 on medical devices, the issue of liability of the producers of silicone implants is regulated by Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member States concerning liability for defective products.

The Commission together with Member States will keep under review the issues related to the safety of these products. However, the results of currently available scientific evidence do not seem to justify the ban of silicone implants.

1. Further Commission communication, received on 19 August 1999:

Following the request for information on bans on silicone implants, please find herewith information available to date from third countries such as United States, Canada, Australia, New Zealand, South Korea, South Africa and Brazil. Information on actions at European and Member States’ level have also been included.

**UNITED STATES**

* 14 November 1991 - US Food & Drug Administration, General and Plastic Surgery Devices Panel concludes that breast implants serve a public health need, they should remain on the market, and additional data should be collected with regard to their safety and efficacy.
* 6 January 1992 ‑ US Food & Drug Administration requested a temporary moratorium on the further use of silicone gel‑filled breast implants pending advice from an advisory panel of independent experts related to the leakage of silicone, inflammatory reactions, rupture of the implant and possible association with autoimmune and connective tissue diseases.
* 16 April 1992 ‑ US Food & DrugAdministration announced that silicone gel-filled breast implants were available for women, under controlled clinical studies, for reconstruction after breast cancer surgery, and denied pre-market approval applications for distribution and use of these devices for cosmetic purposes or for the augmentation of healthy breasts. Decision reflected the recommendations of the General and Plastic Surgery Devices Panel and required studies to determine the safety of silicone breast implants.
* 1 August 1995 ‑ US Food & Drug Administration Commissioner, David Kessler, stated before select members of US Congress that silicone gel implants do not cause a large increase in traditional connective tissue disease in women who have implants. However, published studies simply cannot rule out either a smallbut statistically significant increase in risk for traditional connective tissue disease or the risk of atypical disease in some women. He also called for more information related to the rupture rate of silicone breast implants and how the rate changes over time.
* 1997 ‑ Silicone gel‑filled breast implants continue to be available for reconstruction and augmentation under controlled clinical studies.
* 1 December 1998 - The 706 National Science Panel found no proven links between silicone breast implants and diseases.

**CANADA**

* 8 January 1992 - Canada’s Minister of Health requested all surgeons stop implanting silicone gel breast implants and asked all manufacturers to suspend, temporarily, distribution of the devices.
* March 1992 - Canada’s Minister of Health requested all implant manufacturers/distributors to withdraw all silicone gel breast implants from the Canadian market.
* April 1992 ‑ Canada’s Minister of Health released the Baines report which indicated that the existing scientific information was inconclusive and more data was required on safety of implants.
* 13 January 1993 ‑ Minister of Health announcedthe withdrawal of Notices of Compliance from all manufacturers for the sale of silicone breast implants in Canada, and indicated that additional scientific information would be required before the reintroduction of these devices would be considered.
* 15 November 1996 ‑ Health Canada announced a plan to fund the first phase of an Ontario and Quebec Breast Implant Study which would focus on risk of cancer and would involve 40,000 women in Ontario and Quebec who received implants. Final report is due in 1999­.
* December 1996 ‑ Health Minister confirmed his intention to issue an information document for women with breast implants.
* 17 September 1998 - Health Canada published a pamphlet, “*It’s Your Health*, BREAST IMPLANTS”, which states that only saline-filled breast implants, including smooth and textured implants, are available for sale in Canada.

### **AUSTRALIA**

* January 1992 - Therapeutic Goods Administration placed a moratorium on the sale of silicone breast implants.
* Moratorium lifted, manufacturers may apply to have silicone gel‑filled breast implants registered.
* Silicone breast implants available on anindividual patient use basis.
* December 1996 ‑ After reviewing the most recently published investigations, the Biomaterials Panel reported to the Therapeutic Devices Evaluation Committee (TDEC) that there was no convincing evidence to link the use of silicone breast implants with systemic connective tissue disorders.
* July 1997 ‑ Australia’s Therapeutic Devices Evaluation Committee concluded that there was no strong evidence linking an association with breast implants and alleged diseases. Further, it recommended to the government regulator (Therapeutic Goods Administration) that breast implants continue pre-market evaluation, and once registered, monitored to determine the extent of local complications.

