HOUSE BILL NO. 37

IN THE LEGISLATURE OF THE STATE OF ALASKA

NINETEENTH LEGISLATURE - FIRST SESSION

BY REPRESENTATIVE B.DAVIS

Introduced: 1/16/95
Referred: Labor and Commerce, Health, Education and Social Services, Finance

A BILL

FOR AN ACT ENTITLED

"An Act relating to silicone implants; and providing for an effective date."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

*** Section 1.** AS 08.64 is amended by adding new sections to article 3 to read:

Sec. 08.64.363. REMOVAL OF BREAST IMPLANT. A physician who removes a breast implant shall send the breast implant to a laboratory for testing that is approved by the Department of Health and Social Services. The laboratory shall send the results of its test to the physician and to the department. The results are confidential information, not subject to inspection or copying under AS 09.25.110 - 09.25.120.

Sec. 08.64.364. PROHIBITION AGAINST SILICONE BREAST IMPLANTATION. A physician may not operate on a patient to insert a breast implant. In this section, "breast implant" means a surgically inserted pocket or envelope under the skin that consists of soft silicone gel, a combination of soft silicone gel and saline solution, or silicone covered by polyurethane foam.

*** Sec. 2.** AS 08.64.364 is repealed and reenacted to read:

Sec. 08.64.364. BREAST IMPLANTATIONS. The board shall adopt regulations necessary to ensure that physicians licensed under this chapter are required to clearly and fully inform a patient who is considering a breast implant about the advantages, disadvantages, and risks associated with the procedures and materials involved. The board shall consider the informed consent requirements adopted by the federal Food and Drug Administration when developing the regulations required under this subsection. The board's regulations must require that the physician and the patient sign a form that attests that the patient has received the information required under the board's regulations before the physician may perform a breast implantation procedure on the patient. The signed form shall be retained by the physician in the patient's medical file. In this section, "breast implant" means a surgically inserted pocket or envelope under the skin that consists of soft silicone gel, a combination of soft silicone gel and saline solution, or silicone covered by polyurethane foam.

*** Sec. 3.** AS 18.05 is amended by adding a new section to read:

Sec. 18.05.048. BREAST IMPLANT REMOVALS; REGISTRY; REGULATIONS. (a) The department shall maintain a registry of the

(1) names of patients from whom breast implants are removed;

(2) names of the patient's children who were born after the patient received a breast implant if the patient is a woman; and

(3) test results received under AS 08.64.363.

(b) The commissioner shall adopt regulations regarding removed breast implants, including regulations

(1) establishing a procedure to ensure confidentiality of information obtained by the department in carrying out this section;

(2) governing the delivery and storage of removed breast implants;

(3) setting requirements for laboratory procedures for the testing and storage of removed breast implants;

(4) establishing the types of test that must be performed on removed breast implants;

(5) governing the compilation, evaluation, and disclosure of the test results; and

(6) establishing a system for testing and monitoring the health of patients who have received breast implants, patients from whom breast implants have been removed, and the children of both groups of patients.

(c) In this section, "breast implant" means a surgically inserted pocket or envelope under the skin that consists of soft silicone gel, a combination of soft silicone gel and saline solution, or silicone covered by polyurethane foam.

*** Sec. 4.** AS 21.09 is amended by adding a new section to read:

Sec. 21.09.202. INFORMATION ABOUT COVERAGE OF BREAST IMPLANTS. (a) An insurer authorized under this chapter to offer, issue for delivery, deliver, or renew a disability insurance policy in the state, or a hospital or medical service corporation authorized under AS 21.87 to offer or renew a subscriber's contract shall provide to the director the following information in a form and manner, including frequency, determined by the director under regulations that the director may adopt to implement this section:

(1) the coverage provided under the various plans of the insurer or corporation for breast implant removals and breast implant-related conditions; and

(2) the provisions of the various plans of the insurer or corporation regarding preexisting conditions for individuals with breast implants.

(b) Upon request of an individual, the director shall make available to the individual the information received under (a) of this section. The director may include a notice that the provision of the information does not mean that the director guarantees the accuracy of the information. The director may set a fee to cover the costs of providing information to an individual under this subsection.

(c) Failure to file the information required under (a) of this section is subject to a civil penalty of $100 for each day the failure continues.

(d) In this section, "breast implant" means a surgically inserted pocket or envelope under the skin that consists of soft silicone gel or saline solution, a combination of soft silicone gel and saline solution, or silicone covered by polyurethane foam.

*** Sec. 5.** TRANSITIONAL PROVISION. The first report required under AS 21.09.202(a), enacted by sec. 4 of this Act, is due December 31, 1995.

*** Sec. 6.** Section 2 of this Act takes effect on the date the Food and Drug Administration makes a final decision that confirms the safety and effectiveness of breast implants that contain silicone. The commissioner of health and social services shall monitor the Food and Drug Administration's activities in this area and immediately notify the revisor of statutes of the date, if any, when the Food and Drug Administration makes the final decision described in this section.