#### NEW ZEALAND

* January 1992 ‑ New Zealand Department of Health placed a moratorium on silicone gel-filled breast implants.
* 6 July 1992 ‑ New Zealand Department of Health lifted its moratorium on silicone gel‑filled breast implants.
* Silicone breast implants available on an Informed Consent basis.
* Silicone breast implants are a registrable device.

#### SOUTH KOREA

* The manufacture, sale, distribution or implantation of breast implants has not been restricted.

##### **SOUTH AFRICA**

* The manufacture, sale, distribution or implantation of breast implants has not been restricted.

**BRAZIL**

* The manufacture, sale, distribution or implantation of breast implants has not been restricted.

###### **EUROPEAN UNION**

* Silicone implants are medical devices within the scope of Directive 93/42/EC (O.J. L 169 of 12.7.1993). In the context of implementation of this Directive, issues related to safety and certification of silicone implants were discussed between the Commission and Member States.
* A working party made up of the European Committee for Standardisation (CEN) and certification bodies have accepted a series of standards and guidance documents which aim to ensure a high level of protection of patients.
* 1998 - European Committee On Quality Assurance & Medical Devices In Plastic Surgery (EQUAM) prepared a detailed protocol and consent form on which patients’ representatives have also been consulted.

**ITALY**

* 1994 ‑ Italy lifted its moratorium on silicone breast implants.

# B BELGIUM

* 1994 ‑ Based on scientific evidence to date, silicone‑filled breast implants remain available.

**THE NETHERLANDS**

* 1994 ‑ Based on scientific evidence to date, silicone‑filled breast implants remain available.

**GERMANY**

* Germany never introduced a ban on the use of silicone gel‑filled breast implants (where 90% are used for reconstruction).
* April 1998 - Germany’s Federal Institute for Medicine and Medical Products concluded that there was no need for the prohibition of breast implants according to the available scientific knowledge. Further, they stated that a prohibition would not be useful given the lack of alternative materials.

**UNITED KINGDOM**

* 1992 - United Kingdom Department of Health set up an Expert Advisory Groupto examine all evidence related to breast implants and connective tissue disease.
* February 1995 ‑ United Kingdom Medical Devices Agency published a report reaffirming the lack of evidence for an increased risk of connective tissue disease in patients. There was, therefore, no scientific case for changing practice or policy in the UK with respect to breast implantation.
* February 1997 ‑ United Kingdom Medical Devices Agency, in a summary of the current situation relating to silicone gel breast implants, supported their findings of February 1995.
* Silicone breast implants remain available without restrictions.
* 14 July 1998 - United Kingdom Independent Review Group (IRG) found no conclusive evidence of a link between silicone implants and connective tissue disease, nor a link with abnormal immune response.
* 8 March 1999 – Withdrawal of trilucent breast implants (consisting of a silicone elastometer shell with a lipid filler based on soya bean oil) from the UK market.

**DENMARK**

* 10 March 1999 – The Danish Medicines Agency issued a safeguard action against sale or use of trilucent breast implants on the Danish market.

**FRANCE**

* May 1996 - Andem (National Agency for the Development and Medical Evaluation) published a report recommending that the prescription of the EU directive 93/42/EEC should be fully applied for “CE marking” breast implants and that breast implants filled with material other than saline solution should be marketed only if toxicological and clinical evaluations were strengthened.
* May 1996 – Decree announcing that all breast implants other than those filled with saline solution may be used in France if they have French approval (according to Specific French guidelines) and EC approval and meet toxicological and mechanical/resistance testing and ongoing clinical surveillance.
* May 1998 – Decree on the suspension (for 1 year) of the placing on the market of breast implants(except those filled with physiological serum) and of liquid injectable silicone for aesthetic reasons, unless they are CE marked and on a specific list, or used for clinical trials.

V. Further Commission communication, received on 3 April 2000, reads:

The Commission services have examined the supplementary information transmitted by the petitioner concerning petition No 470/98 on silicone implants.

After a detailed analysis they concluded that their substance was not such as to justify further comment on the subject.

1. Further Commission communication, received on 20 November 2000, reads:

Following a petition concerning health problems associated with silicone breast implants, the European Parliament ordered a study carried out by a team led by Prof. Moreno.

Breast implants are products covered by the Medical Devices Directive.

The Moreno report proposed three options to the European Parliament, i.e. (i) a ban of silicone breast implants, (ii) no specific action at all, and (iii) “No complete ban, but the adoption and implementation of critical specific measures to increase and improve information for patients, tracking and surveillance, quality control and assurance and key research”.

Both the Commission and the European Parliament’s Environment, Public Health and Consumers Policy Committee in its opinion prepared by Ms. Catherine Stihler, MEP, favour the third option.

The Commission is therefore preparing specific actions focused on the following points, approved by the Member States in a meeting on July 11-12, 2000:

1. Elaboration of a Commission Communication explaining in detail how existing essential requirements apply to silicone breast implants, including requirements increasing monitoring and reporting by manufacturers.

A draft has been sent late July to Member States for comments. The meeting to discuss the subject, originally scheduled for October, had to be moved to November 2000.

2. Provide CEN with a specific standardisation mandate, indicating the areas in which European standards or standardisation work should be reinforced.

The mandate will be provided once the document, as referred to in point 1, has been approved.

3. Introduce a system of informed patient consent, i.e. require Member States to ensure that all relevant information on risks and benefits to the patient be provided and explicit consent be given by the patient.

This subject will be dealt with in co-operation with the relevant Commission’s

Directorate Generals and Member States.

4. Continue Research and Development, so as on a constant basis to reduce risks and promote alternatives presenting less risk.

Member States have been invited to inform the Commission on on-going research at national level, and to make proposals on the way to deal with the subject, to be further examined in the meeting of November referred to above.

<EntPE></EntPE><TitreType>**OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH**

**AND CONSUMER POLICY**</TitreType>

<TitreRecueil></TitreRecueil>

<TitreRecueil1>for the {PETI}Committee on Petitions</TitreRecueil1>

<Titre>on the petitions n° 470/98 and 771/98 on silicone-gel breast implants</Titre>

<Commission>{ENVI}Committee on the Environment, Public Health and Consumer Policy</Commission>

Letter from the committee chairman to Nino Gemelli, chairman of the {PETI}Committee on Petitions

Brussels, <Date>{11/10/2000}11 October 2000</Date>

Dear Mr Gemelli,

The {ENVI}Committee on the Environment, Public Health and Consumer Policy considered the above subject at its meetings of {29-08-2000}29 August 2000 and 10 October 2000.

At the latter meeting it adopted the following conclusions[[2]](#footnote-2).

In March 1999 after many years of campaigning, two petitions calling for an immediate European Parliament ban on silicone implants were tabled by self-help groups of women who claimed to be suffering adverse effects from silicone-gel breast implants. The Parliament has now responded by asking for formal replies to the Petitions Committee and seeking the counsel of the Environment Committee, the Committee on Women’s Rights and the Committee on Research. This Opinion from the Environment Committee is presented in the form of a letter to the Petitions Committee. It gives a brief subject background; notes the policy options identified in the recent STOA research report; and the concerns expressed by self-help groups of sufferers from problems linked to silicone implants. Recommendations for action are given in the Rapporteur’s Conclusions.

In May 2000 Dr Martín-Moreno and Ms Wisbaum of the Spanish National School of Health in Madrid presented their study, ‘Health risks posed by silicone implants in general with a special reference to breast implants’ to the Committee on Petitions.

Silicone implants were used for years before there was regulation or surveillance of their use. Health concerns about the use of silicone–gel breast implants surfaced in the US and Canada in the 1980s, spreading to Europe in the 1990s. Since 1992 in the US silicone breast implants are only available for women with special medical needs who need breast reconstruction and are willing to become part of a clinical trial approved by the US Food and Drugs Administration (FDA). In Canada a moratorium on the marketing and use of silicone-gel filled breast implants was passed in 1992. Saline-filled breast implants are available.

All EU member states – except France – have no restrictions on the use of silicone-gel breast implants. In France since 1992 silicone breast implants have been restricted. In 1995, all breast implants except saline-filled implants were banned. Surgeons must apply for exemptions in the case of specific medical needs (reconstruction after mastectomy) for silicone implants.

The focus on silicone-gel implants since the 1990s has led to many different epidemiological studies which have consistently showed no evidence of serious risk for major diseases. However, as the studies have started so recently, most cannot look at long-term effects, have mainly focused on links with certain systemic diseases, especially cancer and connective tissue diseases, and have not always controlled for the different types of implants. Hundreds of different types have been marketed and used since they were introduced in 1962. Alongside the medical studies a significant body of women claimed to be experiencing symptoms which they think are linked with their implants.

In the light of this ‘complex reality’ the recent STOA report identified three possible policy options, as follows:

‘Option 1: Status quo; no ban; keep application of current legal framework.

Option 2: Ban on silicone breast implants due to lack of complete information regarding risks and petitions by some groups.

Option 3: no complete ban, but the adoption and implementation of critical specific measures to improve information for patients, tracking and surveillance, quality control and assurance and key research’.

The concerns expressed by self-help groups of sufferers from problems linked to silicone implants are varied but include:

* A lack of information on the potential risks with breast implants. Information was lacking in two critical areas. Patients need to know that implants are not for life and may need to be replaced or removed. Rupture occurs significantly, from 5-51% according to studies. Some studies point to a rupture rate of 50% after 7-10 years and up to 95% after 20 years.
* Many women have implants for cosmetic purposes and self-help groups argue that if fuller information on risks and implications was given before surgery fewer women would opt for implants.
* Lack of registration of implants in Europe means that the overall numbers of women with implants are unknown.
* Many women report the same inexplicable serious symptoms. The STOA study found information from women in six different European countries ‘remarkably, eerily similar’.
* There are shortcomings of the existing research, e.g., lack of long-term data, no figures for numbers of implants, mixing of different implant types in studies.

In drafting the recommendations below the Committee on the Environment, Public Health and Consumer Policy has tried to balance the views of members of self-help groups, plastic surgeons, and women who have had breast implants either after mastectomy or due to breast deformity and for cosmetic purposes. She also noted the views expressed by colleagues on the Environment Committee in the initial exchange on this topic in August. She welcomes the Commission’s revision of its earlier view that nothing need be done and its stated intention to introduce new regulations on the basis of Option 3 of the STOA report.

###### **CONCLUSIONS**

Action must be taken to meet the concerns raised and the status quo (Option 1) is not an acceptable option.

The Committee on the Environment, Public Health and Consumer Policy unanimously recommends the introduction of proposals on the basis of Option 3 in the STOA report. Option 3 calls for ‘no complete ban, but the adoption and implementation of critical specific measures to improve information for patients, tracking and surveillance, quality control and assurance and key research’.

The further measures proposed by the report include the following:

1. To facilitate consensus on a breast implant consent form, including information relating to alternatives, benefits and risks.
2. Guaranteed marketing control over breast implants to avoid incorrect and misleading information.
3. Improved certification, technical standards and regulation.
4. Promotion of elaboration of clinical guidelines, standards of care and the development of quality assurance systems.
5. To facilitate consensus, promotion and support of effective surveillance systems to report adverse effects and long-term effects.
6. To consider silicone breast implants a health priority and make funds available in the EU research programmes, specifically focusing on the shortcomings of some of the research to date.
7. To foster tolerance and self-esteem and other conceptual alternatives to breast implants, in collaboration with active groups in this field.

The Committee on the Environment, Public Health and Consumer Policy further recommends that the following points are incorporated into new regulations:

1. All patients should have access to free, comprehensive information. All potential patients should have access to free, comprehensive information drawn up by independent experts.
2. Advertisements of ‘cosmetic surgery’ breast implants should contain a statement that relevant information is available.
3. Advertising of ‘cosmetic surgery’ breast implants should carry clear bold health warnings.
4. ‘Before and after’ pictures should not be used in such advertisements.
5. Details of breast implant operations should be recorded in the EU by compulsory National Breast Implant Registration in each member-state.
6. Manufacturers should supply only to surgeons who observe the European register. This should be monitored by an independent monitoring body and the results of the monitoring should be published..
7. The cost of breast implants should include the following - pre-meeting with the surgeon involved; clear informed discussion of the implications of having implants, as well as the alternatives, with a properly trained and accredited independent counsellor with no financial interest in the patient's eventual decision; a cooling-off period of no less than two weeks; detailed pre-implant case history; post-implant counselling and periodic review.
8. There should be comprehensive national lists of registered private clinics and trained plastic surgeons expert in breast implant surgery and in the expert removal of old, ruptured or torn implants.

Yours sincerely,

Catherine Stihler Caroline Jackson

Rapporteur Chairman

22 November 2000

<TitreType>**OPINION OF THE COMMITTEE ON WOMEN'S RIGHTS AND EQUAL OPPORTUNITIES**</TitreType>

<TitreRecueil1>for the {PETI}Committee on Petitions</TitreRecueil1>

<Titre>on petitions Nos. 470/98 and 771/98 on silicone breast implants</Titre>

<Commission>{FEMM}Committee on Women's Rights and Equal Opportunities</Commission>

Letter from the committee chairman to Nino Gemelli, chairman of the {PETI}Committee on Petitions

Brussels, <Date>{22/11/2000}22 November 2000</Date>

Dear Mr Gemelli,

The {FEMM}Committee on Women's Rights and Equal Opportunities considered the above subject at its meeting of 22 November.DT(d MMMM yyyy)@INTDAT@

At that meeting it adopted the following conclusions[[3]](#footnote-3):

Numerous petitions on this subject were declared admissible by the Committee on Petitions following complaints from many women who claimed to be suffering adverse effects and wanted an immediate ban on silicone breast implants. The European Parliament has asked the Committee on Petitions to submit a formal reply, seeking the counsel of the Committee on the Environment, the Committee on Women’s Rights and the Committee on Industry. This opinion, in the form of a letter from the Committee on Women’s Rights and Equal Opportunities to the Committee on Petitions, sets out the background to this subject briefly and notes the recommendations in relation to the recent STOA research report.

The Commission was asked to provide information in relation to Directive 93/42/EEC concerning medical devices and Directive 85/374/EEC concerning liability of the producers of silicone implants. The Commission appears to wish to draw up new provisions on the basis of the proposals contained in the STOA report. The main aim of this study, drawn up by Dr Moreno and Ms Wisbaum of the Spanish National School of Health, is to present to the European Parliament realistic, relevant and well-founded alternatives with regard to the policy on silicone breast implants so as to assist Parliament to take legislative and policy decisions on silicone with full knowledge of the facts.

**BACKGROUND**

Breast implants have been used for many years but were not subject to any regulation until the 1990s. Regulation first occurred in the United States where the authorities required manufacturers to submit an application for marketing authorisation containing data on the safety of using implants. Because of the lack of adequate data on the safety of using the implants, they have not been available since 1992, except for women with special medical needs, in particular for breast reconstruction. However, saline-filled implants were authorised to remain on the market with no restrictions on their use, although subject to regular checks.

All the countries of the European Union have complied with the requirements for placing devices on the market of Directive 93/42/EEC, namely respect for the principles of safety and the elimination of risks as far as is possible. Moreover, the standards required for CE marking indicating conformity are linked to technological standards, tests on the materials used and assessment of their biocompatibility. However, only France adopted restrictive measures and since 1992 has banned the use of breast implants. Since 1995 it has banned the use of all other implants except for those containing saline solutions. A request for authorisation must be submitted in the case of specific treatment (reconstruction following a mastectomy). It should be noted that Norway is in the process of setting a minimum age limit of 18 for cosmetic surgery involving the use of breast implants.

Despite a fairly long period of empirical use of implants, very recent epidemiological studies do not as yet provide evidence of the existence of a major risk of serious illnesses associated with breast implants. Recent research does not allow an analysis to be made of the long-term effects. Despite this fact, many women complain of symptoms and this should be seen in relation to the fact that the many recent studies are based on small samples with no verification of the type of implant used and that these studies mainly concern cancer and connective tissue diseases. All the research and the complaints deal mainly with links with certain systemic diseases and especially cancer, neurological diseases, illnesses associated with autoimmune disorders; disorders (skin, memory) and symptoms (joint pains) which could be linked to the immune system.

**STOA** **PROPOSALS**

In view of this ‘complex reality’ the report suggested three possible policy options:

Option 1: Status quo; no ban; keep application of current legal framework.

Option 2: Ban on silicone breast implants due to lack of complete information regarding risks incurred.

Option 3: no complete ban, but the adoption and implementation of critical specific measures to develop and improve information for patients, tracking and surveillance, quality control and assurance and research.

The STOA report chooses option 3 and proposes additional measures which appear in the conclusions.

**CONCLUSIONS**

In the light of the proposals made to us, the Committee on Women’s Rights and Equal Opportunities wishes to respond to the concerns of women. In view of the complexity of this problem, and the committee is aware that there is a demand on the part of women for breast implants, both for aesthetic reasons and for reconstruction, but that at the same time other women would like to see silicone implants banned because of the lack of information. It notes that the alternatives to silicone implants, namely saline-filled implants, involve risks, and in particular the risk of rupture.

The Committee on Women’s Rights and Equal Opportunities recommends that proposals are made on the basis of Option 3 in the STOA report, namely ‘no complete ban, but the adoption and implementation of critical specific measures to improve information for patients, tracking and surveillance, quality control and assurance and key research’.

The Committee on Women’s Rights and Equal Opportunities is in favour of the additional measures proposed in the STOA report:

1. To facilitate consensus on a breast implant consent form, including information related to alternatives, benefits and risks.

2. To guarantee marketing control over breast implants in order to avoid any kind of incorrect and misleading information.

3. To improve certification, technical standards and regulation.

4. To promote the elaboration of clinical guidelines, standards of care and the development of quality assurance systems.

5. To facilitate consensus, promotion and support of effective surveillance systems to report adverse effects and long-term effects.

6. To consider silicon breast implants a research priority and make funds available in the EU research programmes, specifically focusing on some of the shortcomings of research to date.

7. To foster tolerance and self-esteem and other conceptual alternatives to breast implants, in collaboration with active groups in this field.

The Committee on Women’s Rights and Equal Opportunities recommends that the following points are incorporated:

- stresses that research programmes must be established so that there is evidence to assure European harmonisation with the aim of increasing and improving the measures designed to improve protection for women and their health in the European Community;

- considers it essential, in view of the number of implants on the market and in particular the number of products with which they are filled, to undertake research in order to establish a definition of the products which are least harmful;

- considers that the Commission must do everything possible to be consistent with the philosophy underlying the criteria of the European precautionary principles;

- specific measures must therefore be implemented to increase and improve information for patients;

- calls for the adoption of specific measures for tracking and surveillance;

- wishes to see the compulsory introduction of national breast implant registers together with detailed information common to all European countries;

- considers that all advertising should be accompanied by the necessary information, in particular concerning health;

- recommends a national register listing the plastic surgeons specialising in breast implant operations;

- recommends that the Council and the Member States set a minimum age limit of 18 for cosmetic breast implant surgery;

- calls on the Council and the Member States to implement as quickly as possible the seven measures proposed in addition to Option 3 in the STOA report.

Yours sincerely,

Maj Britt Theorin

1. PE 168.396/Fin.St. [↑](#footnote-ref-1)
2. The following took part in the vote: Caroline F. Jackson, chairman; Ria G.H.C Oomen-Ruijten, vice-chairman; Catherine Stihler, draftsman; Hiltrud Breyer, Dorette Corbey, Chris Davies, Avril Doyle, Marialiese Flemming, Robert Goodwill, Roger Helmer, Eija-Riitta Anneli Korhola, Bernd Lange, Torben Lund, Minerva Melpomeni Malliori, Bill Miller (for María Sornosa Martínez), Rosemarie Müller, Riitta Myller, Karl Erik Olsson, Encarnación Redondo Jiménez, Dagmar Roth-Behrendt, Guido Sacconi, Karin Scheele, Phillip Whitehead. [↑](#footnote-ref-2)
3. The following were present for the vote: Theorin, chairman, Van Lancker, vice-chairman, Evans, vice-chairman, Aviles Perea, Dybkjær, Fraisse, Gröner, Karamanou, Klaß, Müller E.F., Prets, Sörensen and Stihler (for Ghilardotti pursuant to Rule 153(2)). [↑](#footnote-ref-3)